2025

Innopharma Insights

Volume 1

Contents

Editor's Introduction

As Editor-in-Chief of this inaugural issue of Innopharma Insights, it is my pleasure to welcome you to our journal. This publication represents a significant milestone for Innopharma Education, showcasing the exceptional work and research of our learners and faculty across various disciplines within the pharmaceutical, medical device/med tech and food science sectors. In this debut issue, we present a diverse array of content that reflects the breadth and depth of expertise within our community, all centred around the theme of innovation. From cutting-edge research articles to insightful opinion pieces, Innopharma Insights aims to bridge the gap between academia and industry, fostering innovation and knowledge exchange.

We are particularly proud to include an interview with our Managing Director and President, Orla Callan, who shares her vision for Innopharma Education and insights into the evolving landscape of pharmaceutical, medical device and food science education.

This issue presents four research articles, each derived from original dissertations completed across our Level 9 master's programmes. Three of these programmes, the MSc in Medical Device Technology & Business, the MSc in Digital Transformation (Life Science) and the MSc in Pharmaceutical Business and Technology are delivered in partnership with Griffith College Dublin.

The fourth, the MSc in Food Business Management & Technology, is run in collaboration with Technological University Dublin – Tallaght Campus.

These four dissertations have been distilled into article format, allowing us to share the innovative research and insights generated by our talented learners.

Our featured articles span a wide range of topics, including:

- The potential of snail meat as an alternative protein source
- Applications of wearable technologies in pharmacovigilance
- Machine learning's role in optimising pharmaceutical manufacturing processes
- Regulatory challenges faced by medical device manufacturers under the new MDR framework

Additionally, we showcase the creativity and ingenuity of our Higher Diploma (Level 8) Food Science and Technology learners through their innovative food product presentations. These projects demonstrate the practical application of

knowledge gained throughout their studies and highlight the potential for future innovations in the food industry. The work of our Level 6 & 7 learners is also featured, Wojciech Parczyk presents his capstone project providing a digital solution to enhance low production capacity utilisation and William Moore compares two books related to sustainability and industry. Two of our Innopharma Education lecturers also contributed to this first issue; Kathleen Moore advocates for sustainable innovation in the medical device industry and Finbarr Sheehy emphasises the growing importance of critical thinking skills in education to help learners navigate information overload, misinformation, and digital challenges.

As we launch this journal, we invite our readers - learners, faculty, industry professionals, and researchers - to engage with the content, share your thoughts and consider contributing to future issues.

Innopharma Insights is not just a platform for disseminating knowledge; it is a catalyst for collaboration and innovation within our community. I would like to express my gratitude to all contributors, reviewers, and the editorial team who have made this first issue possible. Your dedication and expertise have set a high standard for the journal, and we look forward to building upon this foundation in future issues. We hope you find this inaugural issue of Innopharma Insights both informative and inspiring.

Happy reading!

Colm O'Connor, College Librarian & Research Specialist

Editor-in-Chief

Innopharma Insights Editorial Team

Editor-in-Chief: Colm O'Connor

Associate Editors: Aine Behan, Jennifer Campbell, Jennifer Manning, Michelle Ryan, Victoria Buckley

Graphics and Illustrations: Jennifer Manning

Interview with Orla Callan

In this interview, Victoria Buckley, Head of Teaching and Learning, talks to Orla Callan, the Managing Director and President of Innopharma Education. With a wealth of experience in the education sector, Orla shares her vision for the institution, its core mission, and how it has evolved since its inception in 2009

Could you please introduce yourself and explain your role at Innopharma Education?

I am the Managing Director and President of Innopharma Education, where I oversee the strategic direction and operational management of the institution. My role involves collaborating with academic and industry partners, and overall responsibility for academic quality, financial health, learner experience and governance of the college.

What is the core mission of Innopharma Education?

Our core mission is to contribute value to society by re-skilling, up-skilling, and life-skilling our learners. We aim to empower individuals to grow personally and professionally, enabling them to build rewarding careers in high-tech manufacturing sectors such as pharmaceuticals, medical devices and food technology.

How do you envision our journal - Innopharma Insights - fitting into the broader mission of the college?

Innopharma Insights will serve as a platform for sharing innovative research and discussions that align with our mission. By highlighting diverse research activities, it will foster collaboration among learners and staff while engaging a broader academic audience in topics

relevant to industry advancements and educational practices.

How has Innopharma Education evolved since its establishment in 2009, and what key milestones have been achieved in support of the core mission?

Since our establishment in 2009, Innopharma Education has grown significantly. Key milestones include achieving QQI institutional validation allowing us to develop and validate our own programmes, expanding our course offerings to include higher diplomas and bachelor's degrees and more recently programmes of Further Education and Training, establishing strategic partnerships with institutions like Griffith College, TU Dublin and the ETBI.

The role of industry and enterprise engagement in our growth has been critical in bridging the gap between academia and the real-world needs of businesses and industries and we are proud to have strong connections with the Higher Education Authority, the Regional Skills Fora, IDA, Enterprise Ireland, Skillnet Ireland, and IBEC, plus over 130 life sciences companies. These ties have enhanced our capacity to deliver quality education tailored to industry needs.

What sets Innopharma Education apart from other educational institutions?

Innopharma Education distinguishes itself through its strong industry connections and a curriculum designed with direct input from sector leaders. Our unique approach—referred to as "*The Innopharma Way*"—emphasises the significant input from industry in ensuring that all education programmes contain a combination of practical skills development, alongside theoretical knowledge plus a blend of transversal skills, ensuring that our graduates are not only knowledgeable but also job-ready.

Can you elaborate on "The Innopharma Way" and how it provides support to learners?

"*The Innopharma Way*" is centred on a learner-focused approach that combines academic rigor with practical application. Our programme management teams ensure that all applicants are given an opportunity to discuss the benefits of enrolling on a particular programme, and ensuring from the start, that the programme aligns with their individual career goals. Programmes are delivered by industry experts, again allowing our learners to gain from current and future facing practices in the sectors. This provides our learners with immediate access to networking opportunities within the industry to support their career enhancement. Every programme has a

dedicated career development module enabling all learners to become proficient in CV writing, interview performance and offering participation in in-house, practical assessment days.

In addition, we offer personalised career coaching. Our career hub is a dedicated online resource containing supplementary career enhancing resources and live open roles from companies who contact us to allow our learners apply directly for their open positions This holistic support system ensures that learners are well-equipped to navigate their career paths successfully.

How does this approach impact learner outcomes and career readiness?

Our approach significantly enhances learner outcomes by fostering a culture of continuous improvement and practical learning. Graduates leave with not only academic qualifications but also the confidence and skills necessary for immediate employment in their chosen fields, resulting in high employability rates within the pharmaceutical, medical device and food industries.

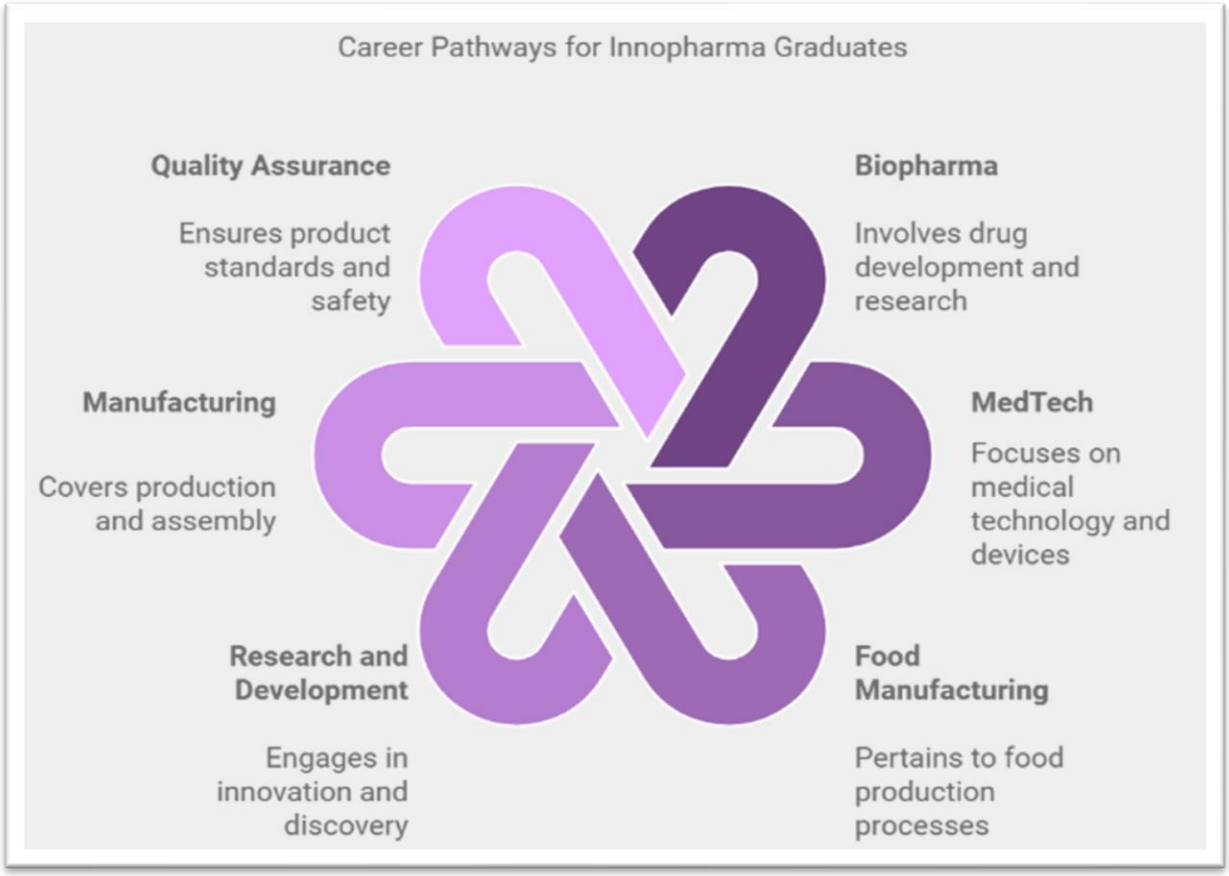
How do your strategic collaborations with institutions like the Technological University (TU) Dublin Tallaght and Griffith College enhance the educational experience for learners?

Collaborating with institutions like TU Dublin and Griffith College allows us to leverage their expertise in programme design and delivery. These partnerships enable us to offer accredited qualifications that meet industry standards while providing learners access to a wider range of resources, research initiatives, and networking opportunities that enrich their educational experience.

What are the typical career paths for graduates of Innopharma Education, and what percentage of graduates go into roles in the pharma, medical device/Medtech, or food industry

Graduates of Innopharma Education typically pursue careers in the biopharma, medtech, food and beverage manufacturing, and supporting industries. Depending on the graduates' academic level and programme, our graduates can work across various disciplines such as research and development (R&D), manufacturing, quality assurance, regulatory affairs, biostatistics and data science, supply chain and logistics as well as sales and marketing.

Over 80% of our graduates have reported a significant change in their careers either making their first step into the sector or by enhancing their careers through promotion.


Career Pathways for Innopharma Graduates
Quality Assurance
Ensures product standards and safety
Biopharma
Involves drug development and research
Manufacturing
Covers production and assembly
MedTech
Focuses on medical technology and devices
Research and Development
Engages in innovation and discovery
Food Manufacturing
Pertains to food production processes

What challenges does Innopharma Education face in the current educational landscape, and how are these being addressed?

One challenge that all colleges face is keeping ahead of rapid technological advancements within high-tech industries. Given our strong history of industry and enterprise engagement, we can keep addressing this, as we continuously update our curriculum based on industry feedback and trends while investing in innovative teaching methods that incorporate new technologies into learning experiences.

What are the long-term plans for Innopharma Education, and how do you see the institution evolving to meet future industry needs?

The life sciences manufacturing sector is evolving rapidly due to advancements in technology, changing regulatory landscapes, and increased demand for personalised medicine and sustainable production. To stay competitive, professionals in this field will need to develop future-ready skills that address these trends. Innopharma Education's long-term plans include expanding our course offerings to continue to encompass emerging fields such as digital and automation skills, sustainability and green manufacturing practices, personalised medicine and precision manufacturing and of course keeping a focus on those transversal skills which are critical to cross-functional teams such as leadership, collaboration and critical thinking.

We aim to enhance our research capabilities further while maintaining strong ties with industry partners to ensure that our programmes remain relevant and aligned with future labour market demands.

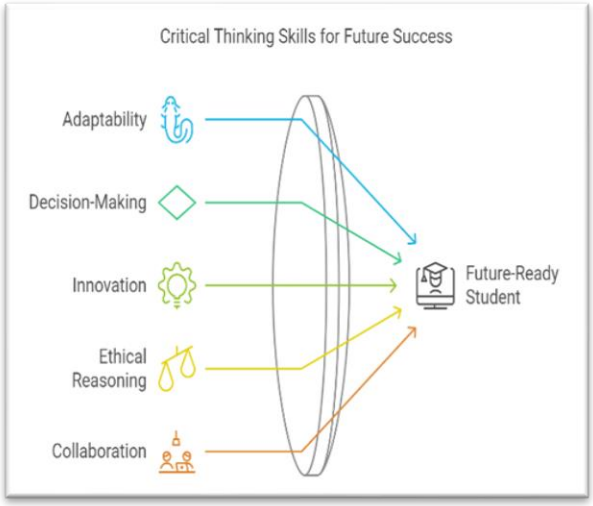
Thanks to Orla for taking the time to answer our questions and informing our readers of the aims and core ethos of Innopharma Education.

The Indispensable Mind: Critical Thinking in the Digital Age

Author: Finbarr Sheehy

Finbarr is the Director of Postgraduate Programmes in Innopharma Education. Finbarr lectures on the topics of Lean, Six Sigma and Operational Excellence across our courses.

In the rapidly evolving landscape of the 21st century, where information is abundant and easily accessible, the importance of critical thinking in education has become more crucial than ever before. As we navigate through the digital age, learners are faced with an unprecedented volume of data, diverse perspectives and complex global challenges. This article explores the significance of cultivating critical thinking skills in educational settings, examining its impact on student learning, future workforce readiness, and societal progress in an increasingly digitalised world.



Defining Critical Thinking in the Digital Context

Critical thinking, at its core, involves the ability to analyse, evaluate and synthesise information to form reasoned judgments and make informed decisions. In the digital age, this skill set extends to include the capacity to navigate vast online resources, discern credible sources from misinformation and apply logical reasoning to complex, interconnected issues (Indah *et al.*, 2022).

The Digital Landscape and Its Challenges

The proliferation of digital technologies has transformed the way we access and interact with information. Social media platforms, online news outlets and digital learning resources offer unprecedented access to knowledge.

However, this abundance of information also presents significant challenges:

Information Overload: Learners are bombarded with data from multiple sources, making it difficult to focus on relevant and reliable information.

Misinformation and Disinformation: The spread of false or misleading content online and in mainstream media requires individuals to be vigilant and discerning consumers of information.

Echo Chambers: Digital algorithms often reinforce existing beliefs, potentially limiting exposure to diverse perspectives.

Rapid Technological Advancements: The fast-paced evolution of technology demands continuous adaptation and learning.

In this context, critical thinking becomes an essential tool for learners to navigate the digital landscape effectively and responsibly (Thornhill-Miller *et al.*, 2023).

Critical Thinking as a Cornerstone of Digital Literacy

Digital literacy, the ability to use information and communication technologies effectively, is incomplete without strong critical thinking skills.

Critical thinking in the digital age involves:

Source Evaluation: Assessing the credibility and bias of online sources.

Fact-Checking: Verifying information across multiple reliable sources.

Logical Analysis: Identifying fallacies and logical inconsistencies in arguments.

Synthesis of Information: Combining insights from various sources to form comprehensive understanding.

Ethical Consideration: Reflecting on the moral implications of digital content and its use.

By integrating these skills into the curriculum, lecturers can empower learners to become discerning digital citizens capable of navigating the complexities of the online world (Stanikzai, 2023).

Impact on Learning and Academic Performance

Research consistently demonstrates the positive impact of critical thinking on academic performance. Learners with strong critical thinking skills are better equipped to conduct effective online research, evaluate the quality of digital learning resources, engage in meaningful online discussions and collaborations and apply knowledge creatively to solve real-world problems (Lestari and Dharma, 2022).

Preparing for the Future Workforce

The World Economic Forum's "Future of Jobs Report 2023" highlights critical thinking as one of the top skills required for the workforce of the future. As

automation and artificial intelligence continue to transform industries, the ability to think critically, solve complex problems and make nuanced judgments becomes increasingly valuable.

Critical thinking skills prepare learners for:

- Adaptability in rapidly changing work environments
- Effective decision-making in data-rich contexts
- Innovation and creative problem-solving
- Ethical reasoning in complex situations
- Collaboration in diverse, global teams

By fostering these skills, education systems can ensure that graduates are well-prepared for the challenges and opportunities of the future job market (Stanikzai, 2023).

Societal Impact and Civic Engagement

Beyond individual benefits, critical thinking skills are crucial for the health of democratic societies in the digital age. As social media platforms become primary sources of news and political discourse, the ability to critically

evaluate information and engage in reasoned debate is essential for informed civic participation (Kadrija *et al.*, 2023).

Challenges and Strategies for Implementation

Despite its importance, integrating critical thinking into educational curricula presents several challenges, including the focus on standardised testing, lack of teacher training, time constraints and digital distractions.

To address these challenges, lecturers and colleges can consider strategies such as curriculum reform, professional development for lecturers, implementation of project-based learning, development of comprehensive digital literacy programmes, encouragement of collaborative learning and teaching of strategies such as Socratic questioning (Kong and Pek, 2023).

Conclusion

The importance of critical thinking in education in the digital age cannot be overstated. As we prepare learners for a future characterised by rapid technological change, information abundance, and complex global challenges, the ability to think critically becomes not just an academic skill but a fundamental life skill.

By fostering critical thinking, educational institutions can empower learners to navigate the digital landscape

effectively, excel in their academic and professional pursuits and contribute meaningfully to society.

In the words of educational philosopher John Dewey, "We do not learn from experience... we learn from reflecting on experience." In the digital age, this reflection must be critical, discerning, and deeply engaged with the vast sea of information at our fingertips. Only then can we truly harness the power of the digital revolution to advance knowledge, foster innovation, and promote human progress.

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Sustainable Innovation in Medical Devices: The Case for Transforming Towards 'Green' Asthma Inhalers

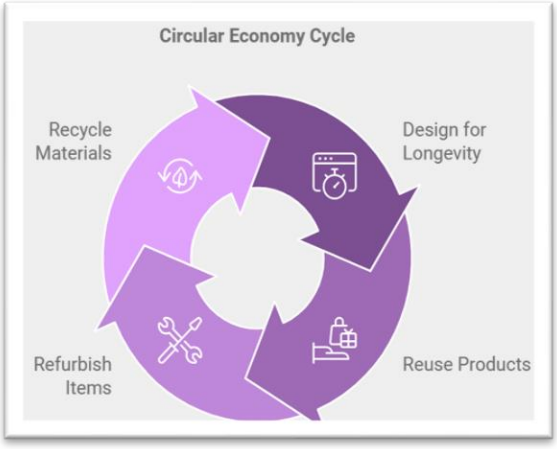
Author: Kathleen Moore

Kathleen Moore developed and lectures on sustainability in industry modules on our BSc in Process Digitalisation courses. Furthermore, Kathleen founded the Environmental Social Governance (ESG) committee at Innopharma and now works in the SEAI as a Sustainable Energy Communities Executive.

Like all industries, current innovation in the medical device industry is being driven by increasing environmental concerns and regulatory pressures. In Ireland, a global hub for Medtech, the market for medical devices is thriving. With revenues projected to reach approximately US$1,175 million in 2024 and an annual growth rate of 4.27% from 2024 to 2028 (Statista, 2024), the industry is buoyant. However, as this market grows, so does the need for sustainable innovation.

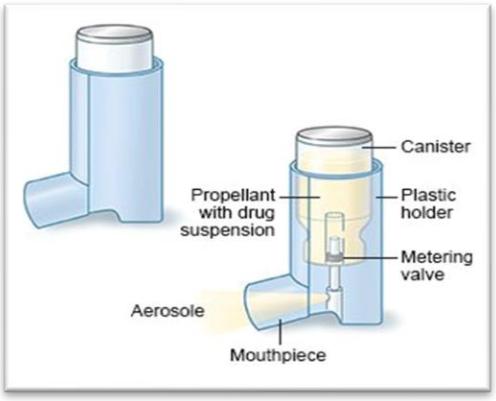
What does it mean to be 'sustainable'?

Sustainability decisions in medical device manufacturing need to be made during the design phase. This enables various aspects of sustainability to be incorporated from the outset, such as whether the materials used are virgin or recycled; how water, energy and waste intensive the manufacturing processes are, and what is the end-of-life strategy for the product once used. This move towards sustainability in how we make products is often referred to as 'circular design'. The circular economy is more sustainable than our current linear economy, which is 'take, make, waste' in approach. Opposingly, the circular economy aims to design waste out of that process, so that products stay in use for as long as possible, either through re-use, refurbishment or recycling. Circular economy thinking is thus most crucial for sustainable manufacturing of any kind. If a product cannot be repaired or recycled to stay in-use and maintain its value to the end consumer, its sustainability will be poor.



How can we know if a product is 'sustainable' or 'green'?

A 'green' product is just a simple signifier of environmentally-friendliness without a common definition or clear agreed-upon parameters. It is a mental short-cut adopted to identify a sustainable product. But the most transparent way of measuring sustainability is through its carbon footprint. The carbon footprint is the total amount of greenhouse gas (GHG) emissions, associated with the activities of a product, process, organisation or a person.



The unit of carbon footprints is kilogram or tonnes of CO_2e or carbon dioxide equivalents and is a very useful way to understand the environmental impacts goods or services have. Reducing the carbon footprint of medical devices will be a core objective of the industry into the future, products such as inhalers used for respiratory illnesses.

The Environmental Impact of Inhalers

Inhalers, especially pressurised metered dose inhalers (pMDIs), are a critical area of environmental concern. These devices, commonly used to manage chronic respiratory conditions like asthma, have a significantly higher carbon footprint compared to alternatives such as dry-powder inhalers (DPIs) and soft mist inhalers (SMIs). While the latter emit less than 1kg of CO_2e, pMDIs can produce between 11 and 28 kg of CO_2e per device (Ahmed *et al.*, 2022; Christer *et al.,* 2020; Bickhardt *et al.,* 2022).

Despite this, pMDIs account for 60% of inhaler prescriptions in Ireland and Europe (Irish Doctors for the Environment, 2022).

Given the chronic nature of respiratory diseases, the environmental impact of inhaler usage over a patient's lifetime is substantial. This reality underscores the urgent need for product innovation focused on sustainability.

Transitioning to Low-Carbon Solutions

A significant portion of the emissions from pMDIs is due to the propellant used in the aerosol spray. As a result, the industry has been shifting towards DPIs and SMIs, which have lower carbon footprints. However, as companies aim to achieve net zero emissions by 2050, the focus must expand beyond just propellant transition to include the entire lifecycle of the product, including the materials used in manufacturing (Mannheim & Simenfalvi, 2020).

Polypropylene (PP), the primary material used in inhaler components like the plastic holder, mouthpiece, cap, and actuator, is a major contributor to GHG emissions. Lifecycle assessments (LCA) calculate that PP production generates between 2.18 kg and 3.67 kg of CO_2e during the production phase and an additional 1.27 kg to 2.15 kg of CO_2e during disposal (Mannheim & Simenfalvi, 2020). These emissions highlight the need for alternatives that are not only low-carbon but also recyclable.

Challenges in Recycling and Material Innovation

Currently, less than 1% of PP is recycled, and most of it ends up in landfill or is incinerated, leading to long-term environmental damage (EPA, 2019; Bora, Wang & You, 2020). Additionally, consumer behaviour exacerbates this problem as many patients dispose of their inhalers with household waste, further contributing to landfill volumes (Murphy *et al.,* 2023). Such consumer behaviour reflects a broader challenge in the industry: the need for circular solutions that make it easier for end-users to recycle, or to educate their customers on how to properly dispose of medical devices, alongside clear and simple industry take-back schemes. Previous attempts at inhaler recycling programmes by companies like GSK and Teva have been discontinued, underscoring the need for more effective solutions. The challenge lies not only in finding a recyclable material but also in ensuring it meets the stringent requirements for medical devices, such as biocompatibility, corrosion, resistance, and mechanical robustness (Ashter, 2022; Sastri, 2022).

The Need for Cost-Effective, Sustainable Alternatives

The medical device industry is highly competitive, and so it follows that any sustainable alternative to PP must also be cost-effective. Plastic is inexpensive, with current European prices for PP ranging from €1,360 to €1,375 per metric tonne (Polymer Update, 2024). Therefore, sustainable materials must compete on both price and performance.

Corporate Sustainability Reporting Benefits

Despite these challenges, there is a growing market for recycled, recyclable (note: there is a difference) and compostable plastics. By introducing these materials, medical device companies can gradually phase out PP, providing consumers with more environmentally friendly products. These alternatives would significantly reduce the overall environmental impact of inhalers, reducing a company's Scope 3 emissions. Scope 3 GHG emissions are those resulting from indirect activities of the company and includes those from the consumers' use of the company's products. Being out of the direct control of the company, Scope 3 emissions are, as such, notoriously difficult to reduce. Such innovations will help companies align with regulatory shifts and corporate sustainability commitments, including the pursuit of net zero targets.

Sustainability-driven Competitive Leadership

The future of the medical device industry lies in sustainable innovation. Companies that successfully develop and integrate low-carbon, recyclable materials into their products will not only reduce their environmental footprint but also gain a competitive edge in an increasingly eco-conscious market. Research tells us that 65% of consumers are more mindful of the environmental impact of their consumption and 64% of consumers feel happier buying sustainable products (CapGemini, 2023).

The challenge to deliver is complex, and thus the opportunity is clear; by embracing sustainable materials and designing products with the environment - as well as the human - in mind, medical device companies can lead the way in creating a more sustainable future.

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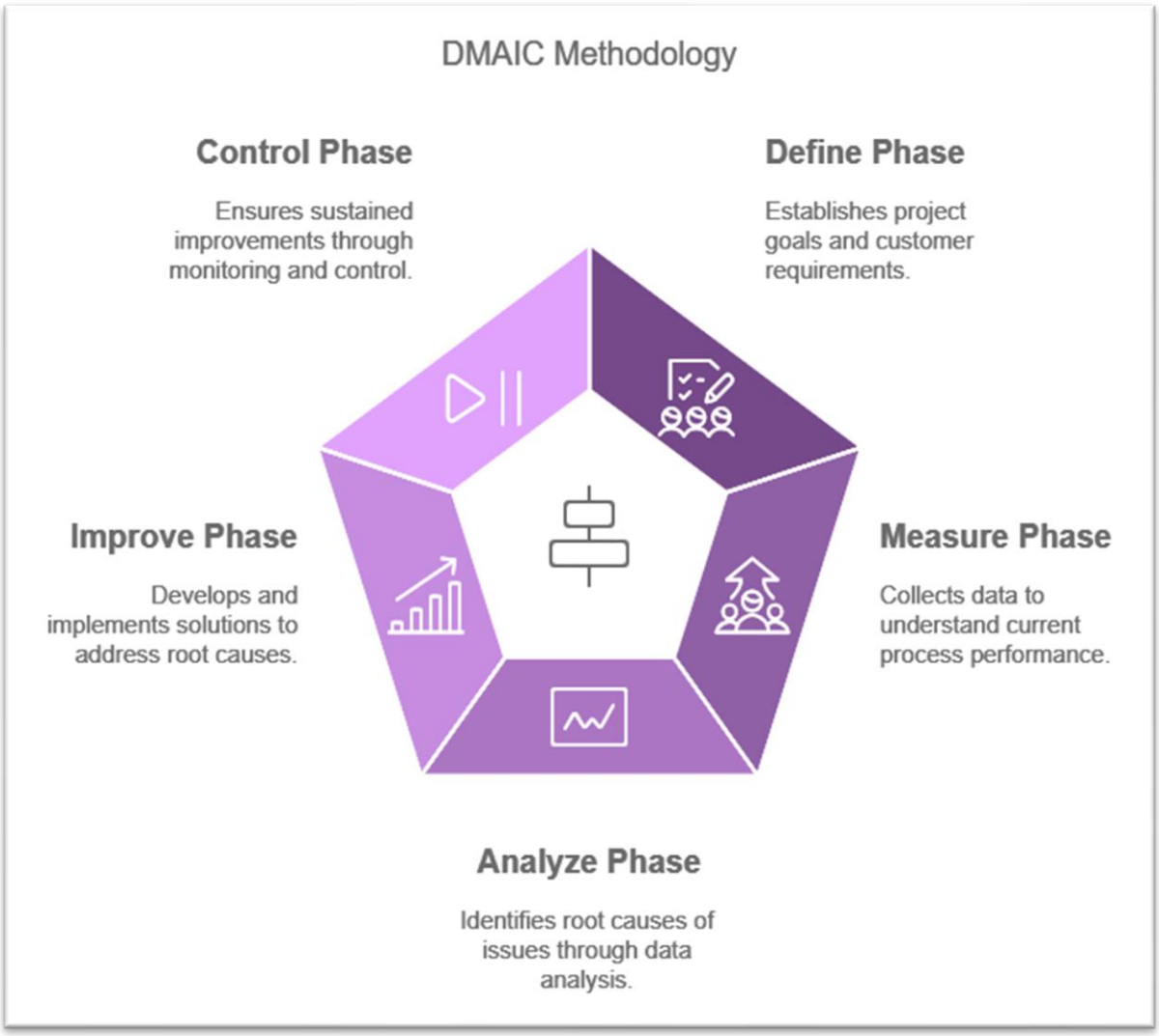
Capstone Project: A Digital Solution to Labour Allocation and Efficiency

Author: Wojciech Parczyk

Lecturer Introduction: Finbarr Sheehy

Programme: Higher Certificate in Process Digitisation, Innopharma Education

This is a summary of a capstone project where learners are required to develop a digital solution to a conceptual analogue process. The project demonstrates the competencies developed during the level 6 Certificates in Operational Excellence and Information Technology for Process Digitalisation using the DMAIC methodology. This project culminates and capstones the Higher Certificate award.



Define Phase

CathMed Ltd. Is a medical device factory located in Ireland manufacturing coronary catheters. During the rough-cut capacity planning, the company realised that the production capacity utilisation is low and there is a large gap between the Design Capacity and the Effective Capacity. The Line Leaders find it tedious and difficult at times, to effectively organise work on the line relating to, but not limited to, different work in progress (WIP) levels at each step, availability of subcomponents and differences in process targets.

The company wanted to develop a digital solution to the problem, utilising the availability of data and the integration of multiple enterprise systems.

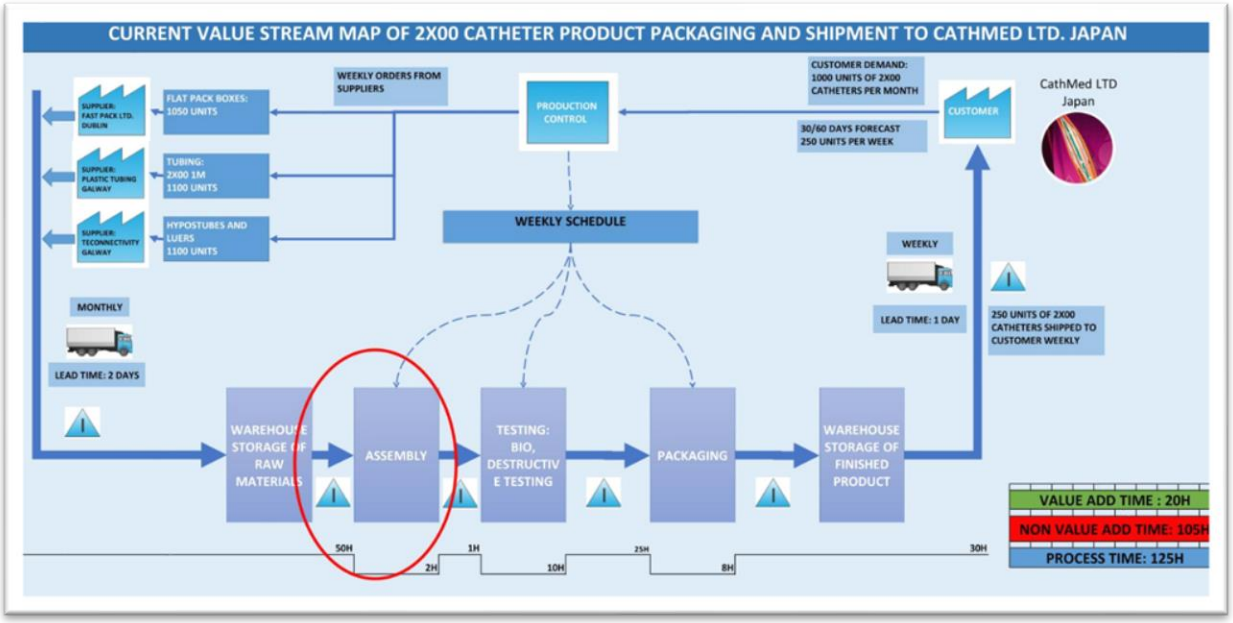
Measure Phase

The value stream below represents the process of understanding customer demand and the supply of catheters on a monthly basis.

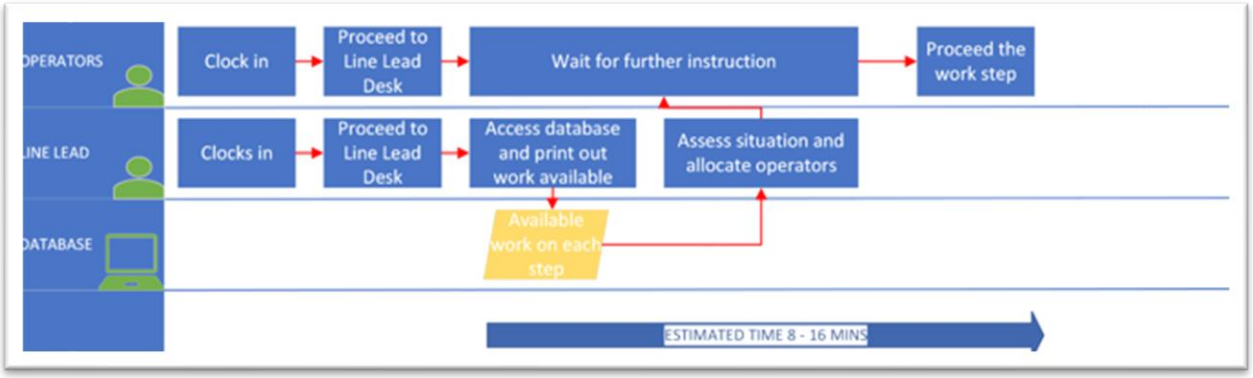
One aspect of the identified downtime was the manual allocation of employees to tasks, based on who was on shift and their capabilities. This resulted in approximately 16 minutes of non-value add time at the start of every shift.

What is a Value Stream Map?

A value stream map is a graphical representation of the steps involved in a process, from the initial request to the final delivery of a product or service. It highlights both value-adding and non-value-adding activities, allowing organizations to identify waste, streamline processes, and improve overall efficiency. By visualizing the entire process, teams can better understand how each step contributes to the final outcome and where improvements can be made.



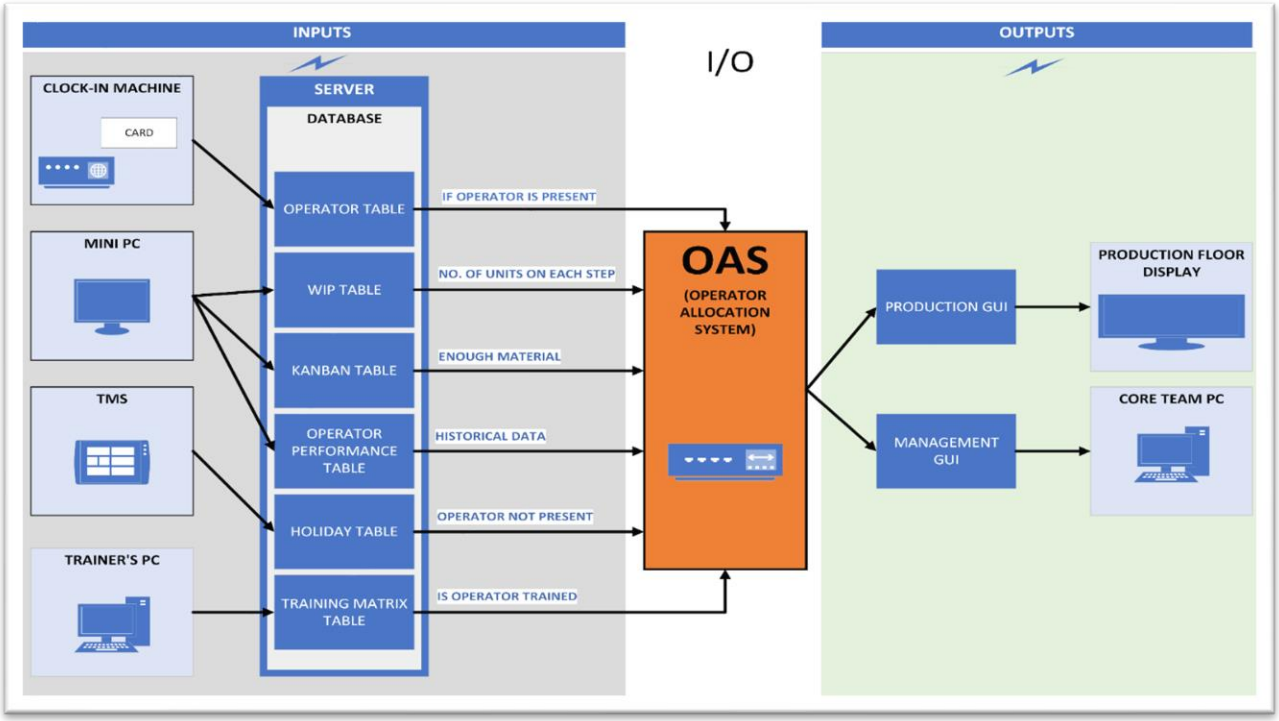
Value Stream Map of Catheter Manufacturing, excerpts from the Capstone Project



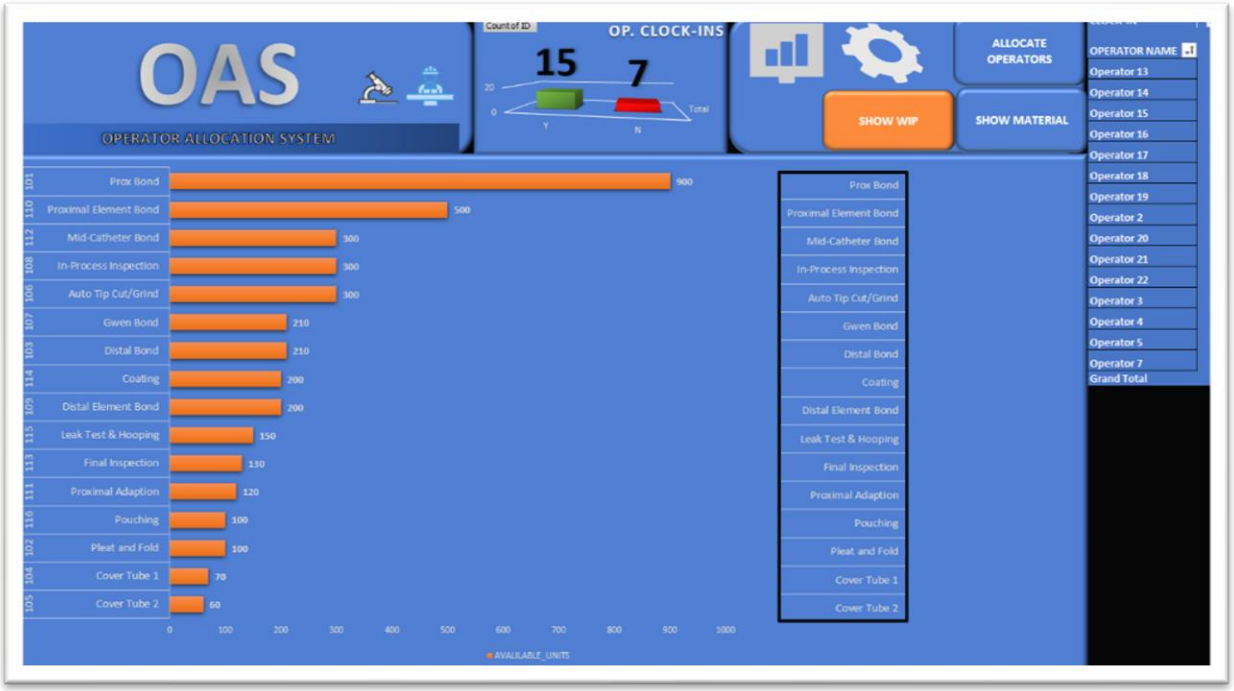
Process flow of task allocation by Line Lead at start of each shift, excerpts from the Capstone Project

Design Phase

The conceptual digital solution is an Operator Allocation System (OAS), which is the integration of a series of enterprise and local systems, used to identify the most appropriate operators on shift, based on their training, experience and past performance. The system overview is outlined below.



Proposed digital solution for Operator Allocation, excerpt from the Capstone Project



Graphical User Interface Design, except from the Capstone Project

The system extracts real time data from the clock-in system to see who is on shift, combined with holiday schedule.
The system has a graphical user interface for Line Leads and Production Operators to communicate the daily schedles, as well as changeover times and work centre allocation.
This system generates a shift work plan immediately, once the operator clocks in to the Time and Attendance system. It can also recalculate work patters based on real time performance, material availability, machine downtime and changes in demand.

Control Phase

To ensure the new digital system is fully implemented and sustained, a series of control measure need to be implemented.

- Develop a training programme to educate all Line Leads on the digital solution.
- Identify and input training competency data for all employees
- Develop a standard operating procedure (SOP) outlining the operation of the process.
- Integrate the system into the organisational digital infrastructure roadmap.

Conclusion

This capstone project serves as a prime example of how the principles taught in the Higher Certificate in Process Digitisation can be applied to real-world scenarios, resulting in tangible improvements in operational efficiency.

It underscores the importance of digital solutions in modern manufacturing and highlights the potential for further innovations in process digitisation across various industries.

Book Review: The Burning Case for a Green New Deal & Confessions of a Radical Industrialist

Author: William Moore

Lecturer Introduction: Kathleen Moore

Programme: BSc in Process Digitalisation, Innopharma Education

As part of the continuous assessment for the module 'Progressing Towards Sustainable Industry', learners were tasked with exploring how digitalisation and sustainable development, referred to as the "twin transformation", can be addressed in an industrial context. This assignment involved selecting two books from a diverse list of works on sustainability—ranging from ecological, industrial, and even theological perspectives—and comparing their approaches.

This exercise is rooted in the understanding that evaluating the sustainability of any system requires input from a wide range of stakeholders, each bringing unique yet equally important perspectives on what a sustainable future entails. A sustainable solution to any unsustainable problem requires transdisciplinary teamwork and expertise.

In the following book review William Moore offers his comparative analysis of two thought-provoking works: Naomi Klein's The (Burning) Case for a Green New Deal, and Ray C. Anderson's Confessions of a Radical Industrialist. William's review delves into these contrasting viewpoints, one advocating for systemic societal change and the other showcasing a business-led approach to sustainability. His reflections reveal valuable insights not only into the books' key arguments but also into how these lessons can be applied in today's industries.

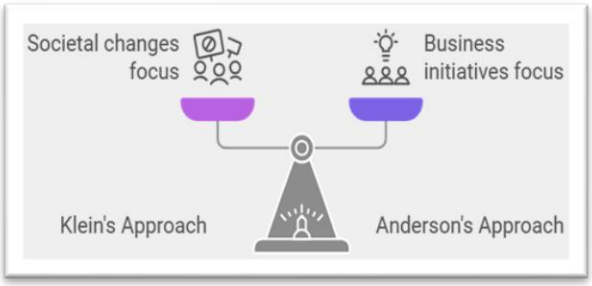
The Burning Case for a Green New Deal

Naomi Klein's book, 'The (Burning) Case for a Green New Deal', published in 2020 is a collection of essays in which Naomi Klein argues that the only way to solve the environmental, economic, social and political crisis which we are facing is for the introduction of a green new deal. The green new deal calls for a public policy to address climate change in tandem with achieving other social aims such as job creation (in renewable/ sustainable industries), sustainable economic growth and reducing the world's economic inequality.

The book provides details on events such as the Deepwater Horizon disaster, the bleaching of the Great Barrier Reef and the Pacific Northwest wildfires, and their effects on local communities and the environment. Klein calls for a radical change to the current economic system which she links in its origins to colonialism, slavery and climate change. She emphasises a shift away from the current neoliberal consumerism, which she describes as the 'constant now,' towards a new sustainable economic model that prioritises environmental respect.

In terms of societal change, Klein argues that the individualistic way we conduct our lives today is not effective and that for change to occur we need to act together - 'to change everything it takes everyone'. Klein believes we need to organise ourselves into groups, locally and globally, whether this is in unions, climate strikes, occupy Wall Street or campaigns against big brands to apply pressure and effect real change.

On the theme of politics, Klein argues that divisive politicians, for example Donald Trump, feed off fear, the fear of change and the fear of 'others' (such as immigrants) which resulted in Trump being elected despite his racism and misogyny. Klein argues that the progressive left is partly to blame, fighting for climate and economic justice, but not letting the marginalised groups which are directly impacted by these issues lead the fight. Klein calls for a broad coalition of groups to come together to face up to hard historical issues such as land grabbing, genocide and misogyny.



Confessions of a Radical Industrialist

Ray C. Anderson's book 'Confessions of a radical industrialist; profits, purpose, people: doing business by respecting the earth' published in 2009, is a story of how Interface Inc., the company Anderson established to manufacture carpet tiles, changed from being a business heavily dependent on fossil fuels to one with sustainability as its key business driver, creating along the way a new paradigm for how a manufacturing business can be successful whilst also respecting the environment.

The book explores themes on sustainability, hope, government and business, leadership and the need for a new business model.

In terms of sustainability, the company developed its Mission Zero plan which established targets of zero waste, fossil fuel energy use and wastewater by 2020. Anderson also established InterfaceRAISE consultancy to share the learnings from Mission Zero with other companies (including Walmart). The company addressed the issue of hope by demonstrating that there does not need to be a trade-off between being green and profitability, as it is 'a business case brought to life'. In relation to government and business, Anderson argues that government is too slow to address the climate crisis and disagrees with governments belief that business is best suited to use innovation and self-interest (i.e. the pursuit of profit, 'good greed') to achieve environmental goals. The author

calls for government to provide the vision (as Kennedy did with the space programme) and reward those businesses that adopt sustainable business practices. That the Government would act more as a referee letting the players (business) get on with the game.

In terms of leadership, Anderson established the vision and kept Mission Zero on course but allowed it to evolve as time went on. He engaged stakeholders at all levels of the business. Many of the initiatives to achieve sustainability came from the bottom up or locally, not micromanaged by Anderson, with a strong culture of independence and ownership within the company which led to Interface Inc. being named one of Fortune's top 100 companies to work for. Anderson raises the issue of the need for a new business model that looks beyond financial costs and quarterly reporting periods, measuring benefits from all human activities and nature—activities often unaccounted for—which Anderson characterizes as 'not keeping honest books.' This also includes addressing 'externalities' (e.g. cleaning up the mess).

Leadership

Although Interface Inc. succeeded in their goals it is the style of leadership and holistic approach that I find the most insightful. Anderson was the founder and chairman of Interface Inc. but realised that to achieve his vision of better environmental performance and the creation of a better work environment he needed to engage more than his management team. Although it started internally it eventually led to suppliers and customers being involved. Anderson also took decisive action with his senior management team when he felt they had acted inappropriately resulting in approximately 50% leaving the company. Anderson also inspired others to become more sustainable through his consultancy arm, InterfaceRAISE, and took on a prominent national role as co-chair of the "President's council on Sustainable Development" and co-chair of the Presidential Climate Action Plan in 2008.

An example of this from my own career was when as a Store Manager for a prominent retail business - our parent company launched a Customer Aftersales Team (CAST), an initiative to lower returns and waste which accounted for £125 million in costs to the company. This was launched to Area Managers and due to it not being a performance measure, it was never communicated. After accidentally finding the programme online I took on the role of CAST specialist in Ireland, devising a training programme, communicating this to management teams and staff representatives to ensure everyone including senior operations managers were engaged.

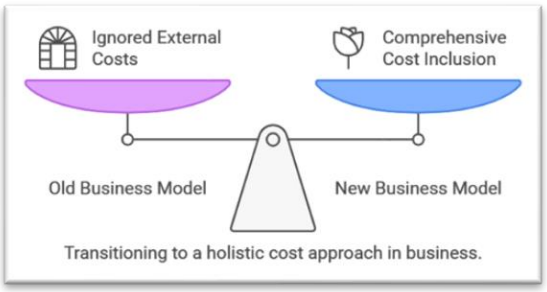
After reducing returns by 45% in Ireland, the programme was rolled out to the entire company with mixed results. However, I was unable to drive this programme further as I was not authorised to engage with the buying department or provide feedback to manufacturers which could have reduced waste further.

The need for a new form of business

Anderson believes that the old way of doing business doesn't work anymore and that a new system is needed which fully addresses all costs, costs that are currently regarded as 'externalities'.

For example, how would a company's financial performance look if they were responsible for the entire life cycle of their products? If a company in the fossil fuel industry was held financially liable for the pollution caused by the extraction of the oil, its transportation and use, would they be as profitable as they are today? Would the company be forced to raise their prices to such a level that renewables would be an attractive financial as well as ethical alternative?

This argument also holds true with the fast fashion industry; if it was responsible for ensuring the workers involved in the production of the raw materials and garments had good pay and conditions and the garments were recycled, would it be able to keep their prices low and profits high?



There were two themes that I did not fully agree with which are the theme of social movement and politics in Naomi Klein's book and the theme of politics versus business in Ray Anderson's book.

Social Movement and Politics

The recent growth in social movements such as Climate Strikes, Sunrise Movement and Occupy Wallstreet is indicative of a welcome and growing consciousness of the effects of climate change amongst the young. While Klein puts a big emphasis on these movements as a way forward, I wonder is it enough and will it be fast enough to effect change for the Climate Emergency that is no longer in our future but in our present?

Take for example - Australia and the Climate Strikes by students, in 2019 the total number of students in Australia who went out on strike only equated to 3.8% of school going students (Australian bureau of statistics, 2019). In the recent 2022 elections, the Australian Green party won only 4 seats in the lower house and 12 senate seats.

It was a traditional party, Labour, who defeated the ruling Liberal party and formed the new government (Australian Electoral Commission 2022 election 01-07-2022). The emergence of local and global movements is a welcome phenomenon and can pressurise politicians, but when measured against the traditional political establishment they only count as a very small minority. More encouraging is the percentage of the voters who raise climate as a concern perhaps because of the movements listed previously. This needs to carry through to mainstream politics and the enaction of tougher environmental legislation.

Politics versus Business

In terms of the theme of politics verses business, Anderson is very sceptical of the role government can play in driving sustainability noting several negative experiences he had dealing with the government in America. This allied with the fact that his own company was

successful, leads him to believe that business is the most effective vehicle to drive sustainability. However, Anderson had several advantages, key to this being he had founded Interface Inc. in 1973 and served as chairman in 1994 which put him in a strong position to implement a radical 25-year plan. Most companies must answer to shareholders and investors who could attempt to derail any plans which do not show an immediate gain to the bottom line as the example of Unilever shows.

When the CEO Paul Polman who had previously stated that 'if we keep shareholders in the driver's seat, we cannot build a system that optimises for well-being for all, which requires long-term thinking' (Moore, K. 2023) Polman was challenged by Terry Smith, CEO of an investor group who stated '[Unilever] are obsessed with publicly displaying sustainability credentials at the expense of focusing on the fundamentals of the business' (Moore, K. 2023).

In my opinion, government's role needs to be more than just a referee. The way forward is for governments to take inspiration from proactive companies, such as Interface Inc., create the vision, drive engagement with all stakeholders, ensure compliance and introduce a progressive taxation system with sustainable companies given tax breaks and non-sustainable companies taxed heavily.

Career Lessons

Both books contain career lessons. The methods Anderson employed to achieve sustainability in Interface Inc., such as creating and sharing a vision; engaging and challenging suppliers, team members and customers; setting goals and empowering teams to look at creative solutions to problems; these are all methods which can be used in any business. There is a temptation in business to focus on achieving short-term targets, which is not always sustainable in the long term. Instead, it is beneficial to allow for setbacks, recognise progress, and adapt to new challenges, overcoming barriers while maintaining focus on the main goal. Another lesson to be taken from both books is interconnectedness. Klein demonstrated the impossibility of separating the issue of climate change from racism, misogyny and justice, while Anderson realised that Interface Inc. could not achieve sustainability without a happy workforce. Ensuring that any team prioritises people first and remains respectful and inclusive is essential.

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Food Innovation: Sustainable Solutions and Flavourful Innovations - A Learner Showcase in Food Science

Author: Jennifer Campbell

Jennifer Campbell is the Programme Lead and Programme Chair for the Food Science and Technology Programmes at Innopharma Education. Jennifer lectures, recruits, manages and here - grades the presentations of the Food Product Innovation module on the level 8 Higher Diploma in Food Science and Technology programme.

Innopharma Education/Technological University Dublin – Tallaght Campus, Level 8 Higher Diploma in Food Science and Technology learners presented an array of innovative food products in April 2024 as part of their Food Product Innovation module. A wide range of products were presented; ranging from flavoured vegan spreads, seaweed infused beverages, free-from desserts and vitamin-rich fruit shots.

A highly rewarding project for the Food Product Innovation and Development module, our learners work in groups with the challenge of creating a unique food product. The brief had them follow the lifecycle of a food product from conception to formulation, complete with packaging, pricing and launch plan.

The semester concluded with showcase events in both Innopharma Education Dublin and Cork.

Groups presented on all aspects of their product. The lifecycle was presented and a taste test undertaken as the assessment. Always a very rewarding and exciting day for our foodies!

Elizabeth Russell, Lecturer for the Food Product Innovation and Development module remarked: *"The final product presentation of the innovative food products help to develop team working skills, critical thinking and bringing to fruition a shelf-ready food/beverage product. Each project team uses the knowledge from the course by identifying a consumer need through market research and develops a formulation.*

Every year exceptional products are developed by the class".

Vitamin drinks, flavoured falafel, free-from products and even seaweed were all the order of the day, with healthy eating, sustainability, free-from and convenience featuring trends throughout, showcasing our learners' ability to incorporate the learnings of the course with their unique talents.

One of the judges, Jennifer Manning, Lecturer and Head of Academic Programmes praised the exceptionally high standards of the food products and the learners' enthusiasm, dedication and commitment to the project commenting *"The Higher Diploma in Food Science and Technology is one of our most innovative programmes and attracts such talented learners, amazing to see the learnings be so tangible and edible, well done everyone".*

Showcasing the teams

Free-from and Vegan-focused Products

The food industry is rapidly evolving, and the growing demand for "free-from" and vegan products is leading the charge. Consumers are increasingly seeking options that cater to dietary restrictions and preferences, whether due to health, ethical, or lifestyle choices.

This trend was on full display during our learner presentations, where several standout products captured this movement.

Organic Rainbow Falafel

One of the highlights was an innovative *Organic Rainbow Falafel* product, offering four distinct falafel flavours in a convenient snack-box style packaging and infused with different vegetables and spices. This product not only celebrates the vibrant diversity of plant-based eating but also delivers on convenience — key for today's on-the-go consumer.

Group Members (Left to Right): Abhishek Tiwari, Rachel Beirne, Frances Watters

Choco Fit

For dessert, was *Choco Fit*, a duo of vegan "chocolate" desserts that wouldn't be out of place in a 5-star restaurant.

"Common allergen"-free, low in calories, and high in protein, these desserts embody the perfect blend of indulgence and health-conscious eating.

It's a modern and creative example of how plant-based products are transcending traditional boundaries, proving that vegan options can be both decadent and nutritious – changing the perception of vegan food.

Group Members (Left to Right): Taragh Tobin, Rachel Carey, Gabriella Bristott

Nutri-Bliss

Another noteworthy product featuring in this trend was *Nutri-Bliss*, a vegan nut bar that's gluten-free, high in fibre, and packed with protein. Catering to a wide range of food preferences this is a sweet treat for everyone.

With the rise in snack bars catering to health-focused consumers, *Nutri-Bliss* hit all the right notes, offering a wholesome, satisfying snack that's aligned with the free-from trend.

Group Members (Left to Right): Aline Nodari, Loren O'Brien, Darren Quinn.

Butterfly Vegan Spread

Finally, *Butterfly* introduced a series of flavoured butter-alternative vegan spreads, ideal for crackers, toast, or even cooking. As more consumers seek plant-based alternatives to traditional dairy products, *Butterfly* offered versatile and flavourful options that were sure to appeal to a broad audience.

Flavour options included garlic and chive, semi sundried tomato, and lemon and dill.

These products not only reflect current trends within the food industry but also showcase the potential for continued innovation in the free-from and vegan sectors.

With their creativity, dedication, and focus on consumer needs, our learners are clearly positioned to contribute meaningfully to the future of food – well done to all teams.

Group Members (Left to Right): Kenia Teixeira, Rachael Butler

Convenience

The convenience food market is constantly evolving, with consumers increasingly seeking healthier alternatives, particularly snacks, that don't compromise on taste or ease of use.

Totopos

This product is a perfect example of this trend—a portion-controlled, all-in-one "chips and dip" offering that combines convenience with mindful eating. Translated from Spanish into English, Totopos was chosen as the product name as it means "tortillas that are noisy to chew" in short, tortilla chips!

This innovative product features a zesty tomato salsa paired with home-made tortilla chips all wrapped up in convenient on the go packaging. Designed for those who want a quick, tasty, and nutritious snack, *Totopos* is a great option for health-conscious consumers looking to make smarter choices without sacrificing convenience.

It's the ideal solution for anyone on the go who still wants to enjoy their favourite snacks in a more balanced way.

Group Members (Left to Right): Kieran Reilly, Ciara Fox, Siobhan Feery, Doori Smko

Health and Sustainability

The rise of health shots packed with vitamins has taken the market by storm, offering a quick and convenient way for consumers to boost their nutrient intake and start their day with a zing. Tapping into this trend, one of our groups created *Naturablend – Beet Fusion* - a vibrant cold pressed shot drink made from beetroot, cherries, blackcurrants, black kale, orange, lemon and a host of herbs and spices, that stands out with its rich, deep red-purple colour. Served chilled, this tangy and refreshing drink is designed to kickstart your day with a powerful dose of nutrients, making it an ideal morning breakfast offering.

But the innovation didn't stop there. In a brilliant nod to sustainability and the need to reduce food waste, the team repurposed the byproducts from the *Beet Fusion* shot to create a second product: delicious vegan breakfast muffins. These muffins not only complement the health shot but also align with the growing consumer demand and sustainability goals for a more circular economy.

Naturablend – Beet Fusion is a perfect example of how health, taste, and sustainability can come together in a single offering, reflecting the evolving preferences of today's health-conscious and on-the-go consumers.

Group members (Left to Right): Irina Cascaval, Pamela Dowling, Sharon Quinn

Seaweed Refreshments

The beverage industry is seeing a surge in demand for natural, health-oriented drinks, and *Aigean*, a Seaweed & Elderflower infused water, fits perfectly into this evolving landscape.

This innovative product, aptly named after the Irish word for ocean, taps into the growing consumer interest in botanical-infused beverages and the use of seaweed, which is celebrated for its nutrient-rich properties.

As consumers increasingly seek out drinks that offer both hydration and functional benefits, *Aigean* stands out with its unique combination of seaweed and elderflower.

The use of seaweed introduces a mineral-rich, sustainable ingredient that resonates with eco-conscious consumers, while elderflower adds a delicate floral note, enhancing the overall drinking experience.

Incorporating elements from both land and sea, *Aigean* reflects the broader trend of blending traditional ingredients with innovative, health-focused concepts. This product not only aligns with the growing preference for clean-label, plant-based beverages but also highlights the potential for creativity in the functional drinks sector.

As consumers continue to look for new and exciting ways to stay healthy and hydrated, *Aigean* positions itself as a refreshing and forward-thinking option in the marketplace.

Group Members (Left to Right): Karen Hourigan, Simone Eynard, Julia Rodon

Jennifer Campbell, Programme Chair for the Food Science and Technology programmes commented, *"Attending the product presentations is always a highlight of the semester and this year was no exception. This project brings together a combination of science, business, culinary and marketing skills. It was fantastic to witness the creativity, dedication and teamwork displayed by our learners in this regard. Their innovative spirit and collaborative efforts truly shined through in their culinary creations"*.

Conclusion

The Food Product Innovation module showcase by our Food Science and Technology learners demonstrated an impressive array of innovative food products that align with current market trends. This module has real life applications and can be a starting point for product development for those seeking the first steps.

From free-from and vegan offerings to convenient snacks, health-focused beverages, and sustainable solutions, the learners showcased their ability to blend culinary creativity with scientific knowledge and market awareness.

These projects not only developed crucial skills such as teamwork and critical thinking but also resulted in shelf-ready products that address real consumer needs.

The high standards of the presentations and the learners' dedication were praised by the judges, highlighting the programme's success in preparing future food industry professionals to contribute meaningfully to the evolving landscape of food innovation.

Thank you to all the learners who allowed us to showcase their products in this article and well done on working so well together.

Exploring the Potential of Wearable Devices in Pharmacovigilance: Insights from Irish Consumers

Author: Iram Naz Ansari Original Dissertation Supervisor: Phillip Byrne

Programme: MSc in Pharmaceutical Business & Technology, Innopharma Education/Griffith College

Abstract

Wearable devices have emerged as a promising tool for enhancing pharmacovigilance, the process of monitoring and detecting adverse drug reactions (ADRs). This study aims to explore the feasibility and potential of using wearable technologies to improve ADR monitoring and reporting in Ireland.

The research employs a mixed-methods approach, combining quantitative and qualitative methods to gather insights from both healthcare professionals and the general public. A survey questionnaire is used to assess patient perceptions, attitudes, and experiences towards using wearable devices for health monitoring and ADR reporting, as well as to evaluate the potential of wearables to detect and report ADRs in real-time.

The findings show that the majority of participants are already using wearable devices, primarily for health monitoring and physical activity tracking. Participants identified several wearable device features and data points, such as heart rate, sleep patterns, and activity levels, as having the greatest potential for detecting and reporting ADRs in real-time. However, concerns were also expressed about the accuracy and reliability of wearable data, as well as patient privacy and data security issues.

Despite these challenges, the study participants generally expressed a positive outlook on the potential of wearable devices to enhance pharmacovigilance practices, particularly in the detection of uncommon, chronic, and subtle ADRs. The research also identified several strategies to encourage patient adoption and engagement with wearables for pharmacovigilance purposes, including improving device user-friendliness, providing education and awareness, offering financial incentives, and ensuring robust data privacy and security measures.

The findings of this study can inform the development of more effective and patient-centric pharmacovigilance systems, ultimately improving drug safety and patient outcomes in Ireland. The research also highlights the need for the development of ethical guidelines and regulatory frameworks to govern the collection, storage, and use of wearable data for pharmacovigilance purposes.

Introduction

Wearable devices have emerged as a promising tool for enhancing pharmacovigilance, the process of monitoring and detecting adverse drug reactions (ADRs). These devices can continuously collect real-time physiological data, potentially enabling earlier identification of ADRs compared to traditional methods (Berrewaerts *et al.*, 2016). This study aims to explore the feasibility and potential of using wearable technologies to improve ADR monitoring and reporting.

The research focuses on understanding current pharmacovigilance practices, assessing patient engagement with wearable devices, and evaluating the capability of wearables to detect ADRs. By gathering insights from both healthcare professionals and the general public, the study seeks to identify opportunities and challenges in leveraging wearable technologies to strengthen pharmacovigilance efforts (Smuck *et al.*, 2021). Specifically, the study aimed to answer the following research questions:

1. What are the current limitations and challenges in traditional pharmacovigilance practices for identifying uncommon, chronic, and subtle ADRs?

2. How willing are patients to use wearable devices for health monitoring and reporting of ADRs, and what are their perceptions and concerns?

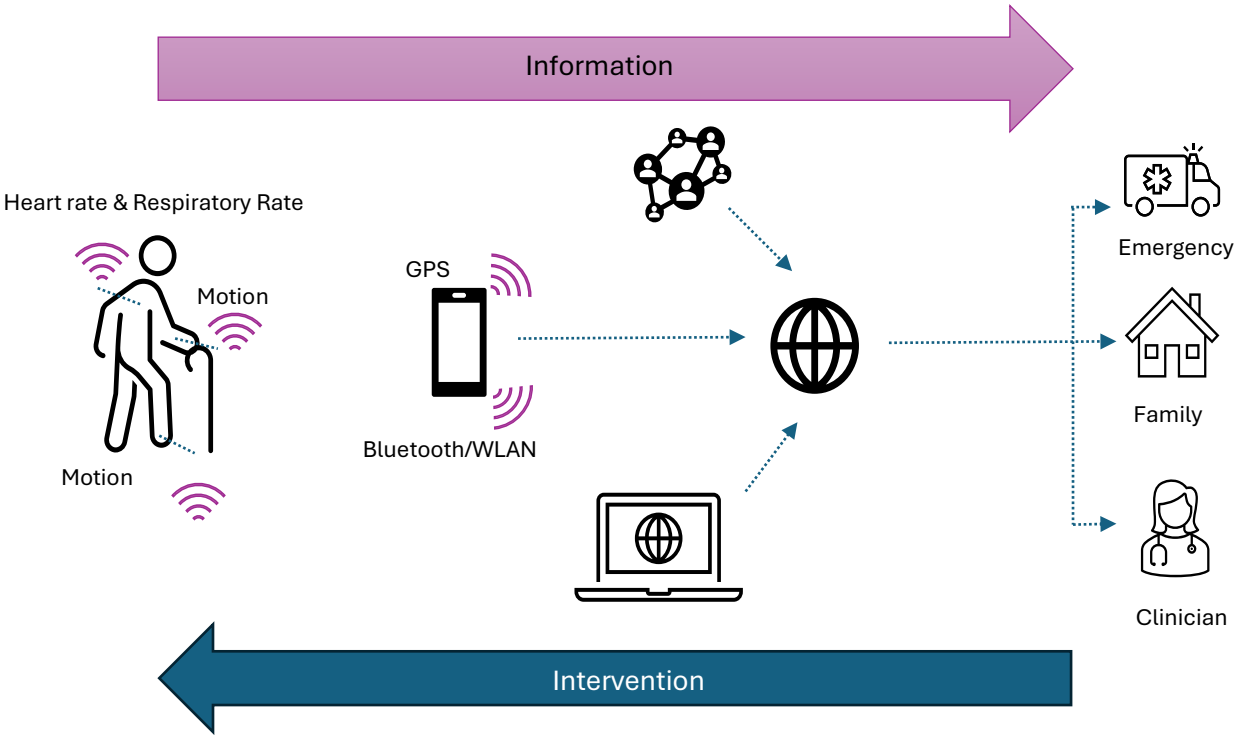
3. Which wearable device features and data points have the greatest potential for detecting and reporting ADRs in real-time?

4. What strategies can be employed to encourage patient adoption and engagement with wearables for pharmacovigilance purposes?

5. What are the key ethical and regulatory considerations in using wearable data for ADR monitoring and reporting?

Significance of the Research

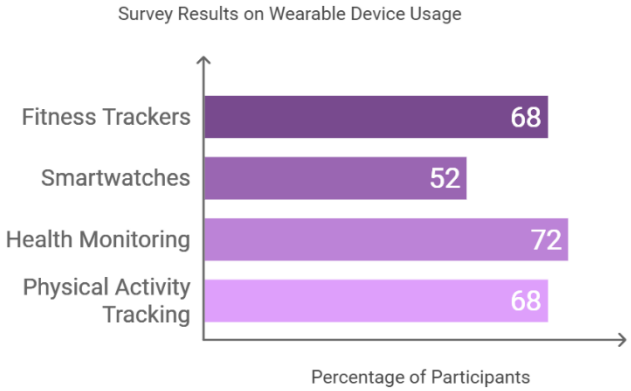
This study contributes to the growing body of research on the application of wearable technologies in healthcare, with a specific focus on enhancing pharmacovigilance practices. By exploring the perspectives of both healthcare professionals and the general public, the research provides a comprehensive understanding of the opportunities and challenges in leveraging wearables for real-time ADR detection and reporting the findings can inform the development of more effective and patient-centric pharmacovigilance systems, ultimately improving drug safety and patient outcomes.



Literature Review

Wearable Devices and Pharmacovigilance

Wearable devices have the potential to revolutionize pharmacovigilance by providing continuous, real-time physiological data that can be used to detect ADRs earlier and more accurately (Guan et al., 2022). These devices can monitor a wide range of health parameters, such as heart rate, activity levels, sleep patterns, and even biomarkers, which can serve as indicators of potential ADRs (Vijayan et al., 2021). Traditional pharmacovigilance methods, such as spontaneous reporting systems and clinical trials, have limitations in identifying uncommon, chronic, or subtle ADRs. Wearable devices can address these limitations by providing a more comprehensive and continuous view of a patient's health status, potentially enabling the detection of ADRs that may have been missed or underreported (Kaur, 2021).



Challenges and Opportunities in Wearable-Enabled Pharmacovigilance

One of the key challenges in using wearable devices for pharmacovigilance is the accuracy and reliability of the data collected. Wearable sensors can be susceptible to various sources of error, such as environmental interference, user error, and device limitations (Huhn *et al.*, 2022). Ensuring the validity and reliability of wearable data is crucial for its effective use in ADR detection and reporting. Another challenge is the integration of wearable data into existing pharmacovigilance systems. Seamless data exchange and interoperability between wearable devices, Electronic Health Records (EHRs), and pharmacovigilance databases are necessary to enable the effective use of wearable data for ADR monitoring (Vijayan *et al.*, 2021).

Despite these challenges, the opportunities presented by wearable-enabled pharmacovigilance are significant. Wearable devices can provide a more comprehensive and continuous view of a patient's health status, potentially enabling the detection of ADRs that may have been missed or underreported using traditional methods (Fossouo, Mcdonald and Wickramasinghe, 2022).Additionally, the real-time nature of wearable data can facilitate faster identification and response to emerging safety signals, leading to improved patient safety and drug development processes (Wadhwa *et al.*, 2021).

Ethical and Regulatory Considerations

The use of wearable data for pharmacovigilance raises important ethical and regulatory considerations. Ensuring patient privacy, data security, and informed consent are critical to maintaining public trust and adhering to data protection regulations, such as the General Data Protection Regulation (GDPR) (Berrewaerts *et al.*, 2016).

Ethical guidelines and regulatory frameworks need to be developed to govern the collection, storage, and use of wearable data for pharmacovigilance purposes. This includes addressing issues of data ownership, data sharing, and the potential for unintended use or misuse of the data (EMA, 2017).

Conceptual Framework

The conceptual framework for this study is based on the integration of wearable technologies, pharmacovigilance practices, and patient-centred care. The framework emphasises the importance of leveraging wearable data to enhance ADR detection and reporting, while also

considering the ethical and regulatory implications of this approach.

The framework consists of the following key components:

Wearable device features and data points: Identifying the most suitable wearable devices and data points for ADR monitoring and reporting.

Patient engagement and adoption: Understanding patient perceptions, attitudes, and willingness to use wearables for health monitoring and ADR reporting.

Pharmacovigilance practices and challenges: Examining the current limitations and challenges in traditional pharmacovigilance methods.

Ethical and regulatory considerations: Addressing the ethical and regulatory implications of using wearable data for pharmacovigilance.

Strategies for effective implementation: Developing approaches to encourage patient adoption and engagement with wearables for pharmacovigilance purposes.

Methodology

Research Philosophy and Approach

This study was guided by a pragmatic research philosophy, which emphasised the practical application of wearable technology to enhance patient safety and drug development. The research also aligned with the principles of evidence-based medicine, which prioritised the use of the best available data and real-time evidence to inform clinical practice and decision-making.

The research followed a mixed-methods approach, combining quantitative and qualitative methods to gather a comprehensive understanding of the research problem. This approach allowed for the collection of both numerical data and in-depth insights from participants, providing a more holistic view of the topic.

Research Strategy and Data Collection

The research strategy involved a cross-sectional study design, where data was collected at a specific point in time to evaluate the current state of wearable technology use and pharmacovigilance practices.

The primary data collection method was a survey questionnaire, which included both closed-ended and open-ended questions. The survey targeted two main groups of participants:

1. The general public who used or were considering using wearable devices, and
2. Healthcare professionals involved in pharmacovigilance programmes.

The survey questions covered the following key areas:

1. Participant demographics and background.

2. Experiences and perceptions of wearable devices.

3. Current pharmacovigilance practices and challenges.

4. Potential of wearable devices for ADR detection and reporting.

5. Ethical and regulatory considerations.

6. Strategies for encouraging patient adoption and engagement.

Sampling and Participant Selection

The study employed a combination of convenient and snowball sampling techniques to recruit participants. The survey was distributed through various online channels, including social media platforms and professional networks.

The inclusion criteria for participants were:

- Individuals living in Ireland who had used or were considering using wearable technology
- Healthcare professionals involved in pharmacovigilance programmes.

Data Analysis

The quantitative data from the survey was analysed using statistical software, such as SPSS or R. Descriptive statistics, correlation analyses, and regression

models were used to identify patterns, trends, and relationships between variables. The qualitative data from the open-ended survey questions was analysed using thematic analysis. The responses were coded, categorized, and synthesized to identify emerging themes and insights.

Ethical Considerations

The study adhered to the following ethical principles:

Informed consent: Participants were provided with a clear explanation of the study's purpose and their rights, and their consent was obtained before participation.

Data privacy and security: Participant data was anonymized, and strict data protection measures were implemented to ensure confidentiality.

Voluntary participation: Participants were informed that their participation was voluntary, and they could withdraw from the study at any time without consequences.

Minimising harm: The survey questions were designed to avoid causing any distress or harm to the participants.

Limitations and Delimitations

The study had several limitations, including:

1. Reliance on self-reported data from participants, which may have been subject to bias or inaccuracies.

2. The cross-sectional nature of the study, which may not have captured long-term trends or changes in wearable technology use and pharmacovigilance practices.

3. The focus on the Irish population, which may have limited the generalisability of the findings to other geographical regions.

The study was delimited to the following:

1. Exploring the use of wearable devices for pharmacovigilance, rather than other healthcare applications.

2. Focusing on the perspectives of the general public and healthcare professionals, rather than regulatory bodies or pharmaceutical companies.

3. Addressing ethical and regulatory considerations within the context of the Irish healthcare system and data protection regulations.

Results

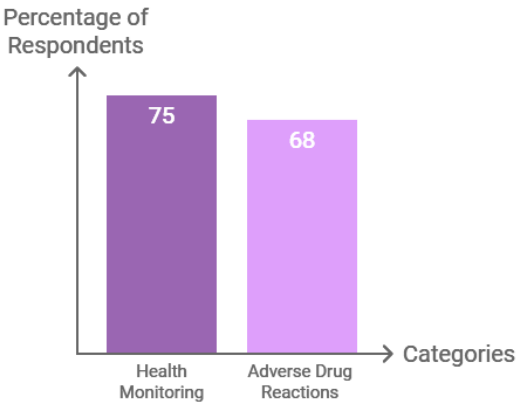
Participant Characteristics

A total of 101 participants completed the survey, with 100% of respondents indicating that they had read and understood the study's purpose. All participants provided informed consent to participate in the study. The majority of participants were female (64%), and the age distribution was relatively even, with the largest group being 31-40 years old (35%). Most participants were healthcare professionals (57%), with the remaining being members of the general public (43%). Regarding experience in pharmacovigilance, 42% of participants reported having some level of involvement, while 58% had no prior experience in this area.

Wearable Device Usage and Perceptions

The survey results showed that 82% of participants currently use or have used wearable devices, with the most common devices being fitness trackers (68%) and smartwatches (52%). The primary reasons for using wearables were health monitoring (72%) and physical activity tracking (68%).

When asked about their perceptions of wearable devices, participants generally had a positive outlook. Approximately



Perceptions of Wearable Devices

75% of respondents agreed that wearables are useful for health

monitoring, and 68% believed that these devices could help detect adverse drug reactions.

However, concerns were also expressed, with 52% of participants indicating that they were worried about the accuracy and reliability of wearable data, and 47% expressing concerns about data privacy and security.

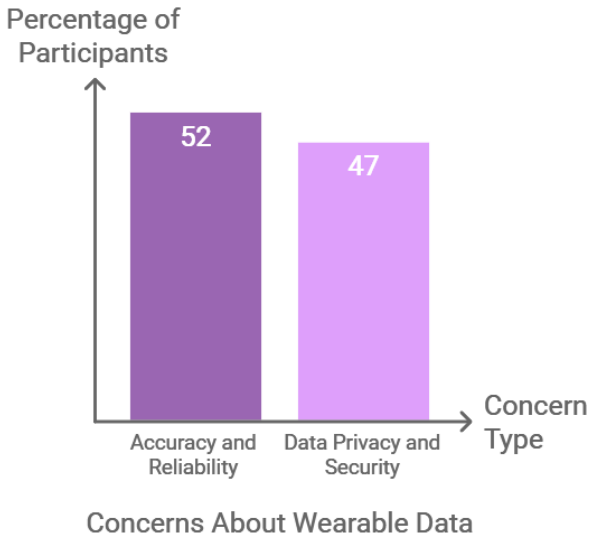
One respondent commented "Privacy by design and privacy by default should be the root of any wearable devices which step into the market. I believe the privacy factor should not be an afterthought. It should be integrated into a device rather than apply the principles of data privacy or security later on. Additionally, one has to keep in mind the device is going to be used by every spectrum of age. One should give more attention to privacy when making a device for elders as they might not understand privacy and security issues as an [younger] adult can."

Pharmacovigilance Practices and Challenges

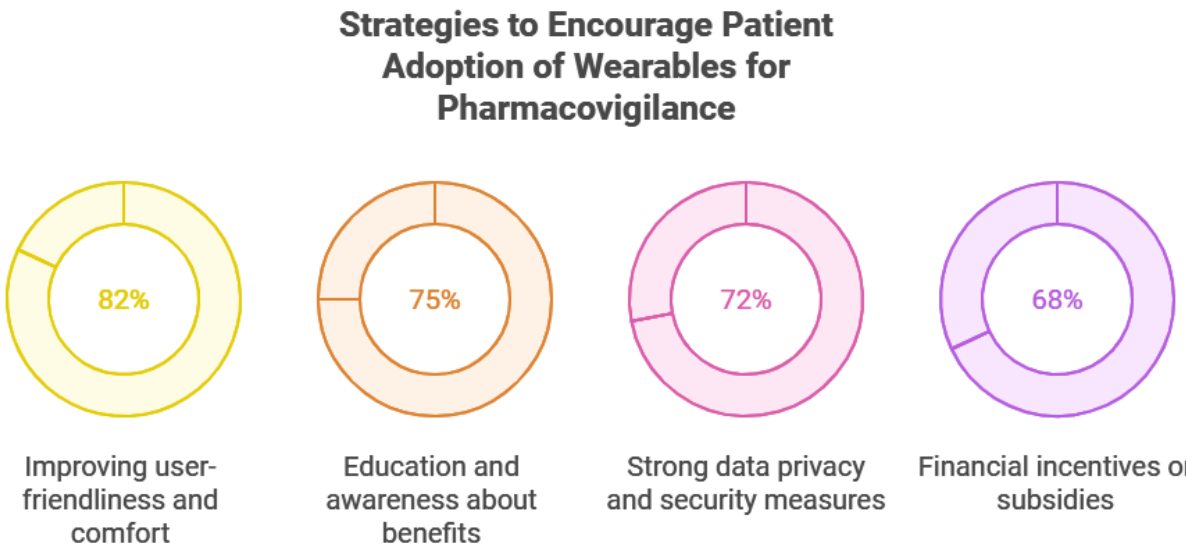
The survey revealed that 42% of participants were familiar with pharmacovigilance practices, while the remaining 58% had little to no knowledge in this area. Participants highlighted the limitations of current spontaneous reporting systems and clinical trials in detecting these types of ADRs, suggesting that technological advancements, such as wearable devices, could potentially improve pharmacovigilance efforts.

Wearable Devices for ADR Detection and Reporting

Participants also provided suggestions for additional wearable device features and data points that could be beneficial for pharmacovigilance, including blood pressure, body temperature, and biomarkers.



Concerns About Wearable Data



The majority of participants (72%) believed that wearable devices could help improve the detection and reporting of adverse drug reactions, with 68% indicating that they would be willing to use these devices for this purpose.

Strategies for Encouraging Patient Adoption

Participants suggested several strategies to encourage patient adoption and engagement with wearables for pharmacovigilance, including:

- Improving user-friendliness and comfort of devices (82%)
- Providing education and awareness about the benefits of using wearables for ADR reporting (75%)
- Offering financial incentives or subsidies to make wearables more affordable (68%)
- Ensuring strong data privacy and security measures to address patient concerns (72%)

Participants also emphasised the importance of clear communication about how wearable data would be used for pharmacovigilance and the need for transparent data governance policies.

Discussion

The findings of this study provide valuable insights into the potential of wearable technologies to enhance pharmacovigilance practices and improve the detection and reporting of adverse drug reactions (ADRs). The research aligns with the growing body of evidence suggesting that wearable devices can play a significant role in addressing the limitations of traditional pharmacovigilance methods (Vijayan *et al.*, 2021; Guan *et al.*, 2022;

Kargarandehkordi, Slade and Washington, 2024).

Wearable Devices and ADR Monitoring

The survey results indicate that the majority of participants are already using wearable devices, primarily for health monitoring and physical activity tracking. This suggests a general familiarity and openness among the public to engage with these technologies, which could be leveraged to improve pharmacovigilance efforts. Participants identified several wearable device features and data points, such as; heart rate, sleep patterns and activity levels, as having the greatest potential for detecting and reporting ADRs in real-time. This aligns with the existing literature, which highlights the ability of wearables to provide a more comprehensive and continuous view of a patient's health status, potentially enabling the identification of ADRs that may have been missed or underreported using traditional methods (Vijayan *et al.*, 2021; Guan *et al.*, 2022; Kargarandehkordi, Slade and Washington, 2024)

Challenges and Opportunities

The study findings also reveal the key challenges and concerns associated with the use of wearable devices for pharmacovigilance, including the accuracy and reliability of wearable data, as well as patient privacy and data security issues.

Despite these challenges, the study participants generally expressed a positive outlook on the potential of wearable devices to enhance pharmacovigilance practices, particularly in the detection of uncommon, chronic, and subtle ADRs.

Strategies for Encouraging Patient Adoption

The study identified several strategies to encourage patient adoption and engagement with wearables for pharmacovigilance purposes: including improving device user-friendliness, providing education and awareness, offering financial incentives, and ensuring robust data privacy and security measures.

Ethical and Regulatory Considerations

The study also explored the ethical and regulatory considerations surrounding the use of wearable data for pharmacovigilance. Participants expressed concerns about data privacy, security, and informed consent, which are critical factors in maintaining public trust and adhering to data protection regulations, such as the GDPR.

Limitations and Future Research

The study's limitations include the reliance on self-reported data, the cross-sectional nature of the research, and the focus on the Irish population, which may limit the generalisability of the findings. Future research could explore the long-term trends and changes in wearable technology use and pharmacovigilance practices, as well as expand the study to include other geographical regions and stakeholders, such as regulatory bodies and pharmaceutical companies.

Conclusion

This study aims to explore the feasibility and potential of using wearable technologies to enhance pharmacovigilance practices, with a focus on improving the detection and reporting of adverse drug reactions (ADRs). By gathering insights from both healthcare professionals and the general public, the research provides a comprehensive understanding of the opportunities and challenges in leveraging wearables for real-time ADR monitoring.

The findings of this study can inform the development of more effective and patient-centric pharmacovigilance systems, ultimately improving drug safety and patient outcomes. The research also addresses the ethical and regulatory considerations surrounding the use of wearable data for pharmacovigilance, ensuring that the implementation of these technologies is guided by principles of privacy, security, and informed consent.

The “mixed-methods” approach, combining quantitative and qualitative data, allows for a deeper exploration of the research problem and the generation of actionable insights. The study's pragmatic philosophy and alignment with evidence-based medicine ensure that the findings are grounded in practical solutions and the best available data.

Overall, this research contributes to the growing body of knowledge on the application of wearable technologies in healthcare, with a specific focus on enhancing pharmacovigilance practices. The findings can inform policymakers, healthcare professionals, and technology developers in their efforts to leverage wearable devices for improved drug safety and patient-centred care.

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Regulatory Challenges and Market Implications of MDR 2017/745 for Legacy Medical Devices

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Abstract

The transition of the Medical Device Directive (MDD) into the Medical Device Regulation (MDR) 2017/745 across the European Union has introduced significant regulatory and financial challenges for manufacturers of 'legacy' medical devices, particularly intra-articular devices used in the treatment of osteoarthritis. This study aims to explore the regulatory burden imposed by the MDR on these manufacturers and assess the potential impact on market availability and patient access.

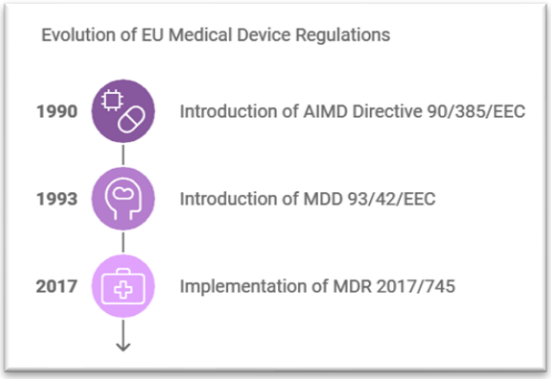
A mixed-method approach was employed, collecting data from surveys and interviews with industry professionals and MDR and legacy device subject matter experts to gather both quantitative and qualitative insights.

The findings indicate that the MDR's stringent requirements for clinical evidence and safety evaluations necessitate comprehensive clinical data, which many legacy devices lack due to their long-standing presence under the MDD. This has led to revisions in intended purpose, indications, and contraindications, potentially impacting patient access and market availability. The study highlights the disparity between the EU and US regulatory frameworks, with the US allowing for 'grandfathering' and substantial equivalence, facilitating easier market access. The increased regulatory burden poses significant financial and operational challenges, particularly for smaller manufacturers, potentially leading to market withdrawal and reduced patient access to essential treatments.

The study concludes that while the MDR aims to enhance patient safety and device quality, its implementation presents significant challenges for manufacturers and potential risks for patients. Recommendations include exploring collaborative approaches to data collection and sharing among manufacturers and providing more specific guidance on methodologies for collecting clinical evidence. This balanced approach is essential to ensure patient safety while facilitating market access and innovation.

Introduction

The regulatory landscape for medical devices in the European Union has undergone significant transformation with the introduction of the Medical Device Regulation (MDR) 2017/745. This regulation replaces the previous Medical Device Directive (MDD) 93/42/EEC and the Active Implantable Medical Device Directive (AIMD) 90/385/EEC, imposing more stringent requirements on manufacturers. The MDR's intention was to enhance patient safety by ensuring that medical devices meet high standards of quality and performance, but it also introduces substantial challenges for manufacturers, particularly those producing legacy devices.



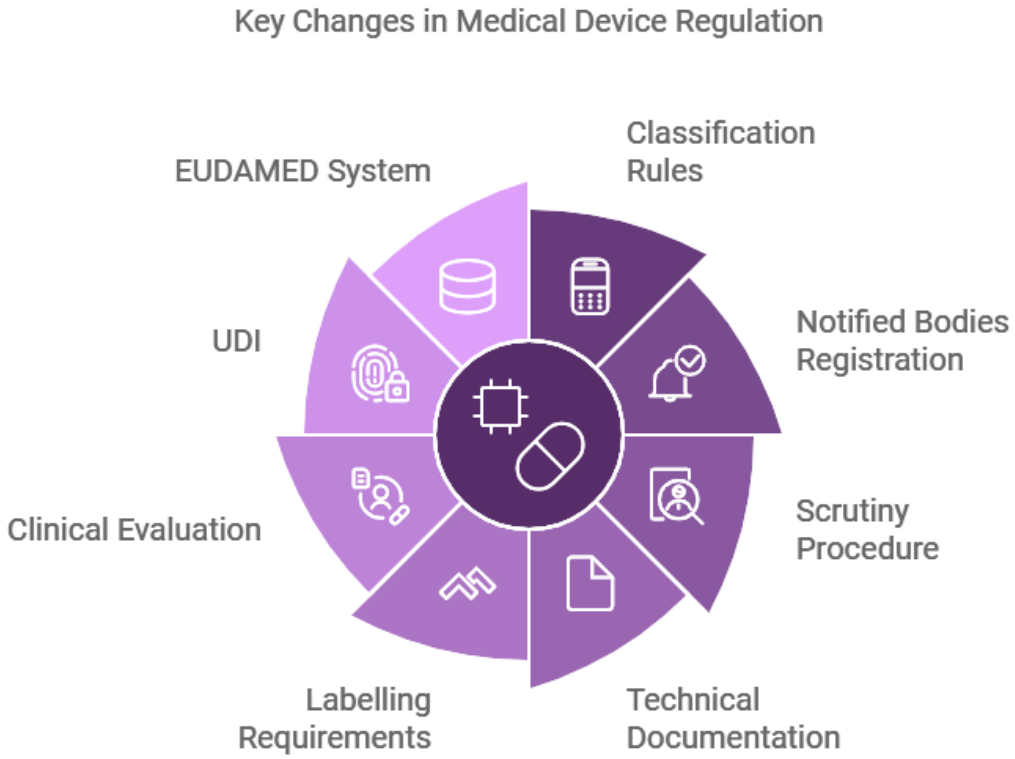
Legacy Devices

Legacy devices are older, long-established medical devices that have been on the market for a significant period, often before the modern regulatory frameworks were fully established. Legacy devices, such as intra-articular medical devices used for the treatment of osteoarthritis, face a unique set of challenges under the MDR. These devices, which have been available on the market for many years, now require re-evaluation to comply with the new regulatory standards. The MDR does not provide for 'grandfathering', meaning that all devices must be reassessed regardless of their history of use and safety record. This has significant implications for manufacturers, who must now provide comprehensive clinical evidence to demonstrate compliance with the MDR's General Safety and Performance Requirements (GSPRs).

From MDD to MDR

The transition from MDD to MDR presents a potential risk of market shortages, as manufacturers may struggle to meet the new requirements, possibly leading to the withdrawal of products from the market. This is particularly concerning for patients who rely on these devices for the management of osteoarthritis, a condition that significantly impacts quality of life. Osteoarthritis is prevalent among adults over 50 years of age and is characterised by joint pain and reduced mobility, which can lead to disability and a decrease in overall quality of life.

This study aimed to explore the regulatory burden imposed by MDR 2017/745 on manufacturers of legacy



Intra-articular devices and to assess the potential impact on market availability and patient access. It examined the key compliance challenges faced by manufacturers, compared the EU regulatory framework with that of the US, and evaluated the potential consequences for patients in the event of market shortages. The study also proposed possible solutions to ensure the continuity of supply and access to these essential medical devices.

Literature Review

Legacy Medical Devices under MDR

Legacy medical devices, such as intra-articular devices used for osteoarthritis treatment, face substantial challenges under the MDR. Unlike the US regulatory system, which allows for 'grandfathering' of existing products, the MDR requires all devices to be recertified, imposing a significant burden on manufacturers. The MDR's stringent requirements for clinical evidence and safety evaluations necessitate comprehensive clinical data, which many legacy devices lack due to their long-standing presence in the market under the previous Medical Device Directive (MDD) 93/42/EEC.

The MDR introduces new concepts such as 'clinical data', which refers to information concerning safety or performance generated from the use of a device. This data must be sourced from

clinical investigations, scientific literature, or post-market surveillance. The lack of grandfathering provisions means that even devices with a long history of safe use must undergo rigorous re-evaluation to comply with the MDR's standards. This has led to concerns about the potential withdrawal of legacy devices from the market, impacting patient access to essential treatments.

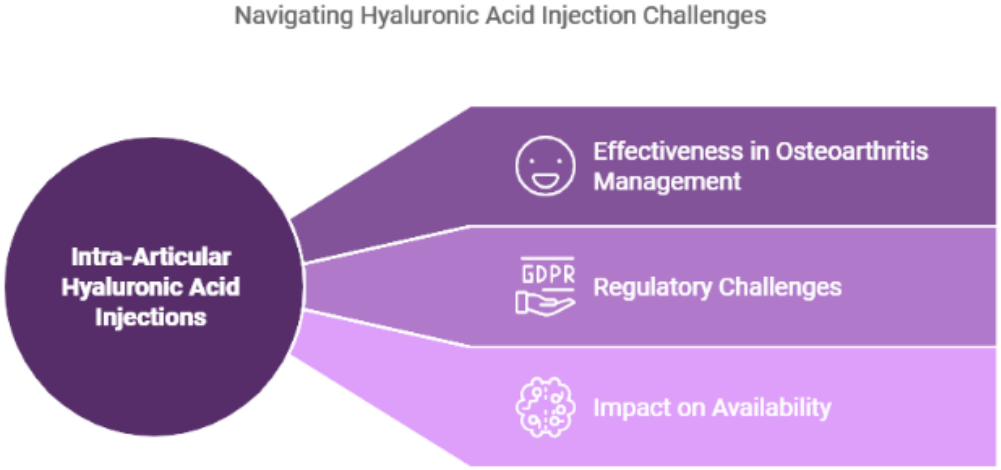
Differences between EU and US Regulatory Approaches

The US Food and Drug Administration (FDA) employs a risk-based classification system and allows for the use of predicate devices to demonstrate substantial equivalence, facilitating easier market access for legacy products. In contrast, the MDR's lack of grandfathering and more rigorous clinical evidence requirements make compliance more challenging for manufacturers in the EU. This disparity raises concerns about potential market shortages and reduced innovation within the EU (Maresova *et al.*, 2020).

The FDA's approach includes the 510(k) pathway, which allows manufacturers to demonstrate that a device is substantially equivalent to an existing product, thereby bypassing the need for extensive clinical trials. However, this system has been criticised for allowing devices with limited safety data to enter the market, as seen in the case of surgical meshes. The MDR's stricter requirements aim to prevent such issues by ensuring that all devices meet high safety standards, but this comes at the cost of increased regulatory burden for manufacturers (Zargar and Carr, 2018).

Benefits and Challenges of the MDR

While the MDR aims to enhance patient safety and device quality, it also poses significant compliance challenges for manufacturers. The regulation



mandates comprehensive clinical evaluations and continuous documentation, which can be particularly burdensome for smaller companies. The lack of specific guidance on collecting sufficient clinical evidence further complicates compliance efforts, as highlighted by the Medical Device Coordination Group's guidance documents (*Guidance - MDCG endorsed documents and other guidance - European Commission*, 2024).

The MDR's emphasis on clinical evaluation and investigation is intended to improve patient safety by ensuring that devices are thoroughly tested before reaching the market. However, the increased regulatory burden has led to concerns about potential market shortages of essential medical devices, such as those used in osteoarthritis treatment. Studies have shown that intra-articular hyaluronic acid injections are effective in managing osteoarthritis symptoms, but the stringent MDR requirements may limit their availability (Rosen, Niazi and Dysart, 2020).

Impact on Manufacturers and Patients

The increased regulatory burden has led to concerns about potential market shortages of essential medical devices, such as those used in osteoarthritis treatment. Studies have shown that intra-articular hyaluronic acid injections are effective in managing osteoarthritis symptoms, but the stringent MDR requirements may limit their availability. The potential withdrawal of legacy devices from the market could significantly impact patient access to these treatments, particularly for those who are ineligible for alternative therapies like NSAIDs (Bowden *et al.*, 2017). The MDR's requirements for clinical evidence have led many manufacturers to revise the intended purpose, indications, and contraindications of their devices to avoid costly clinical investigations. This has resulted in a reduction in the availability of devices for certain patient populations, potentially impacting patient access and quality of life (Kearney and McDermott, 2023).

Methodology

The research involved a mixed-methods approach, combining both qualitative and quantitative data collection techniques to provide a comprehensive understanding of the issues at hand.

Research Design

The research was structured around a pragmatic paradigm, utilising both deductive and inductive approaches to explore the research questions. The deductive approach involved testing existing theories and hypotheses about the regulatory challenges posed by the MDR, while the inductive approach

focused on generating new insights from the data collected.

Data Collection Methods

A structured survey was developed and disseminated via Microsoft Forms and LinkedIn to professionals within the medical device industry. The target profile was Quality and Regulatory Affairs professionals, aiming to gather quantitative data on the impact of the MDR on clinical evaluation processes and business operations.

The questionnaire included both closed and open-ended questions to capture a range of responses. Semi-structured interviews were conducted with subject matter experts, including clinicians, pharmacists, and marketing professionals, to gather qualitative insights into the real-world impact of the MDR on patient care and market availability. These interviews provided an opportunity to explore participants' experiences and perspectives in depth.

A comprehensive review of existing literature was conducted to identify gaps in current research and to inform the development of the research questions and data collection instruments. Key regulatory documents and academic studies were analysed to understand the broader context of the MDR's impact on legacy medical devices.

Data Analysis

The data collected from the surveys and interviews were analysed using thematic analysis for qualitative data and descriptive statistics for quantitative data. Thematic analysis involved identifying, analysing, and reporting patterns within the data, allowing for the exploration of key themes related to regulatory challenges and patient impact. Descriptive statistics provided a summary of the quantitative data, highlighting trends and patterns in responses.

Ethical Considerations

The research adhered to ethical guidelines to ensure the integrity and confidentiality of the data collected. Participants were fully informed of the study's purpose and their rights, including the right to withdraw from the study at any time. Informed consent was obtained from all participants, and data were anonymised to protect participants' identities.

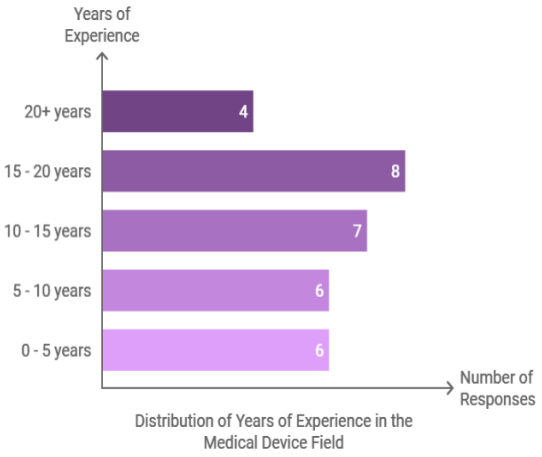
Limitations

The study faced certain limitations, including a relatively small sample size and potential biases in self-reported data. The findings may not be generalisable to all manufacturers or regions, and further research with larger and more diverse samples is recommended to validate the results.

In summary, this study employed a robust mixed-methods approach to investigate the regulatory challenges posed by the MDR 2017/745 on legacy intra-articular medical devices, providing valuable insights into the potential impact on market availability and patient access.

Results

The results were derived from a combination of surveys and interviews with industry professionals and subject matter experts.



Distribution of Years of Experience in the Medical Device Field

Survey Findings

Demographics and Expertise: The survey included 31 participants, primarily experienced professionals in regulatory affairs and quality assurance, with most having over five years of experience in the medical device industry. The majority were based in the European Union, providing insights into the regional impact of the MDR.

Device Classification and Reclassification: Respondents indicated that their devices were predominantly high-risk, legacy devices, with 17 out of 31 reporting reclassifications under the MDR. This reclassification reflects the increased regulatory scrutiny and complexity introduced by the MDR.

Understanding of MDR Requirements: Participants generally agreed that they understood the MDR requirements, including Notified Body scrutiny procedures, Economic Operator registration, EUDAMED functionality, and Technical Documentation. However, 20 out of 31 respondents noted that increased scrutiny of the supply chain posed significant challenges.

Clinical Evidence and Equivalence: Under the previous MDD, manufacturers heavily relied on equivalence data to meet clinical evidence requirements. With the MDR, data is now sourced from literature searches, clinical investigations, and post-market

surveillance. The guidance documents (MDCG 2020-5 and MDCG 2020-6) were deemed adequate, but the clinical evidence gathered under the MDD was often insufficient to meet the MDR's requirements, leading to revisions in intended purpose, indications, and contraindications.

Impact on Market and Sales: A third of surveyed manufacturers anticipated a decrease in patient access to their devices, and 50% expected a reduction in sales. This reflects the financial and operational burden of complying with the MDR, potentially leading to market withdrawal.

Interview Insights

Interviews with clinicians and marketing experts highlighted the critical role of intra-articular medical devices in managing osteoarthritis, particularly for patient's ineligible for NSAIDs. One interview participant noted that "Intra-articular therapies play a pivotal role in the management of the disease for those patients who present with Kellgren and Lawrence grade 2 and 3". The potential market shortage of these devices could significantly impact patient quality of life, leading to increased reliance on less effective treatments like NSAIDs, which have more side effects.

While Platelet Rich Plasma (PRP) therapy is emerging as an alternative, its widespread adoption is limited by insufficient clinical data supporting its efficacy and safety under the MDR. One experienced surgeon referred to PRP as "expensive and messy".

Experts noted that the MDR's stringent clinical evidence requirements pose a barrier to both legacy and innovative products, potentially stifling innovation and limiting patient access to effective treatments.

"Question 5 answers -

All interviewees agreed. Systemic drugs (such as oral NSAIDs) should be used with caution and according to patient medical history. Dosage of NSAIDs impacts the likelihood of side effects. Well-known possible side effects of NSAIDs are impacts to gastric mucosa, renal system, cardiovascular system, hepatic system. HA intraarticular injections compared to oral NSAIDs represent a safer option in those patients (i.e. elderly and those with comorbidities)."

Discussion

Regulatory Challenges

The MDR's requirement for comprehensive clinical data has posed a significant challenge for manufacturers of legacy devices, which were previously certified under the MDD. The lack of grandfathering provisions means that all devices must be re-evaluated,

regardless of their market history. This has led to a reliance on literature searches, clinical investigations, and post-market surveillance data to meet the MDR's clinical evidence requirements.

However, the study found that the clinical evidence gathered under the MDD is often insufficient to support the intended purpose, indication statements, and associated clinical benefits of the devices under the MDR. This has necessitated revisions to the intended purpose, indications, and contraindications of many devices, potentially impacting patient access and market availability.

Impact on Manufacturers

The increased regulatory burden has significant financial and operational implications for manufacturers. The study revealed that preparing technical documentation and clinical evaluation reports has been both costly and labour-intensive, often requiring additional resources and personnel. Many manufacturers have had to outsource these activities, further increasing costs. The potential for reduced sales, as indicated by nearly half of the respondents, places manufacturers in an unfavourable financial position, potentially leading to market withdrawal.

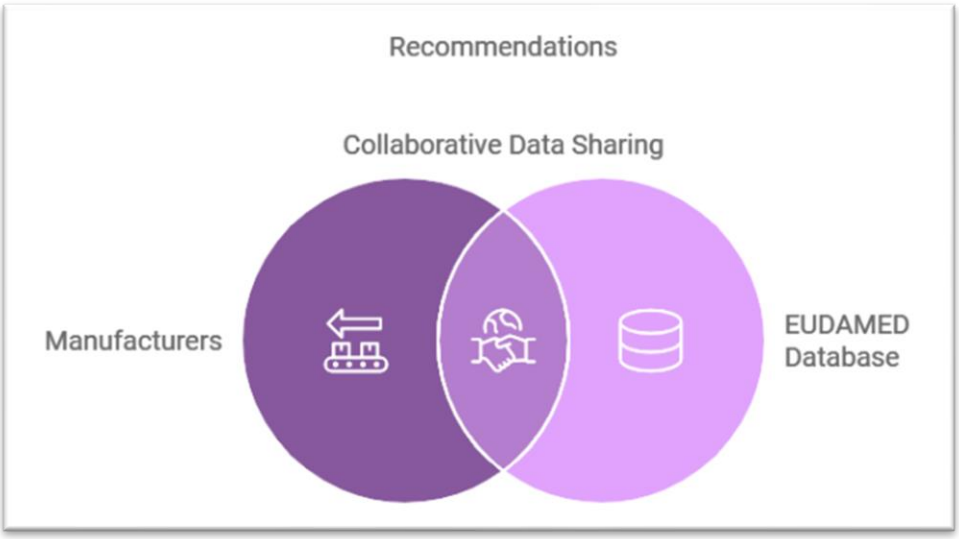
Patient Implications

The potential market shortage of intra-articular medical devices represents a serious concern for patients, particularly those with osteoarthritis who rely on these devices for symptom management. The study found that intra-articular hyaluronic acid injections are an effective and well-tolerated treatment for osteoarthritis, providing significant pain relief and improving quality of life.

However, the stringent MDR requirements may limit the availability of these devices, impacting patient access to essential treatments. This is particularly concerning for patients who are ineligible for alternative therapies, such as NSAIDs, due to other health issues.

Comparison with US Regulatory Framework

The study highlights the differences between the EU and US regulatory frameworks, with the US system allowing for grandfathering and substantial equivalence, facilitating easier market access for legacy products. In contrast, the MDR's lack of grandfathering and more rigorous clinical evidence requirements make compliance more challenging for EU manufacturers. This disparity raises



concerns about potential market shortages and reduced innovation within the EU.

Recommendations for Industry and Regulators

To address these challenges, the study recommends exploring collaborative approaches to data collection and sharing among manufacturers, potentially leveraging the EUDAMED database. This could facilitate the sharing of clinical data and reduce the burden on individual manufacturers.

Additionally, regulators should consider providing more specific guidance on methodologies for collecting sufficient clinical evidence, tailored to different device classes and technologies.

While the MDR aims to enhance patient safety and device quality, its

implementation poses significant challenges for manufacturers and potential risks for patients that need to be duly supported in the context of historic legacy devices. A balanced approach that ensures patient safety while facilitating market access and innovation is essential to address these challenges and ensure the continued availability of essential medical devices.

Conclusion

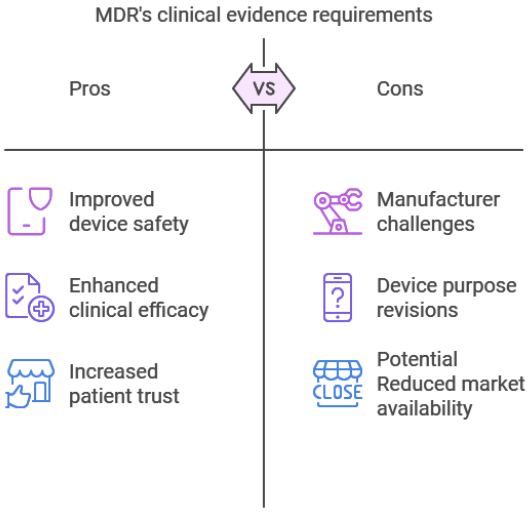
The study examined the regulatory challenges posed by the Medical Device Regulation (MDR) 2017/745 on manufacturers of legacy intra-articular medical devices and the potential impact on market availability and patient access. The findings underscore the significant regulatory and financial burdens introduced by the MDR, which require comprehensive clinical evidence and safety evaluations for all devices, including those with a long history of market presence under the previous Medical Device Directive (MDD).

The transition from the MDD to the MDR has not only increased the complexity of compliance for manufacturers but has

also raised concerns about the potential withdrawal of essential medical devices from the market. The study revealed that manufacturers face challenges in meeting the MDR's stringent clinical evidence requirements, often necessitating revisions to the intended purpose, indications, and contraindications of their devices. These changes could lead to reduced market availability and patient access, particularly for those who rely on these devices for managing osteoarthritis symptoms. The increased regulatory burden has significant financial and operational consequences for manufacturers, particularly smaller companies that may lack the resources to comply with the MDR.

The financial and operational challenges associated with preparing technical documentation and clinical evaluation reports could lead to market withdrawal, impacting patient access to essential treatments. The potential market shortage of intra-articular medical devices poses a significant risk to patients, particularly those with osteoarthritis who rely on these devices for symptom management.

To address these challenges, the study recommends exploring collaborative approaches to data collection and sharing among manufacturers, potentially leveraging the EUDAMED database. This could facilitate the sharing of clinical data and reduce the burden on individual manufacturers.



Additionally, regulators should consider providing more specific guidance on methodologies for collecting sufficient clinical evidence, tailored to different device classes and technologies.

In conclusion, while the MDR aims to enhance patient safety and device quality, its implementation poses significant challenges for manufacturers and potential risks for patients. A balanced approach that ensures patient safety while facilitating market access and innovation is essential. The study highlights the need for ongoing dialogue between regulators and industry stakeholders to develop practical solutions that support both regulatory compliance and patient access to essential medical devices.

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Revolutionising Pharmaceutical Manufacturing: The Role of Machine Learning in Process Optimisation

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Abstract

The pharmaceutical industry is experiencing a profound transformation through the integration of digitisation, automation, and big data analytics. This shift is particularly evident with the growing reliance on advanced computational techniques such as machine learning (ML). ML offers the potential to significantly enhance the effectiveness, efficiency, and cost optimisation of pharmaceutical manufacturing processes. By analysing critical process parameters and leveraging historical data, ML algorithms can optimise complex production processes, improve product safety and quality, and reduce development time, manufacturing time and costs.

This study aims to identify key areas in pharmaceutical manufacturing that could benefit from ML applications by evaluating the knowledge and awareness of operators and production managers regarding these technologies. Through a comprehensive analysis of existing literature and primary data collected from industry professionals, the study provides a critical overview of ML's current and potential applications in the sector.

The findings indicate a growing awareness of ML among pharmaceutical professionals, with significant potential identified for process optimisation, predictive maintenance, and quality control. However, challenges such as data quality, model interpretability, regulatory compliance, and skill gaps in the workforce remain significant barriers to widespread ML adoption. The study highlights the need for high-quality data, robust validation frameworks, and collaboration between industry and regulatory bodies to address these challenges.

Overall, this research underscores the transformative potential of ML in pharmaceutical manufacturing, offering insights that can guide future research and development efforts. By addressing the identified challenges, the industry can leverage ML to achieve more efficient, cost-effective, and high-quality pharmaceutical production processes.

Introduction

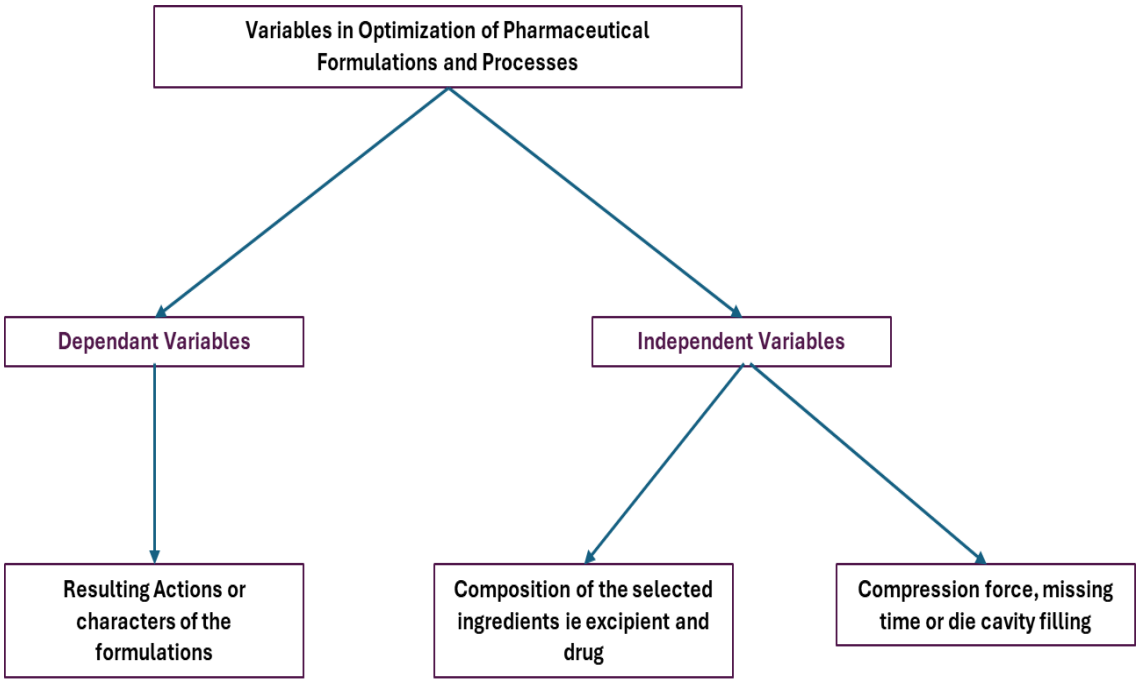
The pharmaceutical industry is undergoing a significant transformation through the implementation of digitisation, automation, and the use of big data generated throughout production processes (Mondal *et al.*, 2023). This has resulted in a full revolution of the industry at large.

The growing demand for the development of pharmaceutical products with a strong dependence on advanced computational techniques, such as machine learning (ML), has the potential to shift the pharmaceutical industry towards a more effective, efficient, and cost-optimized paradigm (Reklaitis, Khinast and Muzzio, 2010).

Pharmaceutical manufacturing involves numerous complex processes that can benefit from overall process optimisation and control through the use of ML models by analysing critical process parameters based on existing data and knowledge. This AI-driven approach has the potential to improve the safety, efficacy, and cost-effectiveness of drug production while also reducing the time and resources required for product development and manufacturing (Vora *et al.*, 2023).

The purpose of this study is to identify key areas of manufacturing that ML could potentially improve in the pharmaceutical sector by evaluating the knowledge and awareness of operators and production managers regarding the processes involved in manufacturing in pharmaceutical facilities.

The study aims to provide a critical overview of how ML can be applied during various stages of the manufacturing process through a comprehensive analysis of existing literature and primary data collected from professionals actively involved in pharmaceutical manufacturing processes. By understanding the current state of ML adoption and the potential benefits it can offer, this study aims to contribute to the growing body of knowledge on the application of AI and ML in the pharmaceutical industry and provide insights that can guide future research and development efforts in this area.



Literature Review

Overview of Pharmaceutical Process Optimisation

Pharmaceutical manufacturing processes are highly complex, involving numerous variables that require real-time monitoring (Tulsyan, Garvin and Ündey, 2018). According to Stranzinger *et al*. (2021) the quality of the material being processed is particularly sensitive to the powder density of the material entering the unit operation, as well as variations in density throughout the processing. As stated in a review by Shelke *et al* (2021), proficiency in statistical techniques, including design of experiments (DoE), optimisation, and multivariate data analysis, is crucial for examining the multi-factorial relationship and variable interaction to develop a product with appropriate quality attributes. The incorporation of advanced technologies such as artificial and manufacturing intelligence, in-process control, automation, digitalisation, and cloud architecture in pharmaceutical development can help resolve process variabilities of starting raw materials and ensure consistent product quality (O'Mahony *et al.*, 2022).

Pharmaceutical manufacturing processes are designed to produce safe, effective, and high-quality drug products while adhering to strict regulatory requirements. These processes involve a series of interconnected unit operations, each with its own set of critical process parameters (CPPs) and critical quality attributes (CQAs). Optimising these processes requires a deep understanding of the relationships

between the various input variables, such as raw material properties, process conditions, and equipment settings, and their impact on the final product quality (Khuat *et al.*, 2024). Traditional optimisation methods, such as one-factor-at-a-time (OFAT) experiments, are time-consuming, resource-intensive, and often fail to capture the complex interactions between variables. In contrast, modern optimisation techniques, such as design of experiments (DoE) and response surface methodology (RSM), enable researchers to explore the design space more efficiently and identify the optimal combination of process parameters that maximize product quality and minimize variability (Jariwala *et al.*, 2023).

Application of Machine Learning in Pharmaceutical Manufacturing Processes

Machine learning has the potential to significantly impact manufacturing process analysis and improvements, demonstrating successful outcomes across several pharmaceutical industrial sectors. However, the challenges associated with this technology and procedures are dependent on the type of data gathered by the industry and the specific manufacturing processes being optimised (Almanei *et al.*, 2021). ML has been applied in various areas of pharmaceutical manufacturing, including;

APIs and Solid Dosage Manufacturing

ML techniques, such as artificial neural networks (ANNs) and support vector machines (SVMs), have been used for tablet defect detection, process optimisation, and predictive modelling. These methods can help identify critical quality attributes (CQAs) and their relationships with critical process parameters (CPPs), enabling better process control and optimisation. For example, according to Zhou *et al (*2020) computer vision combined with neural networks has been used to detect tablet defects with high accuracy, reducing the need for manual inspection and ensuring consistent product quality.

Semisolid Dosage Manufacturing

The inherent instability of emulsions makes them challenging to process, and utilising manufacturing vessels equipped with programmable logic controllers (PLCs) optimises the precision and dependability of regulating the mixing speed, flow rate, and duration. ML algorithms can help predict the stability of emulsions and optimise the manufacturing process parameters to ensure consistent product quality and reduce waste (Sakthivel *et al.*, 2021).

Biopharmaceutical Manufacturing

ML algorithms, both supervised and unsupervised, have been applied in various stages of biopharmaceutical

manufacturing, such as process development, optimisation, and predictive maintenance. Supervised learning methods, such as artificial neural networks (ANNs) and support vector machines (SVMs), have been used to predict critical quality attributes (CQAs) and optimise process parameters. Unsupervised learning methods, such as principal component analysis (PCA) and k-means clustering, have been used to identify process trends and outliers, enabling early detection of process deviations and improved process control (Rathore *et al.*, 2023).

Benefits of Using Machine Learning for Pharmaceutical Process Optimisation

The incorporation of ML in pharmaceutical manufacturing processes can provide several benefits, including:

Improved product quality and consistency

ML algorithms can help identify critical process parameters (CPPs) and their relationships with critical quality attributes (CQAs), enabling better process control and optimisation. According to Tulsyan *et al* (2018) by monitoring and controlling key process parameters in real-time, ML can help ensure consistent product quality and reduce the risk of out-of-specification batches.

Reduced manufacturing costs

ML-based predictive models can help optimise process parameters, reduce waste, and minimize the need for costly trial-and-error experiments. By identifying the optimal combination of process parameters that maximize product quality and minimize variability, ML can help reduce the number of failed batches and the associated costs of raw materials, energy, and labour (Rathore *et al.*, 2023).

Faster product development

ML-based models can accelerate the development of new drug products by enabling rapid screening of formulations and process parameters as explored by Vamathevan *et al (*2019). Through leveraging historical data and predictive models, researchers can explore the design space more efficiently and identify promising candidates for further development, reducing the time and resources required for product development.

Improved equipment maintenance and reliability

ML algorithms can be used to predict equipment failures and optimise maintenance schedules, reducing downtime and improving overall equipment effectiveness (OEE). By analysing sensor data and historical maintenance records, ML can identify

patterns and trends that indicate impending failures, enabling proactive maintenance and reducing the risk of unplanned downtime (Rai *et al.*, 2021).

Challenges and Limitations Encountered in Machine Learning Incorporation

While ML has significant potential in pharmaceutical manufacturing, there are several challenges and limitations to its implementation, including:

Data quality and availability

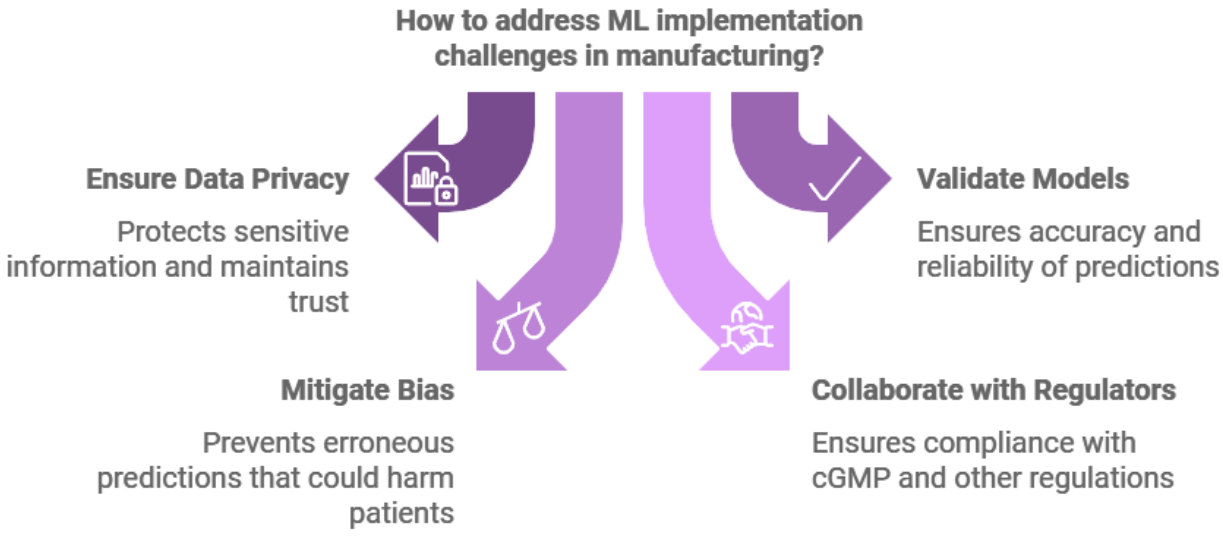
The success of ML models depends on the quality and quantity of data available for training. Pharmaceutical manufacturing data may be incomplete, inconsistent, or biased, which can lead to poor model performance. Ensuring data quality and availability is a critical challenge that must be addressed before implementing ML in anufacturing processes (Wuest *et al.*, 2016).

Regulatory and ethical concerns

The use of ML in pharmaceutical manufacturing raises regulatory and ethical concerns related to data privacy, model validation, and the potential for biased or erroneous predictions that could impact patient safety. Pharmaceutical companies must work closely with regulatory agencies to ensure that ML-based systems are compliant with current Good Manufacturing Practices (cGMP) and other relevant regulations.

Skill gaps and workforce training

Implementing ML in pharmaceutical manufacturing requires a workforce with specialised skills in data science, machine learning, and process engineering. Many pharmaceutical companies lack the in-house expertise required to develop and deploy ML models and must either hire new talent or invest in training existing employees. Bridging the skill gap is a critical



challenge that must be addressed to drive widespread adoption of ML in the industry (Flores-García *et al.*, 2023).

Methodology

The study utilized a mixed-methods approach, combining a comprehensive literature review with a quantitative survey of professionals actively involved in pharmaceutical manufacturing processes.

Research Philosophy and Strategy

The study adopted a pragmatic research philosophy, which focuses on the research problem and uses multiple methods to derive knowledge about the phenomenon of interest. The research strategy was a cross-sectional survey, as data was collected from participants at a single point in time. This approach was chosen because it allows for the collection of data from a large sample of participants in a relatively short period of time, enabling the researchers to gain a snapshot of the current state of ML adoption and perceptions in the pharmaceutical industry.

Questionnaire Development and Data Collection

A structured questionnaire was developed based on the literature review and input from subject matter experts. The questionnaire consisted of three sections: demographics, awareness of ML in pharmaceutical manufacturing, and the application of ML for process optimisation. The survey was administered online to a sample of 90 participants, including process managers, operators, industry experts, and quality assurance and control officers in Ireland. The online format was chosen because it allows for easy distribution to a geographically dispersed sample and enables participants to complete the survey at their convenience.

The questionnaire was designed to collect both quantitative and qualitative data. Quantitative questions were used to gather information on the participants' familiarity with ML, their perceptions of its benefits and challenges, and their opinions on specific applications of ML in pharmaceutical manufacturing. Qualitative questions were used to gather more detailed information on the participants' experiences and perspectives, and to identify any additional factors that may influence the adoption of ML in the industry.

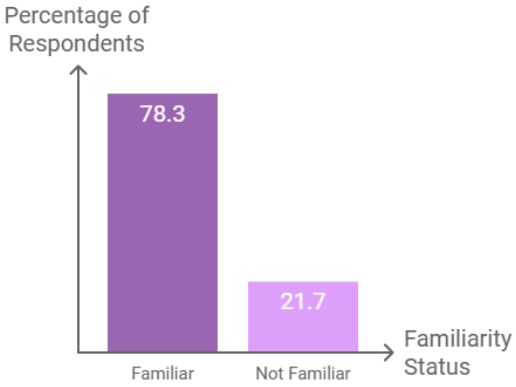
Data Analysis

Quantitative data from the survey was analysed using descriptive statistics, such as frequencies, percentages, and measures of central tendency. Statistical software was used to analyse the data, with results presented in tables, charts, and graphs. This approach was chosen because it allows for the identification of patterns and trends in the data and enables the researchers to draw conclusions about the overall population based on the sample.

Qualitative data from the open-ended questions was analysed using thematic analysis. The researchers identified key themes and patterns in the responses and used these themes to supplement and contextualise the quantitative findings. This approach was chosen because it allows for a more in-depth understanding of the participants' perspectives and experiences and enables the researchers to identify any additional factors that may influence the adoption of ML in the industry.

Results

The study achieved an overall response rate of 69%, with the majority of participants being process managers (35%) and quality assurance/control officers (30%). Most participants had 5-10 years of work experience in the pharmaceutical industry (45%).



Familiarity with ML and AI

Key findings from the survey include:

Awareness of ML in pharmaceutical manufacturing

60% of participants were familiar with ML techniques, with the most commonly known algorithms being artificial neural networks (ANNs) and support vector machines (SVMs). This finding suggests that while there is growing awareness of ML in the industry, there is still room for improvement in terms of educating professionals about the potential applications and benefits of these technologies.

Potential areas for ML application

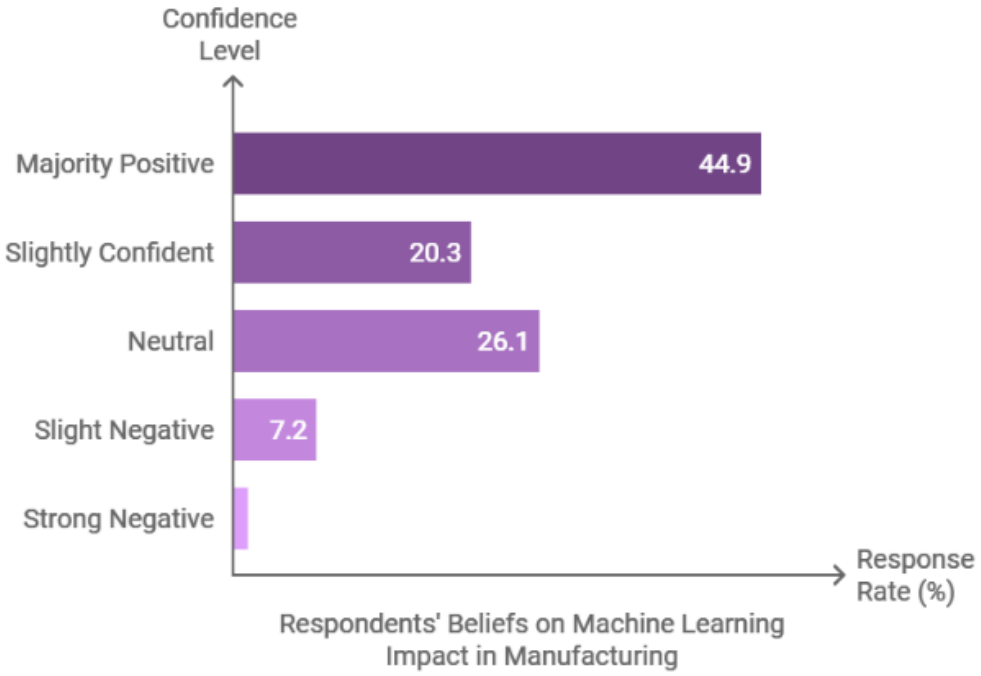
Participants identified several areas where ML could potentially improve pharmaceutical manufacturing, including process optimisation (70%), predictive maintenance (65%), and quality control (60%). These findings align with the literature, which suggests that ML has significant potential to enhance various aspects of

pharmaceutical manufacturing, from optimising process parameters to predicting equipment failures and ensuring consistent product quality.

Challenges in implementing ML

The most prevalent challenges in implementing ML, according to participants, were data quality and availability (75%), regulatory concerns (65%), and interpretability of ML models (55%). These findings highlight the importance of addressing these challenges in order to drive widespread adoption of ML in the pharmaceutical industry, investing in data infrastructure, develop robust validation and governance frameworks for ML models, and engage with regulatory agencies to ensure compliance.

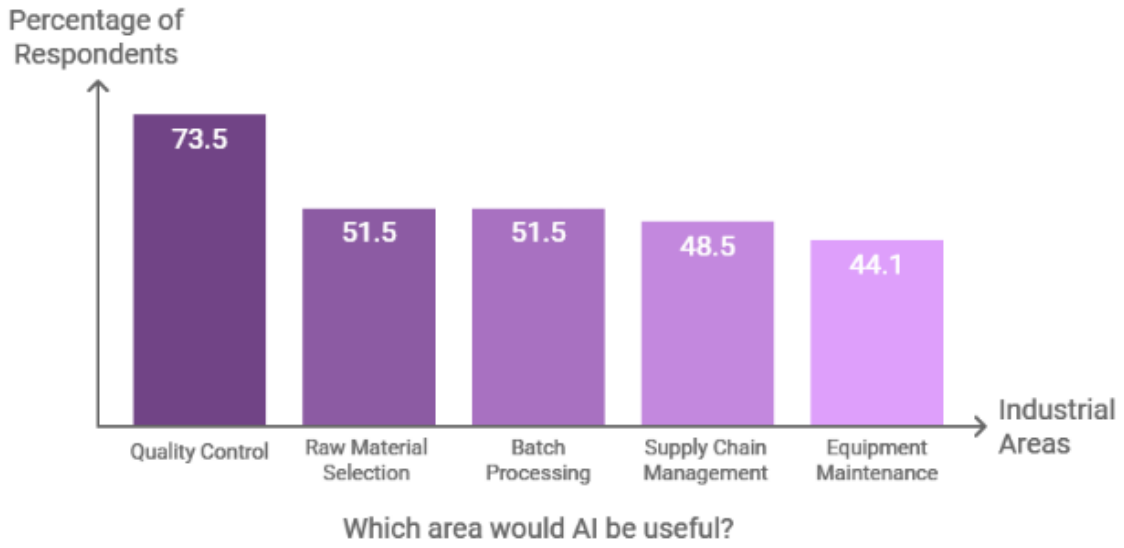
Impact of ML on critical process parameters



80% of participants believed that ML could help monitor and control critical process parameters (CPPs) more effectively, with the most important CPPs being mixing time, temperature, and pressure. This finding suggests that professionals in the industry recognise the potential of ML to enhance process control and optimise product quality.

Awareness of specific ML algorithms

Participants were most familiar with artificial neural networks (ANNs, 55%) and support vector machines (SVMs, 45%). This finding suggests that these algorithms are the most used and well-known in the pharmaceutical industry, likely due to their proven effectiveness in various applications



such as tablet defect detection, process optimisation, and predictive modelling.

Perceptions of ML benefits

Participants were generally positive about the potential benefits of ML in pharmaceutical manufacturing, with 75% indicating that they believe ML can improve product quality and consistency, and 70% believing that ML can reduce manufacturing costs. These findings align with the literature, which suggests that ML has significant potential to enhance various aspects of pharmaceutical manufacturing, from improving product quality to reducing costs and accelerating product development.

Challenges in implementing ML

In addition to the challenges identified above, participants also highlighted the need for specialised skills and training as a key barrier to implementing ML in the industry. 60% of participants indicated that a lack of in-house expertise in data science and machine learning is a significant challenge, and 50% believe that workforce training is necessary to drive adoption of these technologies. These findings suggest that pharmaceutical companies must invest in upskilling their workforce and attracting talent with specialised skills in order to successfully implement ML in their manufacturing processes.

Discussion

The findings of this study align with the existing literature on the application of ML in pharmaceutical manufacturing. The potential benefits of ML, such as improved product quality, reduced manufacturing costs, and faster product

development, are well-documented. However, the challenges and limitations identified in this study, such as data quality, interpretability, and regulatory concerns, are also consistent with the literature.

The survey results highlight the growing awareness and interest in ML among pharmaceutical professionals. However, the adoption of ML in the industry is still limited, likely due to the challenges and concerns raised by participants. To overcome these barriers, pharmaceutical companies need to invest in data infrastructure, develop robust validation and governance frameworks for ML models, and engage with regulatory agencies to ensure compliance.

One key finding from the study is the importance of specific ML algorithms in pharmaceutical manufacturing. Participants were most familiar with ANNs and SVMs, which have been widely used in various applications such as tablet defect detection, process optimisation, and predictive modelling. This suggests that these algorithms may be the most promising for driving adoption of ML in the industry, as they have a proven track record of success and are well-understood by professionals.

Another important finding is the need for specialised skills and training to implement ML in pharmaceutical manufacturing. Participants highlighted the lack of in-house expertise in data science and machine learning as a significant barrier to adoption. This suggests that pharmaceutical companies must invest in upskilling their workforce and attracting talent with specialised skills to successfully implement ML in their manufacturing processes.

Overall, the findings of this study provide valuable insights into the current state of ML adoption in the pharmaceutical manufacturing industry and the key areas where ML can potentially improve process optimisation. The results suggest that while there is significant potential for ML to enhance pharmaceutical manufacturing, there are also several challenges that must be addressed before widespread adoption can occur.

Conclusion

This study provides valuable insights into the current state of ML adoption in the pharmaceutical manufacturing industry and the key areas where ML can potentially improve process optimisation. The findings suggest that while there is significant potential for ML to enhance pharmaceutical manufacturing, there are also several challenges that need to be addressed before widespread adoption can occur.

One of the key challenges identified in this study is the need for high-quality data and robust data infrastructure to support the development and

deployment of ML models. Pharmaceutical companies must invest in data governance frameworks, data cleaning and preprocessing tools, and secure data storage solutions to ensure that their data is of sufficient quality and quantity to train accurate ML models.

Another important challenge is the need for interpretable and explainable ML models that can be easily understood and validated by regulatory agencies and quality assurance professionals. While black-box models such as deep neural networks may offer superior performance, they can be difficult to interpret and may not meet the stringent requirements for explainability in highly regulated industries like pharmaceuticals. Developing ML models that balance performance and interpretability is an active area of research and development.

Regulatory and ethical concerns are also a significant barrier to the adoption of ML in pharmaceutical manufacturing. Pharmaceutical companies must work closely with regulatory agencies to ensure that their ML-based systems are compliant with current Good Manufacturing Practices (cGMP) and other relevant regulations. They must also address ethical concerns related to data privacy, model bias, and the potential for erroneous predictions that could impact patient safety.

Future research should focus on developing ML models that are more interpretable and explainable, while also ensuring that they are robust, reliable, and compliant with regulatory requirements. Collaboration between industry, academia, and regulatory agencies will be crucial in driving the adoption of ML in pharmaceutical manufacturing and realising its full potential for improving product quality, reducing costs, and accelerating drug development.

In conclusion, this study highlights the significant potential of ML to enhance pharmaceutical manufacturing processes, from optimising process parameters to predicting equipment failures and ensuring consistent product quality.

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Exploring Consumer Perceptions and Willingness to Consume Snail Meat as an Alternative Protein Source in Ireland

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Abstract

The growing global population and increasing demand for protein-rich foods has led to the exploration of alternative protein sources, especially those that are sustainable and environmentally friendly. Snail farming (SF) has emerged as a promising alternative to conventional meat production, offering a protein-rich food with a lower environmental impact. This study aimed to investigate consumer perceptions and willingness to consume snail meat in Ireland. A mixed-methods approach was used, involving a questionnaire (n=56) and interviews with snail farmers (n=4). The results revealed that while awareness of SF was relatively low, those who had tried snails had a positive perception. Key factors influencing willingness to consume snails included affordability, availability, safety, and social acceptance. The findings suggest that increasing consumer education and availability of snail products could enhance the adoption of snail meat as an alternative protein source. Further research is needed to explore the scalability and commercialization of SF to meet the growing demand for sustainable protein.

Introduction

The global population is expected to reach 9-10 billion by 2050, leading to an increased demand for protein-rich foods. This escalating demand for protein-rich foods could strain agricultural resources and exacerbate challenges in sustainably feeding the world (Food and Agriculture Organization of the United Nations, 2018). Conventional meat production has significant environmental impacts, including greenhouse gas emissions, deforestation, and water pollution (Oosting *et al.*, 2022). To address these environmental and food security concerns, there is a growing interest in exploring alternative protein sources that are more sustainable and environmentally friendly (Ismail *et al.*, 2020).

Snail farming (SF) has emerged as a promising alternative to conventional meat production. Snails are a protein-rich food source with a lower environmental impact compared to traditional livestock (Ghosh, Jung and Meyer-Rochow, 2016; Hatziioannou *et al.*, 2021).

Snails have higher feed conversion efficiency and produce fewer greenhouse gas emissions compared to traditional livestock producing equivalent protein.

Given the potential benefits of snail meat, consumer acceptance and willingness to consume it as an alternative protein source are crucial for its widespread adoption. Understanding consumer perceptions and the factors influencing their willingness to consume snail meat can inform strategies to promote its acceptance and integration into the food system.

This study aimed to investigate consumer perceptions and willingness to consume snail meat as an alternative protein source in Ireland. Specifically, the study explored the following research questions:

1. What are the current levels of awareness and perceptions of snail farming and consumption among consumers in Ireland?
2. What factors influence consumers' willingness to consume snail meat?
3. How do consumers perceive the potential contribution of snail consumption to addressing global food security?

Literature Review

Snail Farming and Snail Meat as an Alternative Protein Source

Snail farming is the practice of raising snails for human consumption or other commercial purposes. Snails are cold-blooded invertebrates that can be raised in various farming systems, including outdoor, indoor, and mixed systems (Zucaro *et al.*, 2016). As a protein-rich food source, their potential as a sustainable alternative to conventional meat production has been discussed by several authors (Forte *et al.*, 2016; Ghosh, Jung and Meyer-Rochow, 2016; Zucaro *et al.*, 2016).

Hayes and Mora (2021) discuss the potential of snail meat as a valuable source of nutrition; it is high in protein and has an excellent amino acid profile, making it a potentially valuable source of nutrition. Several researchers have examined the environmental benefits of consuming snail meat. Compared to traditional meat sources like beef, pork, and chicken, snail meat has a lower carbon footprint. It also requires fewer resources to produce the same amount of protein-rich meat. (Forte *et al.*, 2016; Shafiullah *et al.*, 2018).

The feed conversion ratio (FCR) is a metric used to measure the efficiency of an animal in converting feed into weight gain. Snails have a significantly lower FCR compared to larger livestock, indicating their higher efficiency in converting feed into biomass (Rygało-Galewska, Zglińska and Niemiec, 2022). This efficiency, combined with their lower resource requirements, makes snails a more sustainable protein source.

Environmental Impact and Sustainability of Snail Farming

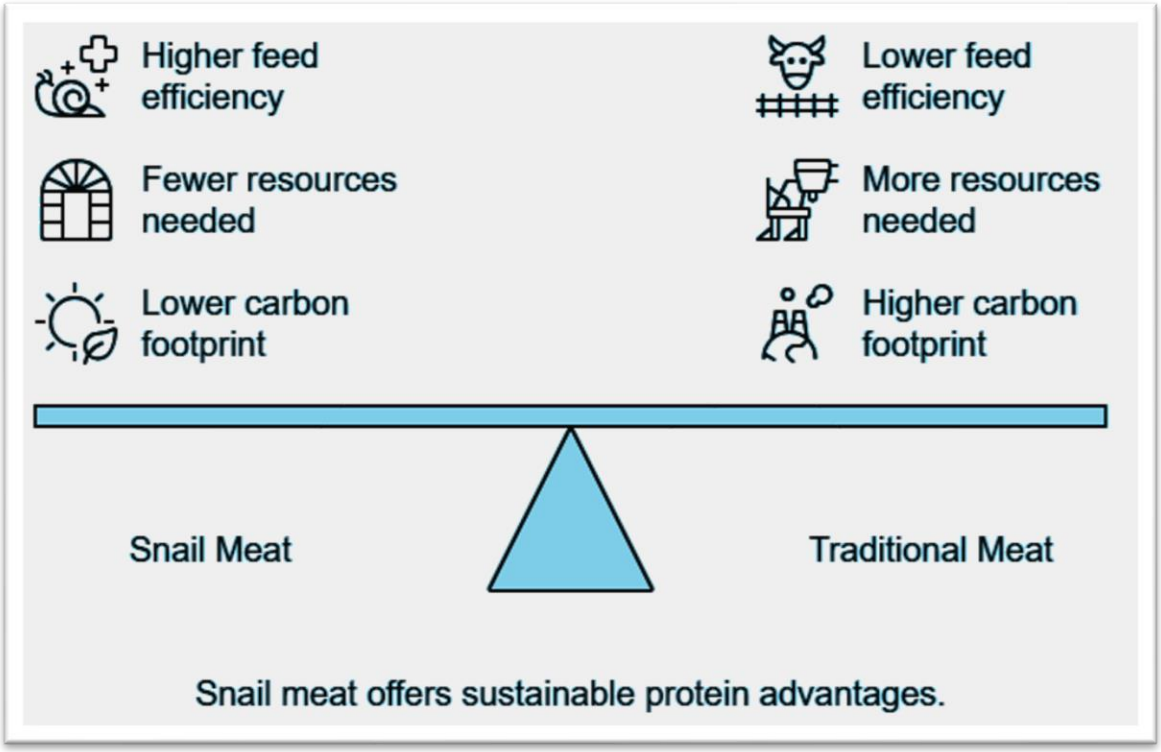
The environmental impact of SF has been studied in relation to its contribution to global warming. Several studies have found that snail meat production has a lower carbon footprint compared to conventional meat sources (Forte *et al.*, 2016; Grossi *et al.*, 2019; Hatziioannou *et al.*, 2021). Snails can also bind carbon dioxide in their shells, further reducing their environmental impact (Forte *et al.*, 2016).

In addition to lower greenhouse gas emissions, SF has other environmental advantages. Snails can be fed with a range of waste products, such as maize shafts and succulent vegetables, reducing the strain on global food production (Ghosh, Jung and Meyer-Rochow, 2016). SF also requires less land compared to traditional livestock farming, as there is no need for additional land expansion for feed production (Zucaro *et al.*, 2016).

The sustainability of SF is further enhanced by its low capital investment and low-technology management requirements, making it a more accessible and scalable option for protein production (Zucaro *et al.*, 2016).

Consumer Perceptions and Willingness to Consume Snail Meat

Exploring consumer perceptions and willingness to consume snail meat is crucial for the successful integration and acceptance of this alternative protein source into the food system. Ismail *et al* (2020) looked at factors that may influence consumer acceptance and found they included include awareness, familiarity, cultural preferences, and concerns about food safety and sustainability.



Studies have shown that consumer awareness and familiarity with snail consumption can vary significantly across different regions and cultures. In some regions, snail consumption is more common, while in others, it may be perceived as unfamiliar or even undesirable (Tuhumury, 2021).

Pissia *et al* (2021) found that concerns about food safety, such as the presence of toxins or bacteria, can also impact consumer openness to snail meat. Proper processing and handling of snails, including the removal of the hepatopancreas, are essential to ensure food safety.

Other factors that may influence consumer willingness to consume snail meat include affordability, availability, and social acceptance. Consumers may be more willing to try snail meat if it is easily accessible, competitively priced, and socially accepted within their communities (Ismail *et al.*, 2020).

Understanding the factors that influence consumer perceptions and willingness to consume snail meat can inform strategies to promote its adoption as an alternative protein source. This includes educational campaigns, improving product availability and affordability, and addressing any food safety concerns.

Methodology

This study employed a mixed-methods approach, combining a questionnaire and semi-structured interviews, to investigate consumer perceptions and willingness to consume snail meat in Ireland.

Questionnaire

A questionnaire was developed using Microsoft Forms and distributed online to a sample of consumers in Ireland. The questionnaire consisted of the following sections:

1. Demographic information: Age, gender, and location.
2. Knowledge and perception of snail farming: Participants were asked if they had heard of snail farming and their perception of it (positive, neutral, or negative).
3. Snail consumption: Participants were asked if they had tried snails and their perception of the experience (liked, neutral, or did not like).
4. Willingness to consume snails: Participants were asked to rate their likelihood of consuming snails under different conditions (e.g., if the snails were disguised in a food they liked, if the snails were affordable, if the snails were easily available) on a 5-point Likert scale.
5. Factors influencing snail consumption: Participants were asked to identify any concerns or factors that would influence their willingness to consume snails.
6. Perception of snail consumption's contribution to global food security: Participants were asked to rate their perception of the potential contribution of snail consumption to addressing global food security.

Interviews

Semi-structured interviews were conducted with four snail farmers in Ireland to gain a deeper understanding of snail farming practices and the industry's perspective. The interview questions covered the following topics:

- Snail farming methods and production processes
- Challenges and opportunities in the snail farming industry
- Perspectives on consumer perceptions and willingness to consume snail meat
- Strategies for promoting the adoption of snail meat as an alternative protein source

Data Analysis

The quantitative data from the questionnaire was analysed using descriptive statistics, including frequencies, percentages, and measures of central tendency. The qualitative data from the interviews was transcribed and analysed using thematic analysis to identify key themes and insights.

Results

Questionnaire Results

A total of 56 participants completed the questionnaire. Most participants were female (64.3%) and aged between 25-34 years (35.7%).

Awareness and Perceptions of Snail Farming

The results showed that 56% of the participants had heard of snail farming, with the majority (57.1%) having a neutral perception of it. Only 14.3% had a positive perception, while 28.6% had a negative perception.

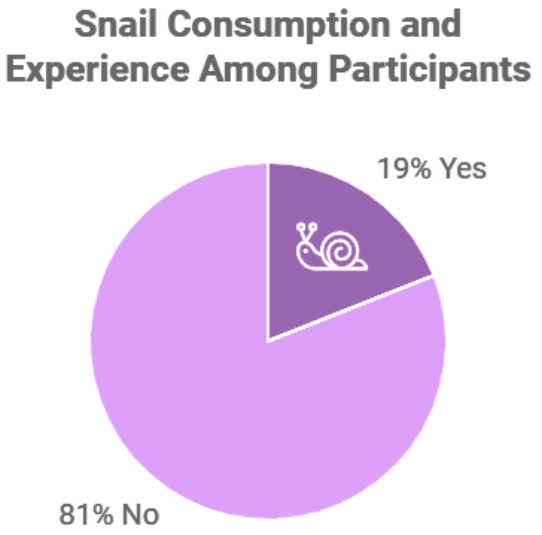
The primary sources of information about snail farming were social media (35.7%) and personal experience (28.6%).

Snail Consumption

Only 35.7% of the participants had tried snails, and of those, 50% had a positive perception, 40% had a neutral perception, and 10% did not like the experience.

Willingness to Consume Snails

Participants were most willing to consume snails if they were disguised in a food they liked (mean = 3.57) or if the snails were affordable (mean = 3.54). They were least willing to consume



snails as a substitute for meat (mean = 2.89).

Factors Affecting Willingness to Consume Snails

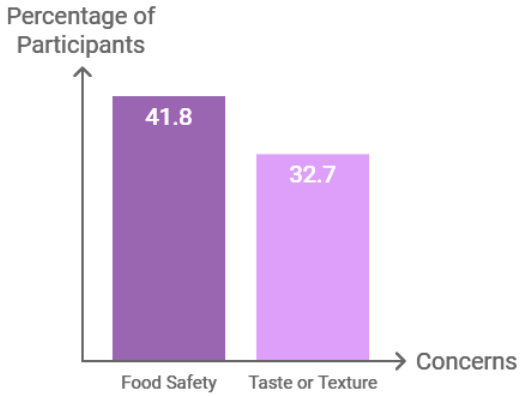
The primary concerns that would affect participants' willingness to consume snails were food safety (41.8%) and the taste or texture of snails (32.7%).

Perception of Snail Consumption's Contribution to Global Food Security

Participants had a generally positive perception of the potential contribution of snail consumption to addressing global food security, with 46.4% rating it as "somewhat positive" and 25% rating it as "very positive".

Interview Results

The interviews with four snail farmers in Ireland offered valuable insights into the snail farming industry and consumer attitudes toward incorporating snail meat into their diets.



Primary Concerns Affecting Willingness to Consume Snails

Snail Farming Practices

The snail farmers described their farming methods, which included both outdoor and indoor systems. The outdoor systems utilised natural environments, such as pastures and wooded areas, while the indoor systems involved the use of polytunnels and feeding tables.

The farmers emphasized the importance of proper handling and processing of the snails to ensure food safety, including the removal of the hepatopancreas. The hepatopancreas is an organ found in many invertebrates, including snails. It functions similarly to the liver and pancreas in vertebrates. The hepatopancreas is responsible for the production of digestive enzymes, the absorption of nutrients, and the storage and metabolism of various substances.

Challenges and Opportunities in the Snail Farming Industry

The snail farmers highlighted several challenges, such as seasonal production, the need for specialized knowledge, and limited consumer awareness and acceptance.

However, they also recognised the potential opportunities in the snail farming industry, particularly in addressing environmental and food security concerns, as well as the growing demand for alternative protein sources.

Strategies for Promoting Snail Meat Consumption

The snail farmers suggested that increasing consumer education and awareness, improving product availability and affordability, and addressing food safety concerns could help promote the adoption of snail meat as an alternative protein source.

Discussion

The findings of this study provide valuable insights into consumer perceptions and willingness to consume snail meat as an alternative protein source in Ireland.

The relatively low awareness of snail farming among the participants suggests that more educational efforts are needed to inform consumers about the benefits and sustainability of this alternative protein source. Increasing awareness and familiarity could help overcome any negative perceptions and foster greater acceptance of snail consumption.

Factors such as affordability, availability, and food safety, which influence consumer interest in trying snails, align with previous research on the acceptance of alternative protein sources (Ismail *et al.*, 2020). Addressing these concerns through targeted marketing, product development, and regulatory measures could enhance the adoption of snail meat.

The recognition of the potential contribution of snail consumption to global food security is a positive finding, as it suggests that consumers are aware of the need for sustainable protein sources to meet the growing demand. Leveraging this awareness and promoting the environmental and nutritional benefits of snail meat could further drive its acceptance.

The insights from the snail farmers provide valuable industry perspectives on the challenges and opportunities in the snail farming sector. Addressing the barriers to production, such as seasonality and specialised knowledge requirements, could help increase the availability and affordability of snail products, making them more accessible to consumers.

The study's limitations include the relatively small sample size and the focus on a single geographic region

(Ireland). Future research could explore consumer perceptions and willingness to consume snail meat in other countries and regions, as well as investigate the scalability and commercialisation of snail farming to meet the growing demand for sustainable protein.

Conclusion

This study provides valuable insights into consumer perceptions and willingness to consume snail meat as an alternative protein source in Ireland. The findings suggest that while awareness of snail farming is relatively low, those who have tried snails generally have a positive perception. Key factors influencing willingness to consume snails include affordability, availability, safety, and social acceptance.

The recognition of the potential contribution of snail consumption to global food security is a promising finding, indicating that consumers are aware of the need for sustainable protein sources. Addressing the barriers to snail farming and promoting the environmental and nutritional benefits of snail meat could enhance its adoption as an alternative protein source.

Further research is needed to explore consumer perceptions and willingness to consume snail meat in other regions, as well as the scalability and commercialization of snail farming to meet the growing demand for sustainable protein. Nonetheless, this study highlights the potential of snail meat as a viable and environmentally friendly alternative to conventional meat production.

Snail meat has the potential to serve as a sustainable and nutritious alternative protein source, particularly in light of the growing global population and increasing demand for protein-rich foods. Snails are a protein-rich food source with a lower environmental impact compared to traditional livestock, requiring fewer resources and producing lower greenhouse gas emissions (Forte *et al.*, 2016; Ghosh, Jung and Meyer-Rochow, 2016; Hatziioannou *et al.*, 2021)

The findings of this study suggest that while awareness of snail farming and consumption is relatively low in Ireland, those who have tried snails generally have a positive perception. Key factors influencing willingness to consume snail meat include affordability, availability, food safety, and social acceptance. Participants also recognised the potential contribution of snail consumption to addressing global food security.

To promote the adoption of snail meat as an alternative protein source, it is crucial to address the barriers to consumption, such as lack of awareness and concerns about food safety. Increasing consumer education and awareness through media campaigns and hands-on experiences, such as cooking classes,

could help overcome these barriers (Mustonen and Tuorila, 2010; Siegrist, Sütterlin and Hartmann, 2018; Baker *et al.*, 2022). Improving product availability and affordability, as well as ensuring proper processing and handling of snails, are also essential to enhance consumer acceptance (Ismail *et al.*, 2020).

Promoting the environmental and nutritional benefits of snail meat could further drive its acceptance as a sustainable protein source.

While this study provides valuable insights into consumer perceptions and willingness to consume snail meat in Ireland, further research is needed to explore these factors in other regions and investigate the scalability and commercialisation of snail farming to meet the growing demand for sustainable protein. Nonetheless, this study highlights the potential of snail meat as a viable and environmentally friendly alternative to conventional meat production, with the ability to contribute to global food security.

Snail farming has the potential to address the growing demand for protein-rich foods while mitigating the environmental impact of conventional meat production. Research shows that consumption to addressing global food security, with 46.4% rating it as "somewhat positive" and 25% rating it as "very positive". To encourage snail

snails are a highly efficient protein source, requiring fewer resources and producing lower greenhouse gas emissions compared to traditional livestock. The sustainability of snail farming is further enhanced by its low capital investment and low-technology management requirements, making it a more accessible and scalable option for protein production (Zucaro *et al.*, 2016).

Despite the potential benefits of snail meat, consumer acceptance and willingness to consume it as an alternative protein source are crucial for its widespread adoption. This study aimed to investigate consumer perceptions and willingness to consume snail meat in Ireland, exploring the current levels of awareness, factors influencing willingness to consume, and perceptions of snail consumption's contribution to global food security.

The findings suggest that while awareness of snail farming is relatively low in Ireland, those who have tried snails generally have a positive perception. Key factors influencing willingness to consume snails include affordability, availability, food safety, and social acceptance. Participants also recognized the potential contribution of snail

consumption, taste testing and education are recommended, while government support is necessary to aid Irish snail farmers.

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