# COMPARATIVE STUDY OF QUALITY ASSURANCE AND REGULATORY GUIDELINES BETWEEN IRELAND (H.P.R.A.) AND INDIA (C.D.S.C.O)

**(A Research Study)**

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## Declaration

I confirm that the submitted work is my original creation and that all necessary attributions have been made. I certify that this work has not been submitted for credit toward a degree or diploma at this or any other institution.

Signed: **K. Jahnavi**

Date: 13th May, 2023

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## Abbreviations

EMA-European Medicines Agency

HPRA- Health Products Regulatory Authority

CDSCO- Central Drugs Standard Control Organization

FDA- Food and Drug Administration

GMP- Good Manufacturing Practices

cGMP- current good manufacturing practices

WHO- World Health Organization

CFR- Code of Federal Regulations

ICH- International Conference on Harmonization

RMP- risk management programs

EU- European Union

CAPA- Corrective and Preventive Actions

DMAIC- Define," "Measure," "Analyze," "Improve," and "Control

CI- continuous improvement

QA-Quality Assurance

PAT- Process analytical technologies

ISO- International Organization for Standardization

GLP- Good Laboratory Practice

PQS- Pharmaceutical Quality System

GCP- Good Clinical Practice

DCGI- Drug Controller General of India

TQM-Total Quality Management

CPD- Continuous professional development

## Abstract

Scientific researchers from every corner of the world agree that the most pressing issue facing the pharmaceutical industry today is ensuring that the products it produces are of the highest possible quality. There has been a rise in awareness within the pharmaceutical industry regarding the significance of the product's quality as a result of the coming together of various nations with the goal of harmonizing their practices along with implementing FDA, current Good Manufacturing Practices (GMP). This knowledge is expressed by a variety of standards, rules, and definitions that specify exactly how the quality of pharmaceutical items should be.

Pharmaceutical Quality assurance involves good manufacturing practices, inspection, quality risks management, pharmaceutical quality guidelines, and sampling operations, among others. Pharmaceutical quality assurance is achieved through the following Internal audits, employee training, minimizing or eliminating deviation, documenting control, ongoing improvement of quality management systems, and recurring management reviews. A number of research studies have compared pharmaceutical quality assurance in several countries across the globe, but it is only a few have compared pharmaceutical quality assurance between two countries, i.e., India and Ireland, having different pharmaceutical regulatory systems.

Pharmaceutical quality assurance in nations such as India and Ireland are reinforced based on their respective regulatory bodies, such as CDSCO and HPRA, respectively. The HPRA governs the regulatory guidelines of medicines in Ireland, while CDSCO, on the hand, governs the regulatory guidelines of medicines in India. This research study aims at investigating how the quality assurance regulatory systems are varied in two different nations.

The methodology of this research involves an online survey questionnaire using both a qualitative and quantitative approach. Data were collected from a total number of 99 research participants from both India and Ireland. These participants involved manufacturers, physicians and pharmacists. Secondary research has also been useful in this research study in terms of providing a comprehensive overview concerning the research topic.

The conclusion of this research study was based on the general view of the pharmaceutical quality assurance systems implemented in both India and Ireland. This research study will serve as a reference material for improving the quality assurance system for pharmaceutical products in the two mentioned countries. Also helps for researcher's secondary research when dealing with a related research topic.

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# CHAPTER 1

## 1.1. Introduction:

Today, pharmaceutical products quality within the industry is regarded as the most critical topic by scientific researchers across the globe. Since different nations have come together with the aim of harmonizing their practices as well as guides together with the implementation of the F.D.A, current Good Manufacturing Practices (G.M.P.), within the pharmaceutical sector, there has been a greater understanding of the importance of product quality (Haleem et al., 2015).

Since the year 2002, FDA launched a program to address G.M.P.s for the 21st century to make sure medicinal drugs reaching patients are effective, safe, and of the required quality (Bouwman-Boer and Møller Andersen, 2015). Therefore, this research will compare the quality assurance as well as the related regulatory guidelines between Ireland and India. The research paper will mainly focus on the role played by the Health Products Regulatory Authority (H.P.R.A.) in Ireland and the Central Drugs Standard Control Organization (C.D.S.C.O.) in India regarding quality assurance of pharmaceutical products.

## 1.2. Research Rationale

This study investigates how the quality assurance regulatory systems are varied in two different nations, i.e., Ireland and India. Because India uses CDSCO while Ireland, on other hand, uses HPRA, this research will enable us to gain a comprehensive understanding of how pharmaceutical quality assurance systems operate in the aforementioned nations. The study researches how information (quality guidelines and standards) concerning pharmaceutical quality assurance flows from the relevant authorities to the pharmaceutical manufacturers, physicians, pharmacists, patients, and the general public.

## 1.3. Problem Statement

According to current research, quality assurance is one of the most crucial parts of the entire medication manufacturing process. It not only helps pharmaceutical corporations safeguard their public image, but it also allows them to escape harsh regulatory penalties. This is the major reason why any pharmaceutical organization involved with quality assurance should receive pharma training to help them remain compliant. The main objective of pharmaceutical quality assurance is the medicinal products produced should offer required effect to patients or general public. In addition to that, other researchers have also argued that quality assurance provides a guarantee with no contaminants and the products fulfil the quality requirements as well as be in compliance

with all the related regulations.

Despite being beneficial, there has been a significant increase in cases regarding drug quality issues, i.e., poor quality drugs and drugs with defects being sold in the market. This has resulted in a number of consequences, such as increased healthcare costs, an increase in death cases, a closing down of pharmaceutical organizations, withdrawal of drugs from the market, and a negative reputation, losing licenses among others. To improve the health of the general public, effective pharmaceutical quality assurance is required which closely monitors manufacturing process, and a system to monitor and control medicines quality and report any quality issues for ensuring the safety of the patients and the general public, as well as the high quality of the manufactured drug products. For example, Mulchandani and Kakkar (2019) have revealed that India does not have an effective system for filing complaints concerning drug quality issues because of insufficient awareness among physicians as well as inadequate training on the importance of pharmaceutical quality assurance. To effectively demonstrate how the quality of medicines can be ensured and improved, this research will specifically compare the quality assurance of medicines in Ireland and India using the regulatory bodies; HPRA and CDSCO, respectively.

## 1.4. Research Aim/Purpose and Objectives

### 1.4.1. Research Aim/Purpose

Since the patients, as well as the consumers, are the most important people that must be protected from consuming medicines of low quality, this research will aim at assessing how the pharmaceutical quality assurance and related regulatory guidelines between Ireland (H.P.R.A.) and India (C.D.S.C.O.) are reinforced.

Pharmaceutical quality assurance ensures that medication has the desired effect on the patient. Quality assurance also ensures that no contaminants are present and that the pharmaceuticals fit all quality norms and laws. This definition involves ensuring the safety of the patients and the general public, protecting the reputation of the pharmaceutical manufacturing company from negative publicity, ensuring continuous production efficiency and guaranteeing compliance with any relevant regulation related to pharmaceutical quality assurance. This research involves an evaluation of two different regulatory bodies, i.e., CDSCO and HPRA, from India and Ireland, respectively. Evaluation also involves a comparative analysis of these two different regulatory bodies in terms of their pharmaceutical quality assurance system in their country.

### 1.5.2. Research Objectives

1) To determine if the physicians from Ireland and India have experienced any issues concerning the quality of medicines.
2) To determine if pharmacists from the two countries perceive the quality assurance system as being effective.
3) To identify how the pharmaceutical manufacturers from both India and Ireland ensure the quality of medicines.
4) To evaluate how HPRA and CDSCO ensure the quality of medicines in Ireland and India, respectively.

The topic of research is linked to the following module: Pharmaceutical Technology Transfer, Regulatory Landscape of Pharmaceutical Business.

## 1.6. Research Question

1) Do the physicians from Ireland and India have any experience with quality issues regarding the quality of medicines?
2) Do pharmacists from both India and Ireland perceive the pharmaceutical quality assurance system as being effective?
3) How do pharmaceutical manufacturers from Ireland and India ensure the quality of medicinal drugs?
4) How do HPRA and CDSCO ensure the quality of medicines in Ireland and India, respectively?

## 1.7. Research Hypothesis

**Hypothesis 1:** An effective pharmaceutical quality assurance system guarantees the manufacturing of high-quality medicines and the safety of the patients.

**Hypothesis 2:** Regulatory bodies, i.e., HPRA and CDSCO, play a major role in ensuring patient safety.

### 1.8. Research Summary

The first chapter, which is an introduction, has given a brief overview and background concerning the regulatory bodies in Ireland and India, i.e., HPRA and CDSCO, respectively. Other important sections within the introduction chapter include research significance, research rationale, problem statement, research aim, research objectives, research questions, and research hypothesis.

### 1.9. Dissertation Structure

The whole dissertation will be divided into five main chapters. The first chapter of this dissertation will be the introduction. In this chapter, the research topic has been researched from scratch, just after a comprehensive analysis of the research aim, hypothesis, objective, problem statement, and research question. The second chapter is the literature review, where the most important aspects of the research have been researched concerning the pharmaceutical quality assurance between two different nations, i.e., Ireland (HPRA) and India (CDSCO). The third chapter is the research methodology, where relevant information and strategy is adopted while collecting primary data. The methodology ensures that data occurrence during the process of gathering data will be carried out ethically and legally. The fourth chapter of this dissertation will be data analysis and discussion. SPSS Microsoft software and Tableau is used to analyze the collected primary data within a specific timeframe. This chapter will also include a discussion of the findings from the data analysis process. The last chapter will be recommendations and conclusions, where by the research will provide a summary of the findings based on the analyzed data from the fourth chapter. The research will also provide suggestions for future research.

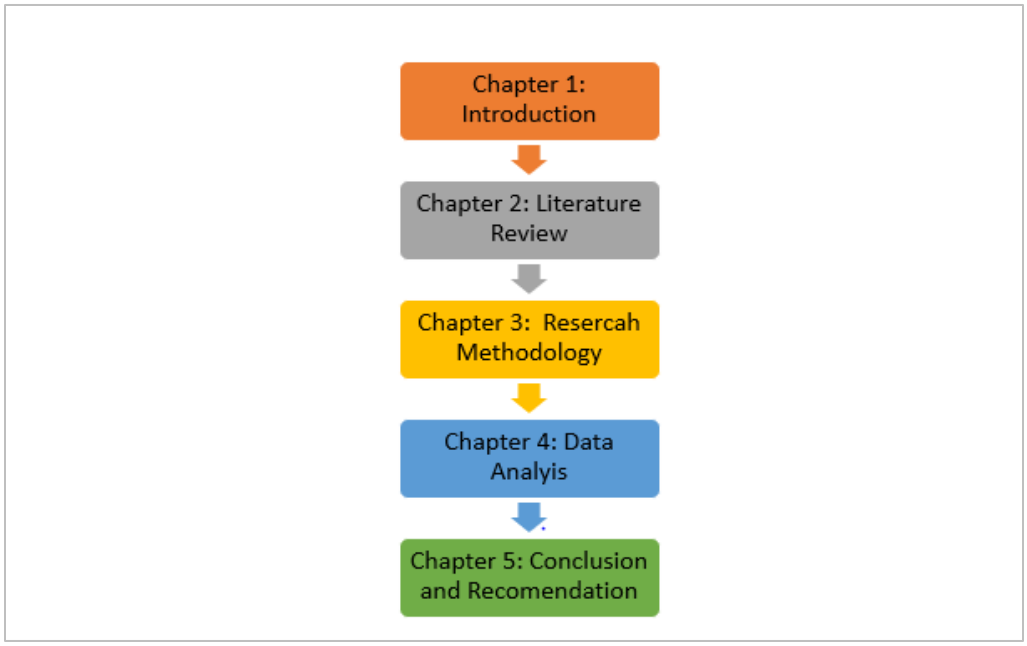



*Figure 1: Dissertation Structure*

# CHAPTER 2: Literature Review

## 2.1. Introduction

In this a review of relevant theories and their significance to study is given. These theories will help to emphasize various quality assurance and regulatory guidelines that help to ensure patient safety and the quality of medicines within industry. Also, this particular chapter will further look at the conceptual framework, whereby both the independent as well as dependent variables. Moreover, research will also cover the empirical review, which involves different research and findings done by other researchers in relation to the topic of research. Thereafter, several critiques will be made from those areas that had not been fully covered by the researchers. Lastly, the research gaps/opportunities for further research will be drawn from previous works, and the theories will serve as a foundation for the research topic.

### 2.1.1. Criteria for Inclusion and Exclusion

| **Inclusion Criteria** | **Exclusion Criteria** |
|---|---|
| Journal articles published in English | Articles that are not published in English |
| Journal articles relevant to the research topic | Articles that are not relevant to the research topic. |
| Articles published from the year two thousand | Articles not published from the year two thousand. |
| Peer-reviewed journal articles, government publications, and books | Non-academic websites such as Wikipedia |

## 2.2. Empirical Review

### 2.2.1. Overview of Quality Assurance within the Pharmaceutical Industry

Pharmaceutical quality assurance is as a hot topic from few years. As a result of international efforts to standardize procedures and establish uniform guidelines, FDA's introduction of its current good manufacturing practices (cGMP) for the 21st century, which increased the importance of pharmaceutical product quality (Haleem et al., 2015). Indicative of this realization is the proliferation of criteria for assessing medicinal efficacy and safety. To update cGMP in this century FDA launched a new program in 2002. The main aim was to re-evaluate current methods used by both regulators and manufacturers to ensure the quality of pharmaceutical products

(Lawrence and Woodcock, 2015).

In their research, Quality in the pharmaceutical industry – A literature review, Mekasha and Usure (2020) aimed to highlight the most important guidelines as well as practices that ensure quality in the pharmaceutical industry. These researchers identified a number of guidelines, such as the World Health Organization (WHO) guidelines, FDA and EU guidelines, as well as the ICH guidelines.

***Guidelines established by WHO***

WHO has released a guidebook focusing specifically on good manufacturing practices (GMP), which is titled Quality assurance of pharmaceuticals, a compendium of guidelines and related materials, Volume 2: good manufacturing practices and inspection (Haleem et al., 2015). The guidebook is made up of 4 main chapters and seven annexes, as shown below.

**Chapters:**

1st Chapter- WHO GMP: major principles for the pharmaceutical goods.

2nd Chapter- GMPs-Starting materials

3rd Chapter-GMP: Specific pharmaceutical goods

4th Chapter-Inspection

**Annexes:**

Annex 3: Radiopharmaceutical goods

Annex 4: GMPs for pharmaceutical goods (primary principles)

Annex 5: GMP Model certificate

Annex 6: Pharmaceutical products which are sterile

Annex 7: GMP inspection guidance

Annex 8: Pre-approval inspection

Annex 9: Quality system requirements for the national GMP inspectorates.

***Guidelines by Food and Drug Administration (FDA)***

The cGMP's of FDA for the 21st century have only recently started to be understood and implemented by the pharmaceutical industry. Risk-Based Approach; the initiative details short-term, intermediate-term, and longer-term stages that the FDA estimates will take two years to implement (Yu et al., 2015).

On the scientific front, the FDA outlines three ideas that will serve as a roadmap for the reevaluation process: developments in the science of risk management, developments in the science of quality management, and developments in pharmaceutical science and manufacturing technology. These are found in 21 CFR Part 210, 2005, as well as 21 CFR Part 211, 2005 (Marshall and Baylor, 2011).

Part 211 of 21 Code of Federal Regulations (CFR) contains regulations that outline minimum current good manufacturing practice that must be followed when creating drug products for human beings or animals (Kaufman and Novack, 2003).

FDA concluded that modern quality systems, when combined with product knowledge and manufacturing processes, are capable of managing changes in facilities, process and equipment without regulatory submission (Pokharana et al., 2010).

***Guidelines by the International Conference on Harmonization***

Regulatory officials from Europe, Japan, and the United States, as well as industry experts from each region, convene annually for a special project known as the ICH for technical requirements for registration of pharmaceuticals for human use (Abraham, 2010). Purpose of harmonization is to expedite the development and distributing new medications globally while retaining safety, quality and efficacy safeguards and regulatory requirements for protecting public health. (Abraham, 2010).

***Guidelines established by the European Union***

Volume 1 and Volume 5 of the publication titled rules governing medicinal products in EU has most of legislation that EU has passed pertaining to the pharmaceutical industry (GMDP, 2014).

- Volume 1 covers the EU's pharmaceutical legislation pertaining to medicines intended to human consumption.
- Volume 5 covers the pharmaceutical legislation of the European Union pertaining to medicines for animals (Verbruggen and Zolle, 2007).

Other guidelines published in below volumes for rules governing medicinal products in EU to provide support for the fundamental legislation that was passed:

- Notice to applicants and regulatory guidelines for medicinal products intended for human use are included in Volume 2.
- Scientific guidelines for medicinal products intended for human use are included in Volume 3.
- Guidelines for GMP to medicinal products intended to both human and veterinary use are included in Volume 4 (GMDP, 2014).
- Notice to applicants and regulatory guidelines for medicinal products intended for use in veterinary medicine are included in Volume 6.
- Scientific guidelines for medicinal products intended for use in veterinary medicine are included in Volume 7.
- Volume 8 talks about maximum residue limits.
- Volume 9 includes the guidelines for pharmacovigilance for medicinal products intended for both human and veterinary use.
- Volume 10 contains guidelines for clinical trials (GMDP, 2014).

### 2.2.2. General quality practices that are applied in the pharmaceutical industry

***Quality Risk Management***

There is always some measure of danger for production process and usage of any product. Because there are too many pharmaceutical industries, each with own unique methods, an organization which plans in implementing effective QRM approach should first reach consensus on a precise definition of what constitutes a risk (Ismael and Ahmed 2020). FDA has initiated the publication of position papers as well as guidelines on what it anticipates finding in Risk Management Programs (Haleem et al., 2015).

Risk management plans must be utilized to identify risk. Decisions can be taken at any point in the process during the product lifecycle. This is what the word QRM refers to: a method for assessing, controlling, communicating, and reviewing risks to drug product quality (Reddy et al., 2014).

***Corrective and preventive actions***

In order to uncover patterns or trends, an examination of nonconformities in the quality

management system and other system defects, such as legal noncompliance, is required. Finding patterns allows the maker to anticipate and avoid potential future problems (Menon and Shabaraya, 2016).

The organization should place its primary emphasis on problem resolution and prevention. In most cases, preventing problems is more cost-effective than fixing them after they have already occurred. In addition to this, the organization needs to start thinking of problems as opportunities for growth (Jain et al., 2022).

In general, the experts at CAPA (Corrective and Preventive Actions) recommend that the process of root-cause investigations as follows (Jain and Jain, 2017):

- Locate cause of issue.
- Determine the degree of the problem, that includes evaluating the associated risk.
- Conduct an investigation and determine who is responsible.
- Conduct research into and keep a record of the underlying cause of the issue.

For instance, Alcon Laboratories Inc. was able to unify all of its preventive and corrective action systems around the world with the assistance of a new corrective action tracking system. As a result, the company was able to reduce the amount of time it took to close out corrective actions, increase both its access to information and the speed with which it received it, and finally, enable quality professionals to concentrate on more pressing concerns (Haleem et al., 2015).

***Quality by Design***

According to the ICH Q8 guidelines, pharmaceutical development should focus on targeting the design of quality in the ingredients, formulation, and manufacturing process to obtain required results in product performance. Applicant should present design space for regulatory evaluation and approval (Peterson, 2008).

Circumstances like these, there may be opportunities to develop regulatory approaches that are more flexible. It is important that the planning and execution of research into pharmaceutical development be in line with the scientific goals that are being pursued (Berridge, 2004).

***Six Sigma***

Six Sigma is a quality-improvement method which focuses on reducing and eventually eliminating faults and inconsistencies in business processes. This is performed by the application of Six Sigma,

a corporate management method (S. Reosekar and Pohekar, 2014).

Six sigma is a technique that aids in the improvement of overall processes and systems by identifying and, eventually, removing impediments that may impede an organization from achieving perfection. This contributes to the organization's progress towards refining its procedures and systems (Patel and Patel, 2021).

Any difficulty that develops throughout an organization's procedures is recognized as a defect and must be eliminated in accordance with the Six Sigma quality management system standards.

Companies that implement the Six Sigma methodology generally assign various levels of achievement to their employees. These levels are known as green belts, black belts, and so on. Six sigma process experts are those who have obtained certification in any of these belts (Gijo et al., 2011).

Any process that does not result in satisfied consumers is deemed a flaw in the Six Sigma technique. To maintain an incredibly high standard of quality in both goods and services, defective processes must be removed from the system (S. Reosekar and D. Pohekar, 2014).

DMAIC model serves as the foundation for Six Sigma projects. It is standard model used throughout the Six Sigma methodology. The letters in the acronym stand for the words Define, Measure, Analyze, Improve and Control. Adds awareness to item recognize the model in certain circumstances (Atmaca and Girenes, 2013). A different facet of the general enhancement as well as breakthrough strategy is dealt with by each one of the components individually.

In the pharmaceutical business, the sigma level is between 2 and 3, resulting in 25-35% product faults (Haleem et al., 2015). One of the pharmaceutical businesses that has implemented the Six Sigma technique is AstraZeneca. Through cross-functional continuous improvement (CI) teams, the company's operations and quality workers have been trained to implement DMAIC concepts every day in order to measure and improve performance. Another pharmaceutical company that has adopted the Six Sigma methodology is Merck (Haleem et al., 2015). Cross-functional CI teams in Westborough, Massachusetts, comprised of members from QA, engineering, and operations, applied the DMAIC principles in order to find solution to a significant capacity issue involving a key product two years ago. The teams uncovered inefficient processes, which resulted in an effective increase of 20 million additional units of capacity annually. Where a capital investment of less than one hundred thousand dollars led to gains in revenue of between sixty and seventy million dollars, without the addition of any new employees (Haleem et al., 2015).

***Process analytical technologies (PAT)***

It is an essential component in achieving quality by design and the incorporation of scientific principles into manufacturing (Glassey et al.,2011). With the implementation of integrated chemical, physical, microbiological, mathematical, and risk analysis methods, its primary purpose is to gain an understanding of and maintain control over the manufacturing process. PAT has been used in industries outside of the pharmaceutical sector for a significant amount of time, resulting in cost reductions and improved production efficiencies.

The application of PAT, has a wide range of advantages, enhancements to various pharmaceutical manufacturing processes. The result is a reduction in production cycle times, an improvement in manufacturing efficiency, a decrease in rejected products, and an increase in production operating time (Simon et al.,2015).

***ISO series***

ISO 9000: The focus of ISO 9000 is quality management. This refers to measures taken by the company to boost customer satisfaction, such as conforming to requisites set forth by customers and authorities and enhancing operations consistently (Martínez-Costa et al., 2009).

Environmental management systems can be certified, registered, or self-declared in accordance with ISO 14000, which describes the requirements for such a system and provides guidance on how to implement one (Aba and Badar, 2013).

This refers to how the company operates in accordance with (ISO 9000 and 14001 in brief, 2009):

- Reduce the negative impacts of its operations on the natural world.
- Achieve progressive enhancement of its ecological functionality.

ISO/IEC 17025:2005 establishes criteria for the competence of testing and calibration laboratories worldwide (Standard, U.N.I. and CIE, E., ISO/IEC 17025: 2005).

ISO 15189:2003, then ISO 15189:2007 (both published on April 19, 2007), is a version of this standard tailored specifically for use in medical laboratories (Karkalousos, 2015).

### 2.2.3. Overview of Pharmaceutical Quality Assurance in India

#### *2.2.3.1. Regulatory Guidelines in India (CDSCO)*

The number of companies that choose to manufacture pharmaceuticals and medical devices in India is rapidly increasing. In general, the costs of manufacturing are lower than China. As a result,

Big medical companies that are manufacturing their medical devices or drugs in India, quality management in India has become an extremely important issue (Evangeline et al., 2017). The Central Drugs Standard Control Organization (CDSCO) is India's national regulatory body for cosmetics, pharmaceuticals, and medical devices. The CDSCO is responsible for approving new medications, supervising clinical trials, establishing drug standards, monitoring the quality of medications imported into the country, and coordinating the efforts of state drug control organizations through the provision of expert advice.

Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP), and Good Clinical Practice (GCP) all need to be complied with by quality management systems in India (Good Clinical Practice). An evaluation of GMP compliance ought to be a part of both the self-inspection and the quality audit. A team of in-house and/or external experts ought to audit the implementation and document any changes that were made (George, 2017). System for controlling quality should have components such as sampling, specifications, testing, documentation, release procedures, and so on.

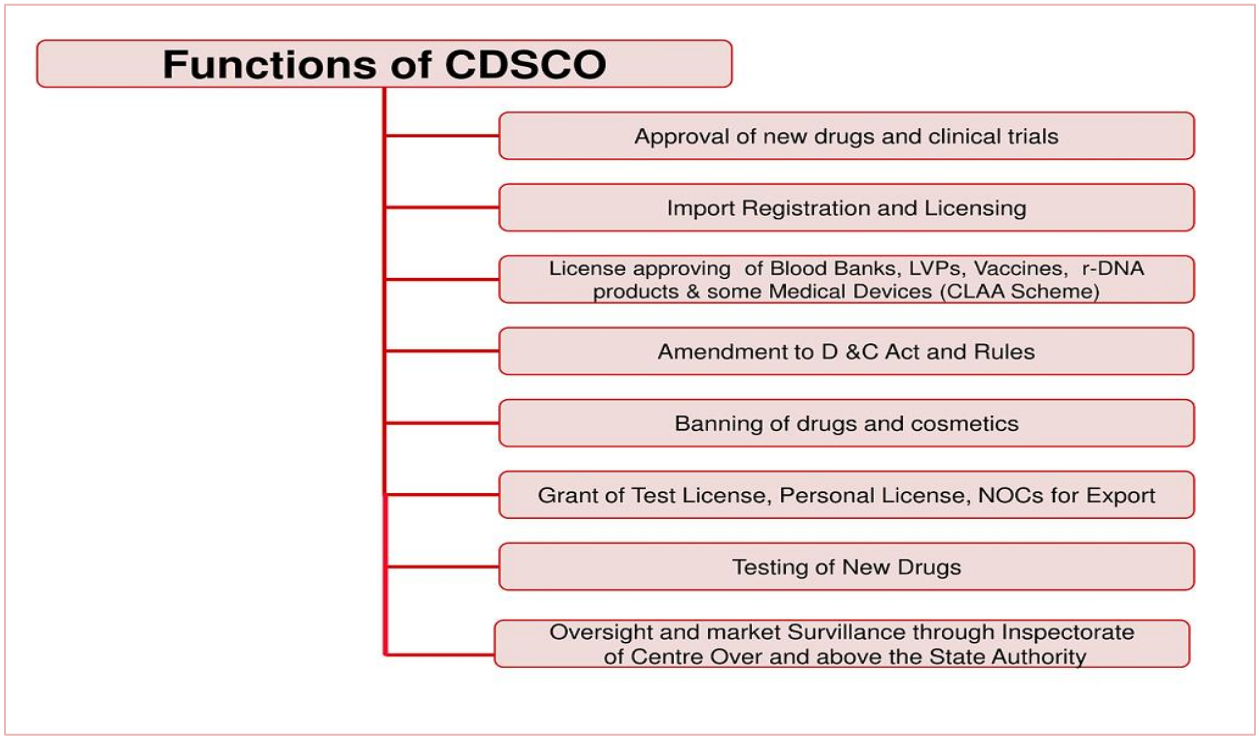



*Figure 2: Overview of CDSCO functions (Joshi, 2015)*

According to Drugs and Cosmetics Act of 1940, a license is necessary for the production of any drug. This license may only be granted to an organization that has its headquarters in India. The

State Government Drug Controllers are able to monitor the production of the majority of different types of drugs (Biswal, 2020). Before a license can be issued, the Drug Controller General of India (DCGI) must first give their stamp of approval to certain products (Evangeline et al., 2017). These products include new drugs, vaccines, large-volume parenteral, and critical IVD kits. R-DNA-derived drugs are also included in this category. The license is valid for the drugs produced in that particular factory as well as the factory itself. To put it another way, there are a variety of licenses available, and they change depending on the product group. Clinical investigators, sponsors, and regulatory bodies are crucial players in ensuring high-quality studies (Evangeline et al 2017).

### 2.2.4. Overview of Pharmaceutical Quality Assurance in Ireland

Recent study conducted by McDermott et al. (2022), concluded the Irish pharmaceutical industry used integrated continuous improvement approaches, with these approaches being used as well as installed in 97% of the manufacturers. Some of the major five tools which are used for continuous improvement include; process mapping, and brainstorming, among others. However, the researchers deemed these tools as being traditional basic tools, thus suggesting the adoption and utilization in basic problem solving as well as continuous improvement.

A research study carried out by Kennedy et al. (2019) found out that education, training reforms such as changes to continuous professional development (CPD) requirements for healthcare practitioners, need more planning, execution to ensure the provision of quality care.

#### *2.2.4.1. Regulatory Guidelines in Ireland (HPRA)*

In order to ensure that patients receive safe, effective, and quality medications, the HPRA conducts both preventative and responsive surveillance programs. Through its Sampling and Analysis program, HPRA keeps an eye on how well medicines are performing. Here, HPRA coordinates its independent surveillance testing and examination of currently available pharmaceuticals using a risk-based strategy. To address reported issues with actual or suspected quality defects in medicines, HPRA has set up a program called Quality Defects and Recall. (A quality defect is medicine or element which is not complying with the marketing authorization/product registration file for that product or component effecting its quality, safety, or efficacy.) Recalling it or issuing warnings about using it until new stock is ready are two possible responses to a quality defect investigation (HPRA).

The HPRA also conducts Regulatory Compliance inspections of Marketing Authorization Holder businesses. The purpose of this risk-based inspection program is to determine how well the

company complies with the regulations of individual countries when it comes to the marketing and distribution of pharmaceuticals. Additionally, HPRA conducts advertising monitoring for Irish pharmaceutical companies. The Market Compliance Department's Advertising Compliance program is responsible for this. By doing this, we make sure that advertisements for pharmacological products aimed at humans are truthful and non-misleading and follow all regulations governing such matters (HPRA). Furthermore, the HPRA manages a system for reporting Exempt Medicinal Products. We are able to track the circulation of illegal pharmaceuticals in the market thanks to this system.

McDermott et al. (2022) in their research noted that the main difference between traditional pharmaceuticals and biopharmaceuticals involves the procedure in which the medicines are produced. Biopharmaceuticals are generated from living things like yeast, bacteria as well as mammalian cells. On the other hand, traditional medicines are generated via several processes of chemical synthesis. USFDA defines medicine as something intended to be used for diagnosing, curing, preventing, and treatment of a given illness. Therefore, because of the benefits brought by medicines as well as the risks they can cause to human beings, their production process is highly controlled. Within the EU and Ireland country being a member, medicinal drugs are regulated more stringently through the laws which control the efficacy, safety as well as quality throughout their product lifecycle, even including pre-marketing and post-marketing. The graph shown below represents data on HPRA concerning the detection of fake medicines as well as other illegal medicines.

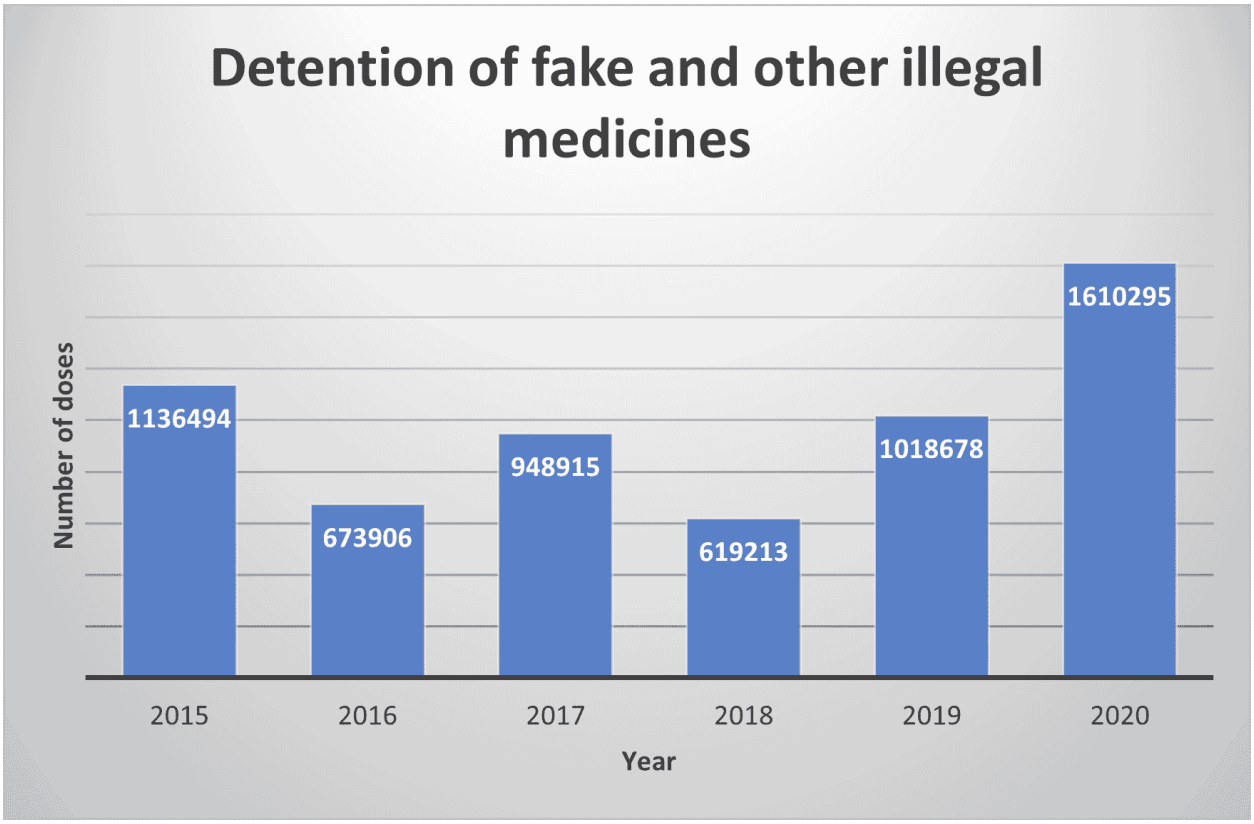



*Figure 3: HPRA 2021 concerning the detention of fake and illegal medicines (PerfomanSC, 2022)*

Prior to the marketing stage, the pharmaceutical manufacturer is required to get marketing permission within the required jurisdiction that he wishes to produce in and also in any country or country where he wishes to export the pharmaceutical products. A good example includes the following; within the EU, medicinal drugs, together with their producers, are governed by EMA, in US, they are regulated by FDA. Based on HPRA, the medicine's related risks need to be reasonable and acceptable, considering that the consumption of any drug comes with some risk, which must be taken into account based on the likely benefit. Therefore, the competent regulatory authority, i.e., HPRA, needs to be aware of any new safety information that might come up, which might also have a direct impact on the balance of benefit and risk (McDermott et al., 2022).

McDermott and his colleagues (2022) found that, as most of the pharmaceutical organizations in Ireland export their products to Europe and have permission to market their products to the United States, they mostly adhere to the FDA and EU regulations as well as other international regulations based on their export markets. Guidelines on human drugs are published by EMA (the Agency) and are standardized by the International Council Harmonization (ICH). The Agency expects all pharmaceutical producers to comply with the ICH Guideline Q10 regarding the requirements for

the Pharmaceutical Quality System (EMA, 2021). In addition to that, ICH Q7 is also a regulatory guideline on good manufacturing practices for active substances (EMA, 2021).


*Figure 4: Pharmaceutical Quality Management system (Haleem et al., 2015)*

According to the research conducted by Singh and Dhalla (2010), the researchers found out that there are several factors that affect the Total Quality Management system of the Indian pharmaceutical industry. These factors include; the top management commitment. Leadership, quality management, people management and training, customer focus, and supplier and vendor quality.

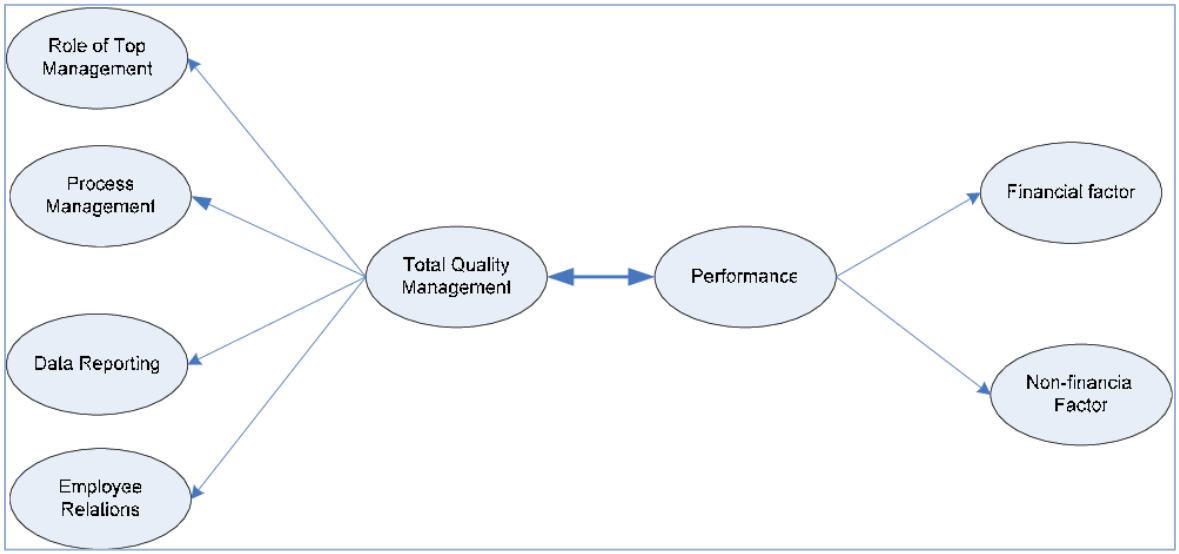



*Figure 5: TQM factors*

Commitment from top management is the factor influencing implementation of TQM. Highest

levels of management at the responding companies accepted responsibility for the quality of their products. Level of dedication, participation demonstrated by senior management has noticeable effects on the company's success. Quality of one's leadership is an essential component of TQM. Efficient, energetic lead steer productive group to victory, which will ultimately result in increased revenue for the company (Singh and Dhalla, 2010).

The availability of quality information and the effective application of that information are both essential components of quality management. It is essential to have accurate and timely information regarding manufacturing process to maintain process control and reduce defective products. Rapid problem resolution ensures that the process remains under control (Singh and Dhalla, 2010).

Training employees is effective method for improving their ability to carry out their jobs more effectively. When an organization makes full use of the talents and abilities of its workforce, it is well on its way toward accomplishing the goals it has set for itself. The primary goal in the design of a good or service should be to meet or exceed the expectation of the customer, which will result in the satisfaction of the customer while still allowing for a reasonable profit. An organization that prioritizes or focuses on satisfying customers is able to keep its advantage over rival businesses.

The quality of the suppliers and vendors is another important aspect of quality management. This is because defective materials, parts, and services can cause issues with product and process. Most important factors in preserving a competitive advantage is keeping up positive relationships with one's suppliers and vendors.

## 2.3. Theoretical Review

This aids in gaining a comprehensive understanding of the research objectives while justifying the current research study. Therefore, the Total Quality Management Theory has been put forth to expound on the research topic as shown below:

### 2.3.1. The Total Quality Management Theory

It is described as managerial theory which is adopted by pharmaceutical producers when it for the manufactured products to be within expected quality. Research has revealed that this theory is potentially important, especially in the manufacturing of medicinal products within the pharmaceutical industry. This is because it ensures that the manufactured products exceed the expectations of the consumers in the market in relation to quality, efficiency, effectiveness, and standards.

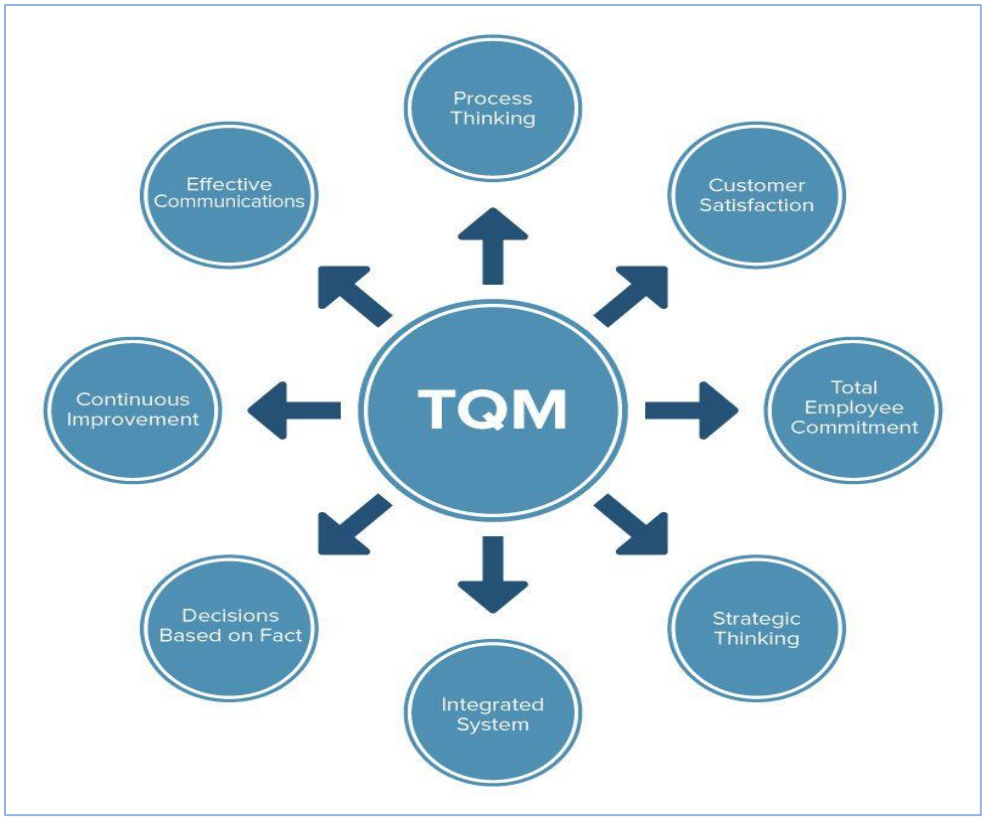



*Figure 6: Total Quality Management Theory (Sharma and Modgil., 2020)*

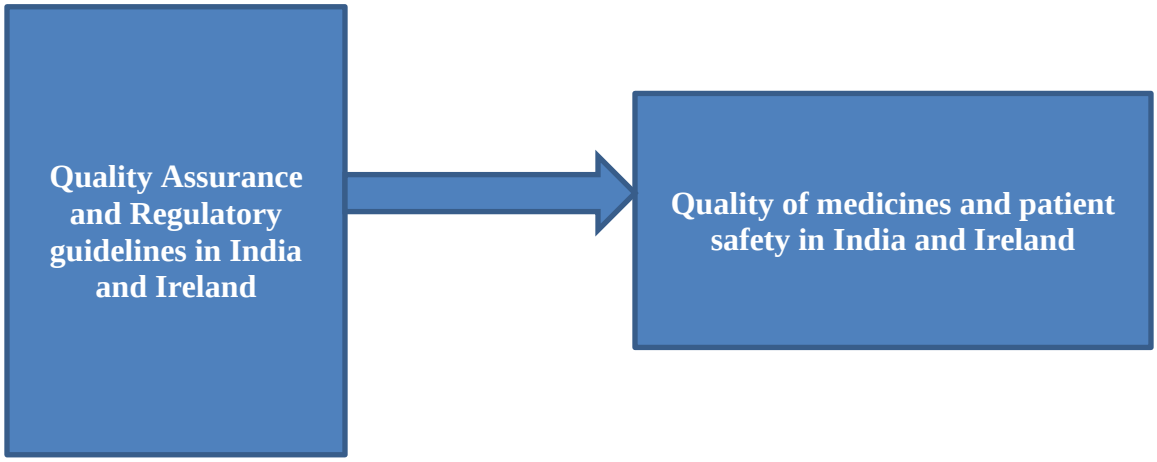
This particular theory argues that pharmaceutical producers play a fundamental role within the healthcare system, and therefore, they are closely regulated by the relevant regulatory bodies, i.e., for this case, HPRA and CDSCO. Any single small mistake in the pharmaceuticals can result in fatal consequences. In our case, pharmaceutical manufacturers are expected to continuously maintain as well as improve their pharmaceutical products through TQM.

TQM include customer focus, employee engagement, and constant improvement. Also, all the company employees are engaged in the quality manufacturing procedure, and they need to participate in the improvement as well as innovation of quality. For constant improvement, this theory argues that the main objective for product quality is an endless procedure whereby the people are constantly trying to improve the features of their products.

## 2.4. Conceptual Framework

This is a visual representation of the relationship between the dependent variables and independent variables; and how they relate to the topic of study.

**Independent Variables** **Dependent Variable**




Based on the conceptual framework shown above, the independent variables include; the quality assurance and regulatory guidelines in India and Ireland. On the other hand, the dependent variable is the quality of medicines as well as patient safety in both India and Ireland. According to the above framework, it can be said that the quality and safety depend on the quality assurance and regulatory guidelines established in India and Ireland.

## 2.5. Opportunities for Further Research

Based on the literature review, it is evident that pharmaceutical quality assurance is a key factor within the pharmaceutical industry across the globe. There has been an increased understanding regarding the importance of pharmaceutical product quality due to the international efforts to standardize the processes as well as establish uniform guidelines. Most of the research carried out in India and Ireland revolves around how the regulatory bodies (such as CDSCO and HPRA) ensure pharmaceutical product quality. There are only a few researchers who have investigated the challenges faced by regulatory bodies when ensuring quality assurance within the pharmaceutical industry. Therefore, this research proposes that further research needs to be done on some of the challenges experienced or barriers to ensuring quality assurance within the pharmaceutical industry. In addition to that, further research needs to be done on the role played by the sponsors/manufacturers and clinical researchers in ensuring quality assurance within the pharmaceutical industry. This is because there is less research done on how the two play their role

in ensuring pharmaceutical quality assurance. This will help to provide a comprehensive understanding and also prove that the two are also important players in ensuring quality assurance within the pharmaceutical industry.

**2.6. Summary**

This chapter has looked at the literature view, which involves a review of other people's work along with main theories and guidelines. An overview of the regulatory framework for both India and Ireland. Therefore, it can be concluded that ensuring the quality and safety of medicines is the ultimate goal. Both CDSCO and HPRA play a major role in ensuring that patients in India and Ireland consume medicines that are of high quality and safe. Therefore, the quality of medicines greatly depends on quality assurance as well as regulatory guidelines put in place.

# CHAPTER 3: Research Methodology

## 3.1. Introduction

This research will adopt a methodology approach, as shown in the Research Onion below. It is a research model which was developed by Saunders, Lewis, and Thornhill (2007). It will help to describe the different decisions that the researcher will need to make when developing the research methodology for this dissertation. The main layers in the methodology, i.e., research philosophy, research approach, methodological choice, research strategy, time horizon, as well as techniques and procedures are used. Includes sampling techniques, research design, inclusion and exclusion criteria, research ethics, accessibility issues, and limitations (Crowther and Lancaster, 2012).

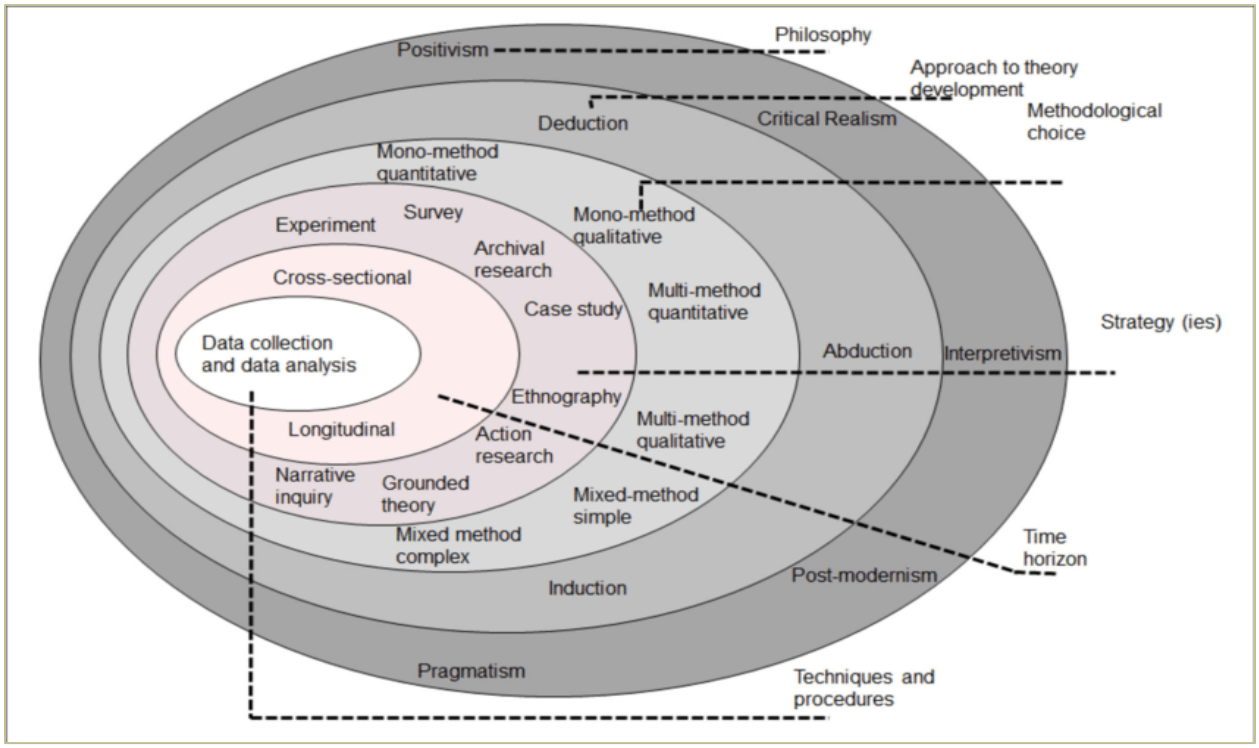



*Figure 7: Research Onion (Saunders et al., 2007)*

## 3.2. Research Philosophy:

Pragmatist research philosophy will be used. This is because this research philosophy is based on facts. It also suggests that the research problem influences the choice of research philosophy. Practical results will be considered important. Based on this type of philosophy, the researcher will have the freedom to choose the procedures, techniques as well as methods that match the research needs and aims (Saunders et al., 2007).

### 3.3. Research Strategy:

This research has carried out an online survey in both India and Ireland regarding quality assurance and regulatory guidelines for medical products by evaluating H.P.R.A. and C.D.S.C.O.

**Research Methodological Choice:** A mono-method quantitative research has been applied in this study. Quantitative research refers to a systematic investigation regarding a given phenomenon through the collection of quantifiable data as well as by conducting mathematical, statistical, or computational techniques. Quantitative research collects data by sending out questionnaires, online surveys, etc. This research has used questionnaires to collect data which will be represented in the form of graphs, charts, or tables for in-depth understanding. Also, closed-ended questions will be created for every research objective (Saunders et al., 2007).

**Research Approach:** This research will use a deductive research approach. This is because this research will involve a scientific investigation. The research will study what other researchers have done and reads the existing literature and theory concerning the topic of research; then, the research will test the hypotheses that will emerge from these theories through data analysis (McNeill, 2006). There are different procedures for collecting data in research studies, that comes under two categories, i.e., secondary and primary data. Primary data refers to data collected for the first time by the researcher, whereas secondary data refers to the data which has already been gathered by other researchers. In this research, both secondary and primary data will be used as both categories will be able to offer complete as well as efficient data for the research study. There are several differences between secondary and primary data. For instance, primary data is original and true, while secondary data, on the other hand, basically involves the analysis as well as the interpretation of the main data. Primary data is collected with the aim of getting a solution to the problem at hand, while secondary data is collected for other reasons. Examples of primary data sources include surveys through questionnaires, while examples of secondary data sources include websites, government publications, published books, and also peer-reviewed journal articles (Mishra and Alok, 2022).

Based on the sampling type, this research will use a simple random sampling process. This is because this process allows the researcher to arbitrarily select the research participants, and therefore every person will have an equal chance to participate in this study (Alvi, 2016).

Time Horizon: This research will be a cross-sectional study. A cross-sectional study is where data is gathered as a whole so as to study a given population at a single point in time. This helps to

examine the relationship between the variables of interest. Based on this, this research will record the collected information regarding the respondents without manipulating the natural environment in which they exist. Through this, the research will also be able to compare the different samples, i.e., India and Ireland, at one given point in time.

### 3.4. Possible Research Ethics

Effective research must consider all the ethical implications. Research ethics needs to be considered by the researcher during primary data collection (Oliver, 2010). Here the following guidelines will be used: only the participants who will genuinely participate are allowed; prior to the collection of data, the participants will be informed fully regarding the aim, purpose of survey. In addition to that, the participants will not be asked to provide their identities, as their information will be kept private and confidential.

**Inclusion Criteria**: Research participants (pharmacist, manufacturers and physicians) must have enough knowledge concerning the quality assurance system of medicinal products and how they participate in ensuring that medicines consumed ny patients and the general public are of high quality.

**Exclusion Criteria:** Research participants with no knowledge on quality assurance of medicines in their respective countries.

### 3.5. Proposed Research Challenges

This research is more likely to face a number of challenges while conducting the primary research. For example, most of the respondents who will be participating in the research study are working-class people. This means that most of them will be busy all the time. Getting them to participate in the online research survey may be a challenge. To overcome such a challenge, the respondents will be sent an email in advance to inform them about the survey.

### 3.6. Techniques and Procedures:

#### 3.6.1. Data Collection

There are two types of research data, i.e., primary and secondary data, primary data involves data gathered for the first time, while secondary data involves data that has already been collected by others (Crowther and Lancaster, 2012). For this research, both primary data and secondary data will be used for getting efficient, accurate and complete data. Additionally, the sources for primary data in this research will include surveys through questionnaires, while secondary data will include published books, peer-reviewed journal articles, and government publications.

### 3.6.2. Data Analysis

This research will use a set of graphs, tableau, and other Microsoft Excel tools to analyze data that will be collected through survey questionnaires. Therefore, quantitative data analysis will be applicable (Cramer, 2003).

# CHAPTER 4: DATA ANALYSIS AND DISCUSSION

## 4.1. Demographic Information

### 4.1.1. Gender

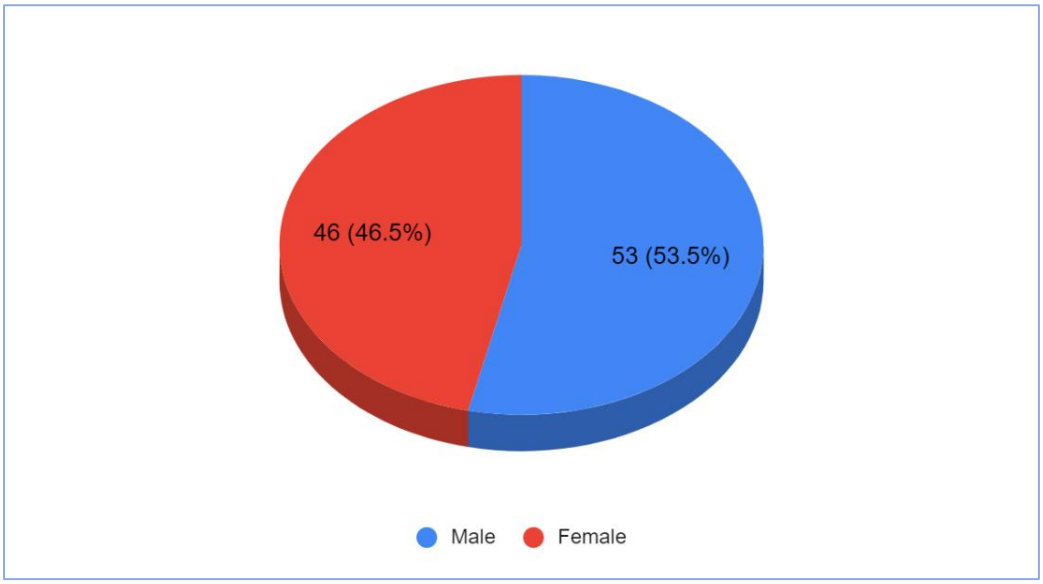



*Figure 8: Gender*

The pie-cart shown in Figure  above represents data for gender. Out of a total of 99 respondents (from both India and Ireland), who participated in the study, 46 of them were female, representing a percentage of 46.5%, and 53 of them were male, representing 53.5%. This demonstrates that male respondents took part in the study at a higher rate than female respondents.

### 4.1.2. Age

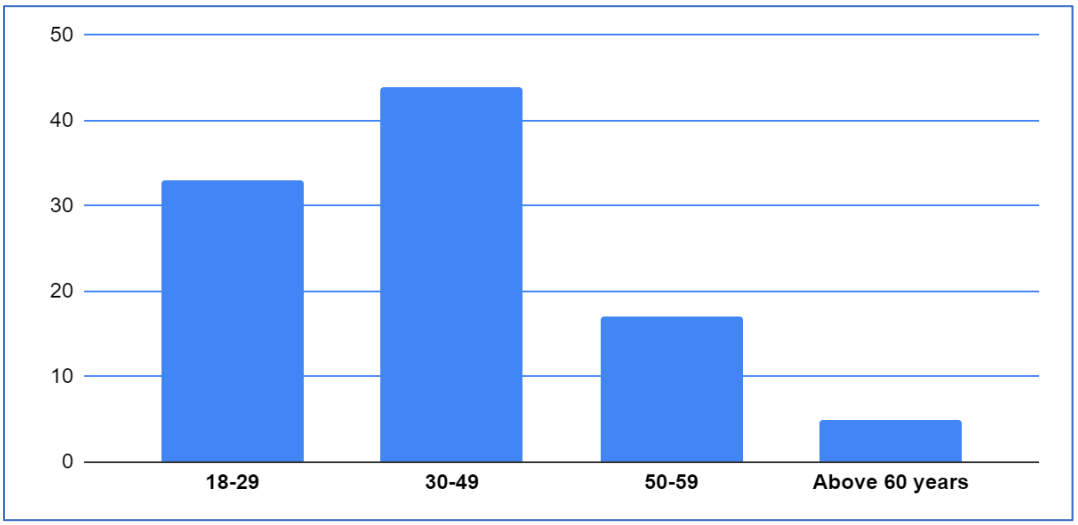



*Figure 9: Age*

The figure shown above is a bar graph showing data collected from the research participants concerning their age. The respondents were asked to specify their age. As shown, the highest number of participants was 44 with an age bracket of 30-39, representing 44.4%, followed by 33 with an age bracket of 18-29 years, representing 33.3%, followed by 17 people with an age bracket of 50-59. The least number of people was 5, with an age bracket of above 60 years. Therefore, it is evident that the highest number of participants had age 30-39 years.

### 4.1.3. Level of education

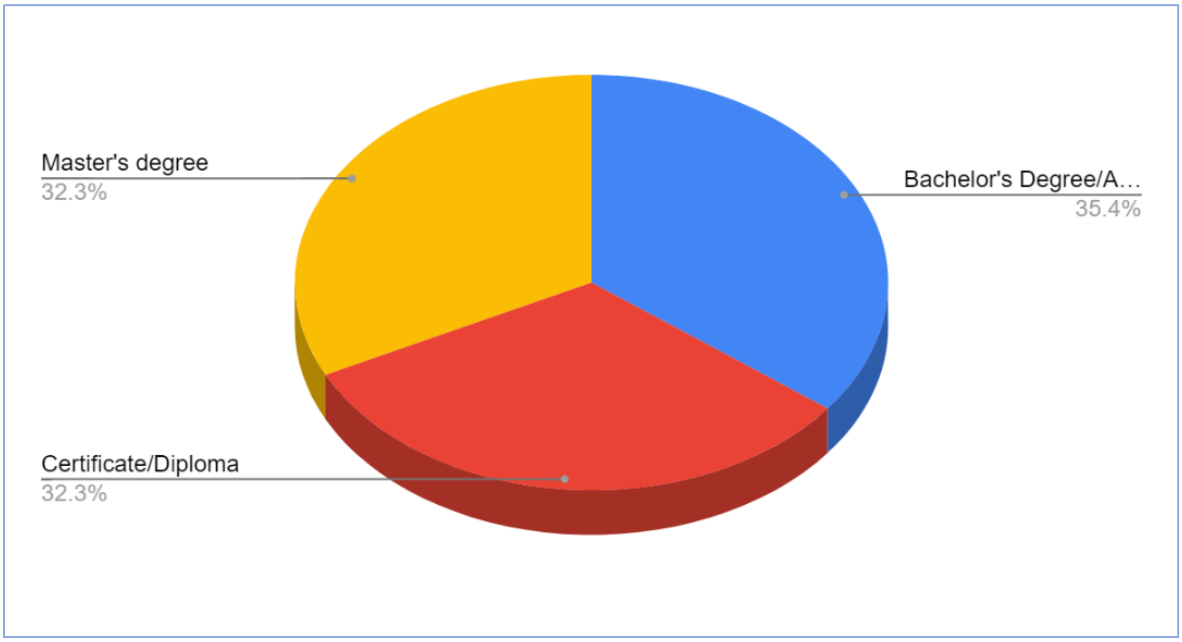



*Figure 10: Level of education*

Figure above, shown above, represents data collected from the respondents based on their level of education. The respondents were asked to choose their level of education. The respondents were given the following option to choose from; certificate/diploma, bachelor's degree/advanced diploma, master's degree, and specify if there was another level not mentioned. Out of a total of 99 respondents who participated in the study, 35.4% (35) have competed their bachelor's degree/advanced diploma, 32.3% (32) had completed their master's degree, and also 32.3% (32) had completed a certificate/diploma level. There are no respondents who chose the option of "other level." Therefore, most participants in this research study have completed their bachelor's degree/advanced diploma.

### 4.1.4. Years of working in the industry

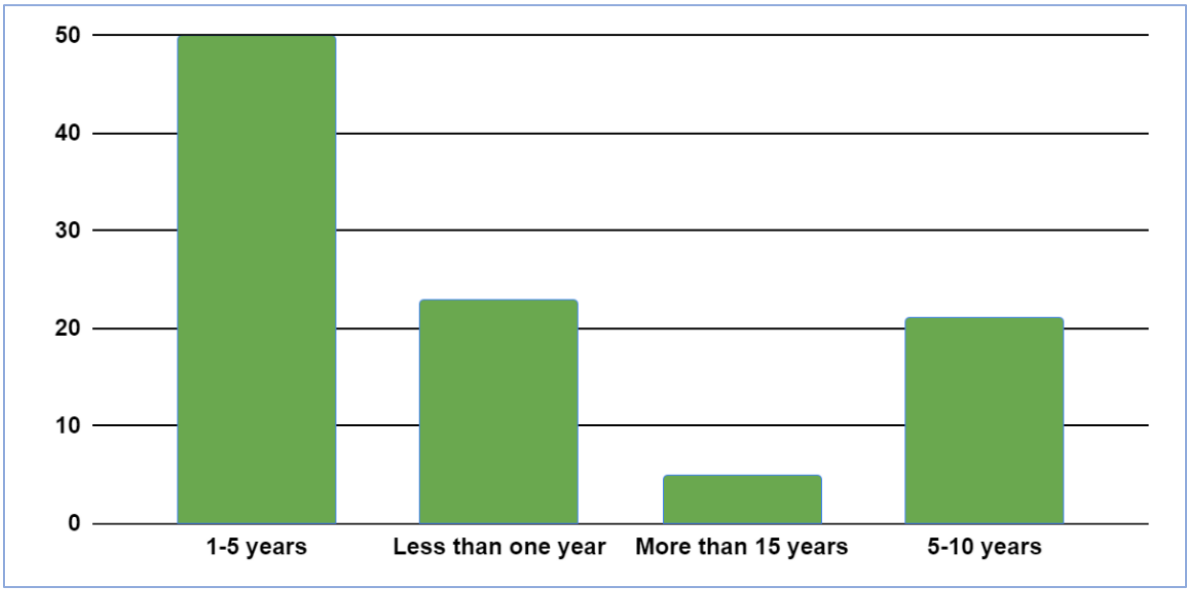



*Figure 11: Years of working in the pharmaceutical industry*

Figure shown above, is a bar graph representing data collected from the respondents based on the period they have worked in the industry. They were to select from the following options: less than one year; 1-5 years; 5-10 years; and more than 15 years. From 99 respondents in the study, the highest number was 50 participants with an experience of 1-5 years, representing 50.5%; it was followed by 23 participants with an experience of less than one year in the industry; followed by 21 participants who have worked for 5-10 years; least was 5 members with more than 15 years' experience.

### 4.1.5. Nationality

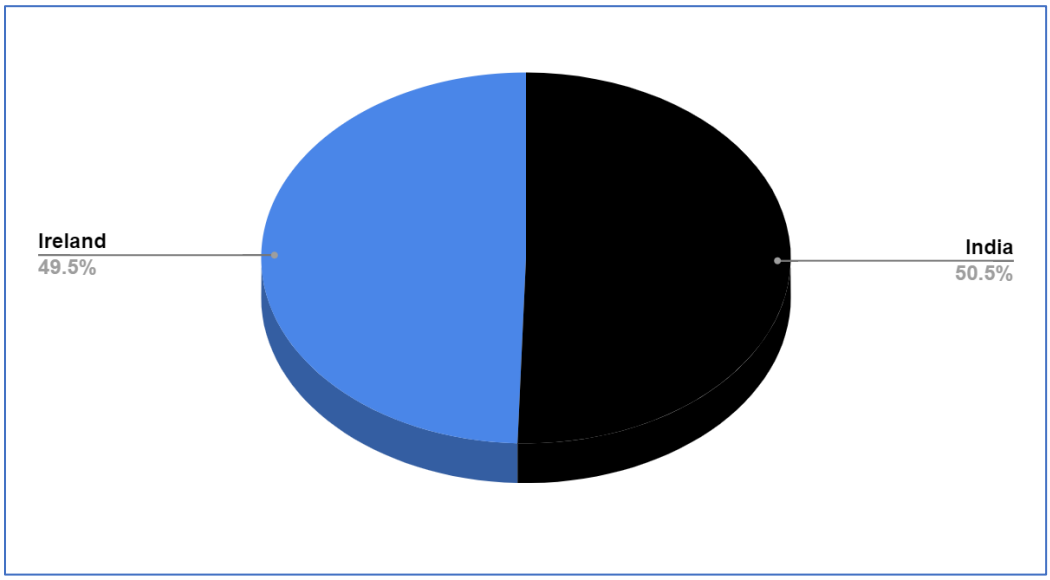



*Figure 12: Nationality*

Figure shown above, represents data for the nationality of the respondents. This research was only limited to people from India and Ireland. The respondents were to choose their country of residence as either India or Ireland. Out of 99 people who participated, 50 of them are Indian nationality representing 50.5%, and 49 of them were from Ireland, representing 49.5%. Therefore, based on this analysis, it can be said that the majority of the respondents were of Indian nationality.

### 4.1.6. Profession

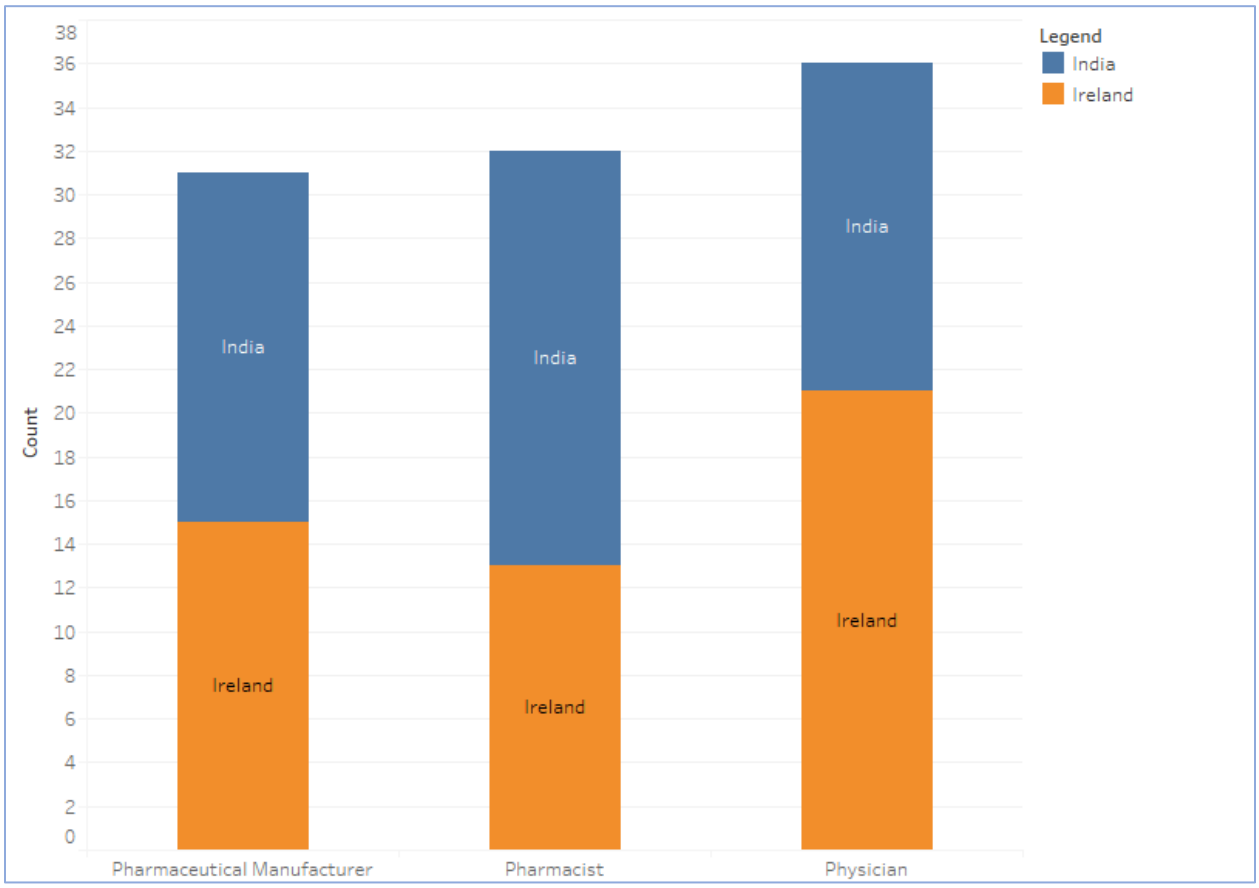



*Figure 13: Profession*

The bar graph shown above represents data for the different types of professions that the respondents chose. The respondents were required to choose their profession as either a physician, pharmacist, or pharmaceutical manufacturer. Out of a total of 99 research participants from both India and Ireland, 36 were physicians (21 from Ireland and 15 from India), representing an overall percentage of 36.4%. A total of 32 were pharmacists (13 of them from Ireland and 19 of them from India), representing 32.3%. The rest (31) were pharmaceutical manufacturers, where 15 of them came from Ireland, and 16 were from India, overall percentage of 31. Majority of the respondents were physicians (36), followed by pharmacists (32), and the lowest number (31) was represented by pharmaceutical manufacturers.

### 4.2. Survey Questions for Physicians

**OBJECTIVE 1: To determine if the physicians from Ireland and India have experienced any issues concerning the quality of medicines.**

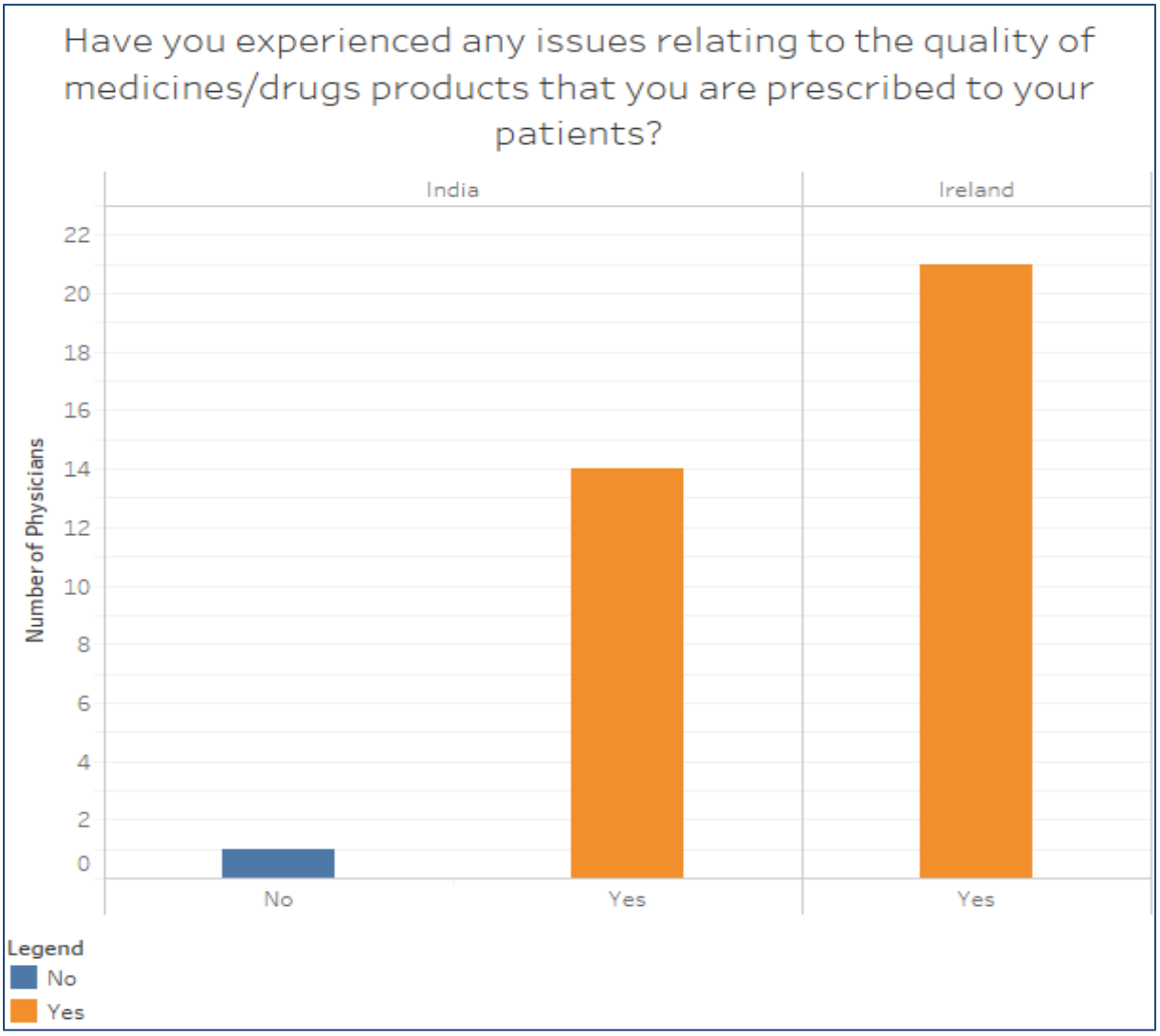



*Figure 14: Experience with issues relating to the quality of medicines*

Shown above is a bar graph with data collected from the physicians regarding whether they have experienced any issues relating to the quality of medicinal products that they have prescribed to their patients. The participants were to respond with a YES or No. Out of a total number of 36 physicians who participated in this research study, 97.2% (35) said YES and 2.8% (1) said NO. A total of 21 physicians from Ireland responded with YES, 14 participants from India responded with also a YES, and only one participant from India responded with a NO. Based on this analysis, most of the physicians from both India and Ireland agreed that they had experienced issues relating to

the quality of medicines. It is only one physician out of a total of 36 reported not having experienced any issues relating to the quality of medicinal products.

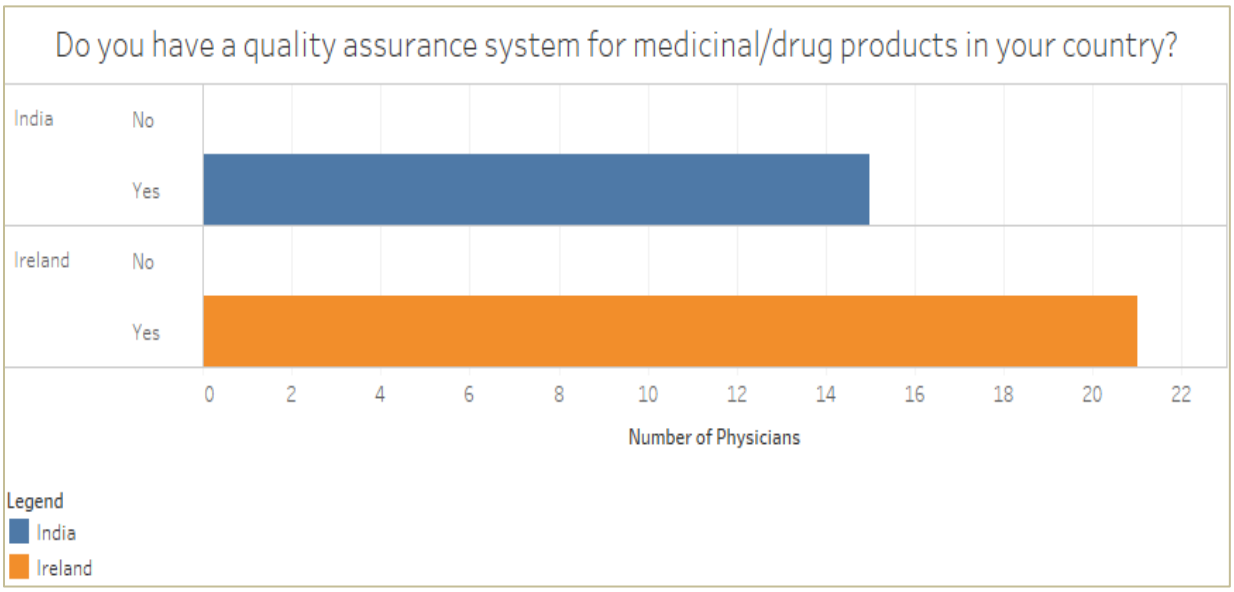



*Figure 15: Quality assurance system in the country*

Figure shown above, represents data collected from physicians (from both Ireland and India). These physicians were asked to respond with a YES or No regarding whether their country of residence has a quality assurance system in place for medicinal products. Out of a total of 36 physicians who participated in the study, all of them (from both India and Ireland) replied with a YES that their country has a quality assurance system for medicines in place. There was no physician from both countries who responded with a NO. Those who responded with a YES from India were 15 in total, and those from Ireland were 21 in total. Therefore, this shows that all the physicians from both countries agree that their respective countries have a pharmaceutical quality assurance system in place, with the majority coming from Ireland.

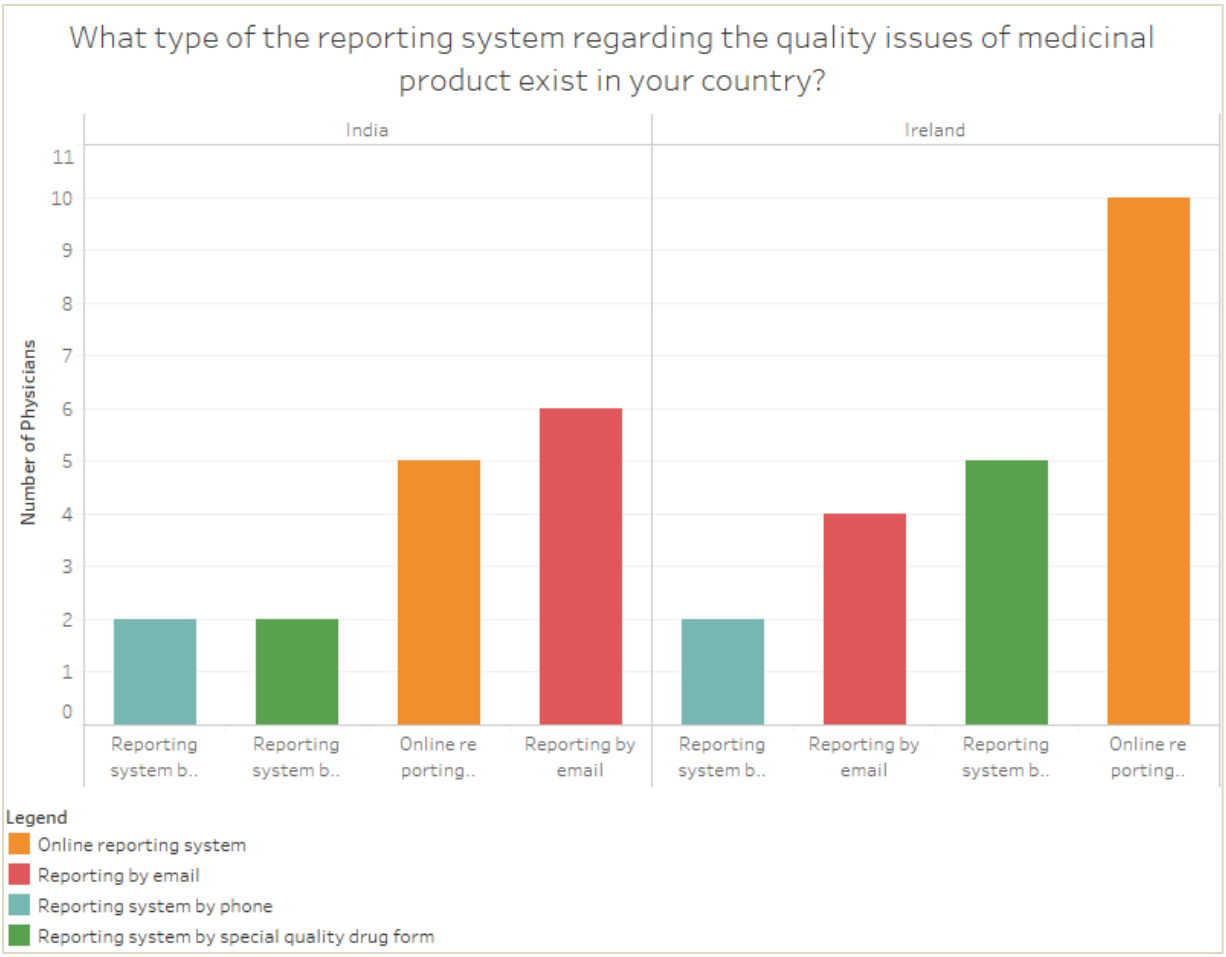



*Figure 16: Type of reporting system present regarding the quality issues of medicinal products.*

The bar graph shown above represents data collected based on the type of reporting system on medicine quality present both in India and Ireland. The participants, i.e., the physicians, were asked to choose the type of reporting system present in their country from the following options; online reporting system, reporting by email, reporting through phone, and reporting using a special quality drug form. Out of a total of 36 physicians who participated in this study, 41.7% (15) responded that they use an online reporting system to report issues related to the quality of medicines; 27.8% (10) responded that they report through email; 19.4% (7) responded that they report using a special quality drug form; and 11.1% (4) report through phone.

Country-wise, in India, two physicians report by phone, two reports through a special quality drug form, 5 of them use an online reporting system, and 6 of their reports by email. When it comes to Ireland, ten physicians use an online reporting system; 5 of them reported using a special quality drug form, 4 of them reported through email, and 2 of them reported through the phone. Therefore,

based on this analysis, the most preferred reporting system for pharmaceutical quality issues in India is reporting by email, followed by an online reporting system, followed by reporting using special quality drug forms, and reporting by phone. In Ireland, the most preferred reporting system includes the online reporting system, followed by reporting through a special quality drug form, followed by reporting by email, and the least preferred method is reporting by phone.

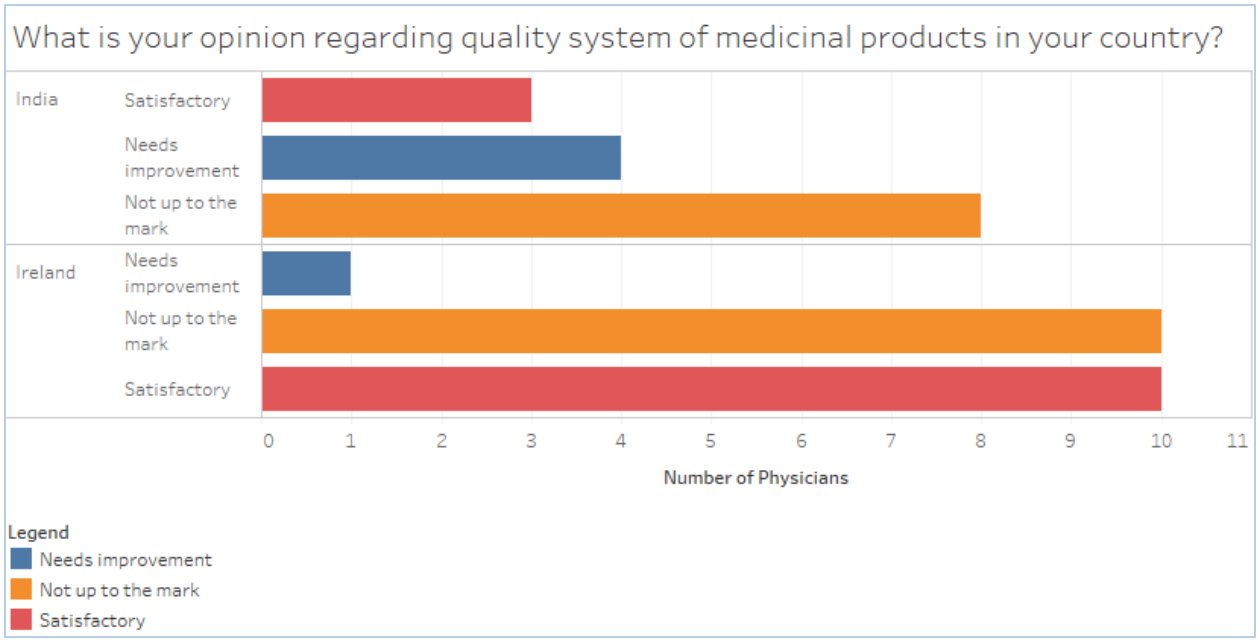



*Figure 17: Opinion regarding the pharmaceutical quality system in the country*

Shown above is a bar graph representing data collected from the respondents concerning their opinion regarding the quality system of medicinal products that exist in their country. The respondents were given the following options to choose from; satisfactory, not up to the mark, and needs improvement. Out of a total number of 36 physicians who participated in this study, 21 came from India, and 15 came from Ireland. Generally, 13 physicians responded that their pharmaceutical system is satisfactory, 18 reported that their system is not up to the mark, and the rest (5) reported that their pharmaceutical system needs improvement. In India, ten physicians reported that their pharmaceutical system is satisfying, another ten reported that it is not up to the mark, and only one reported that the system should be improved. In Ireland, eight reported that their system is not up to the mark, 4 of them reported that it needs improvement, and only three reported that their system is satisfying. Based on this pharmaceutical quality assurance system of India and Ireland are not up to the mark. However, when compared, Ireland has a better pharmaceutical quality assurance system as compared to India.

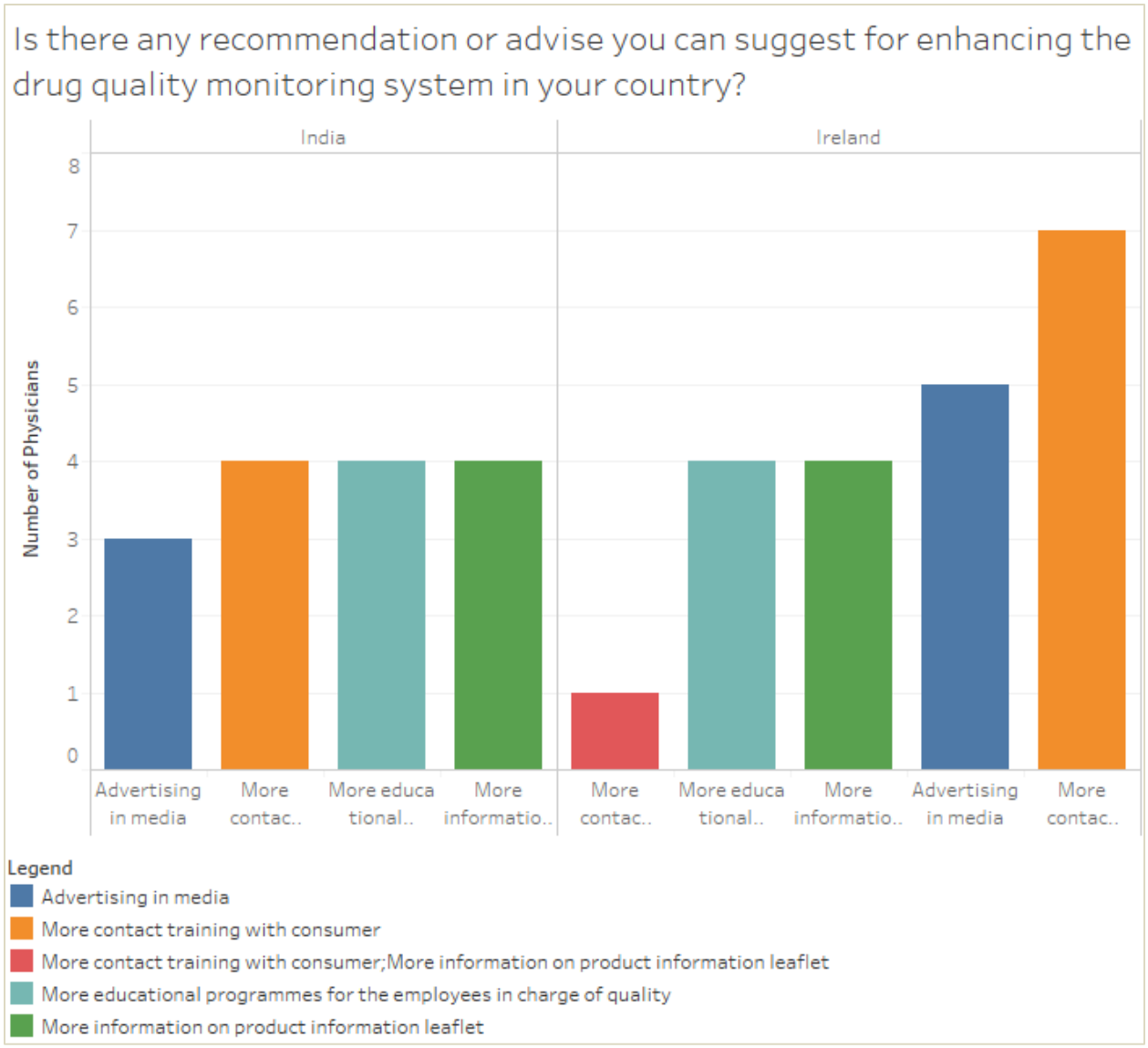



*Figure 18: Recommendation to enhance the monitoring system for the drug quality*

Figure shown above represents data collected from physicians regarding their recommendations or advice they can suggest to enhance the drug quality monitoring system in their respective countries. The respondents were to choose from the following options; advertising in the media, more contact training with consumers, more information on the product information leaflet, and more educational programs for the employees in charge of drug quality. Out of a total of 36 physicians who participated in the study, the majority (12)of them, representing 33.3%, recommended that there is a need for more contact training with the consumers; 8 of them, representing 22.2%, suggested that more educational programs are needed for the employees in charge of the pharmaceutical quality; 9 of them representing 25% suggested that more information

should be included on product information leaflet; and 8 of them representing 22.2% suggested that there is need for more advertising in the media.

Country-wise, 21 physicians came from Ireland, while the other 15 came from India. In Ireland, the majority (7) suggested that there should be more contact training with the consumers, followed by five who recommended that there should be more advertising in the media, followed by four who suggested that more information should be included in the product leaflet information, the other four suggested that there is need for more programs for the employees in charge of pharmaceutical quality and only one physician suggested that there should be more contact training with the consumer and more information on the product information leaflet.

In India, four physicians recommended that more information should be included in the product information leaflet, 4 of them suggested that more educational programs should be provided to the employees in charge of ensuring drug quality, 4 of them recommended that there is a need for more contact training with the consumers and only three recommended that there is need for more advertising in the media. Therefore, more contact training with the end users is needed, as the majority of physicians from both countries suggested so.

### 4.3. Survey Questions for Pharmacists

**OBJECTIVE 2: To determine if pharmacists from the two countries perceive the quality assurance system as being effective.**

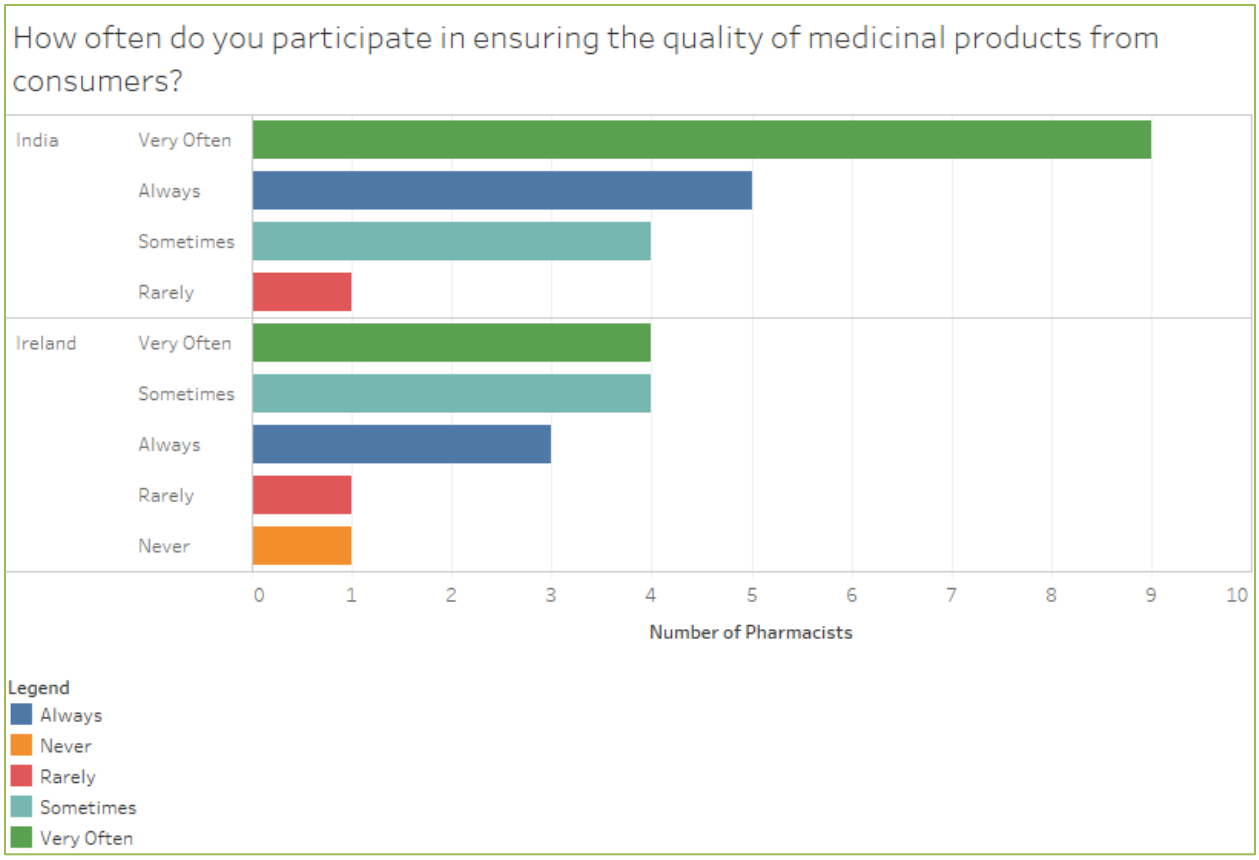



*Figure 19: How often do physicians participate in ensuring the quality of medicinal products*

According to Figure shown above, the respondents, who were pharmacists, were asked to report on how often they participate in ensuring the quality of medicinal products to consumers. They were to be given the following options; always, very often, sometimes, rarely, and never. Out of a total number of 32 pharmacists who participated in the study, 19 came from India, and the other 13 came from Ireland. Generally, the majority of the pharmacists 13 representing 40.6% reported that they often participate in ensuring the quality of medicinal products to consumers, 25% (8) reported that they sometimes, 25% (8) reported that they always, 6.3% (2) reported that they rarely and only 1 (3.1) reported that they never participate in ensuring the quality of medicines to consumers. In India, the majority (9) responded with very often, 5 of them responded with always, 4 of them responded with sometimes, and only one responded with rarely. In Ireland, four pharmacists responded with very often, 4 of them responded with sometimes, 3 of them responded with always, one responded with rarely, and only responded with never. Based on this the pharmacists from both countries participate in ensuring the quality of medicinal products very often. However, it is only a few of them rarely and never participate in ensuring the quality of the

medicinal products to the consumers.

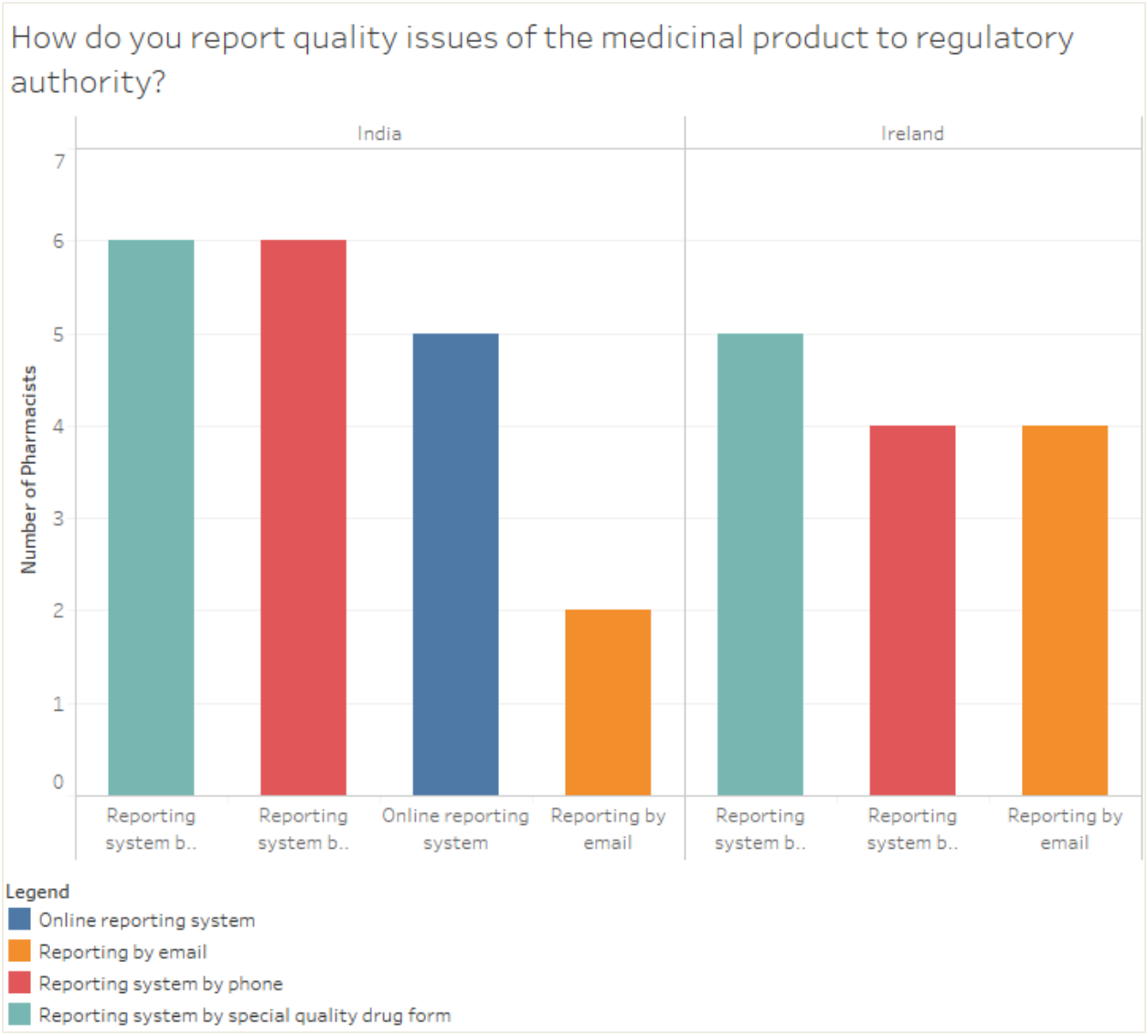



*Figure 20: How pharmacists report quality issues of the medicinal products to the regulatory authority*

Figure shown above, represents data collected from pharmacists concerning the type of reporting system they use to report the quality issues of medicinal products to the regulatory authority. The respondents were to choose from the following options; online reporting system, reporting by email, reporting by phone, and reporting through a special quality drug form. Out of a total number of 32 pharmacists who participated in the study, 19 came from India, while 13 came from Ireland. Generally, 11 pharmacists from both India and Ireland, representing 34.4%, responded that they report the drug quality issues through reporting by a special quality drug form, 31.3% (10) report

by phone, 18.8% (6) report by email, and 15.6% (5) use online reporting system. In India, six reports by a special quality drug form, six by phone, five use an online reporting system, and two reports by email. In Ireland, five pharmacists report through a special quality drug form, four report by phone, and also four pharmacists report by email. Therefore, based on this analysis, it is evident that most of the pharmacists from both India and Ireland report the issues to do with drug quality using a special quality drug form and through the phone.

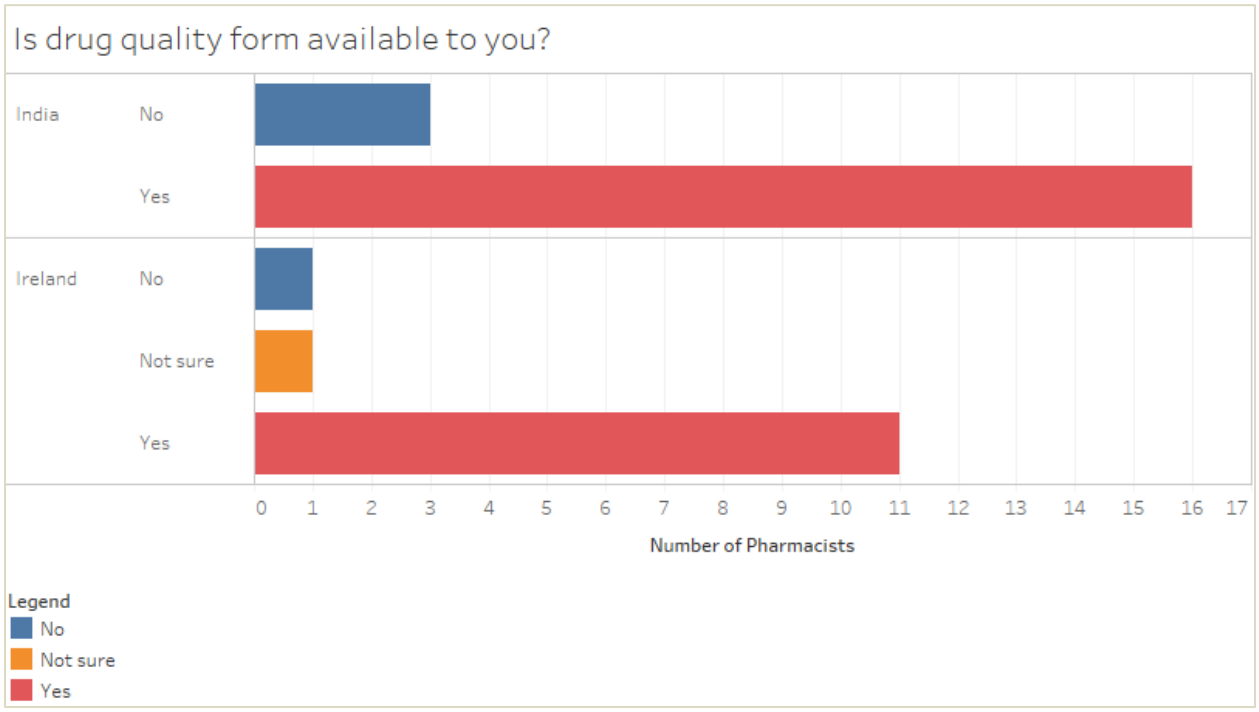



*Figure 21: The availability of the drug quality form*

Figure shown above, represents data collected from Indian and Irish pharmacists concerning the availability of the drug quality form. The respondents were asked to report whether the drug quality form was available to them. They were to choose from the following options; yes, no, and not sure. Out of a total of 32 pharmacists who participated in the study, 19 were Indians, and 13 were from Ireland. Generally, 27 pharmacists from both India and Ireland, representing 84.4%, responded with a YES, 4 (12.5%) responded with a NO, and only 1 (3.1%) was not sure whether the drug quality form was available to them. In India, 16 pharmacists responded with a YES, and only three responded with a NO. In Ireland, 11 responded with a YES, one responded with a NO, and only one responded with not sure. Based on this majority of the pharmacists from India and Ireland have access to the drug quality form. However, it is only a few pharmacists who don't have access

and are not sure whether the drug quality forms are available to them.

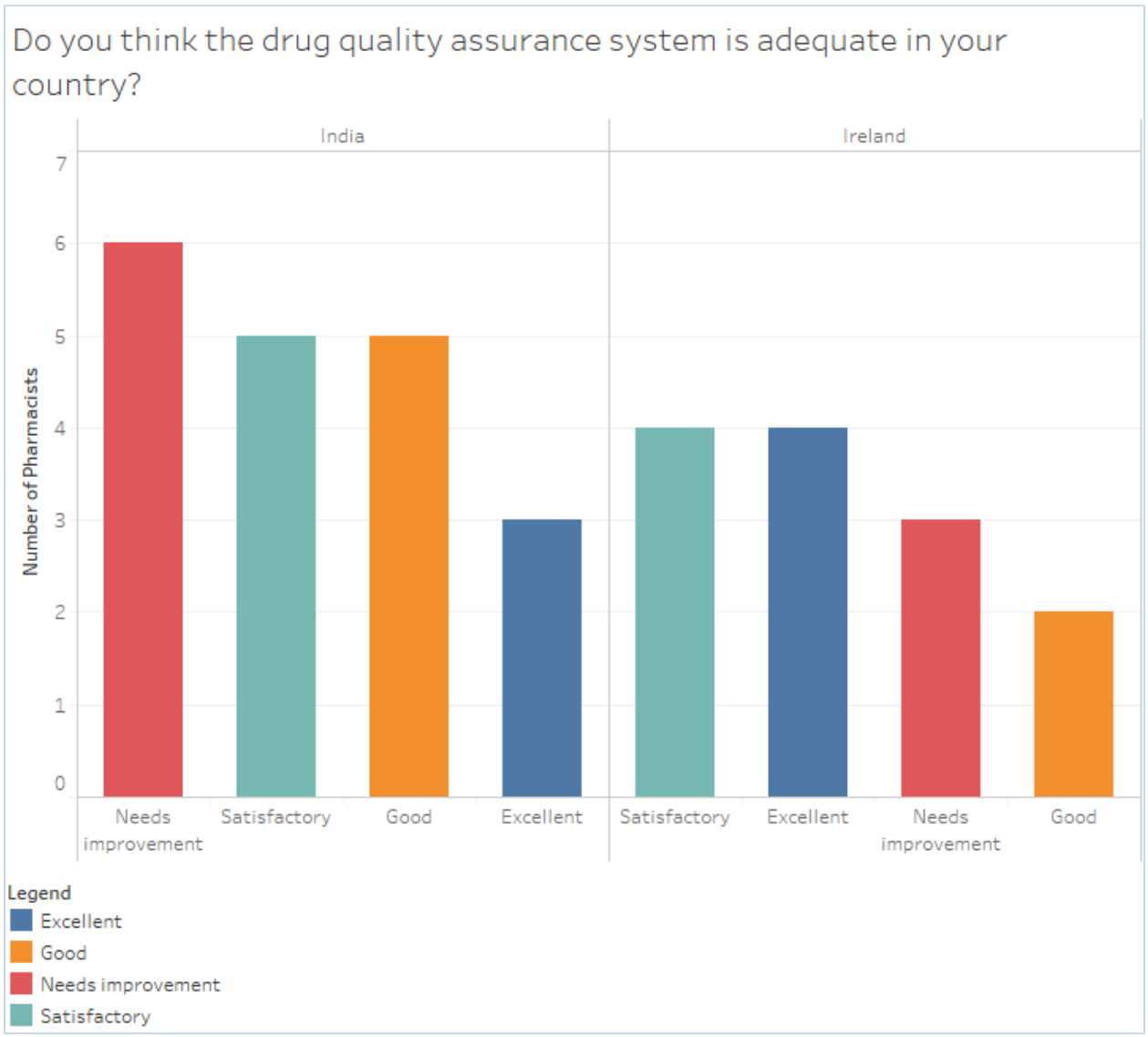



*Figure 22: Whether the drug quality assurance system is adequate in the country*

This represents data collected from pharmacists to determine if the drug quality assurance system is adequate in India and Ireland. The respondents were to pick from the following options; excellent, good, needs improvement, and satisfactory. Out of a total of 32 pharmacists who participated in this study, 28.1% (9) said that their quality assurance system needs improvement, 28.1% (9) said that their system is satisfying, 21.9% (7) said that it is excellent and 21.9% (7) said that their system is good. In India, six reported that their system should be improved, five reported that their system is satisfying, five also reported that their system is good, and only three reported that their system is excellent. In Ireland, four reported that their system is satisfying, four reported

that it is excellent, three reported that it needs improvement, and only two reported that their system is good. Therefore, based on this analysis, the drug quality assurance system in both countries, i.e., India and Ireland are fairly good; however, some improvements are needed.

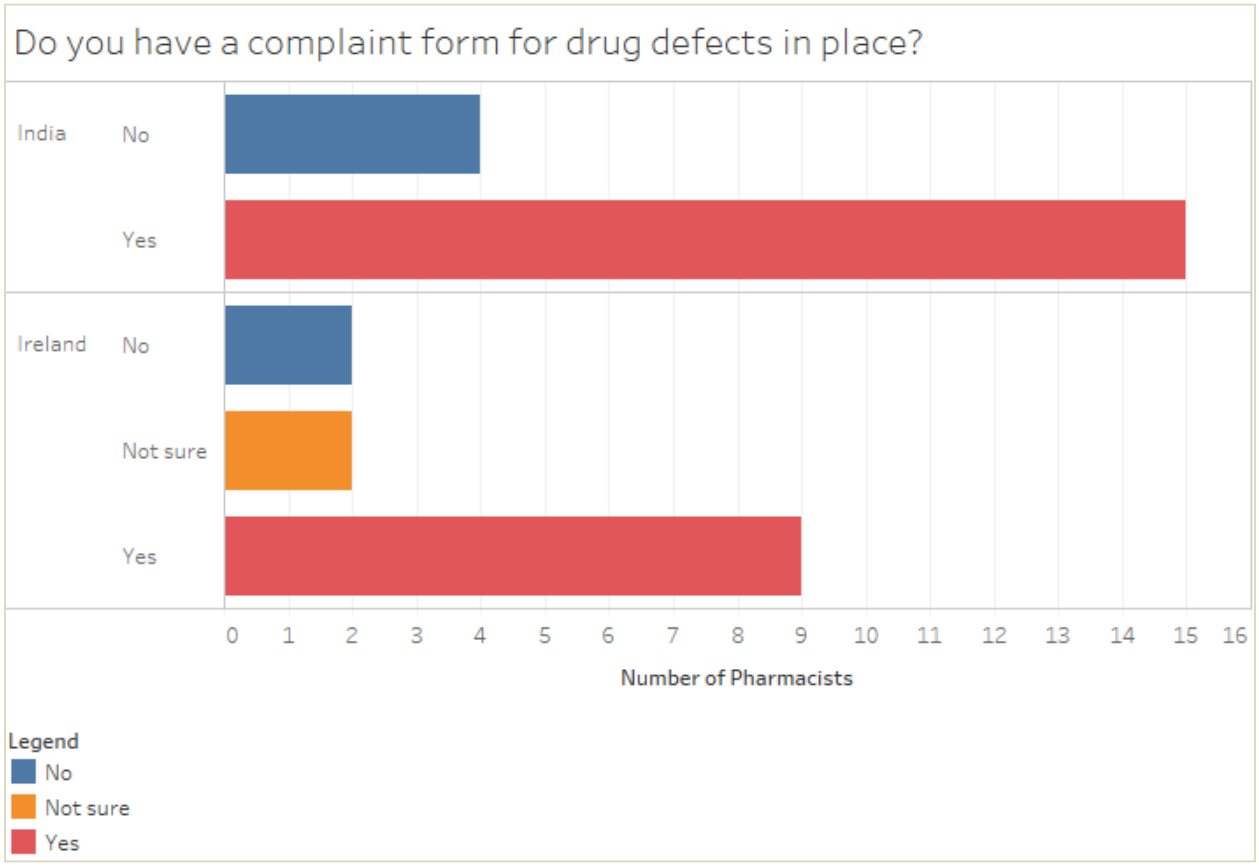



*Figure 23: if there is a complaint form for drug defects in place*

Figure shown above, outlines data collected from pharmacists concerning the availability of the complaint form in place. The respondents were given three options to choose from; YES, NO, and not sure. Out of a total of 32 respondents who participated in the study, 24 of them, representing 75%, responded with a yes, 18.8% (6) responded with a NO, and 2 (6.3%). In India, 15 pharmacists responded with a YES, and four responded with a NO. In Ireland, nine pharmacists responded with a YES, two were not sure, and also two responded with a NO. Therefore, based on this analysis, it can be said that the majority of the respondents from both India and Ireland agreed that they have a complaint form for drug defects in place.

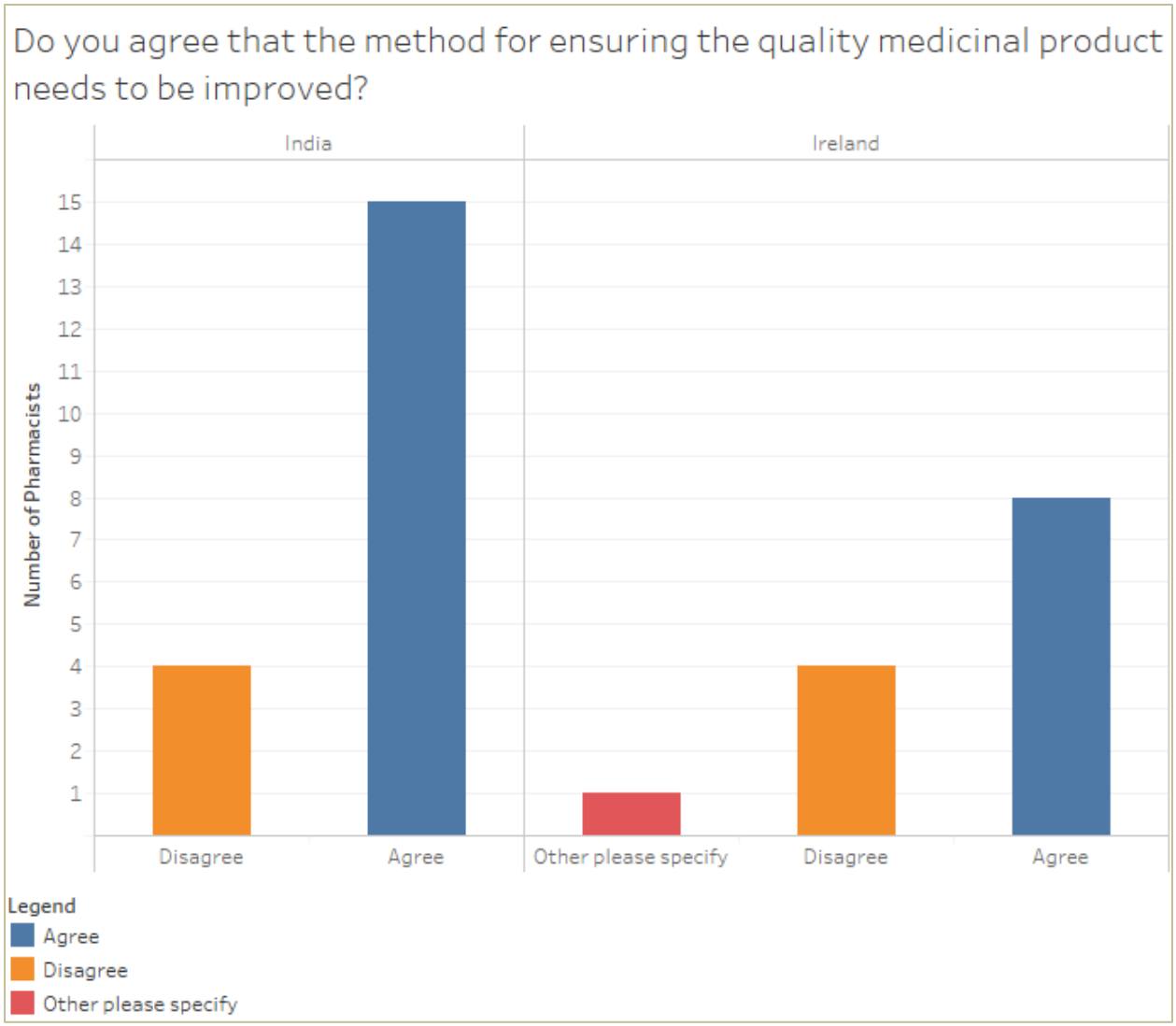



*Figure 24: Improving the method of ensuring drug quality*

Figure shown above represents data collected from the pharmacists concerning whether they agree that the method for ensuring the quality of medicinal products needs to be improved. The participants were expected to either disagree, agree, disagree, or agree. Out of a total of 32 pharmacists, 23 of them, representing 71.9%, agreed, 25% (8) disagreed, and only one (3.1%) was neutral about this. In India, 15 pharmacists agreed, while only 4 of them disagreed. In Ireland, eight pharmacists agreed, four disagreed, and only one was unsure. Therefore, based on this analysis, it can be said that the majority of the pharmacists from both India and Ireland agree that the method of ensuring the quality of medicinal products should be improved.

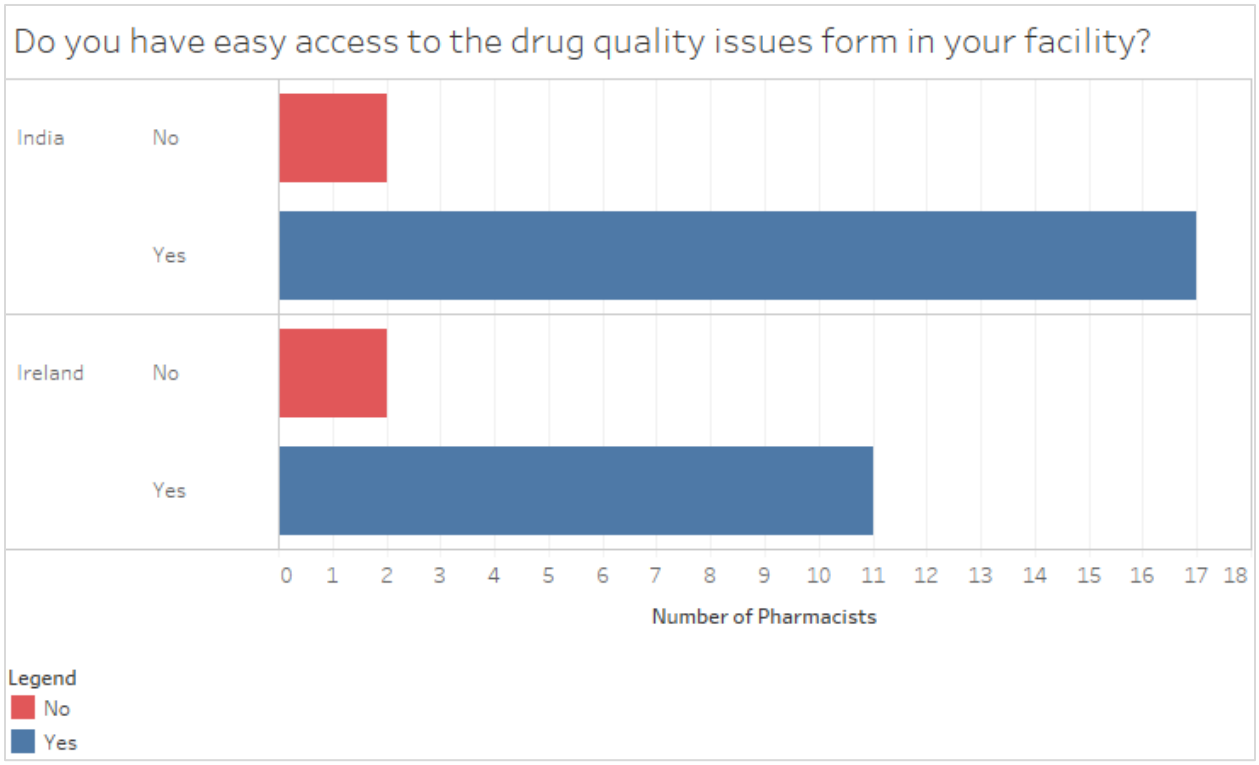



*Figure 25: Access to the drug quality issues form in the facility*

The bar graph shown above shows data collected from the 32 pharmacists who were asked to report whether they have easy access to the drug quality issues form in their facility. The participants were to respond with either YES or NO. Generally, out of a total of 32 pharmacists who participated in the study, 87.5% (28) responded with a YES, and 12.5% (4) responded with a NO. In India, 17 pharmacists responded with a YES, while only two responded with a NO. In Ireland, 11 pharmacists responded with a YES, while only two responded with a NO. Therefore, based on this analysis, the majority of the pharmacists from both India and Ireland agreed that they have easy access to drug quality issues from their respective facilities.

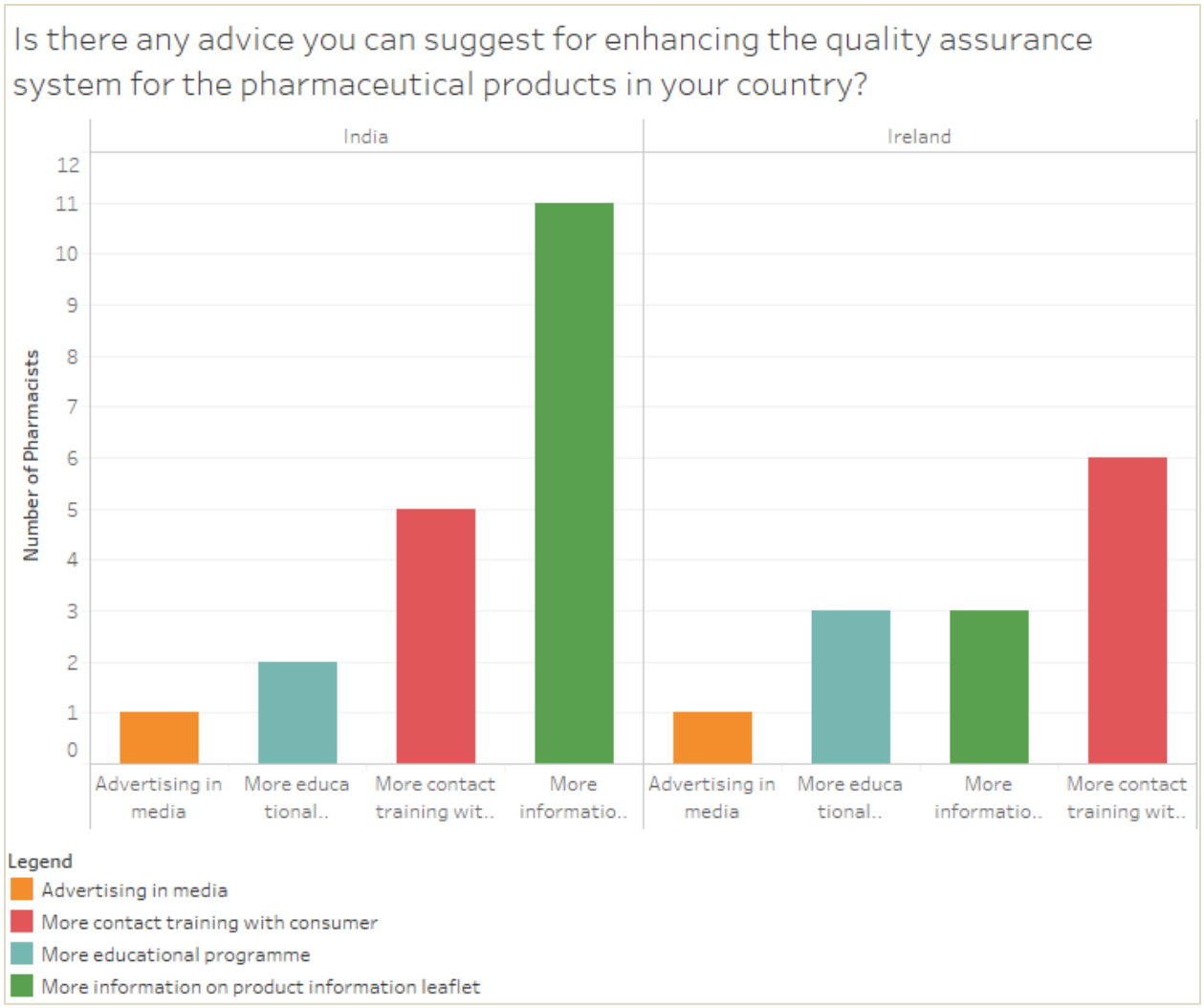



*Figure 26: Advice to enhance the quality assurance system of the pharmaceutical products in the country*

Shown above is a bar graph representing data collected from 32 pharmacists concerning their advice to enhance the quality assurance system regarding the pharmaceutical products in their country. The participants were given the following options to choose from; advertising in the media, more contact training with the consumer, more educational programs, and more information on product information leaflets. Out of 32 pharmacists who participated in this study, 43.8% (14) suggested that more information should be provided on the product information leaflet, 34.4% (11) suggested that there is a need for more contact training with the end users, 15.6% (5) suggested that there is need for more educational program and 6.3% (2) suggested that more advertising should be done in the media. In India, the majority of the pharmacists suggested that

more information should be included in the product leaflet, while in Ireland, it was suggested that more contact training should be done for the consumers.

### 4.4. Pharmaceutical manufacturers

**OBJECTIVE 3: To determine how pharmaceutical manufacturers from both India and Ireland ensure the quality of medicines.**

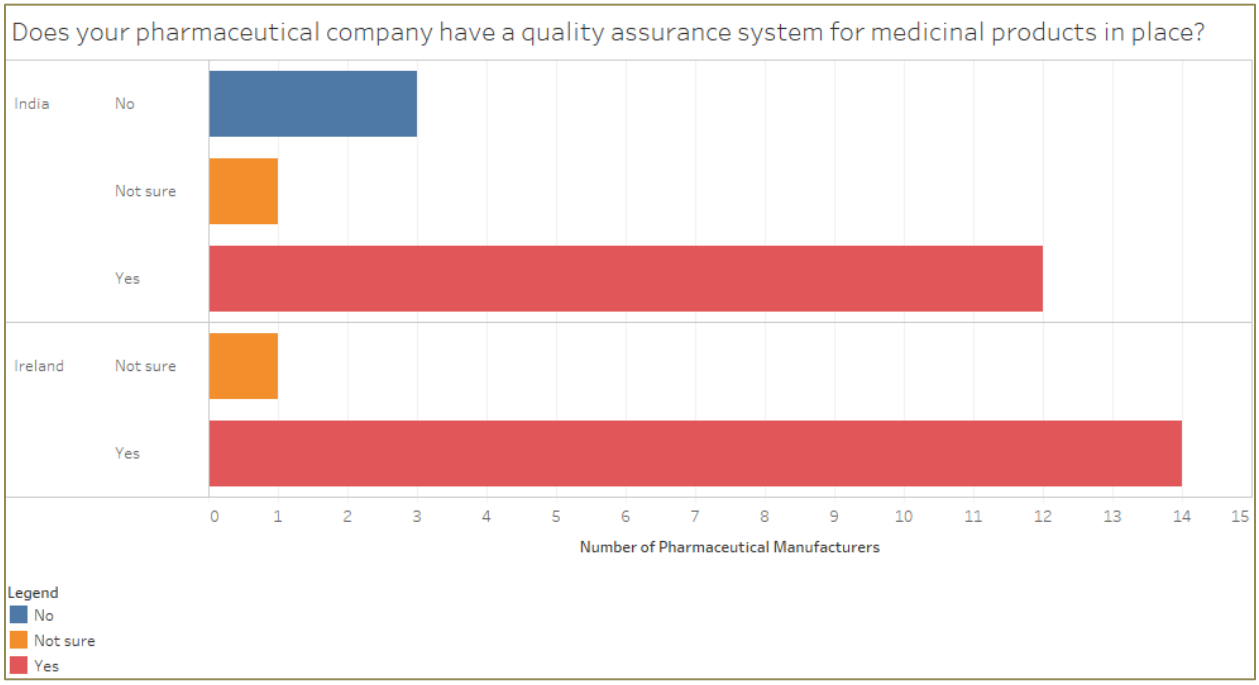



*Figure 27: If the company has a quality assurance system for medicines in place*

Figure shown above shows data collected from pharmaceutical manufacturers. They were asked to respond with a YES, NO, or not sure concerning whether their respective pharmaceutical company has a quality assurance system in place. In India, 12 manufacturers responded with a YES, three responded with a NO, and only one was not sure. In Ireland, 14 responded with a YES, and only one responded with a NO. In general, most of the pharmaceutical manufacturers from both countries, i.e., India and Ireland, 83.9% (26) agree that their companies have a quality assurance system in place.

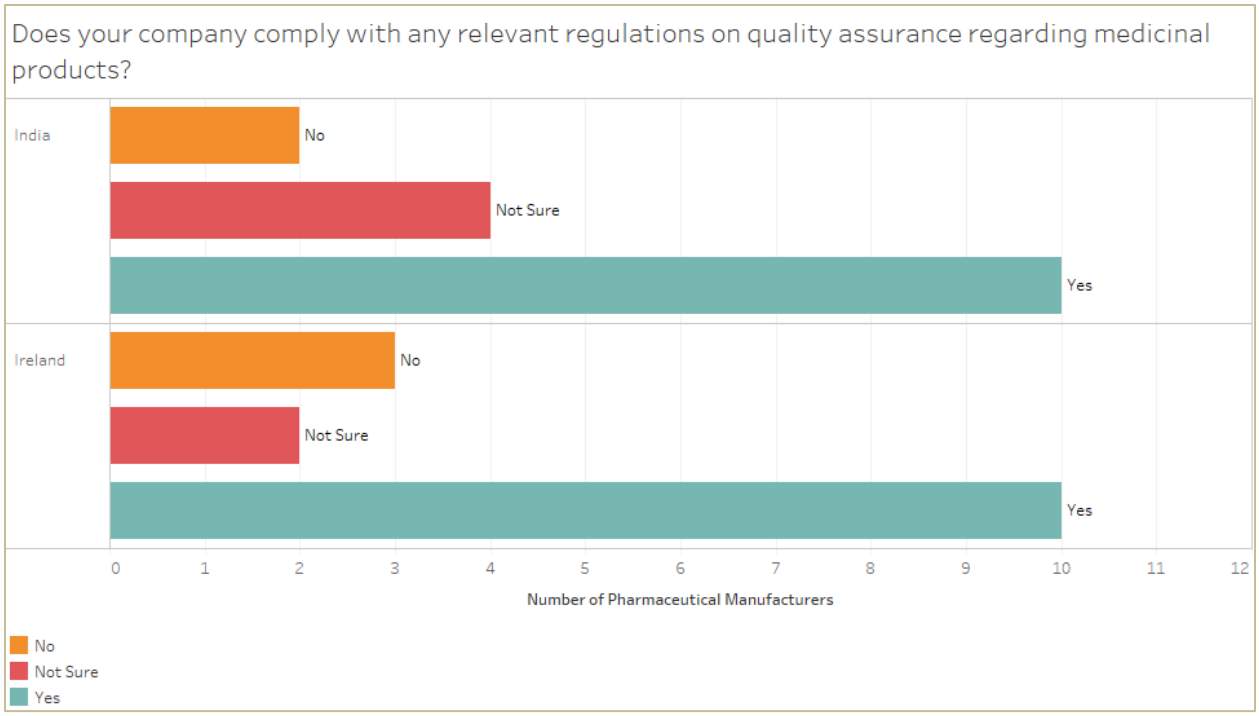



*Figure 28: Complying with any relevant regulations on quality assurance of the medicines*

Figure shown above represents data collected from the pharmaceutical manufacturers to determine whether their companies are in compliance with any relevant regulations on quality assurance of the medicines. The participants were to respond with either a YES, NO, or not sure. In India, ten manufacturers responded with a YES, four were not sure, and two responded with a NO. In Ireland, they responded with a YES, 3 with a NO, and two were not sure. Therefore, based on this analysis, the majority of the pharmaceutical manufacturers from India and Ireland agreed that their companies are in compliance with the relevant regulations on the quality assurance of medicinal products.

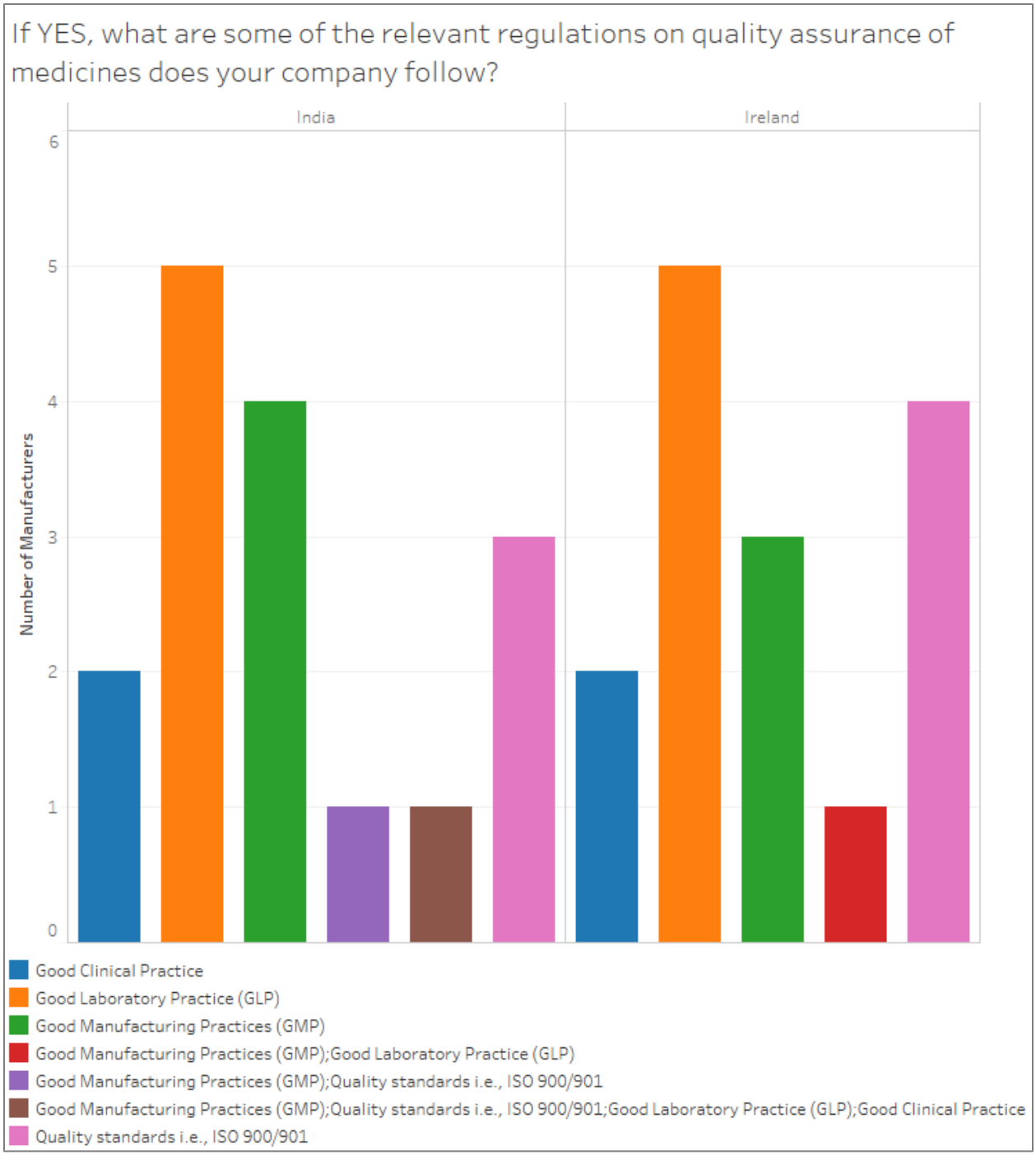



*Figure 29: Relevant regulations on pharmaceutical quality assurance*

The bar graph shown above outlines data regarding the relevant regulations on quality assurance of medicines present in the companies. Out of a total number of 31 manufacturers who participated in the study, 16 came from India, and 15 came from Ireland. In India, five manufacturers reported that their company is in compliance with the Good Laboratory Practices (GLP), four reported that

they use good manufacturing practices (GMP), two said that they follow the good clinical practice, three reported that they adhere to the quality standards such as ISO 900/901 and 2 reported that their company follows a combination of GMP, quality standards, i.e., ISO 900/901, GLP and good clinical practice. In Ireland, five companies use GLP, 4 of their company to the quality standards, i.e., ISO 900/901, 3 comply with the GMP, two comply with the good clinical practice (GCP), and only one complies with both GMP and GLP.

It can be concluded that most of the pharmaceutical manufacturers from both India and Ireland comply with Good Laboratory Practices (GLP), represented by 38.7% (12), followed by GMP at 32.3% (10), followed by quality standards at 29% (9) and Good clinical practice is only used in 5 companies representing 16.1% (5). In India, the most regulations being followed is the good laboratory practice (GLP) and good manufacturing practice (GMP). In Ireland, the most common regulations include good laboratory practice and ISO 900/901.

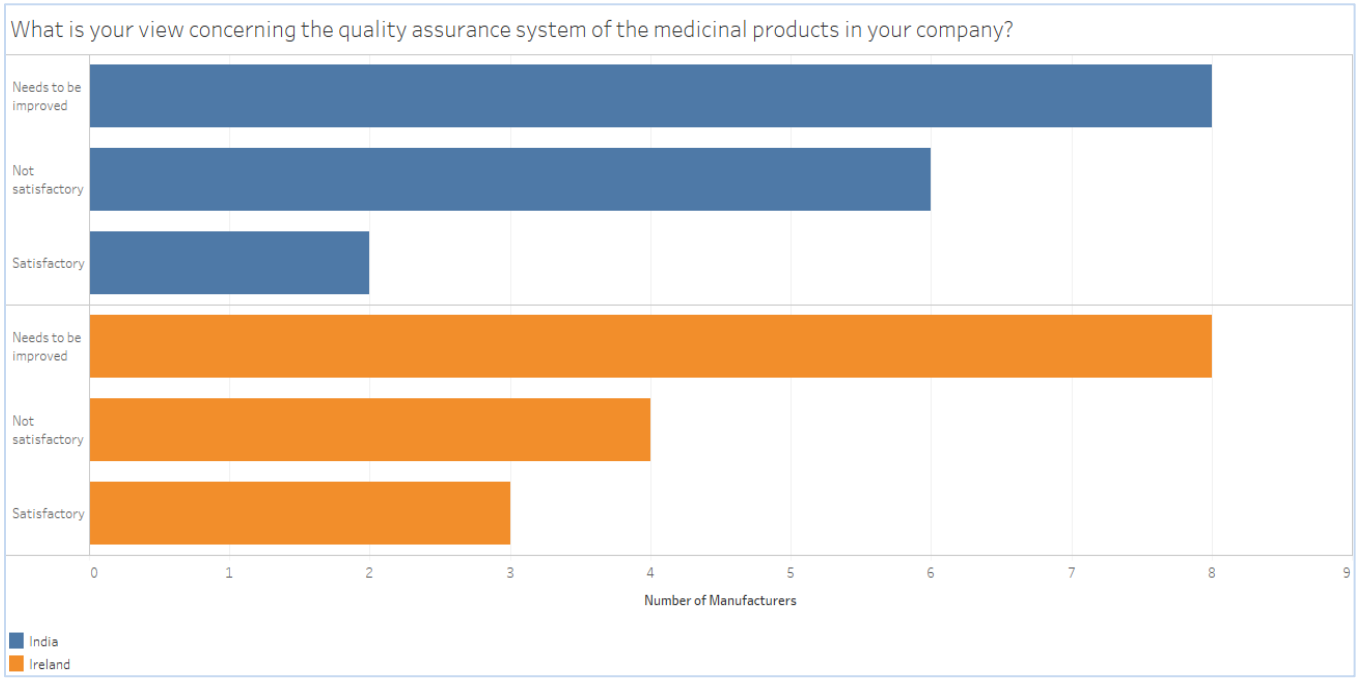



*Figure 30: Opinion concerning the quality assurance system of the medicinal products in the company*

Figure shown above, represents data collected from pharmaceutical manufacturers concerning their view on the quality assurance system of the medicinal products in their company. The participants were to choose from the following options; satisfactory, not satisfactory, needs to be improved, excellent, and not sure. Generally, 51.6% (16) reported that the quality system in the

country needs to be improved, 32.3% (10) reported that they are not satisfied with their system, and only 16.1% (5) reported that their system is satisfying. In India, eight manufacturers reported that their system needs to be improved, six reported that it is not satisfying, and only two reported that they are satisfied with their system. In Ireland, eight reported that their system needs improvement, four reported that they were not satisfied, and only three reported that they were satisfied with their quality assurance system. Therefore, based on this analysis, it can be said that the pharmaceutical quality assurance system of medicines in both India and Ireland is not satisfying, and thus, it needs to be improved.

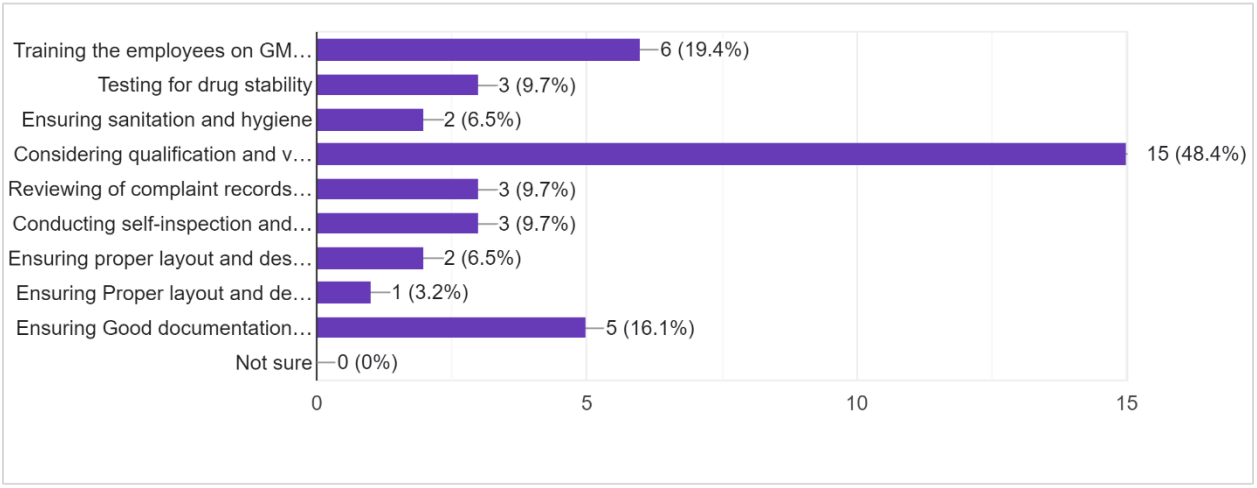



*Figure 31: How the pharmaceutical company ensures the quality of medicinal products*

Figure shown above, represents general data collected from pharmaceutical manufacturers from both India and Ireland. As shown in the bar graph above, the participants were to choose from the following options: conducting self-inspections and quality audits, ensuring good documentation of the pharmaceutical manufacturing procedures, ensuring proper layout and design of premises, ensuring sanitization and hygiene, reviewing complaint records concerning the drug defects, testing for drug stability, training the employees on GMP and other related quality assurance practices and considering qualification and validation procedures. Out of 31 manufacturers who participated in the study, the majority, i.e., 15 of them being represented, with 48.4% from both India and Ireland, reported that the quality of medicines is ensured by considering qualification and validation procedures.

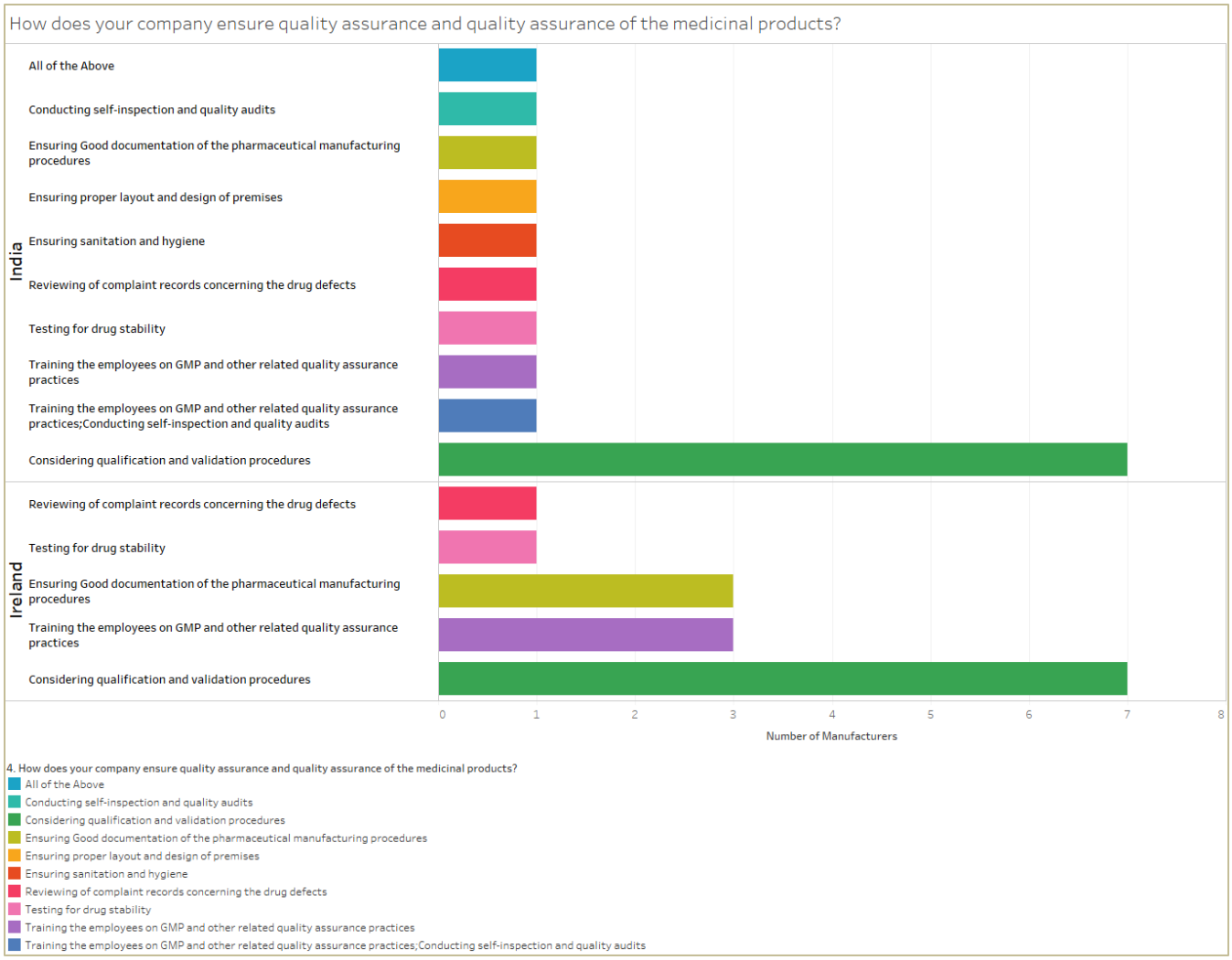



*Figure 32: How pharmaceutical companies ensure the quality of the medicines*

Figure shown above represents data collected from individual countries, i.e., India and Ireland. The participants were to choose from options as outlined in Figure 32. Out of 31 manufacturers who participated in the study, 16 came from India, and the other 15 came from Ireland. In India and Ireland, the most common method of ensuring the quality of medicines is by considering the qualification and validation procedures of the medicinal products.

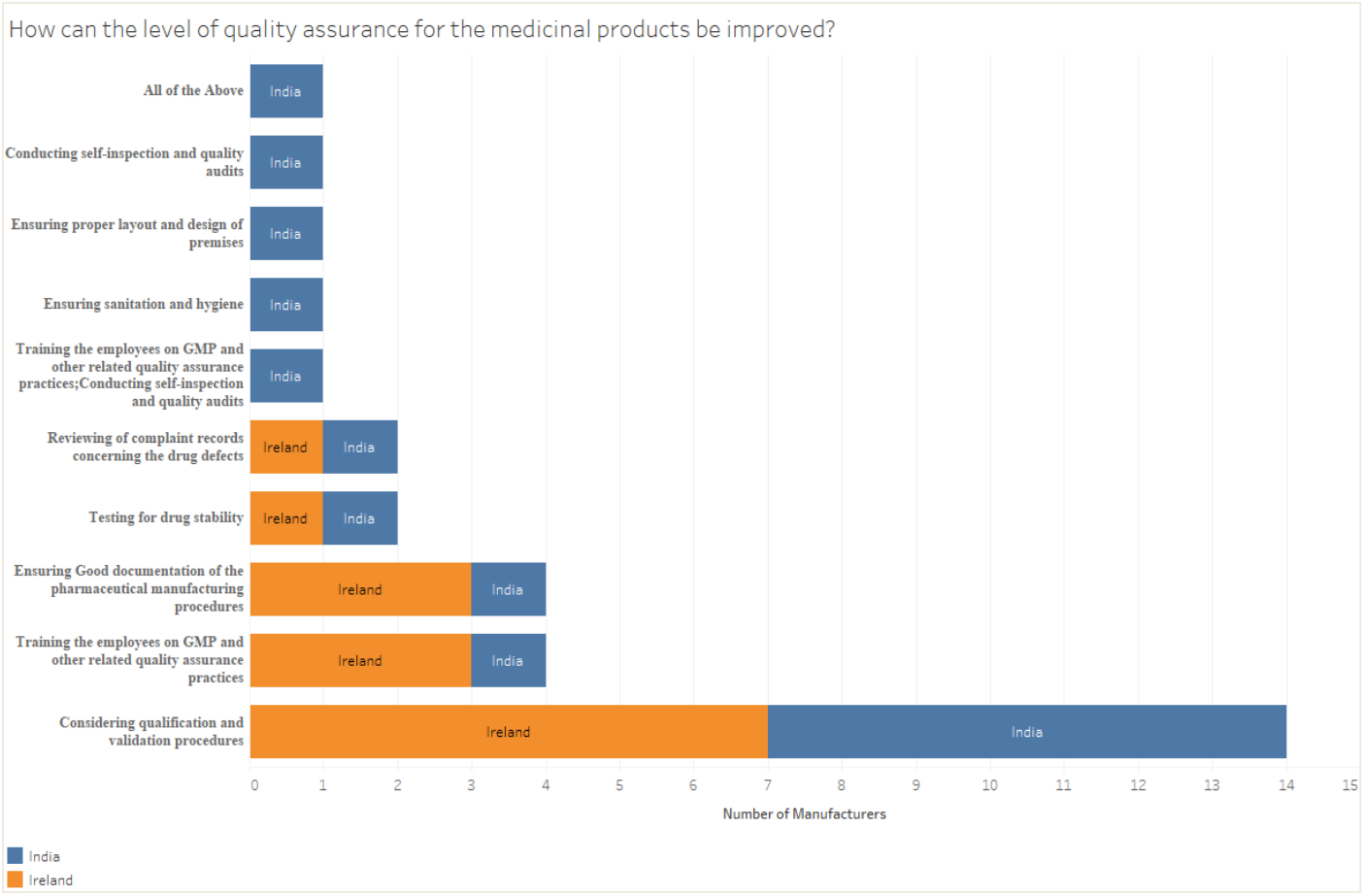



*Figure 33: Improving the level of quality assurance for the medicinal products*

Figure shown above, represents data collected from pharmaceutical manufacturers from both India and Ireland concerning how the level of quality assurance for medicines can be improved in their countries. The participants were given the following options to choose from, i.e., conducting self-inspection and quality audits, ensuring proper layout and design of premises, ensuring sanitization and hygiene, training the employees on GMP and other related quality assurance practices, reviewing complaint records concerning drug defects, testing for drug stability, ensuring good documentation of the pharmaceutical manufacturing procedures, training the employees on GMP and other related quality assurance practices and considering a qualification as well as validation procedures. As shown in the above bar graph, it can be said that manufacturers from both India and Ireland suggest that the quality of the medicinal products can be improved by considering the qualification and validation procedures of the medicinal products.

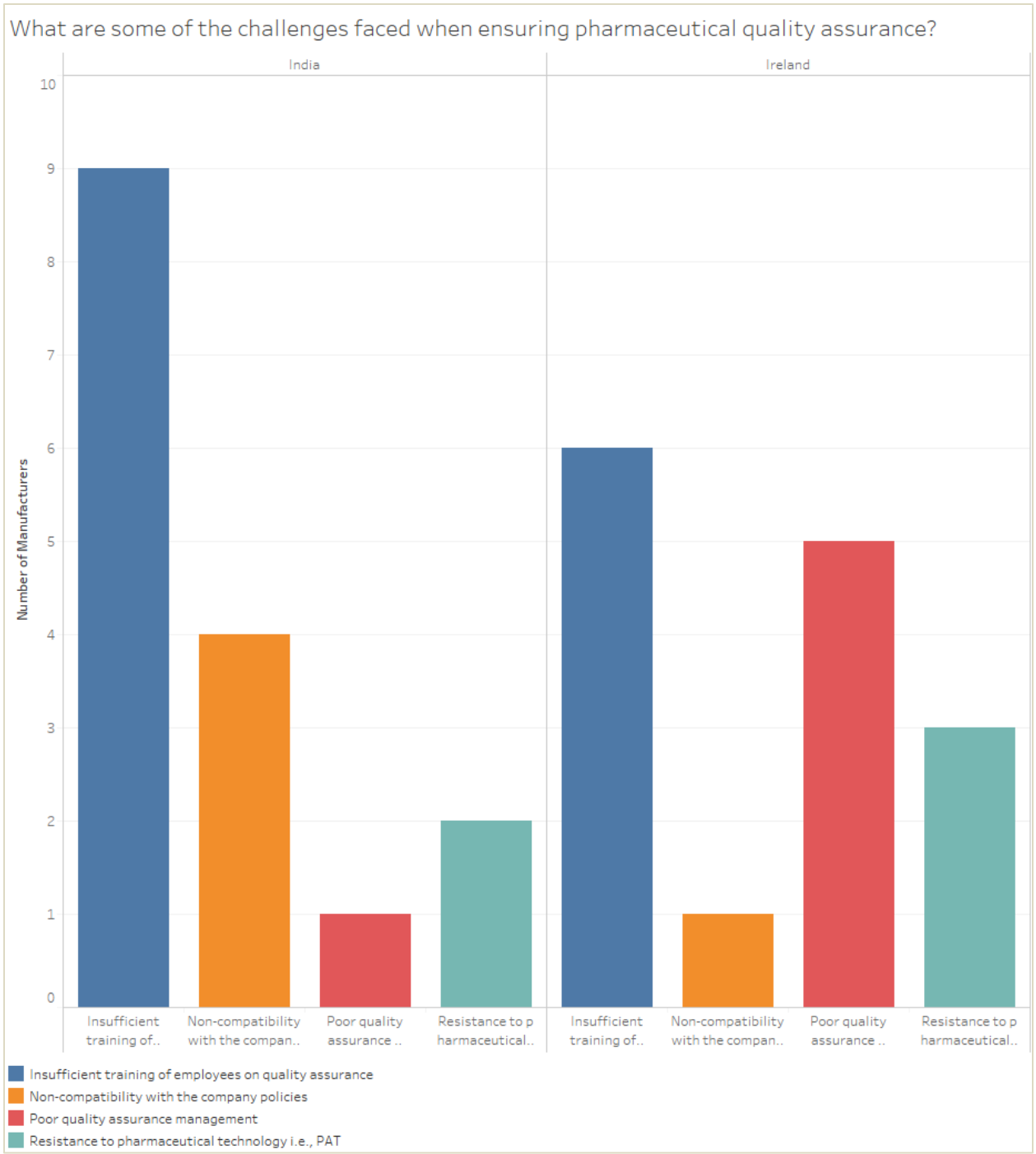



*Figure 34: Challenges faced when ensuring pharmaceutical quality assurance*

In the bar graph shown above, pharmaceutical manufacturers were asked to report some of the challenges that they face when ensuring pharmaceutical quality assurance in their respective companies. The participants were expected to choose from the following options; insufficient training of employees on quality assurance, non-compatibility with the company policies, poor

quality assurance management, and resistance to pharmaceutical technology such as PAT. In India, most (9) of the manufacturers reported that there is a challenge of insufficient training of employees on quality assurance followed by non-compatibility with the company policies. In Ireland, the most common problem is insufficient training of employees on quality assurance and poor-quality assurance management. Therefore, based on this analysis, it can be said that the most common challenge faced when ensuring the quality of medicines in both countries is insufficient training of employees on quality assurance.

## 4.5. General Questions

**OBJECTIVE 4: To determine how HPRA and CDSCO ensure the quality of medicines in Ireland and India, respectively.**

*i. To determine how HPRA ensures the quality of medicines in Ireland.*

**Have you ever heard of the Health Products Regulatory Authority (HPRA)**

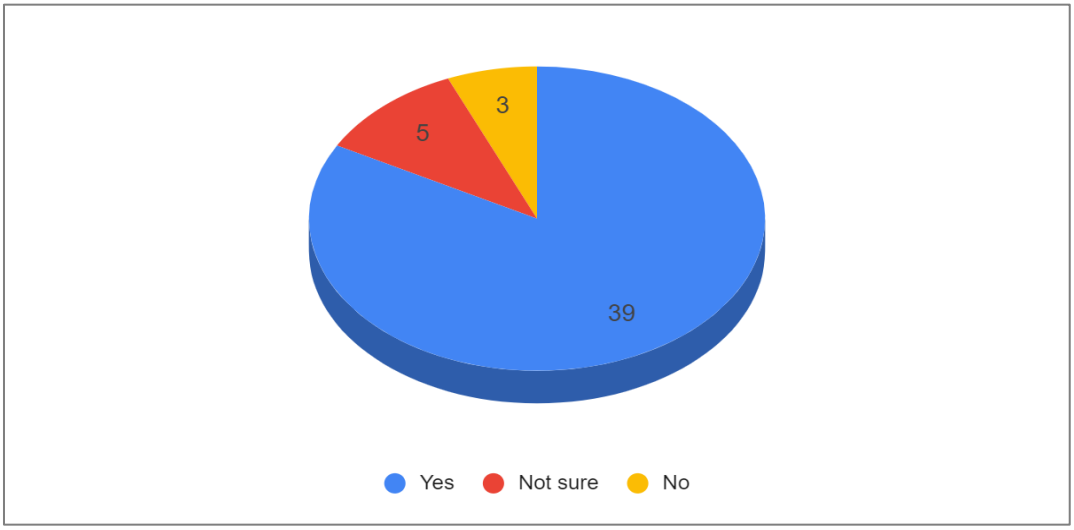



*Figure 35: Have you ever heard of HPRA*

The pie chart shown above represents data collected from all the participants from Ireland. They were to report whether they had ever heard of Health Products Regulatory Authority (HPRA). They were to choose from the following options; YES, NO, and not sure. As shown in the pie chart above, most of the participants, i.e., 39 (83%), agreed that they are aware of HPRA.

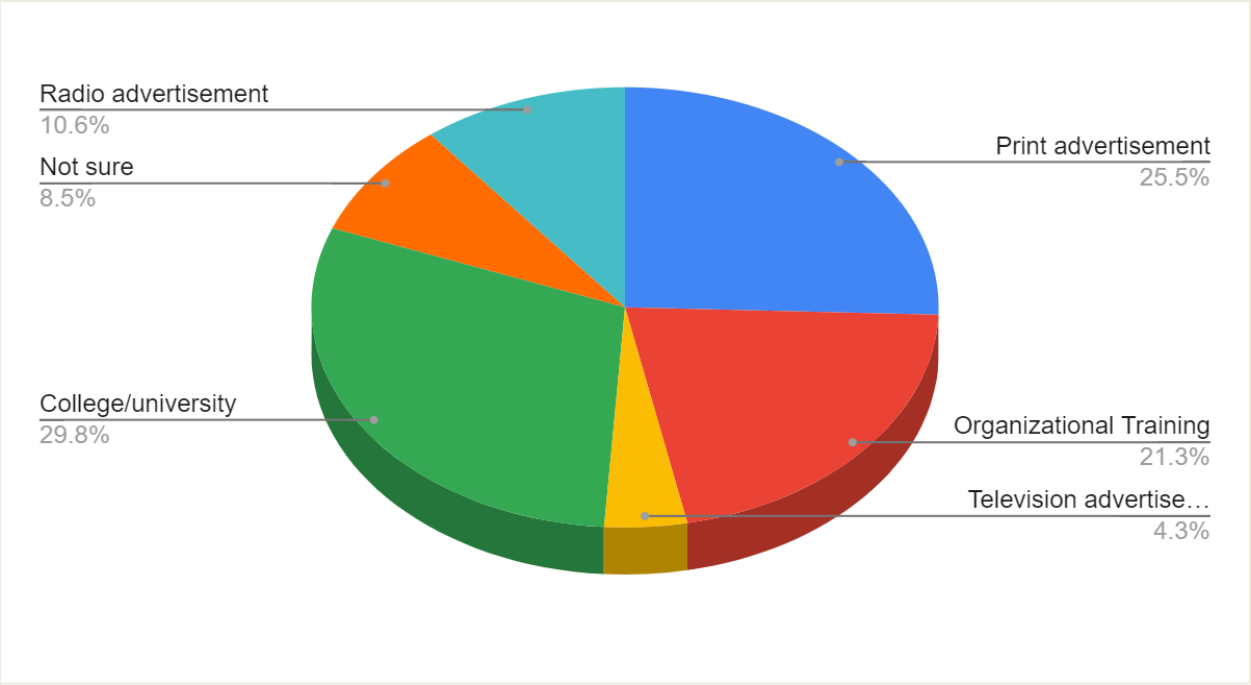



*Figure 36: If yes, how did you hear about HPRA*

The pie chart shown above represents data collected from the Irish participants. They were asked to report how they became aware of HPRA. They were given the following options to choose from; college/university, radio advertisement, television advertisement, print advertisement, organizational training, and not sure. As shown in the pie-chart above, the majority (14) of the participants from Ireland know about HPRA through college/university, 25.5% (12) knew through print advertisement, 21.3% (10) knew through organizational training, 10.6% (5) knew through radio advertisement, 8.5% (4) were not sure, and the rest 4.3% (2) heard through television advertisement. Therefore, based on this analysis, it can be said that the majority of the people from India knew HPRA through college/university, organizational training, and print advertisement.

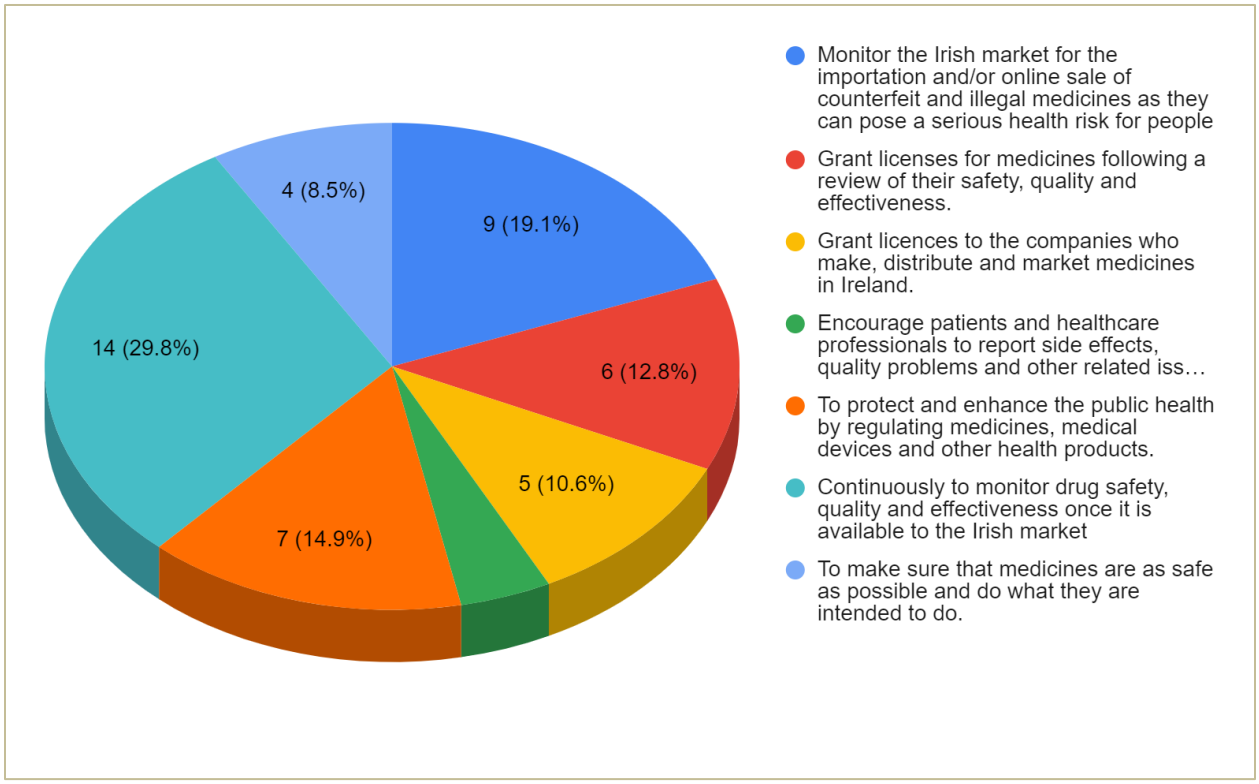



*Figure 37: At a personal level, what do you think is the major role played by HPRA in ensuring pharmaceutical quality in your country?*

According to Figure shown above, participants from India were asked to provide the major role played by HPRA in ensuring pharmaceutical quality. They were given the following options to choose from: To protect and enhance public health by regulating medicines, medical devices, and other health products; To make sure that medicines are as safe as possible and do what they are intended to do; Grant licenses for medicines following a review of their safety, quality, and effectiveness; Continuously to monitor drug safety, quality, and effectiveness once it is available to the Irish market; Monitor the Irish market for the importation and/or online sale of counterfeit and illegal medicines as they can pose a serious health risk for people; Encourage patients and healthcare professionals to report side effects, quality problems, and other related issues to the HPRA through our website or by contacting us directly; and Grant licenses to the companies who make, distribute and market medicines in Ireland. As shown in the pie chart above, the majority (29.8%) responded that the major role played by HPRA is to continuously monitor drug safety, quality, and effectiveness once it is available to the Irish market.

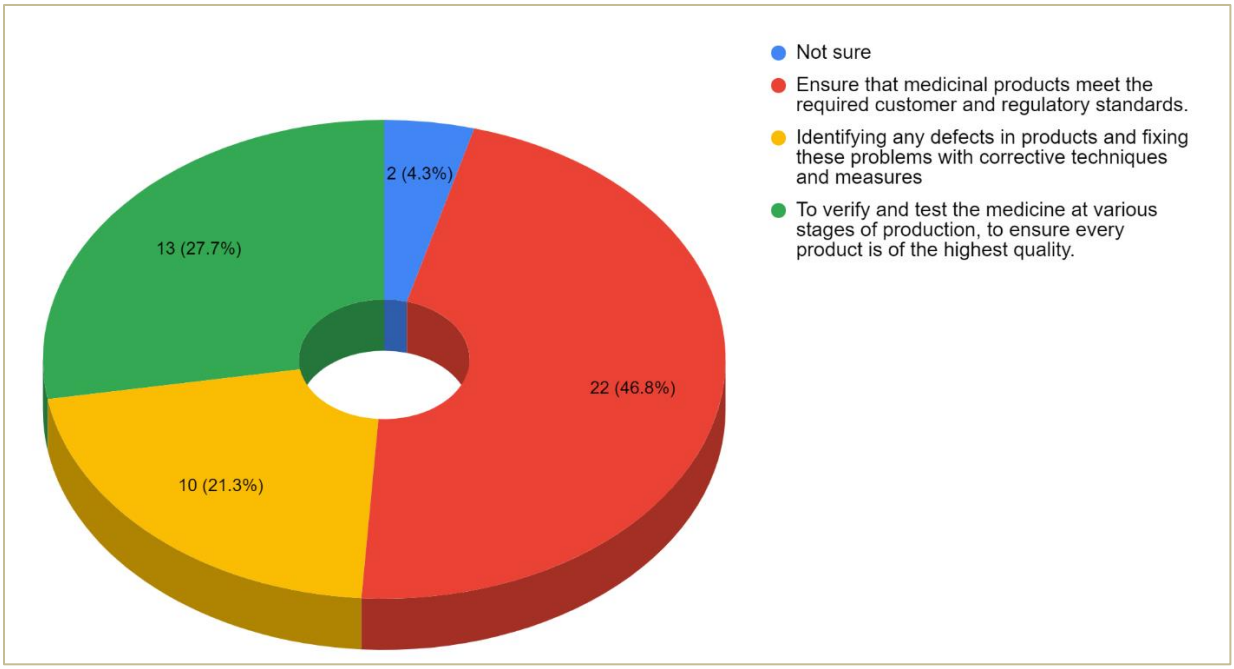



*Figure 38: The importance of ensuring pharmaceutical quality assurance?*

According to the pie chart shown above, the participants from Ireland were asked to give the importance of pharmaceutical quality assurance based on their personal understanding. As shown above, the majority of the participants, represented by 46.8%, said that the primary importance of pharmaceutical quality assurance involves ensuring that medicinal products meet the required customer needs and regulatory standards. However, others noted that it helps to identify any defects in products and fix these problems with corrective techniques and measures, as well as to verify and test the medicine at various stages of production to ensure every product is of the highest quality. It is only a few of them 2 (4.3%) were not sure.

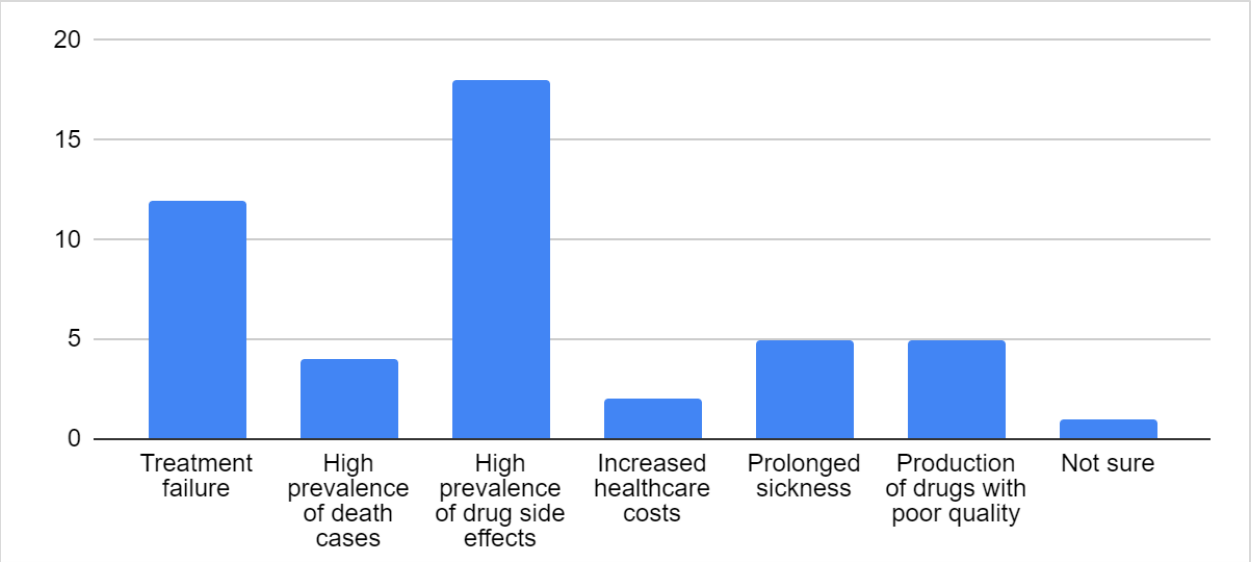



*Figure 39: What is the danger of not ensuring pharmaceutical quality assurance?*

Based on the bar graph shown above, the respondents from Ireland were to report some of the dangers that can result from failing to ensure pharmaceutical quality assurance. The participants were to choose from the following options; increased healthcare costs, production of medicines that have poor quality, high prevalence of adverse drug reactions, prolonged sickness, treatment failure, high prevalence of death cases, and not sure. As shown above, the most common danger (being represented by 18 participants), which was reported, involves a high prevalence of drug side effects or adverse drug reactions then, followed by treatment failure.

*ii. CDSCO (India): To determine how CDSCO ensures the quality of medicines in India.*

**Have you ever heard of the Central Drugs Standard Assurance Organization (C.D.S.C.O.)**

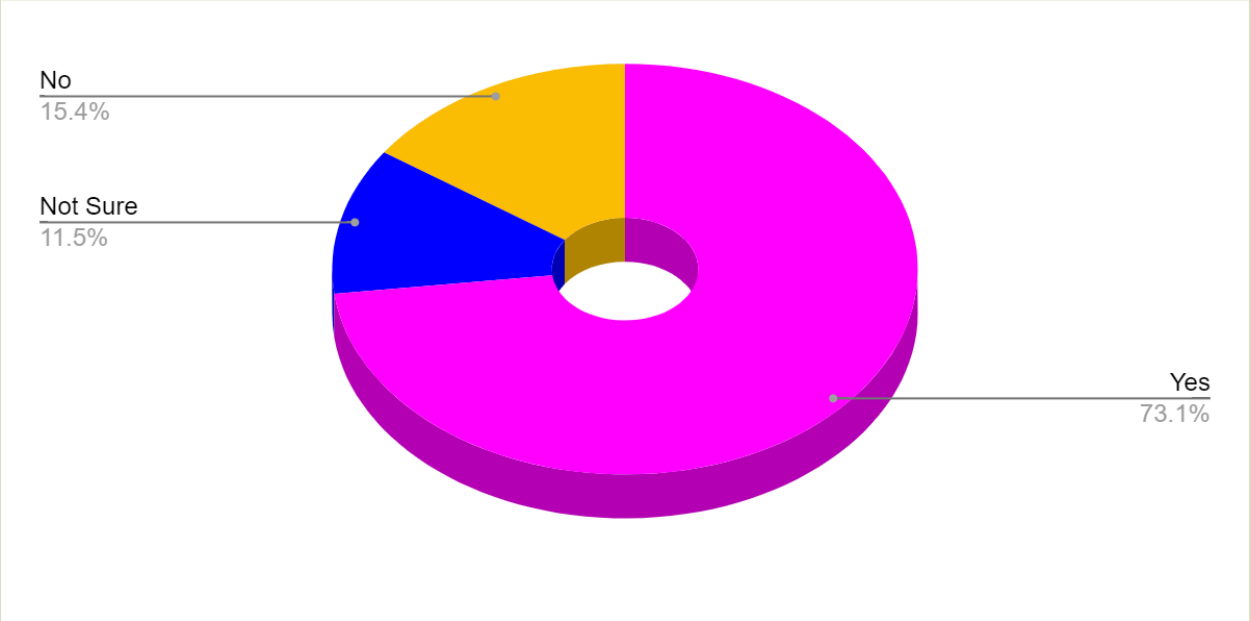



*Figure 40: Have you ever heard of the Central Drugs Standard Assurance Organization (C.D.S.C.O.)*

The pie chart shown above represents data collected from the Indian participants. They were asked to respond with a yes, no, or not sure concerning whether they are aware of Central Drugs Standard Assurance Organization (C.D.S.C.O.). As shown above, the majority of the respondents, i.e., 73.1% (38), reported that they are aware of CDSCO, 15.4% (8) are not aware, and 11.5% (6) are not sure. Therefore, based on this analysis, most of the people living in India are aware of CDSCO.

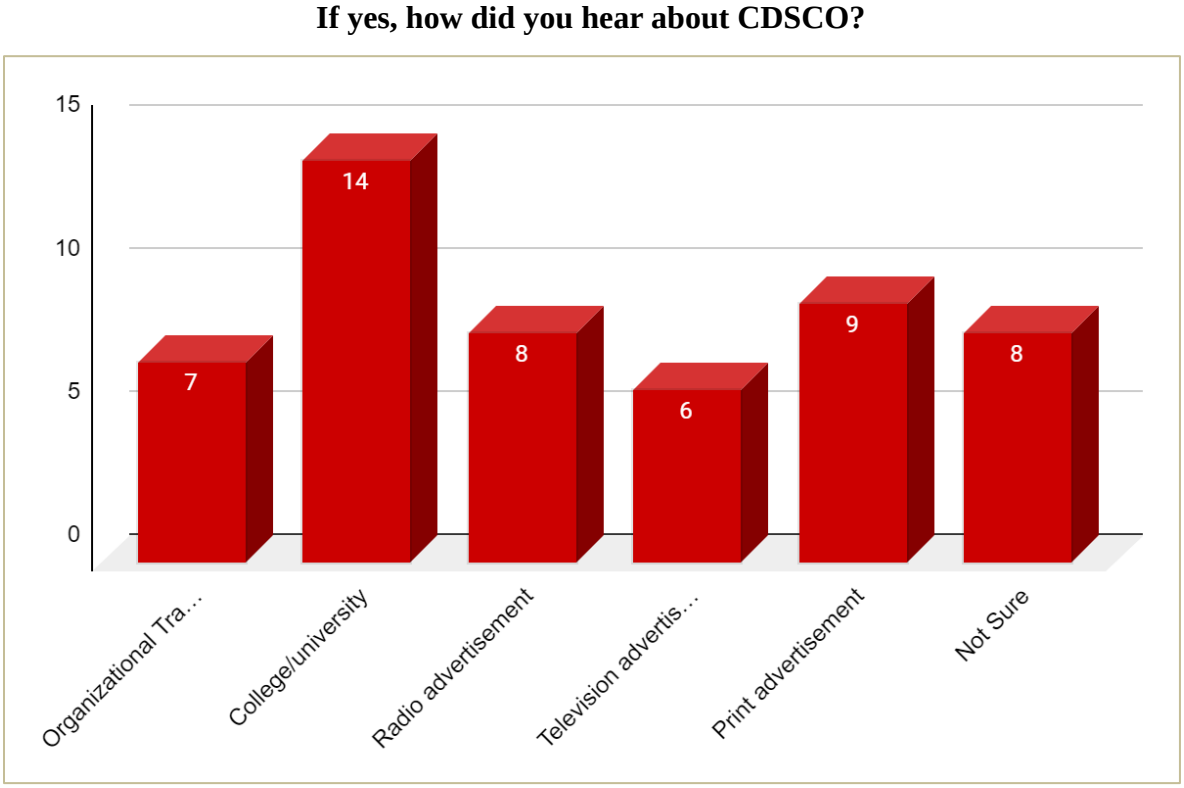



*Figure 41: If yes, how did you hear about CDSCO?*

Figure shown above, represents data collected from the Indian participants showing how they came to know about CDSCO. The respondents were given the following options to choose from; college/university, radio advertisement, television advertisement, print advertisement, organizational training, and not sure. As shown above, 26.9% (14) heard about CDCSO while in college/university, 17.3% (9) knew through print advertisement, 15.4% (8) knew through radio advertisement, 15.4% (8) were not sure and 13.5% became aware through organizational training. Therefore, based on this analysis, most of the Indians became aware of CDSCO through college/university.

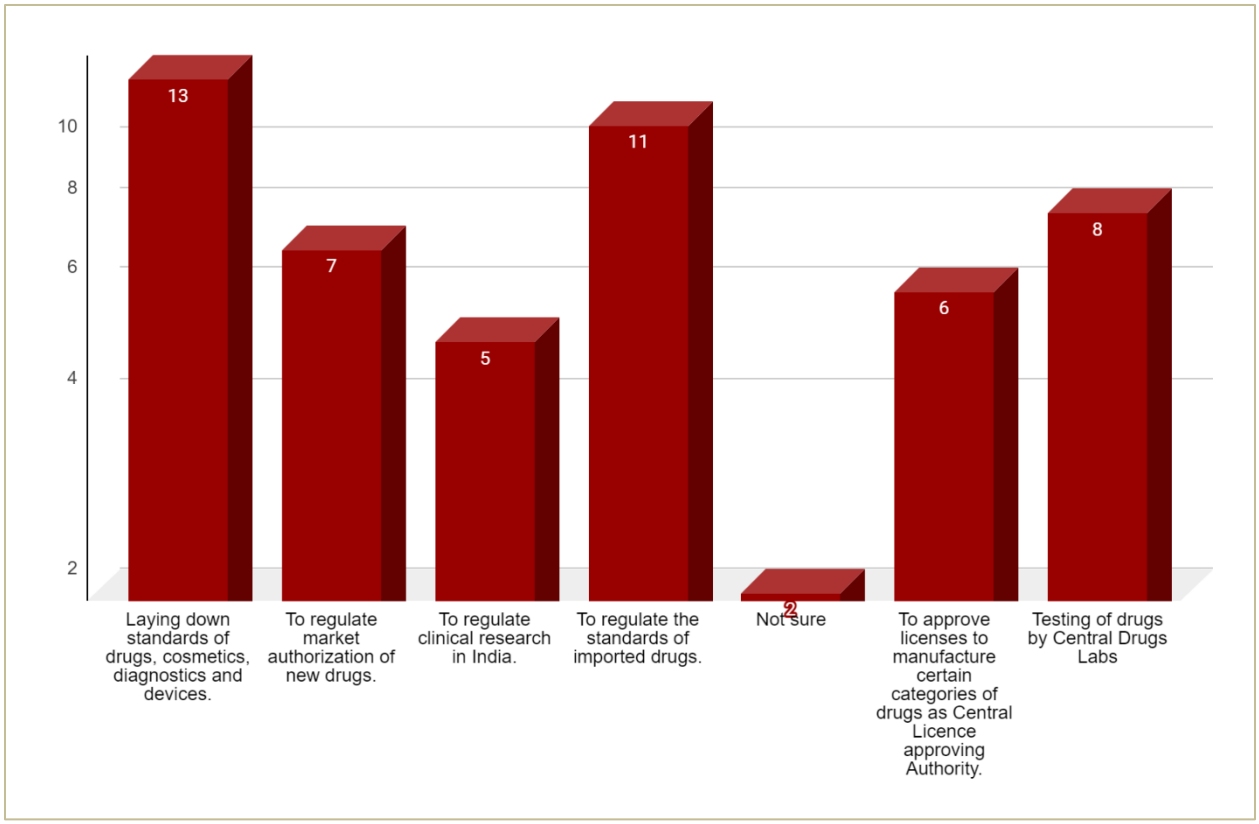



*Figure 42: what do you think is the major role played by CDSCO in ensuring pharmaceutical quality in your country?*

The bar graph shown above represents data collected from the Indian participants. They were asked to provide the major role played by CDSCO when it comes to ensuring pharmaceutical quality in India. They were to choose from the following options: to regulate market authorization of new drugs; To regulate clinical research in India; to lay down standards of drugs, cosmetics, diagnostics, and devices; To regulate the standards of imported drugs; Testing of drugs by Central Drugs Labs; To approve licenses to manufacture certain categories of drugs as Central License Approving Authority; and not sure. As shown in the bar graph above, 13 Indians said that the main role of CDSCO includes laying down standards for drugs, cosmetics, diagnostics, and devices; 11 said that it regulates the standards of imported drugs; 8 said that it plays a role of testing the drugs by central drugs labs 7 reported that it has a role of regulating market authorization of new drugs; 6 said that it approves licenses to manufacture certain categories of drugs as central license approving authority; 5 said that it has a role of regulating clinical research in India and only two were not sure. Based on this analysis, the majority of the Indians (13 and 11) believe that CDSCO

plays a major role in ensuring pharmaceutical quality assurance by laying down the standards of drugs, cosmetics, diagnostics, and devices, as well as regulating the standards of the imported medicinal products.

**Based on your understanding, what is the importance of ensuring pharmaceutical quality assurance?**

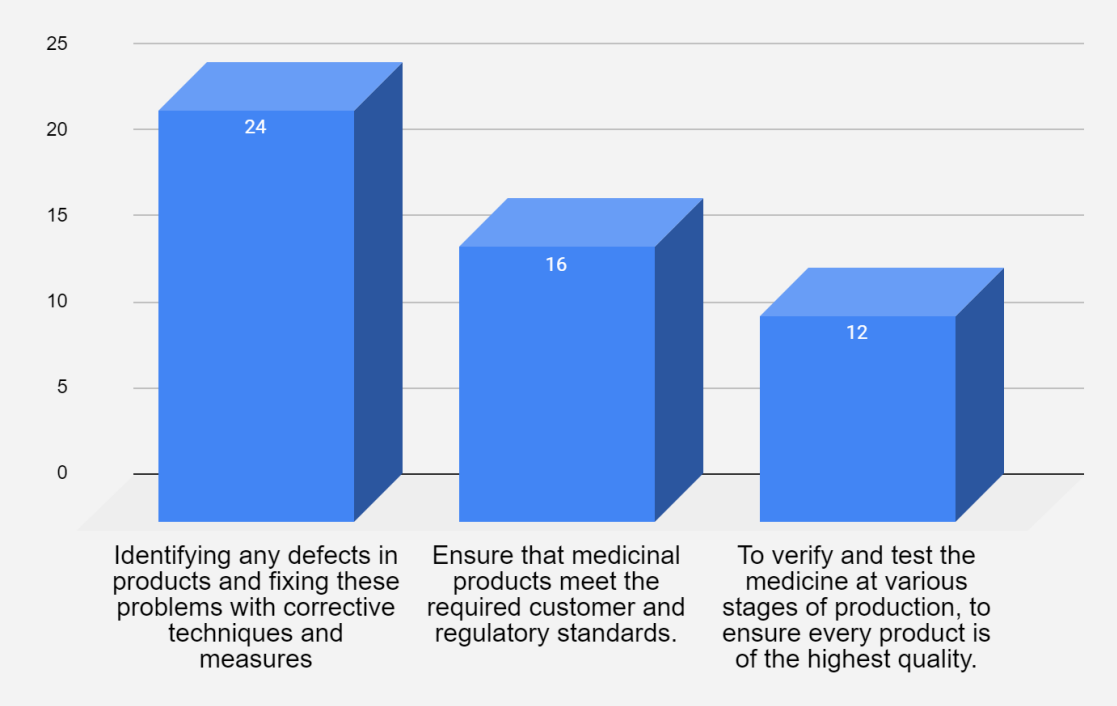



*Figure 43: What is the importance of ensuring pharmaceutical quality assurance?*

According to the bar graph shown above, the Indian participants were asked to give the importance of ensuring pharmaceutical quality assurance. According to the above data, they were to choose from the following options; To verify and test the medicine at various stages of production, to ensure every product is of the highest quality; to identify any defects in products and fix these problems with corrective techniques and measures; Ensure that medicinal products meet the required customer and regulatory and not sure. Based on the bar graph above, 46.2% (24) noted that ensuring pharmaceutical quality assurance helps in the identification of any defects in medicinal products and fixing of these problems with corrective techniques and measures; 30.8% (16) said that it helps to ensure that medicinal products meet the required customer and regulatory standards; and 23.1% (12) noted that it helps to verify and test the medicines at various stages of production, to ensure that every medicinal product is of high quality. Therefore, according to this

analysis, the majority of Indians believe that pharmaceutical quality assurance helps in the identification of any defects in products and fixing these problems with corrective techniques and measures.

**According to your personal understanding, what is the danger of not ensuring pharmaceutical quality assurance?**

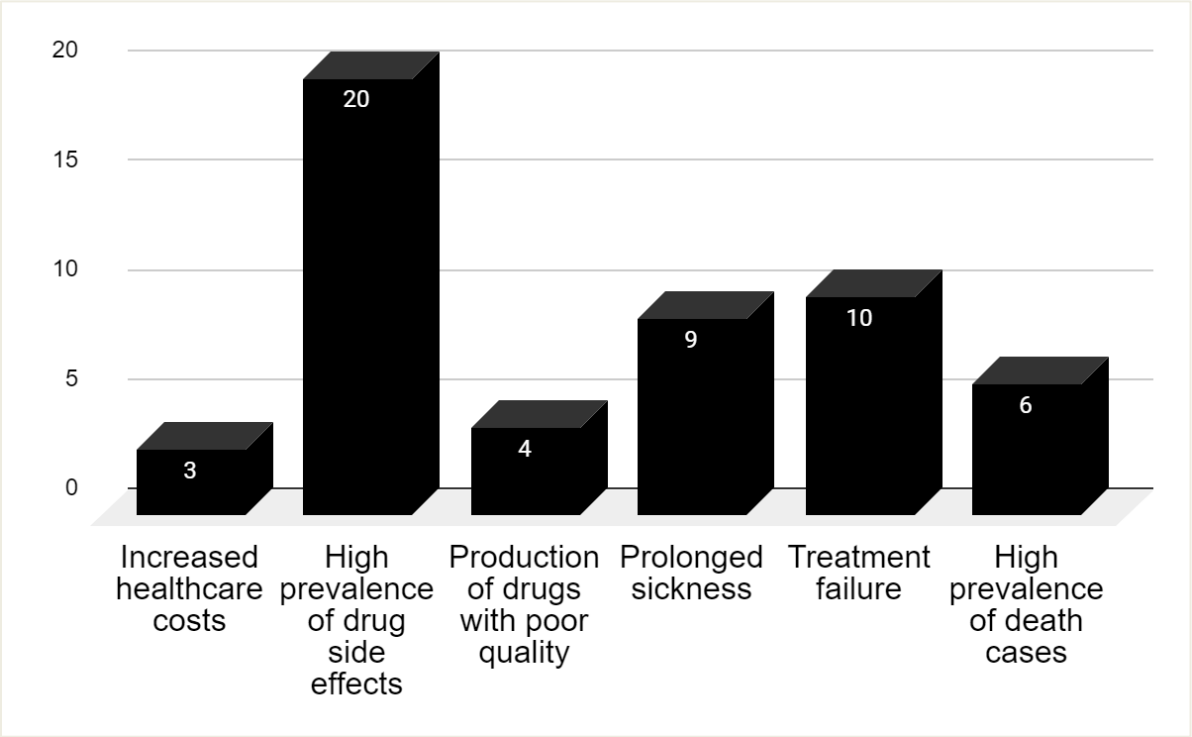



*Figure 44: what is the danger of not ensuring pharmaceutical quality assurance?*

The bar graph shown above represents data collected from Indian participants concerning the danger of not ensuring pharmaceutical quality assurance. The participants were to choose from the following options; increased healthcare costs, production of drugs with poor quality, high prevalence of drug side effects, prolonged sickness, treatment failure, high prevalence of death cases, and not sure. As shown above, 38.5% (20) said that failure to ensure pharmaceutical quality assurance can lead to the high prevalence of drug side effects, 17.3% (9) said that it can lead to prolonged sickness, 19.2% (10) said that it can lead to treatment failure, 11.5% (6) said that it can lead to the high prevalence of death cases, 5.8% (3) said that it could lead to increased healthcare costs and 7.7% (4) reported that it can lead to production of medicines with poor quality. Therefore, based on this analysis, it can be concluded that majority of the Indians believe that failure to ensure pharmaceutical quality assurance leads to a high prevalence of adverse drug reactions.

# CHAPTER 5: CONCLUSION AND RECOMMENDATION

## 5.1. Conclusions

This section is divided into several parts, containing results from different participants who took part in this study. These participants include; pharmacists, physicians, and pharmaceutical manufacturers. Based on this analysis, the majority of the respondents were physicians (36), followed by pharmacists (32), and the lowest number (31) was represented by pharmaceutical manufacturers.

### 5.1.1. Physicians

In this study, the physicians were given a number of questions to determine if they have experienced any issues concerning the quality of medicines, as stated in OBJECTIVE 1. According to the analysis in Chapter 4, most of the physicians from both India and Ireland have experienced issues relating to the quality of medicines. All the physicians from both countries agree that their respective countries have a pharmaceutical quality assurance system in place, with the majority coming from Ireland. The most preferred reporting system for pharmaceutical quality issues in India is reporting by email, followed by an online reporting system, followed by reporting using special quality drug forms, and reported by phone.

In Ireland, the most preferred reporting system includes the online reporting system, followed by reporting through a special quality drug form, followed by reporting by email, and the least preferred method is reporting by phone. The pharmaceutical quality assurance system from both countries, i.e., India and Ireland, are not up to the mark. However, when compared, Ireland has a better pharmaceutical quality assurance system as compared to India. Physicians from both countries have recommended that more contact training with the end users is needed.

### 5.1.2. Pharmacists

Pharmacists in this study were expected to fill a number of questions relating to pharmaceutical quality assurance in their country, i.e., India and Ireland. This was in accordance with OBJECTIVE 2, which aimed at determining if the pharmacists from India and Ireland perceive the quality assurance system as being effective. According to Figure 20, it can be concluded that most of the pharmacists from both countries participate in ensuring the quality of medicinal products very often. However, it’s only a few of them rarely and never participate in ensuring the quality of the medicinal products to the consumers. Most pharmacists from both India and Ireland report the issues to do with drug quality using a special quality drug form and through the phone. The

majority of pharmacists from both India and Ireland have access to the drug quality form. The drug quality assurance system in both countries, i.e., India and Ireland, are fairly good; however, some improvements are needed.

The majority of the respondents from both India and Ireland have a complaint form for drug defects in place. The majority of pharmacists from both India and Ireland agree that the method of ensuring the quality of medicinal products should be improved. When it comes to having access to the drug quality issues form in the facility, the majority of the pharmacists from both India and Ireland have easy access to the drug quality issues form in their respective facilities. In India, the majority of the pharmacists suggest that more information should be included in the product leaflet, while in Ireland, it was suggested that more contact training should be done for the consumers.

### 5.1.3. Pharmaceutical Manufacturers

Pharmaceutical manufacturers in this study were given a series of questions to determine how they ensure the quality of medicines in accordance with objective 3. According to Figure 28, it can be concluded that most of the pharmaceutical manufacturers from both countries, i.e., India and Ireland, 83.9% (26) agree that their companies have a quality assurance system in place. Based on the compliance of relevant regulations on quality assurance of medicinal products, the majority of the pharmaceutical manufacturers from India and Ireland are in compliance with the relevant regulations on the quality assurance of medicinal products. Most of the pharmaceutical manufacturers from both India and Ireland comply with Good Laboratory Practices (GLP), represented by 38.7% (12), followed by GMP at 32.3% (10), followed by quality standards at 29% (9), and Good clinical practice is only used in 5 companies representing 16.1% (5).

In India, the most regulations being followed is the good laboratory practice (GLP) and good manufacturing practice (GMP). In Ireland, the most common regulations include good laboratory practice and ISO 900/901. The pharmaceutical quality assurance system of medicines in both India and Ireland is not satisfying, and thus it needs to be improved. In India and Ireland, the most common method of ensuring the quality of medicines is by considering the qualification and validation procedures of the medicinal products. Manufacturers from both India and Ireland suggest that the quality of medicinal products can be improved by considering the qualification and validation procedures of the medicinal products. The most common challenge faced when

ensuring the quality of medicines in both countries is insufficient training of employees on quality assurance.

### 5.1.4. HPRA

Respondents from Ireland were expected to answer a number of questions relating to the Health Products Regulatory Authority (HPRA) in accordance with OBJECTIVE 4, i.e., to determine how HPRA ensures the quality of medicines in Ireland. According to Figure 36, most of the Irish people, i.e., 39 (83%), are aware of HPRA. The majority of the people from India knew HPRA through college/university, organizational training, and print advertisement. The main role of HPRA involves continuously monitoring the drug's safety, quality, and effectiveness once it is available to the Irish market. The main importance of pharmaceutical quality assurance involves ensuring that medicinal products meet the required customer needs and regulatory standards. The most common danger of failing to ensure pharmaceutical quality assurance involves a high prevalence of drug side effects or adverse drug reactions then, followed by treatment failure.

### 5.1.5. CDSCO

Participants from India were given a number of questions relating to the Central Drugs Standard Assurance Organization (C.D.S.C.O.) as per OBJECTIVE 4 of this study which aims at determining how CDSCO ensures the quality of medicines in India. According to Figure 41, it is concluded that most Indians are aware of CDSCO. Most of the Indians became aware of CDSCO through college/university. In India, CDSCO plays a major role in ensuring pharmaceutical quality assurance by laying down the standards of drugs, cosmetics, diagnostics, and devices. Also, the majority of Indians believe that pharmaceutical quality assurance helps in the identification of any defects in products and fixing these problems with corrective techniques and measures. It can be concluded that majority of the Indians believe that failure to ensure pharmaceutical quality assurance leads to a high prevalence of adverse drug reactions.

## 5.2. Testing of the hypothesis

**Hypothesis 1: An effective pharmaceutical quality assurance system guarantees the manufacturing of high-quality medicines and the safety of the patients.**

This hypothesis is true. For instance, figure 39 shows the importance of ensuring pharmaceutical

quality assurance. Effective pharmaceutical quality assurance helps to verify and test the medicinal products at various stages of manufacturing to ensure that the product is of high quality, thus ensuring patient safety.

**Hypothesis 2: Regulatory bodies, i.e., HPRA and CDSCO, play a major role in ensuring patient safety.**

This hypothesis is true because the analysis conducted in Chapter 4 has revealed that both HPRA and CDSCO play a major role when it comes to ensuring the safety of patients. For example, as shown in Figure 38, HPRA plays a major role in continuously monitoring drug safety, quality, and effectiveness once it is available to the Irish market. Also, HPRA protects patients by monitoring the Irish market for the importation and/or online sale of fake and illegal medicines, as they can pose a serious health risk to the consumers/patients. According to Figure 43, CDSCO plays a major role in protecting the safety of patients by laying down standards for drugs, cosmetics, diagnostics, and devices, as well as regulating the standards of imported medicinal products.

## 5.3. Recommendations

### 5.3.1. Research study recommendations

According to the findings derived from Chapter 4, the pharmaceutical quality assurance system both in India and Ireland needs more improvement as most of the participants reported that their system is not up to the mark. In India, to be able to enhance the drug quality monitoring system, more information should be included in the product information leaflet, more educational training should be done with the employees in charge of quality assurance, and more contact training should be done with the consumers or end users. In Ireland, more advertising concerning the importance of pharmaceutical quality assurance should be done in the media as well as more contact training with the consumers.

Also, drug quality forms should be made available and accessible to pharmacists in both India and Ireland. To be able to improve on the method of ensuring drug quality, pharmaceutical companies in both India and Ireland must comply with all the relevant regulations on the quality assurance of medicinal products. These regulations include the following; good clinical practice, good laboratory practice, good manufacturing practices, and quality standards such as ISO 900/901. Pharmaceutical companies from both India and Ireland should ensure the quality of medicinal products by doing the following; conducting self-inspection and quality audits, ensuring good documentation of the pharmaceutical manufacturing procedures, ensuring proper layout and

design of premises, testing for drug stability and training the employees on good manufacturing practices and other related quality assurance practices. Pharmaceutical manufacturers, physicians, and pharmacists are highly encouraged to work collaboratively to ensure that patients and consumers receive high-quality medicines.

### 5.3.2. Recommendations for future research

This study relied heavily on quantitative techniques. A total of 99 people were surveyed using this technique to acquire the data. The data collection method was a questionnaire. However, this study's analysis reveals that a few extra steps would have been helpful in generating more reliable results. The research's precision may have been improved with more questions asked. A larger number of questions on the questionnaire would allow for a deeper dive into the motivations of respondents. A smaller sample size, i.e., 99, was used in this study. Therefore, it is recommended that a larger sample size could lead to better results and provide more insights to the researcher. Also, this research did not discuss in detail the major factors that hinder pharmaceutical quality assurance within the industry. Such factors can be included in the future so as to improve the results of future research.

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# Appendices

## Appendix I: SURVEY QUESTIONNAIRE

**TITLE: COMPARATIVE STUDY OF QUALITY ASSURANCE AND REGULATORY GUIDELINES BETWEEN IRELAND (H.P.R.A.) AND INDIA (C.D.S.C.O)**

**SECTION A**

**Demographic details**

(Please ✓ against appropriate answer)

1. Gender

☐ Male ☐ Female

2. Please specify your age

☐ 18-29 years ☐ 30-49 years ☐ 50-59 years ☐ 60+ year

3. What is the level of your education

☐ Certificate/Diploma

☐ Bachelor's degree/advanced diploma

☐ Master's degree

☐ Other levels (Specify)

4. What is your profession

☐ Physician

☐ Pharmacist

☐ Pharmaceutical manufacturer

**5.** How long have you worked in the industry?

☐ Less than one year

☐ 1-5 years

- ☐ 5-10 years
- ☐ 10 -15 years
- ☐ More than 15 years

**SECTION B: SURVEY QUESTIONS FOR PHYSICIANS**

**OBJECTIVE 1: To determine if the physicians from Ireland and India have experienced any issues concerning the quality of medicines.**

1. Have you experienced any issues relating to the quality of medicines/drug products that you are prescribed to your patients? (Please tick the appropriate box)

- ☐ Yes
- ☐ No

2. Do you have a quality assurance system for medicinal/drug products in your country?

- ☐ Yes
- ☐ No

3. What type of reporting system regarding the quality issues of a medicinal product exists in your country? (Please tick the appropriate box. If appropriate, choose more than one)

- ☐ Online reporting system
- ☐ Reporting by email
- ☐ Reporting system by phone
- ☐ Reporting system by special quality drug form

4. What is your opinion regarding the quality system of medicinal products in your country? (Please tick the appropriate box. If appropriate, choose more than one)

- ☐ Satisfactory
- ☐ Not up to the mark
- ☐ Needs Improvement

5. Is there any recommendation or advice you can suggest for enhancing the drug quality monitoring system in your country? (Please tick the appropriate box. If appropriate, choose more

than one)

- ☐ More educational programs for the employees in charge of quality
- ☐ More contact training with consumer
- ☐ More information on product information leaflet
- ☐ Advertising in media

**SECTION C: SURVEY QUESTIONS FOR PHARMACISTS**

**OBJECTIVE 2: To determine if pharmacists from the two countries perceive the quality assurance system as being effective.**

(Please ✓ against appropriate answer)

1. How often do you participate in ensuring the quality of medicinal products from consumers? (Please tick the appropriate box)

   ☐ Always

   ☐ Very Often

   ☐ Sometimes

   ☐ Rarely

   ☐ Never

2. How do you report quality issues of the medicinal product to regulatory authorities? (Please tick the appropriate box. If appropriate, choose more than one)

   ☐ Online reporting system

   ☐ Reporting by email

   ☐ Reporting system by phone

   ☐ Reporting system by special quality drug form

3. Is the drug quality form available to you? (Please tick the appropriate box)

   ☐ Yes

   ☐ No

   ☐ Not sure

4. Do you think the drug quality assurance system is adequate in your country? (Please tick the appropriate box)

☐ Needs Improvement

☐ Satisfactory

☐ Good

☐ excellent

5. Do you have a complaint form for drug defects in place?

☐ Yes

☐ No

☐ Not sure

6. Do you agree that the method for assurance ling the quality of medicinal products needs to be improved? (Please tick the appropriate box.)

☐ Agree

☐ Disagree

☐ or other, please specify

7. Do you have easy access to the drug quality issues form in your facility? (Please tick the appropriate box)

☐ Yes

☐ No

8. Is there any advice you can suggest for enhancing the quality assurance system for pharmaceutical products in your country? (Please tick the appropriate box. If appropriate, choose more than one)

☐ More educational program

☐ More contact training with consumer

☐ More information on the product information leaflet

☐ Advertising in media

**SECTION 4: SURVEY QUESTIONS FOR PHARMACEUTICAL MANUFACTURERS**

**OBJECTIVE 3: To determine how pharmaceutical manufacturers from both India and Ireland ensure the quality of medicines.**

1. Does your pharmaceutical company have a quality assurance system for medicinal products in place?

   ☐ Yes

   ☐ No

   ☐ Not sure

2. a). Does your company comply with any relevant regulations on quality assurance regarding medicinal products?

   ☐ Yes

   ☐ No

   ☐ Not sure

   b). If YES, what are some of the relevant regulations on quality assurance of medicines does your company follow?

   ☐ Good Manufacturing Practices (GMP)

   ☐ Quality standards, i.e., ISO 900/901

   ☐ Good Laboratory Practice (GLP)

   ☐ Good Clinical Practice

3. What is your view concerning the quality assurance system of the medicinal products in your company?

   ☐ Satisfactory

   ☐ Not satisfactory

☐ Needs to be improved

☐ Excellent

☐ Not sure

4. How does your company ensure quality assurance and quality assurance of medicinal products?

☐ Training the employees on GMP and other related quality assurance practices

☐ Testing for drug stability

☐ Ensuring sanitation and hygiene

☐ Considering qualification and validation procedures

☐ Reviewing of complaint records concerning the drug defects

☐ Conducting self-inspection and quality audits

☐ Ensuring proper layout and design of premises

☐ Ensuring Proper layout and design of equipment

☐ Ensuring Good documentation of the pharmaceutical manufacturing procedures

5. How can the level of quality assurance for medicinal products be improved?

☐ Innovate to become more efficient at pharmaceutical manufacturing

☐ Consider technologies such as Process Analytical Technologies

☐ Ensuring a continuous and regular inspection of the medicinal products

☐ Ensuring continuous and proper maintenance of manufacturing equipment.

☐ Proper maintenance of the manufacturing premises

☐ Always staying in compliance with the related quality management guidelines

☐ Design a robust and more effective training program for the employees concerning quality assurance of medicines.

☐ Not sure

6. What are some of the challenges faced when ensuring pharmaceutical quality assurance?

☐ Resistance to pharmaceutical technology, i.e., PAT

☐ Insufficient quality equipment

☐ Non-compatibility with the company policies

☐ Insufficient training of employees on quality assurance

☐ Poor quality assurance management

☐ Not sure

**SECTION 5:**

**OBJECTIVE 4: To determine how HPRA and CDSCO ensure the quality of medicines in Ireland and India, respectively.**

**HPRA (Ireland)**

1. Have you ever heard of the Health Products Regulatory Authority (H.P.R.A.)?

☐ Yes

☐ No

☐ Not sure

2. If yes, how did you hear about HPRA?

☐ College/university

☐ Radio advertisement

☐ Television advertisement

☐Print advertisement

☐ Organizational Training

☐ Not sure

3. At a personal level, what do you think is the major role played by HPRA in ensuring pharmaceutical quality in your country?

☐ To protect and enhance the public health by regulating medicines, medical devices, and other health products.

☐ To make sure that medicines are as safe as possible and do what they are intended to do.

☐ Grant licenses for medicines following a review of their safety, quality, and effectiveness.

☐Continuously monitor drug safety, quality, and effectiveness once it is available to the Irish market

☐ Monitor the Irish market for the importation and/or online sale of counterfeit and illegal medicines, as they can pose a serious health risk for people

☐ Encourage patients and healthcare professionals to report side effects, quality problems, and other related issues to the HPRA through our website or by contacting us directly.

☐ Grant licenses to the companies that make, distribute, and market medicines in Ireland.

1. Based on your understanding, what is the importance of ensuring pharmaceutical quality assurance?

☐ To verify and test the medicine at various stages of production to ensure every

product is of the highest quality.

☐ Identifying any defects in products and fixing these problems with corrective techniques and measures

☐ Ensure that medicinal products meet the required customer and regulatory standards.

☐ Not sure

2. According to your personal understanding, what is the danger of not ensuring pharmaceutical quality assurance?

☐ Increased healthcare costs

☐ Production of drugs with poor quality

☐ High prevalence of drug side effects

☐ Prolonged sickness

☐ Treatment failure

☐ High prevalence of death cases

☐ Not sure

**CDSCO (India)**

3. Have you ever heard of the Central Drugs Standard Assurance Organization (C.D.S.C.O.)

☐ Yes

☐ No

☐ Not sure

4. If yes, how did you hear about HPRA?

☐ College/university

☐ Radio advertisement

☐ Television advertisement

☐ Print advertisement

☐ Organizational Training

☐ Not sure

5. At a personal level, what do you think is the major role played by HPRA in ensuring pharmaceutical quality in your country?

☐ To regulate market authorization of new drugs.

☐ To regulate clinical research in India.

☐ Laying down standards of drugs, cosmetics, diagnostics, and devices.

☐ To regulate clinical research in India.

☐ To regulate the standards of imported drugs.

☐ Testing of drugs by Central Drugs Labs

☐ To approve licenses to manufacture certain categories of drugs as Central Licence Approving Authority.

☐ Not sure

6. Based on your understanding, what is the importance of ensuring pharmaceutical quality assurance?

☐ To verify and test the medicine at various stages of production to ensure every product is of the highest quality.

☐ Identifying any defects in products and fixing these problems with corrective techniques and measures

☐ Ensure that medicinal products meet the required customer and regulatory standards.

☐ Not sure

7. According to your personal understanding, what is the danger of not ensuring pharmaceutical quality assurance?

- ☐ Increased healthcare costs
- ☐ Production of drugs with poor quality
- ☐ High prevalence of drug side effects
- ☐ Prolonged sickness
- ☐ Treatment failure
- ☐ High prevalence of death cases
- ☐ Not sure