Human error, human factors and production ergonomics

A discussion from the perspective of biopharmaceutical manufacturing

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Abstract

This article is drawn from a literature review into aspects of training for the biopharmaceutical manufacturing sector. One aspect explored is the apparent neglect of human factors and of production ergonomics in relation to investigations into adverse events, drug shortages and withdrawals, with an over-emphasis on human error and on inadequate training as root causes. The article is discursive in intent, drawing upon literature from other high-risk sectors such as aviation, nuclear energy and engineering. It outlines how concepts of human error, human factors and ergonomics have been differently defined and applied resulting in a dispersed understanding of how best to include them in initial and continuous training. The article ends with a brief discussion around transfer of training and asks if this concept could somehow lead to a more synthesised application of what has been learned about human factors and about ergonomics in investigations into adverse events in high-risk sectors.

Key words: human factors; human error; biopharmaceutical manufacturing; ergonomics; training

Note: *The final draft of this article was prepared in the days following a catastrophic collision between an airplane and helicopter over Washington DC which tragically resulted in sixty-seven deaths and which sparked intensive discussion of safety risk, human error and systems failure issues in aviation generally. While the text of the article was not changed as a result of that tragedy, the points raised within it throw some light on the complexity of a sector which operates at the interstices of engineering, behavioural psychology and human-systems interactions.*

1. Introduction

The application of 'human error' as a root cause of accidents, quality failures and other unintentional outcomes, is essentially stating that human frailties/mistakes are the sole cause of these problems. That view considers the human as the source of the fault and, as such, that by applying tighter controls, increased supervision, repeated training, and rigorous systems, human error can be reduced. The reality is that human error is a consequence or symptom of a complex, deeper problem rather than a simple generic category of behaviour: human error is an outcome. In applying human error as a root cause, the assumption is the human can be separated from the other seemingly blameless contexts of the working environment which encompass the physical, technological, managerial, systemic, cognitive/psychological and organisational perspectives.

This article explores the complexities of human error and its application in the biopharmaceutical manufacturing industry, as well as in other high-risk sectors. It explores concepts of human error and system error, arguing that human errors do not appear randomly, that they are shaped by situations and features that are part of the environment in which the person is functioning.

Models and classifications of human error and performance are discussed with a view to gaining a greater understanding of the complexities of human error including Reason's Swiss Cheese Model, Rasmussen's 'skill-rule-knowledge' (SRK) model and The Department of Defence Human Factors Analysis & Classification System (DoD HFACS).

The article considers that the cause of human error is linked to systems theory, which posits that accidents or deviations are caused by the way the system parts, both engineered and human, fit together and interact, and as such, the inclusion of the scientific disciplines concerned with the understanding of interactions between humans and other elements of a system - human factors and workplace ergonomics - is understandably an essential component of any mitigating strategy.

Finally the article reviews Baldwin and Ford's (1988) framework for the training transfer process, assessing the factors that influence the effect of the positive transfer of training, and in turn how these training experiences transfer from the learning environment to the actual job setting, and subsequently lead to meaningful changes in work performance.

2. Human Error and Human Factors across different industries

Across many industries, including the biopharmaceutical manufacturing industry in which the author works, human error is frequently cited as the cause of accidents, quality failures, product recalls, and potential patient safety issues (Guo and Sun, 2020). Bodmann et al., 2016 argue that human errors account for approximately 50% of quality incidents and related problems within the pharmaceutical manufacturing industry. This statistic is echoed by Wilson et al., 2015 who cite research by the BioPhorum Operations Group (BPOG) estimating that up to 50% of deviations within the biopharmaceutical industry had been attributed to human error.

From a regulatory perspective, deviations within the biopharmaceutical manufacturing context are defined as a '*departure from an approved instruction or established standard*' (ICH, 2001). The regulations further state that any deviation from an approved instruction or established standard must be recorded and justified as outlined in 'CFR 210 and 211 'Production and Process Controls' which state the following:

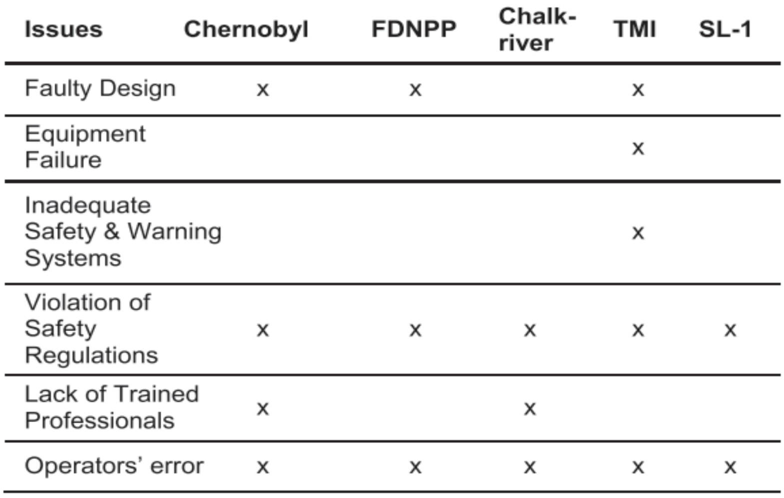
> *Written Procedures and Procedure Deviations*
> (*a) Written procedures for production and process control must be written and followed. These procedures should be designed to assure that the drug products have the identity, strength, quality, and purity they are represented to possess. These procedures must include all requirements given below and must be drafted, reviewed, and approved by the affected organisational units and reviewed and approved by the quality control unit.*
> *(b) When following the above identified procedures, all actions must be documented at the time of performance. Any deviations from the written procedure must be recorded and justified.*
> (Food and Drug Administration (US), 2023).

Indeed, one such findings from the Health Products Regulatory Agency (HPRA) Overview of GMP Inspections 2018 – 2021 stated: 'Human error {is} commonly assigned as root cause without adequate investigation or justification' (Hogan, 2022 p.12).

The emphasis on human error as a focus of accident investigations initially emerged in the 1970s when, in 1979, the nuclear power plant at Three Mile Island, Pennsylvania, experienced an accident during maintenance resulting in the worst nuclear accident in the United States' commercial nuclear industry. Subsequent investigations into the accident established that human operators had initiated and then exacerbated this accident. Inquiries into the accident demonstrated that operator error on the day of the accident resulted from interactions between poorly designed displays, inadequate training for the operators, and mechanical failures – essentially multi-faceted systems failure rather than 'human error' *per se* (Hobbs, 2000; McEvily and May, 2002; Mukhopadhyay, Hastak and Halligan, 2014; Miranda, 2018).

Further large-scale, technological systems accidents which resulted in serious consequences including Bhopal (1984) and Chernobyl (1986) have mainly been attributed to 'operator error' (Meshkati, 1991). This pivot towards human error in investigations supplemented the previous engineering-led focus on equipment and technical failures in investigations (Reason 2008; Read et al., 2021).

Research carried out by Mukhopadhyay, Hastak and Halligan in 2014, specifically related to five major nuclear power plant disasters, provides a comparative analysis of the major causes and issues identified through the extensive literature review across major accidents. That research identified operators' errors as a causal factor in all five accidents. Other matters identified as causes and contributory issues included lack of training/trained professionals, violation of safety regulations[1], equipment failure, inadequate safety warning, and faulty design. The table below illustrates this comparative analysis, identifying the causes and issues across the five major accidents.



Issues	Chernobyl	FDNPP	Chalk-river	TMI	SL-1
Faulty Design	x	x		x	
Equipment Failure				x	
Inadequate Safety & Warning Systems				x	
Violation of Safety Regulations	x	x	x	x	x
Lack of Trained Professionals	x		x		
Operators' error	x	x	x	x	x

Table 1: Comparative Analysis of the Major Issues across Five Major Accidents

(Mukhopadhyay, Hastak and Halligan, 2014, p. 166)

Sites and dates:

- Chernobyl, USSR, 1986;
- FDNPP - Fukushima Daiichi Nuclear Power Plant, Japan, 2011
- Chalk River Incident, Canada, 1952
- TMI (Three Mile Island), US, 1979
- SL-1 (Stationary Low-Power Reactor Number 1), US, 1961.

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[1] Violations are deviations from safe operating practices, procedures, standards, or rules (routine violations. Violations fall into three main groups.
* Routine violations, which entail cutting corners whenever such opportunities present themselves
* Optimising violations, or actions taken to further personal rather than strictly task-related goals (that is, violations for "kicks" or to alleviate boredom)
* Necessary or situational violations that seem to offer the only path available to getting the job done, and where the rules or procedures are seen to be inappropriate for the present situation (Reason, 1995)

Human error continues to be cited as the cause of most accidents in high-risk sectors (Johannesen, et al., 2012; Guo & Sun, 2020; Read et al., 2021; Wilson et al., 2015). According to Guo & Sun (2020 p.1) investigations into the cause of flight accidents estimated that 60% were caused directly or indirectly by human error. Similarly, over 90% of nuclear power plant accidents, 80% of petrochemical industry accidents, and over 75% of maritime accidents, were related to human actions (ibid).

3. Human Error versus Systems Error

The concept of human error, or individual error, attributed as a 'root cause', rather than a symptom of the consequence, is an outdated premise. Almost thirty years ago, Reason, 1995 p.88, argued the importance of a systems approach, stating:

'People do not act in isolation. Their behaviour is shaped by circumstances. The same is true for errors and violations…an unsafe act being committed is heavily influenced by the nature of the task and by the local work-place conditions.'

Reason's concept of behaviour, circumstances, workplace conditions and task design move the focus of errors and mistakes away from simply human error by placing greater emphasis on a holistic systems approach to define root causes of errors. According to Reason, 2000, p.768;

'The basic premise in the system approach is that humans are fallible, and errors are to be expected, even in the best organisations. Errors are seen as consequences rather than causes, having their origins not so much in the perversity of human nature as in "upstream" systemic factors'.

Based on this premise, it may be argued that human errors do not appear randomly: they are in fact shaped by situations and features that are part of the environment in which the person is functioning such as facilities design, effectiveness of training efforts, or adequacy of work instructions and procedures, amongst other systems factors. Therefore, an effective and safe system relies on the interaction of all parts of the system. Ackoff, 1994, cited in Johnston and Harris, 2019, echoes these points stating:

'A system is not the sum of the behaviour of its parts, it is a product of their interactions. The performance of a system depends on how the parts fit, not how they act taken separately.'

Without the term ‘ergonomics’ being used in this context, the definition of workplace ergonomics detailed further below in this article, suggests that the complexity of ‘ergonomics’ as a conceptual lens was beginning to be tacitly understood if not explicitly termed as such.

Defining Human Error and Human Factors

Human Error

The term ‘error’ has a long history derived from the Latin ‘errorem’, meaning ‘a wandering, straying, a going astray; meandering; doubt, uncertainty’; also ‘a figurative going astray, mistake’ (Read *et al.*, 2021). In more recent years, several definitions of human error have been documented in literature.

Reason, 1995 p.81 stated, ‘*error can be defined in many ways…error is the failure of planned actions to achieve their desired goal’*. Reason and Hobbs (cited in Rodriguez-Perez, 2018) expanded on this definition stating that an error is ‘*the failure of planned actions to achieve their desired goal, where this occurs without some unforeseeable or chance intervention.’*

The Fahlbruch *et al.*, (2007) OECD report cites *Rasmussen, Duncan and Leplat* (1987) definitions of an error as ' *... an act which is counterproductive with respect to the person's private or subjective intentions or goals' (p. 14).* A further definition is: ‘*human error as behaviour, or its effects, which lead a system to exceed acceptable limits* (ibid). That report states there are at least twenty different denotations related to the term ‘human error’, leading to the semantic[2] problem of a clear definition of the term, and that therefore the term can be interchanged to mean either the **cause** of something, the event itself (the action), or the **outcome** of the action (ibid). This semantic problem may then pose further issues when seeking to find the true root cause of an error.

Human Factors and Human Error

The term "human factors" includes additional aspects of human involvement, which can be further defined as any factor that influences behaviour at work in a way that can negatively (or positively) effect the output of the process in which the human is involved (Fahlbruch *et al.*, 2007). For example, factors such as time pressure, inadequate equipment, illness, or

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[2] Semantic (adjective) connected with the meanings of words
https://dictionary.cambridge.org/dictionary/english/semantic

tiredness, can directly impact the outputs of any system or process. Whilst there are many error-producing conditions in the workplace, the Pareto principle may also apply here, whereby the problem (effect) can be attributed to relatively few causes (Cox, 2018). In quantitative terms, 80% of the problems come from 20% of the causes (machines, raw materials, operators, etc.), therefore effort aimed at the right 20% can solve 80% of the problems. In the case of manufacturing industries, evidence shows that a relatively limited number of local factors appear more frequently than others (Rodriguez-Perez, 2018).

Human errors, when assigned as the cause of deviations and complaints are typically associated with lack of training or poor-quality training. As such, training breakdowns are considered as one of the main root cause categories for human errors and, in a wider sense, for inadequate human performance in manufacturing industries. Following on from this, retraining of the relevant staff is often used as the key preventative measure for such issues (Poska, 2010; Wilson, Moedler and McAuley, 2015; Bodmann *et al.*, 2016). However, research has shown that, that while human error may be involved in many incidences of deviations, it is often not the only contributory factor. Extensive studies into underground mining accidents by Sanders and Shaw (1988) found no case in which human error was the only factor. Their analysis model, titled “contributing factors in accident causation,” highlighted other factors such as management, social, and psychological variables (in addition to human factor variables) all contributed to accidents (Sanders, M. and Shaw, B. 1988, cited in Poska, 2010).

Whilst it is acknowledged that human error is a contributory factor in many quality issues, it is often not the only factor. As stated earlier, over half of all process-related deviations across the biopharmaceutical industry are currently attributed to human errors despite there being inadequate evidence that human error (rather than system design, or process error) has actually occurred, or due to there being a lack of understanding of what actually constitutes human error. Wickens et al. define human error as “inappropriate human behaviour that lowers levels of system effectiveness or safety, which may or may not result in an accident or injury” (Wickens et al, 2004). In summary, a human error is an action or decision that was not intended, that involved a deviation from an accepted standard, and that led to an undesirable outcome. Further to this, there is also additional classification systems developed to try to group different types of human error into manageable groups, such as the Swain and

Guttmann classification system from 1983 which classified human error by the kind of discrete actions that were taken, thus dividing human error into four main groups as follows:

1. Errors of omission (forgetting to do something)
2. Errors of commission (doing the task incorrectly)
3. Sequence errors (doing something out of order)
4. Timing errors (doing the task too slow, too fast, or too late).

(Hollnagel, 2000; Rodríguez-Pérez, 2018)

Furthermore, according to Rodríguez-Pérez, 2018, human failures can be divided into two broad categories, **errors** and **violations**:

A human ***error*** is an action or decision that was not intended, that involved a deviation from an accepted standard, and that led to an undesirable outcome. For example, an operator setting up a tablet compression machine for a new solid dose production run and unknowingly fails to change all dies to a new dosage form, could result in a wrong dosage form marking on the tablets in a batch/production run.

A ***violation*** is a deliberate deviation from a rule or procedure, for instance, the operator in the previous example deliberately did not check all dies thoroughly before performing the task.

Further schools of thought and classifications systems are outlined below, considering psychological cognitive models and joint cognitive/systems schools, exploring how humans process information and execute procedures.

4. Models of Human Error and Human Performance

Rasmussen's SRK Model

One of the most noted and influential models for identifying the types of error that might occur in different operational situations was developed by Jens Rasmussen of the Risø Laboratory in Denmark. Rasmussen's 'skill-rule-knowledge' (SRK) model established him as a key influential thinker for the last quarter of the 20th century in the safety science field, specifically in human error analysis, human performance and major hazard prevention.

Rasmussen's classification system known as SRK model proposed a (cognitive) engineering and behavioural approach, asserting that human performance can be categorised based on the levels of cognitive control that is supporting the individual's behaviour at a given time. Therefore, errors are likely to occur depending on the different types of information processing demands placed on the individual, or in different operational situations (Hobbs, 2000). Rasmussen's defined three levels of human performance - skill-based, rule-based, and knowledge-based - with each producing characteristic error forms, as follows.

- ***Skill-based*** behaviour is mostly related to frequent, least challenging tasks, whereby performance and functions are carried out as automatic or unconscious processes. These processes have been established and internalised through experience and are triggered by sensory inputs. Only a small degree of conscious thinking activity is required.
- ***Rule-based*** behaviour is related to less-familiar tasks and is based on the experience and capabilities of the person and their ability to modify automatic behaviour as a problem or issue has occurred. Individuals should be trained to manage this occurrence, may have had previous experience of the issue, or have procedures (rules) instructing them what to do. The resultant behaviour compares the information with familiar patterns or rules on an 'if-then' basis, as individuals draw from stored knowledge of rules i.e., if X occurs, then do Y (an occurrence and an action). In rule-based performance, the individual operates largely automatically, matching the situation or occurrence to a stored solution, therefore behaviour and action correspond to explicit rules that are consciously followed to perform specific tasks. Following this, conscious thought may be applied to validate that the correct solution was adopted.
- ***Knowledge-based*** performance requires considerable attention and concentration, whereby the operator is challenged by novel situations, and familiar patterns or rules cannot be automatically or directly applied. It requires a high degree of conscious thinking (Hobbs, 2000; Le Coze, 2014).

Figure 1 below illustrates Rasmussen's SRK Model of Human Failures with Figure 2 further expanding on types of human errors, specifically linking them to skill-based errors and mistakes. Figure 3 shows the characteristics of the three levels of performance, highlighting situations where SRK behaviour is experienced.

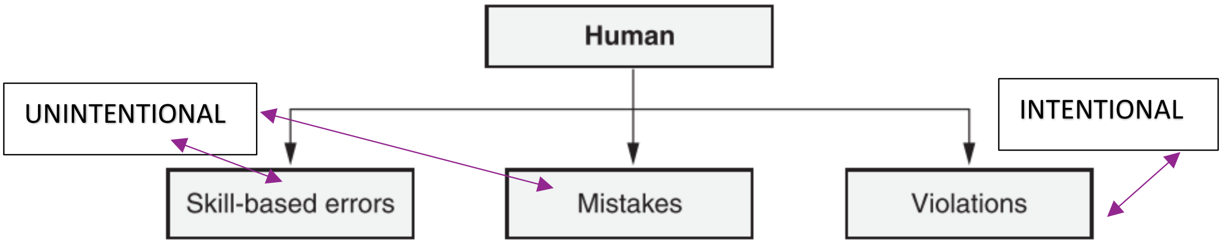


Figure 1. Types of Human Failures (Rodriguez-Perez, 2018)

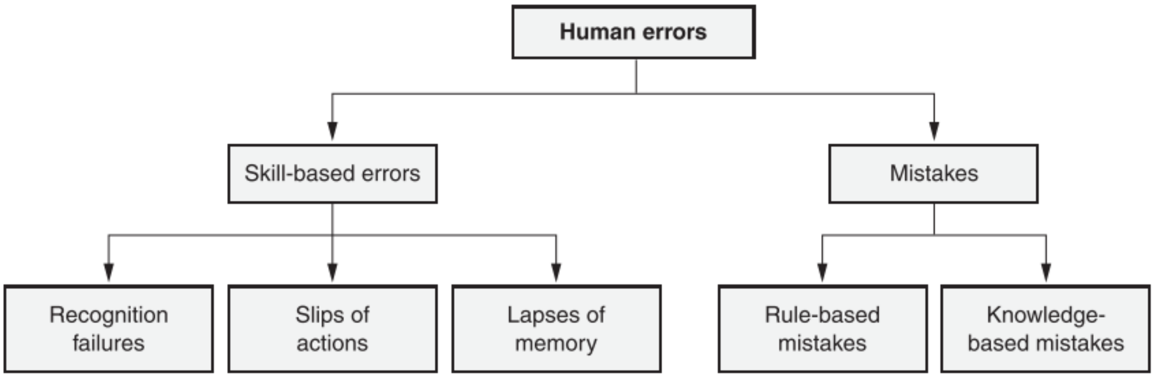
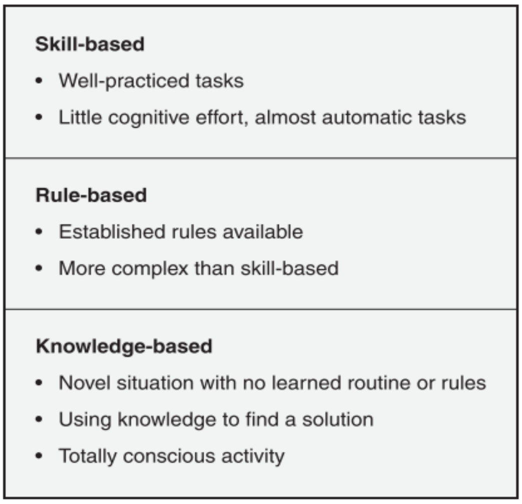


Figure 2. Types of Human Errors (Rodriguez-Perez, 2018)



Skill-based
- Well-practiced tasks
- Little cognitive effort, almost automatic tasks

Rule-based
- Established rules available
- More complex than skill-based

Knowledge-based
- Novel situation with no learned routine or rules
- Using knowledge to find a solution
- Totally conscious activity

Figure 3. Characteristics of the three levels of performance (Rodríguez-Pérez, 2018)

According to Rasmussen's SRK model, whilst human behaviour and capabilities vary considerably, there are three ways in which planned actions may fail to achieve their current goals, as follows:

1. *Unintentional* – Skill-based *errors* which include - attention (slips of actions), memory (lapses), and recognition errors (S)
2. *Unintentional* - Rule-based *mistakes* and knowledge-based mistakes (R)(K)
3. *Intentional – Violations* involve disobeying formal rules and procedures.

Focussing specifically on the unintentional space, it is necessary to understand how **skills-based errors** vary from **rule-based mistakes**.

Skill-based errors occur when a plan of action may be appropriate, but the actions themselves do not go as planned (execution errors). These error types are denominated as skill-based errors and include attention (slips of actions), memory (lapses), and recognition errors (Hobbs, 2000; Le Coze, 2014).

On the other hand, **mistakes are errors in rule or knowledge-based performance** and are a more complex type of human error. Mistakes occur *when an individual does the wrong thing believing it to be right*, therefore their actions may go completely as planned, but the plan is inadequate to achieve the desired goal. Mistakes include errors in perception, judgment, inference, and interpretation (Hobbs, 2000).

Rasmussen's (cognitive) engineering orientation was grounded in the premise that the majority of errors or accidents are initiated during periods with non-routine operations when human operators are exposed to **complex, non-routine situations**. Rasmussen's engineering focus was consequently to help operators to cope with this complexity through improved interface and system design (Rasmussen, 1980; Le Coze, 2014; Rodríguez-Pérez, 2018).

Reason's Swiss Cheese Model

Contrary to Rasmussen's cognitive engineering orientation, James Reason's study of error is grounded in a **psychological tradition.** He is most regarded for his contribution to safety research, and for his model of human error, known as the Swiss cheese model (SCM). The model evolved in 1987-8 while Reason was writing his book 'Human Error: a cognitive psychological account of the nature, varieties, and the mental sources of human error' (Drogoul, 2006 p.4). While writing the book, Reason included a chapter focussing on **latent errors** and **systems disasters**, which was, in part, influenced by the spate of disasters occurring in the late 1970s and 1980s, including Flixborough, Challenger, Three Mile Island, Bhopal, Chernobyl, the Herald of Free Enterprise and the King's Cross Underground fire (ibid). Research carried out by Mukhopadhyay, Hastak and Halligan in 2014, as mentioned above, also focussed on a number of these disasters.

Following extensive investigation into each of these accidents it was reported that the performance of individuals at the 'front-line' or 'sharp end' (people in direct contact with the system - pilots, control room operators, drivers, nurses) was shaped by 'upstream[3]' organisational factors and workplace conditions (Reason, 1995; Drogoul, 2006; Fahlbruch *et al.*, 2007; Read *et al.*, 2021).

Following these investigations, Reason determined it was not possible to establish an effective account of human error without considering these **contextual system issues.** Accordingly, in his book 'Human Error' Reason argues that accidents within complex systems, such as healthcare or multifaceted manufacturing, are caused by a breakdown or absence of safety barriers across four levels within a sociotechnical system (Wiegmann *et al.*, 2022).

In the Swiss Cheese Model (SCM) of human error, Reason defines four levels of human failure, with each level influencing the next. These levels are described as:

- Unsafe Acts – *Active Failure*
- Preconditions for Unsafe Acts – *Latent Failure*
- Supervisory Factors (unsafe supervision) – *Latent Failure*
- Organisational Influences – *Latent Failure*.

The model also distinguishes between active and latent failures. **Latent failures** are failures carried out by people who are *not* at the sharp end of a process and are removed in time and space from operational activities. According to Rodriguez-Perez, 2018, latent failures are

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[3] 'Upstream activities are intended to effect a company-wide convergence of values, priorities, knowledge, and practices underlying workforce performance to enhance coordination and build synergies for achieving the firm's strategic objectives. Upstream considerations include strategic performance management integration and coordination, workforce internal alignment, knowledge management, and organisational learning' (Vance, 2006 p.39).

typically failures in management systems such as design, implementation, or monitoring, that are carried out by designers, decision-makers, and managers. **Active failures**, on the other hand, have an immediate consequence and are usually caused by front-line workers such as machine operators or control room staff. Reason used the term “active failures” to describe factors at the Unsafe Acts level and the term “latent failures” was used to describe unsafe conditions located higher up in the system, as illustrated in Figure 4 below.

Reason’s model is visually similar to a stack of **Swiss cheese slices**, hence the title. Accordingly, every step (or visual slice) in a process has the potential for failure as each hole within the slices are an opportunity for a process to fail. Each slice offers a defensive layer in any process against potential errors, whereby a hole or gap in one layer may permit an error or problem to pass through this layer. However, the problem should be caught in the next layer as the gaps may be in different places. Subsequently for a catastrophic error to occur (a plane crash or the distribution of a pharmaceutical product with an incorrect formulation or dosage form) the holes must align for each step in the process, thus breaking down the processes defences in each stage resulting in an error in the final product or service. Reason’s model asserted that each step in a process is underpinned by organisational influences, (un)safe supervision, preconditions for (un)safe acts and the ultimate (un)safe act itself, hence each of these four levels is a defensive system. The greater the defences (by way of fewer and smaller holes) the more rigorous the process is and the more likely errors will be noticed and avoided (Rodriguez-Perez, 2018). Reason’s model of working backwards from the unsafe act or accident through the four levels of human failure is, in fact, what makes the SCM particularly useful in accident investigation. As the focus of many investigations may concentrate on the unsafe act and ‘active failure’, which are typically the last unsafe actions or inactions of those at the sharp end of the process and that directly linked to the accident, the SCM forces investigations to address latent failures as part of the causal sequence of events (Shappell and Wiegmann, 2000). These latent failures may lie undetected over time, from days to years, until all the elements of the defensive system have been breached, consequently resulting in an adverse result. This emphasis on latent failures is particularly useful in accident and error investigations as it forces the investigation to look at upstream aspects such as organisational influences, supervision and work conditions which may be unintentionally overlooked by investigators (ibid).

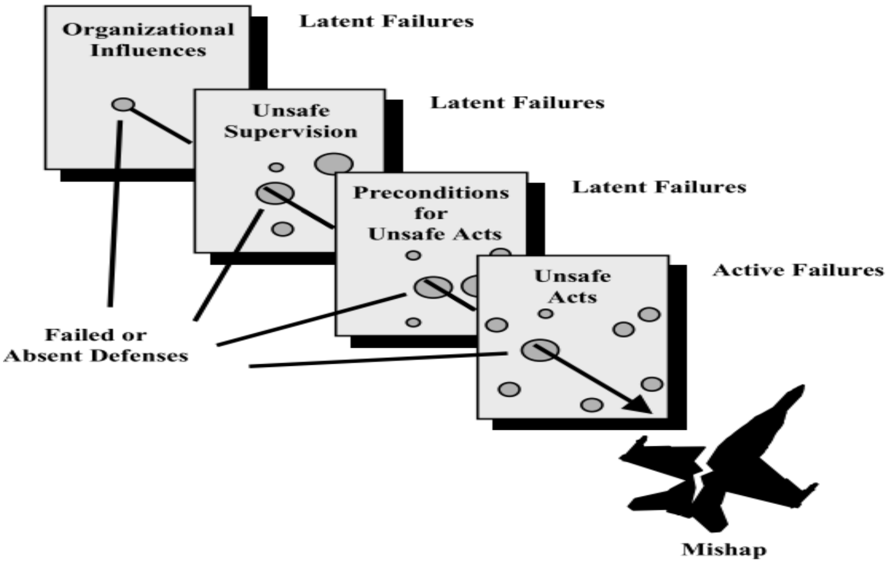

Figure 4. The "Swiss cheese" model of human error causation (adapted from Reason, 1990) (Wiegmann *et al.*, 2022)

Human Factors Analysis & Classification System (HFACS)

Notably, Reason's work extended beyond his initial Swiss cheese framework, as different variations and refinements of the initial model began to emerge and to become the basis for other models and taxonomies. One of these adaptations was the Human Factors Analysis & Classification System (HFACS) developed by Wiegmann and Shappell (2003). The HFACS framework emerged following an initiative by the Department of Defence (DoD) to develop an incident/accident analysis methodology for causal factor analysis in aviation accidents. The subsequent taxonomy (HFACS) is now widely applied across North America and Europe to investigate and analyse the human factors involved in an aviation accident/incident (Drogoul, 2006; Chen *et al.*, 2013). Since this initial application, the framework has expanded to other industries and sectors to investigate the links between contributing factors and subsequent accidents. This expansion, albeit limited, has seen the application of the HFACS in maritime, mining, transportation, and health care industries to investigate accidents and to improve the safety of operations.

Adopting Reason's SCM as their core concept, and drawing upon Reason's (1990) concept of latent and active failures, HFACS describes four levels of failure: 1) Unsafe Acts, 2) Preconditions for Unsafe Acts, 3) Unsafe Supervision, and 4) Organizational Influences. Wiegmann and Shappell's model expands this further by dividing latent and active failures into distinct categories and subcategories of causal factors, drilling deep into contributing factors in accident investigations (Shappell and Wiegmann, 2000). When drawing analogies between James Reason's Swiss Cheese Model and the DoD HFACS model, with active failures (level 1) and latent failures (level 2,3,4), the relationship is expanded in the discussion below.

The DoD HFACS Level 1 (Active Failures – Unsafe Acts)

The DoD HFACS Level 1 (*Active Failure – Unsafe Acts*) involves identifying the unsafe act involved which classifies the failure made at the *active failure* level by the front-line worker which led to the accident or error occurring. At the active failure level there are two categories of unsafe acts: **errors** and **violations**.

Errors are defined as unintentional deviations from correct action, and in the HFACS model errors are further delineated into three basic error types are **decision errors**, **skill-based errors** and **perceptual errors**.

1. **Decision errors** represent *intentional* behaviour that is carried out as intended, yet the action is inadequate or inappropriate for the situation.

2. **Skill-based errors** (SBE) are categorised as attention, memory failures and technique failures. Wiegmann and Shappell (2001, 2003) describe SBE as occurring when there is a breakdown of the basic skills that are performed without significant conscious thought.

3. **Perception based errors** typically occur when one's perception of the world differs from reality. According to Shappell and Wiegmann, 2000 p.5, perceptual errors occur when sensory input is degraded or 'unusual', for example, an experienced pilot basing an action on perception and experience when visual (horizon) cues are absent at night or when flying in adverse weather.

The motivation to distinguish between the different categories of errors is inspired by the seminal work from human factors researchers Jens Rasmussen and James Reason, both of whom studied the underlying cognitive mechanisms which may influence how errors can manifest depending on the task and person (Miranda, 2018).

Violations are deliberate deviations from a correct action and which were not necessarily designed to generate an adverse effect. In HFACS, violations are divided into two subcategories: routine and exceptional.

1. **Routine violations** tend to be habitual in nature, possibly unconscious, may often be tolerated by authority, and referred to as *bending-the-rules* (Miranda, 2018). If routine violations are identified, then there is a supervisory and authoritative failure to enforce the rules.

2. **Exceptional violations** appear as isolated departures from authority and are not necessarily indicative of an individual's typical behaviour. Given their isolated occurrence, exceptional violations are particularly difficult for any organisation to deal with and are particularly difficult to predict (Shappell and Wiegmann, 2000).

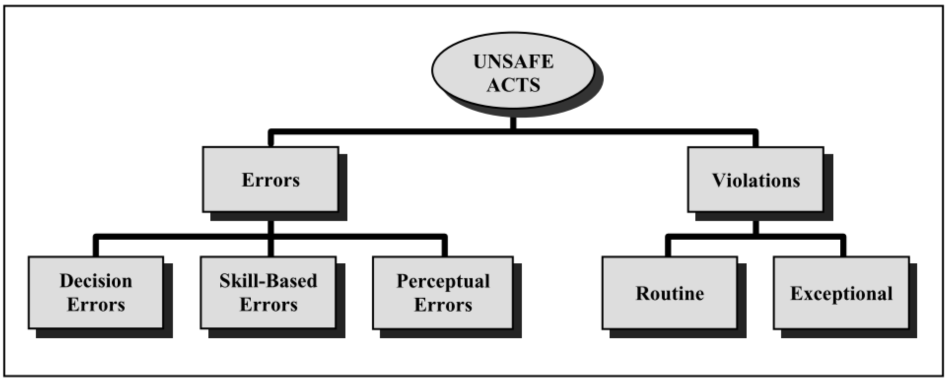

Figure 5. Categories of unsafe acts (Shappell and Wiegmann, 2000)

The DoD HFACS Level 2,3,4 (Latent Failures – (2) Preconditions for Unsafe Acts, (3) Unsafe Supervision, (4) Organizational Influences)

The DoD HFACS distinguishes latent conditions into three tiers as follows:

Tier 1. Preconditions for unsafe acts (HFACS Level 2 - subdivided into three categories).

I. ***Environmental*** (subcategory: technological and physical environment)

II. ***Physical and mental state*** (subcategory: physiological states/personal readiness/mental states/sensory misperception
III. ***Team resource management*** (Lenné *et al.*, 2012)

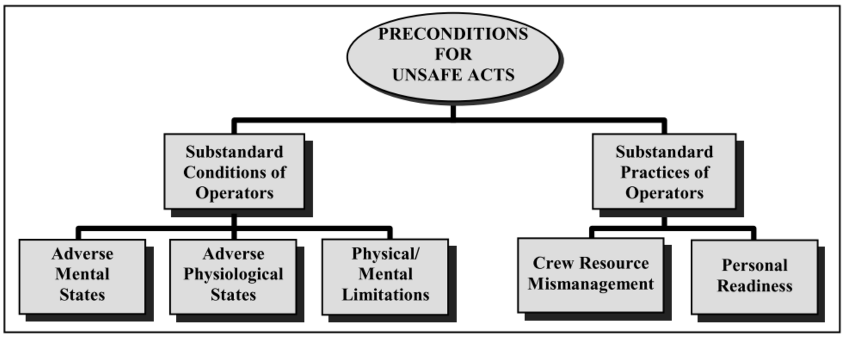

Figure 6. Categories of preconditions of unsafe acts (Shappell and Wiegmann, 2000)

Tier 2. Unsafe supervision (HFACS Level 3 - subdivided into four categories)

I. ***Supervisory violation*** (rules and regulations are wilfully disregarded by supervisors)
II. ***Failure to correct problem***
III. ***Planned inadequate operations*** (poor employee pairing (novice with novice), inadequate opportunity for employee rest or breaks)
IV. ***Inadequate supervision*** (failure to provide proper training, guidance or oversight) (ibid)

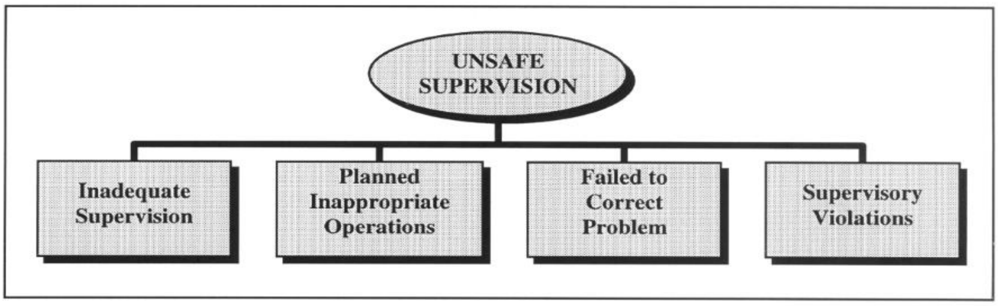

Figure 7. Categories of unsafe supervision (Shappell and Wiegmann, 2000)

Tier 3. Organisational influence (HFACS Level 4 - subdivided into three categories)

I. **Resource management** (staffing/manning, selection, cost cutting, poor design)

II. **Organisational Climate** (structure, policies and culture)

III. **Organisational policy and process** (time pressure, instructions, risk management) (ibid).

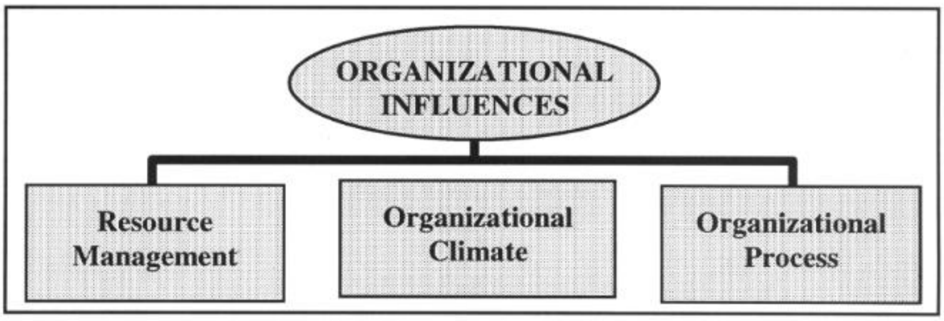

Figure 8. Organizational Influences (Shappell and Wiegmann, 2000)

Figure 9 below, summarises the four levels of failure outlined in the Human Factors Analysis and Classification System (HFACS) taxonomy. As human error is complex and elusive, the framework below drives investigators to seek causes beyond the active failures at the sharp end. It also compels investigators to probe, question and recognise that it is seldom that deviations or accidents are the outcome of one single event or unsafe act. Rather, they result from a combination of multiple factors, *inter alia* environmental, task-related, situational, and organisational factors (Reason, 1995; Berry, Stringfellow and Shappell, 2010). An important consideration of looking beyond the sharp end and focussing attention to the latent conditions is the potential to gain greater results with targeted interventions. Many latent conditions lie dormant in a system, creating unpredictable combinations and hazardous gaps. Thus turning attention to these failures may yield the greatest rewards in preventing errors (Reason, Hollnagel and Paries, 2006).

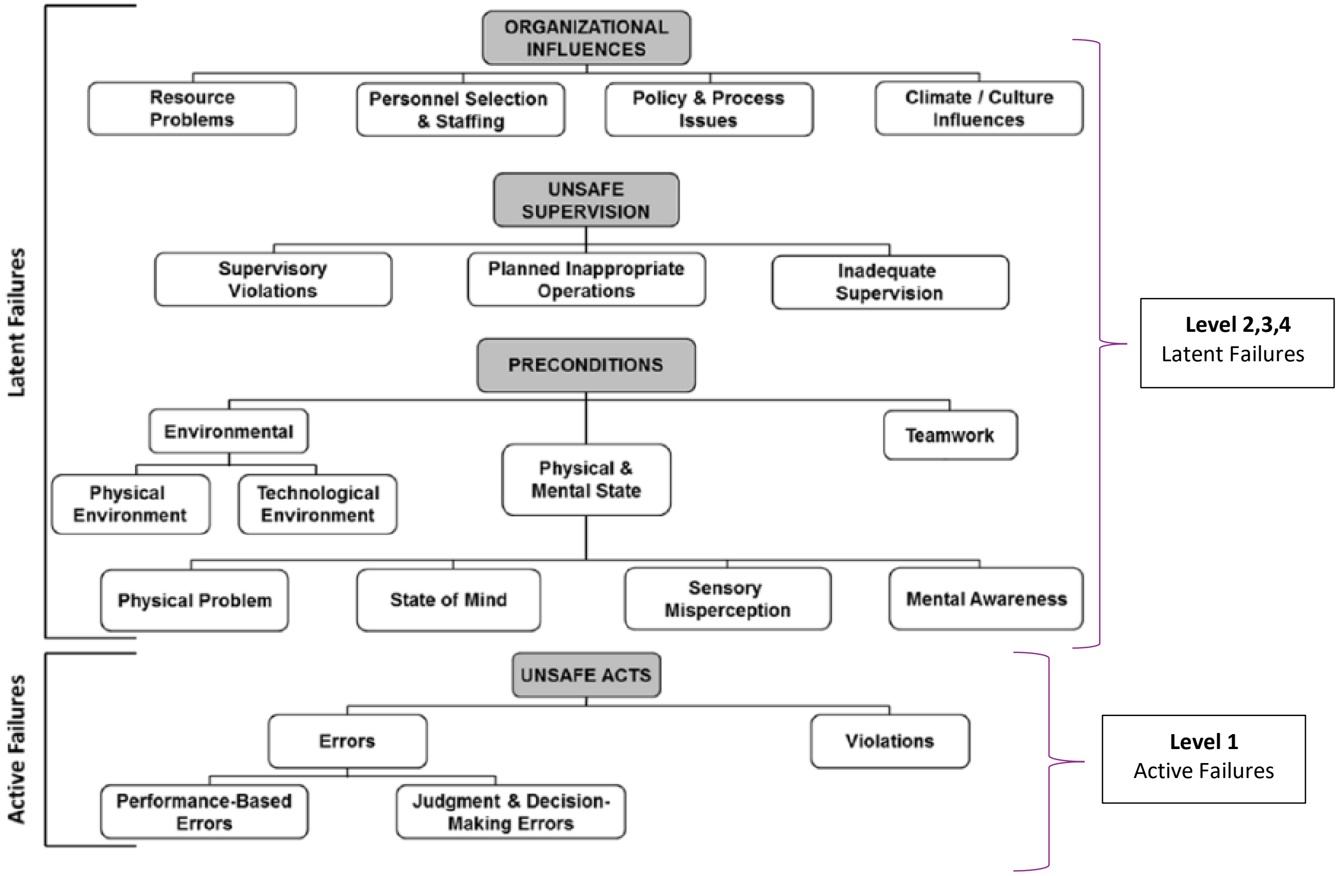

Figure 9. The Department of Defence Human Factors and Analysis Classification System (DoD HFACS 7.0)

5. When 'human factors' invariably leads to 'ergonomics theory'

As outlined above, it may be argued that the analysis derived from the application of various models of human error, including Rasmussens, Reason and Wiegmann & Shappell's HFACS, supports the perspective that errors and accidents are rarely the product of a single, significant mishap. On the contrary, they often involve a chain of errors caused by a combination of many factors, possibly involving several individuals, and that, at the root can be found a ***lack* of human factors** (micro and macro-ergonomics) **considerations** (Meshkati, 1991; Chen *et al.*, 2013). Meshkati (1919 p.113) argues that the causes of human error and the associated commonalities of human factor deficiencies identified in major disasters, has concluded that **system accidents** are caused by the way the (system) parts — engineered and human — fit together and interact. He states:

> *'on many occasions, the error and the resultant failures are both the attribute and effect of such factors (as) complicated operational processes, ineffective training, non-responsive managerial*

systems, non-adaptive organizational designs, haphazard response systems, and sudden environmental disturbances, rather than being their cause.' (Meshkati, 1991 p.141).

Expanding on Human Factors and the Impact of Micro and Macro Ergonomics on Production Systems

Defining Systems

It is argued that many errors leading to accidents or major disasters are directly linked to the interaction of system parts (engineered and human) and how these fit together (ibid). In the context of workplaces, this interaction of systems is inevitable as most activities involve some form of interface between humans and their environment. As systems and human interactions are ubiquitous, the question arises what is meant by the term 'system'?

According to Checkland, 2000, p. S17:

> *"In systems engineering, the word 'system' is used simply as a label for something taken to exist in the world outside ourselves. The taken-as-given assumption is that the world can be taken to be a set of interacting systems, some of which do not work very well and can be engineered to work better.'*

Wilson's, 2014 p.6 definition further describes systems as:

> *'… a set of inter-related or coupled activities or entities (hardware, software, buildings, spaces, communities and people), with a joint purpose, links between the entities which may be of state, form, function and causation, and which changes and modifies its state and the interactions within it given circumstances and events, and which is conceptualised as existing within a boundary; it has inputs and outputs which may connect in many-to-many mappings; and with a bow to the Gestalt, the whole is usually greater (more useful, powerful, functional etc) than the sum of the part.'*

Origins and definitions of Ergonomics

The discipline of ergonomics stresses the role of the humans in a system. Whilst the word ergonomics may be considered a relatively new term, the considerations of interactions between people, systems and working environments is not new and can traced back to writings from ancient Greece (Wilson, 2000).

The origins of modern ergonomics began from the 1939 to 1945 World War. In the United Kingdom (UK) the discipline of ergonomics emerged as ideas and expertise from different disciplines (e.g. anatomy, physiology, psychology, industrial medicine, industrial hygiene, design engineering) with an interest in the effectiveness of human performance. This interest in human performance, combined with an emphasis on theory and methodology, led to the formation of the discipline of ergonomics. This UK discipline emerged with two strong sub-groupings: those of **anatomy/physiology** and **experimental psychology** (ibid).

Beyond the UK, in Germany, The Netherlands and Scandinavia, the discipline of ergonomics was also growing, due to work and research in medicine and functional anatomy, whilst in Eastern Europe the growth was largely from the industrial engineering profession (Wilson, 2000). At the same time, and from an US perspective, the human factors (HF) profession was growing and was strongly influenced by the disciplines of psychology and engineering. This emergence of the disciplines of ergonomics and human factors led to the interchangeable term Human Factors and Ergonomics, as the term HF became more common in the US and the term 'ergonomics' more widely used in other parts of the world.

Ergonomics, as we know it now, became a recognised scientific discipline in the late 1940s under the name of Human Factors/Ergonomics (HFE). Since its emergence, many different, if overlapping, definitions of ergonomics and of human factors exist. An accepted view is that HFE has drawn from the disciplines of **anatomy, physiology and psychology** whilst also being closely linked to the applied disciplines of **engineering and medicine**.

The definition of HFE and HFE specialists (adopted by the IEA in 2000) reflects this body of knowledge as follows (IEA 2000):

'Ergonomics (or human factors) is the scientific discipline concerned with the understanding of the interactions among humans and other elements of a system, and the profession that applies theoretical principles, data and methods to design in order to optimise well-being and overall performance.'

'Practitioners of ergonomics – ergonomists - contribute to the planning, design, implementation, evaluation, redesign and continuous improvement of tasks, jobs, products, technologies, processes, organisations, environments and systems in order to make them compatible with the needs, abilities and limitations of people.'

Thus, the HRE domain may be classified into three key categories as follows:

- **Physical.** This category is concerned with anthropometric[4], anatomical[5], physiological[6] and biomechanical[7] activities are they relate to physical activities. Examples of this include work posture, material handling, workplace layout and health and safety.

- **Cognitive / Psychological.** This classification is associated with mental processes such as memory, perception, reasoning, motor responses and how they may effect interactions with other elements in a system. Examples of this category include decision-making, mental workload, work stress and training.

- **Organisational.** This domain is concerned with optimising socio-technical systems, including organisational structures, policies and processes.

Expanding this further, these categories are then considered from a micro and macro perspective.

Micro and Macro Human Factor Ergonomics

Human factors, at the micro level, specifically micro-ergonomics, is primarily concerned with the *human-machine system level.* This includes the design of individual control panels, visual displays and workstations and seating, paying particular attention to the physical and psychological categories described above, i.e. anthropometry, human skills, cognitive capacity, human decision-making, information processing and error (Meshkati, 1991 p.138). At the macro level - macro-ergonomics - the focus is on the overall *people-technology system level*. This takes a more holistic view beyond the individual systems level. The macro HRE is concerned with the impact of technological systems on organisational, managerial, and personnel (sub)systems (ibid). An interesting example of macro level HFE deficiencies can be traced back to the Bhopal disaster[8]. Meshkati (1989a) argues that effective macro-ergonomics practices would have identified shortcomings in the performance of the poorly trained Third World operators charged with operating advanced technological systems designed by other humans with very different educational, cultural and psychosocial

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[4] adjective: anthropometric - of or relating to the scientific study of the measurements and proportions of the human body.

[5] adjective: anatomical - relating to bodily structure, relating to the study of anatomy

[6] adjective: physiological - relating to the branch of biology that deals with the normal functions of living organisms and their parts, relating to the way in which a living organism or bodily part functions.

[7] *Adjective:* biomechanical - relating to the mechanical laws concerning the movement or structure of living organisms.

[8] Bhopal, India, on December 4, 1984, resulted in the deaths of approximately 3,800 people and the injury of more than 200,000.

attributes. Dul *et al.*, 2012 p.6, expand on this reiterating the importance of considering cultural diversity in the design of production systems and aligning systems to diverse workforces. They argue that in cross-cultural design:

'It is acknowledged that people from different cultures have different capabilities and aspirations, which affect the design of systems of which they are part'.

An important consideration is the cross-reliance between both micro and macro human factors ergonomics (HRE) approaches. Meshkati maintains that both levels build on each other with the overall objective being is to optimise the functions (e.g. quality, safety, efficiency) of the intended systems through the successful introduction, integration and utilisation of technology.

Ergonomics and Quality

According to Dul and Neumann, 2008, the definition of ergonomics infers that the discipline has both a social goal (well-being) and an economic goal (total system performance). As such, ergonomics focusses on the role of humans in a system (physical and psychological human aspects) and on the economic goals of an organisation from a performance perspective. Dul *et al.*, 2012 argue that the three fundamental characteristics of HFE is derived from these descriptions:

- HFE takes a systems approach
- HFE is design driven
- HFE focuses on two related outcomes: performance and well-being.

From the performance perspective, related goals may include output volume, lead time, production flexibility, quality levels and operating cost, among others (Dul and Neumann, 2008 p.3).

According to Drury, 2000 p.1, '*quality is a function of technological and human factors and is greatly influenced by ergonomics'*. When errors occur in a process in biopharmaceutical manufacturing the consequences can result in product unreliability, quality related problems, poor productivity or even injury to the workforce or ultimately to the patient. With respect to biopharmaceutical manufacturing organisations, quality is a critical business criterion and, as such, it could be argued the application of HFE practices may positively influence the quality function (ibid). This prompts the question: **are HFE practices considered in industries where**

human error is routinely defined as a root cause of errors and has a direct negative impact on quality, and if not, why not?

As far back as the early nineties, Rasmussen, 1990 (p.1) identified the need to consider HFE as part of a multidisciplinary issue impacting safety, quality, and risk management, stating:

'The human factors problems of industrial safety in (operation of large-scale systems) not only includes the classical interface problems, but also problems such as the ability of designers to predict and supply the means to control the relevant disturbances to an acceptable degree of completeness, the ability of the operating staff to cope with the unforeseen and rare disturbances, and the ability of the organisation in charge of operation to maintain an acceptable quality of risk management. The human factors problems of industrial safety have become a true cross-disciplinary issue.'

The Challenges for Human Factor Ergonomics

In 2008, Dul and Neumann (p.3) stated that '*during the past 25 years, several authors have emphasised that ergonomics has had a problem being accepted by business managers'*. Over a decade later, this view was again echoed by Greig *et al.* in 2019, as their research indicated that HFE is generally not understood by organisational stakeholders, is separated from an organisation's strategy considerations, and is mainly considered as a reactive mechanism after an error has occurred. Unfortunately, it seems research implies that HFE is often considered only as part of the Occupational, Health and Safety function (H&S) and deemed relevant only for human resources and injury prevention (Dul and Neumann, 2008; Dul *et al.*, 2012; Greig *et al.*, 2019).

Wilson (2000) identifies this lack of distinction from other disciplines such as Health and Safety (H & S) as an obstacle to the application of HRE as a strategic business concept, stating that ergonomics should be represented as a distinct discipline with its own theories, models and practices.

The lack of consideration of HFE as an important element of strategy, also stems from several other factors, including lack of organisational support, lack of clarity as to the tangible benefits of HFE, and the perception that HF is common sense, and as such, not part of a strategic plan. Further factors include the fixed mindset that HFE should only be considered at a startup phase and/or, is primarily the function of health and safety departments, therefore may be delegated to business units that are not connected to strategic decision-making processes.

Wilson also identifies education as a key opportunity to increase awareness of ergonomics and its importance from a human life and production viewpoint. Wilson emphasises the importance of embedding ergonomics within teaching programmes in secondary and, particularly, tertiary education.

Wiggins (2022) p.3 also supports view that there is a lack of consideration of human factors as a strategic, holistic approach to problem solving, stating that there is a tendency to consider it as a *'reactive' approach to the management of deficiencies in the relationship between human performance and technology reflects a broader conflict in the design of human-machine systems where there is often a tension between delivering a product quickly and cost-effectively, and delivering a product that can be assured is safe, efficient and functional'.*

Furthermore, Wiggins states that human factors bring together a number of complementary areas of investigation including psychology, engineering, education and ergonomics (ibid p.3) thus arguing that while the study of ergonomics falls under the remit of human factors, it is, however, a separate discipline and that the two terms are not interchangeable in their description.

A further point of consideration is the limited reference to HFE in FDA and HPRA audit reports and publications despite behaviours and human error identified as deficiencies and observations. Research into many errors, accidents and disasters has linked human factors as a contributory factor to the root cause and, as such, a greater consideration of the value of ergonomics beyond a sideline function of health and safety is warranted. An increased emphasis on human factors, and the interaction between humans and systems from a physical, cognitive/psychological, and organisational perspective, may serve as an important feature in the pursuit of error reduction, human well-being and organisational performance.

7. Re-training as a response to 'human errors'?

However, the solution to human errors in many cases consists of retraining of the relevant staff, therefore, retraining is often used as the key preventative measure for such issues (Poska, 2010). Furthermore, assigning human error as the root cause of incident of noncompliance, and employing a strategy of simply retraining as a key preventative measure, will not necessarily lead to improved performance. As noted in Dekker (2014 p.22)

'a focus on 'human error' very quickly becomes a focus on humans as the cause of safety trouble, and on humans as the target for intervention. But this has long been shown to be a limited safety endeavour, as getting rid of one person does not remove the conditions that gave rise to the trouble they got into'.

Effective, systematic error prevention extends beyond the premise of training or retraining, requiring a greater level of understanding of causative factors including organisational and learning culture.

What has not yet been adequately researched in manufacturing systems responses, is the concept of 'training transfer' rather than simply re-training, as briefly discussed below.

8. Training Transfer Concepts: possible links with human factors and ergonomics

The concept of the transfer of learning has been an enduring problem in psychology and education with research into the history of transfer going back over 100 years, and with debates between Thorndike and Judd positing some of the early hypotheses regarding learning transfer based on the findings of their various experimental results (Barnett and Ceci, 2002). Since then, many researchers and academics have debated the nature, contexts, and prevalence of transfer. Initial questions that may provoke greater interest in transfer of training in manufacturing in recent decades could be as follows:

- How can we transfer what we learn?
- How similar does the learning context have to be to the applied situational context?
- Is context independent of the content we wish to apply?
- What other factors may interfere with learning transfer?

The definition of transfer of learning has evolved over many years with educational theorists and psychologists including Thorndike, Woodworth and Gagne as foundational. Blume *et al.*, 2010 posit that transfer of training consists of two major dimensions:

(a) *generalisation*—the extent to which the knowledge and skill acquired in a learning setting are applied to different settings, people, and/or situations from those trained, and

(b) *maintenance*—the extent to which changes that result from a learning experience persist over time.

Transfer of training, therefore, is much more than a function of original learning in a training programme. It extends beyond the original learning to a situation whereby recipients of training effectively apply the knowledge, skills, and attitudes gained in a training context to the job. The effect of the positive transfer of training is ultimately measured by how effectively the learning that results from a training experience transfers to the job and leads to meaningful changes in work performance. That is the paramount concern and objective of all organisational training efforts (Baldwin and Ford, 1988; Blume *et al.*, 2010).

In addition to dimensions mentioned above regarding training context, setting and time, other factors can affect transfer of learning. Through gaining a better understanding of these factors valuable insights into how to create more successful training transfer processes can be gleaned. One of the most the frequently cited models of training transfer is that of Baldwin and Ford (1988) whereby they organised their qualitative review around a model of training factors - inputs, outputs and conditions of transfer (Baldwin and Ford, 1988). The model suggests these factors are proposed to have both direct and indirect effects on conditions of transfer. These concepts of inputs, outputs and conditions of transfer are expended upon below.

- **Training Inputs**
    - *Trainee characteristics*, including ability, skill, motivation, and personality
    - *Training design*, including the training objectives and methods, and the incorporation of learning principles such as multiple training techniques and opportunities for practice
    - *Work environment factors* which include transfer climate, social support from supervisors and peers, and the constraints on, or opportunities for, performing learned behaviours on the job.
- **Training outputs**
    - The acquisition of knowledge and skills during training
- **Conditions of transfer**
    - Generalisation of knowledge and skills acquired in training to the job and the maintenance of that learning over time on the job.

In Figure 10 below, Baldwin and Ford (1988) presents a framework for understanding the transfer process, whereby the process is described in terms of training-input factors, training outputs, and conditions of transfer. The model purports that both training outputs and input factors apply significant influences on the conditions of transfer. Specifically, it outlines six linkages that facilitate understanding of the transfer process as follows:

1. **Direct Effects on Transfer**:
    - **Training Outputs**: The model suggests that learning and retention have a direct impact on the transfer of skills (Linkage 6) asserting that effective transfer is conditional on the successful acquisition and retention of training material.
    - **Trainee and Work Environment Characteristics**: These factors are considered to have direct effects on transfer, irrespective of initial learning or retention outcomes (Linkages 4 and 5). For example, lack of employee motivation or inadequate supervisory support.

2. **Indirect Effects on Transfer**:
    - **Training Inputs**: The model indicates that training design, trainee characteristics, and work environment characteristics directly influence training outcomes (Linkages 1, 2, and 3). Subsequently, these inputs indirectly effect transfer by impacting learning and retention.

This model highlights the complexity of successful skill transfer, demonstrating the importance of considering environmental factors, training design, individual characteristics, and work environment, all of which, it could be argued, relate back to systems thinking, ergonomics and human factors in determining the effectiveness of skill application in real-world settings.

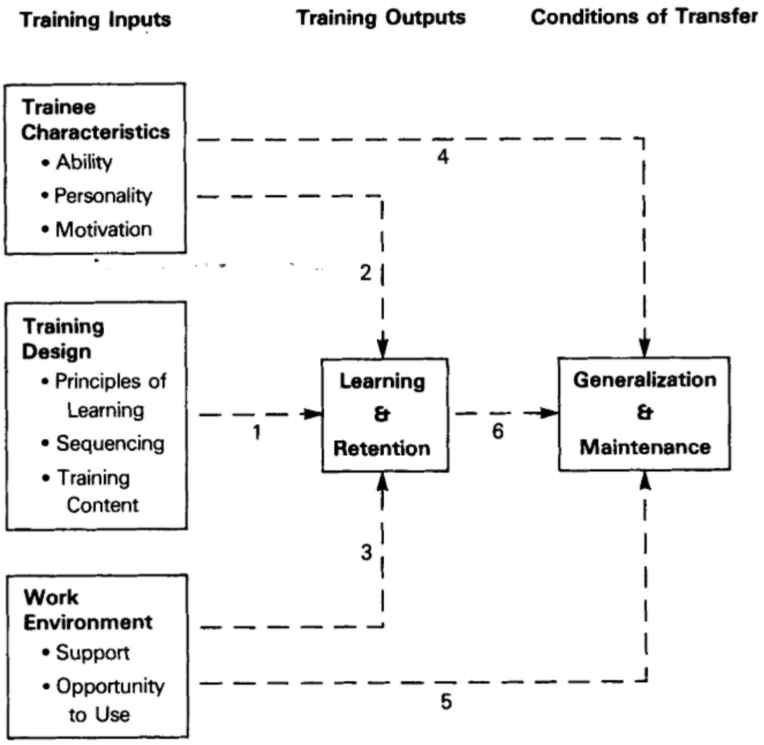

Figure 10. A Model of the Transfer Process Baldwin and Ford, 1988

9. Final remarks

In October 2019 a report by the Drug Shortages Task Force, titled ‘Drug Shortages: Root Causes and Potential Solutions’ was published by a task force convened by the FDA to address the nation’s drug shortage crisis (US Food and Drug Administration (FDA), 2019). The report identified the underlying factors contributing to drug shortages and proposed solutions to address these issues, with its primary focus on economic, regulatory, and quality-related factors contributing to drug shortages. It must be noted the terms human factors and safety systems are not mentioned throughout the report, despite, as outlined early in this paper, approximately 50% of deviations within the biopharmaceutical industry had been attributed to human error.

Two years after this FDA publication, in August 2021, two Japanese men, aged 38 and 30, passed away shortly after receiving their second dose of the Moderna COVID-19 vaccine. Both men were administered doses from the same batch of the vaccine. By September 1, 2021, the Japanese authorities had recalled three batches of the Moderna vaccine, totalling 1.63 million doses, due to concerns over contamination. The same month the Ministry of Health of Japan again reported that another 49-year-old man died after receiving a dose of Moderna COVID-19 vaccine that was among batches later recalled (Han *et al.*, 2020). An investigation into the contamination was carried out at the biopharmaceutical manufacturing site where the vials were filled, and the subsequent report identified that the problem occurred as a result of an incorrect set-up during a manufacturing line changeover. The report cited this inaccuracy in assembly as 'human error' specific to a visual misjudgement related to a 1mm gap (Berry & Wilson, 2023). The report further stated that '*the regulation of that gap is conducted visually…a proper alignment relies on the capability, qualification and experience of the person performing that set up*' (ibid p.32). In essence, the system was totally dependent on one human to prevent this contamination taking place and potentially harming millions of humans. Furthermore the report paid scant attention to the system failure in detecting the contaminants in the vials after the initial contamination, for example manual/automated visual inspection processes (ibid).

There is an unfortunate irony regarding the publication of the 2019 report 'Drug Shortages: Root Causes and Potential Solutions' and the lack of consideration of human factors and systems safety, coupled with the subsequent contamination of Covid 19 vaccines in 2021 due to human error, resulting in multiple deaths and leading to vaccine supply issues while the world was in the grip of a global pandemic.

This article sought to highlight the lack of consideration of human factors and ergonomics when investigating adverse events, drug shortages and recalls, as illustrated immediately above. It also considered the inadequacies of both apportioning 'human error' as a root cause of such events, and application of retraining as a corrective action.

Furthermore, the author considered how differing definitions and understandings of the terms ergonomics and human factors are, in fact, part of the problem with regard to the lack of consideration and application of these disciplines in an industrial manufacturing setting.

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