



Behavioural GMP and Human Error Reduction

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What causes defects?

“ The great majority of reported defective medicinal products has resulted from human error or carelessness, **not from** failures in technology”

MHRA , Orange Guide 2002

Can this really be true?

If most defects are caused by non-compliance with GMPs, and most non-compliances are caused by human error or carelessness, then what causes human errors or carelessness?

How Many Es?

FRED IS A PRODUCTION OPERATOR. FRED IS FEARFUL THAT HE MIGHT ERR IN HIS FIELD OF WORK AND SUBSEQUENTLY FEEL THE IRE OF QA FOR HIS FAILURE TO HIS DUTY OF CARE. FRED WORKS FOR A DEPARTMENT THAT MUST CARRY THE BURDEN FOR HIS ERROR. TODAY WE HOLD INDIVIDUALS ACCOUNTABLE FOR THEIR ERRORS BECAUSE WE SHOULD EXPECT NOTHING LESS THAN FLAWLESS PERFORMANCE FROM A HIGHLY TRAINED AND EDUCATED OPERATOR.

Human Error

Studies tell us that EVERYONE commits errors

Human behaviour explains human error

- Therefore, looking at why and how we behave in certain situations helps to explain why we do what we do.

Human error is rarely random.

- It is connected to the tools, tasks and environment. That is, it can often be predicted, and in some situations, is inevitable.

People want to do the right thing.

- We do what makes sense to us at the time given our focus of attention, knowledge and goals

Perfect Systems need Perfect Humans

- Systems and processes are not inherently compliant
- People must create compliance using tools, systems and technology
- ***Therefore systems that depend on perfect behaviour are inherently flawed***

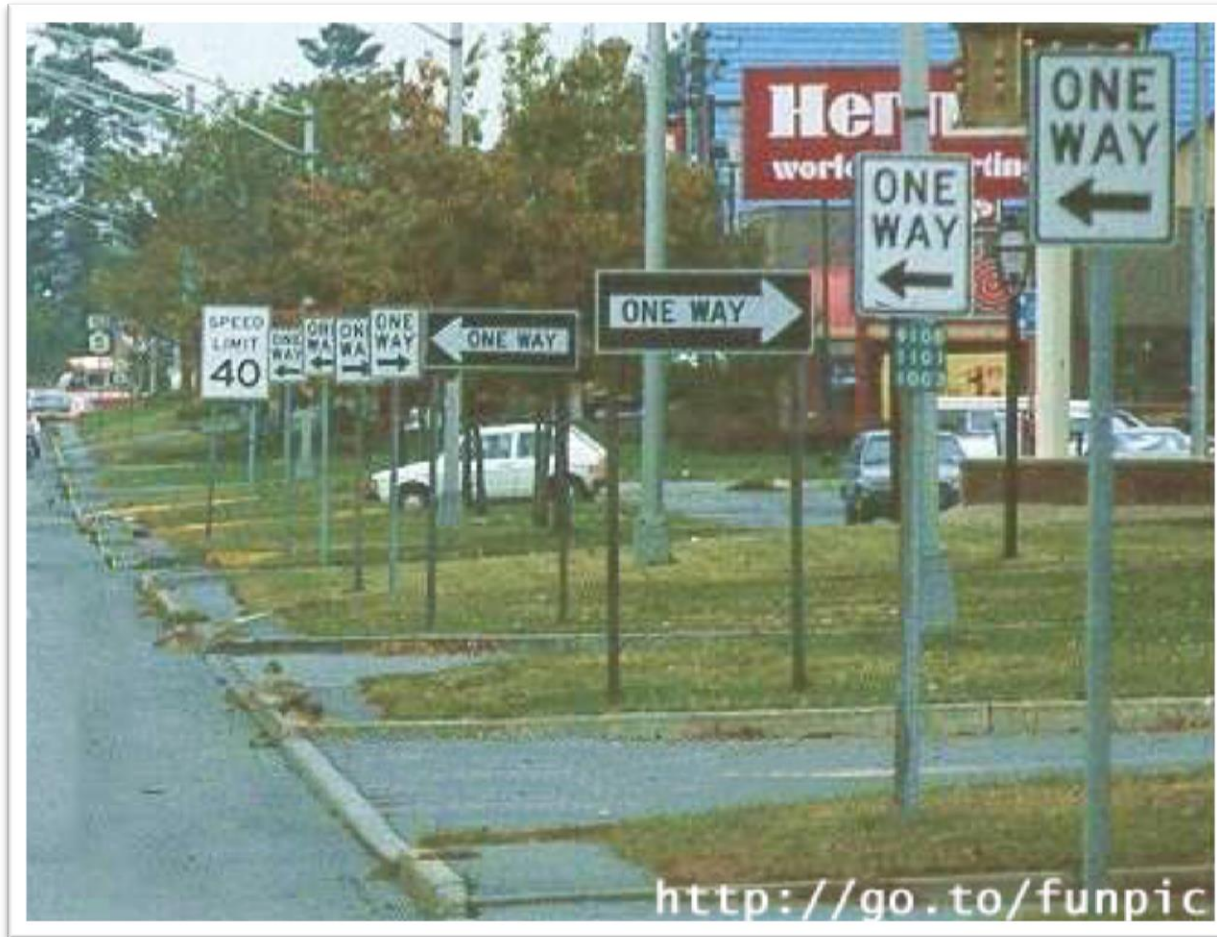
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Human Factors

- Human factors engineering (HFE) is the science of designing systems to fit human capabilities and limitations - in perception, cognition, and physical performance.
- Poka-Yoke is a device or method that prevents people from making mistakes. The word in Japanese means *mistake proofing* or *error proofing*. (Originally the word Baka-Yoke or *idiot proofing* was used!)

Which way did you say?



Left or Right?



Human Factors

Example of human limitations

- **Attention** – may be limited in duration or focus, especially if attention must be spread
- **Memory** – working memory is limited, especially when active processing of information is required
- **Situation awareness** – refers to a person's perception of what's happening around them
- **Automaticity** – consistent, over-learned responses may become automatic and completed without conscious thought

Human Factors

- **Stress** - Occurs when there is a mismatch between what people are expected to do or cope with and the resources available to them
- **Fatigue** - Caused by too much or too little to do, sustained activity, physical / emotional exertion, amount / quality of sleep, time of day.

Source of errors

- Processes may be referred to as having sharp and blunt ends.
 - **Sharp end** –the person actually doing the task
 - **Blunt end** – the influences on the process farther away from the action itself. Management, administration, process & equipment designers, internal regulators

Another View on Errors / Problems

“...most troubles and most possibilities for improvement add up to proportions something like this:

- * - 94% belong to the system (the responsibility of management)
- * - 6% are attributable to special causes.

The New Economics” 1994 – Ch. 2 -The Heavy Losses-, page 33

Often quoted as "The system is responsible for 94% of problems" or "Management is responsible for 94% of the problems“

How do we respond to errors?

- Aviation and Nuclear industries way ahead
- “Name, blame and train” strategy
- We “fix” the person, should “fix” the system
- Find root cause and focus on this
- Implement a “just culture”

Dr Rollin Fairbanks M.D.

BEHAVIOURAL CHOICES

How might we hinder compliance?

- On 25th January 2000, Dr Lucian Leape (a Harvard professor of health) told Congress that the single greatest impediment to error prevention in the medical industry is that ‘we punish people for making mistakes’
- We may be seen as punishing people for reporting their own mistakes or those of others, driving practises underground
- May be removed from the action – not part of the team.

Errors versus choices (behaviour)

- Our physical and mental limitations as humans can explain the unintentional errors we make. These may result in a non-compliance or deviation, but they are not deliberate
- What about the **deliberate** choices we make?

Punishing Non-Compliance

- Should people be punished for deliberate non-compliance?
Should they be held personally accountable?
- Must consider;
 - Unintentional errors
 - Risky behaviour
 - Reckless behaviour

At-Risk Behaviour / Routine Violations

- At-risk behaviour is when the person believes the benefit of **NOT** complying exceeds the benefit of complying. For example
- Following an expired procedure because it still works
- Filling in signatures after the work is done because too busy
- Not reading a document before signing it
- Becomes entrenched because there is no harm caused therefore no blame. Or worse, it may be rewarded because it may help to meet other goals
- There is a risk that certain kinds of (GMP) non-compliant behaviour become the norm and therefore represents (organisational) compliant behaviour.

Reckless Behaviour / Extraordinary Violations

- Reckless behaviour is when the **risk** associated with the behaviour **outweighs the benefits** of the behaviour. For example
- Ad hoc change to manufacturing parameters to speed up the process
- Using a raw material from a different supplier
- Does not mean there is an intent to do harm

Console, Coach, Punish

- Console the human error
- Coach the at-risk behaviour
- Punish the reckless behaviour

.....regardless of the outcome

This is known as a 'Just Culture' – that is, a fair culture.



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