

Reduce Your Errors Through Best Practice Training

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Scope

- **Training**
 - Best practice training: practice-oriented learning
 - Stages of learning
 - Stages of assessment
 - Future of GMP compliance with respect to training
- **After Training**
 - Human error
 - Addressing accidental human error

Practice-oriented Education Model

- An integrated exposure to professional practice through dynamic and multifaceted modes of **practice-oriented** education
- Professional practice situated in a **global workplace**, with international mobility and international and cultural engagement as centre piece
- Learning which is **research-inspired** and integrated, providing academic rigour with cutting edge technology to equip graduates for life-long learning.

McCune & Hounsell, 2005

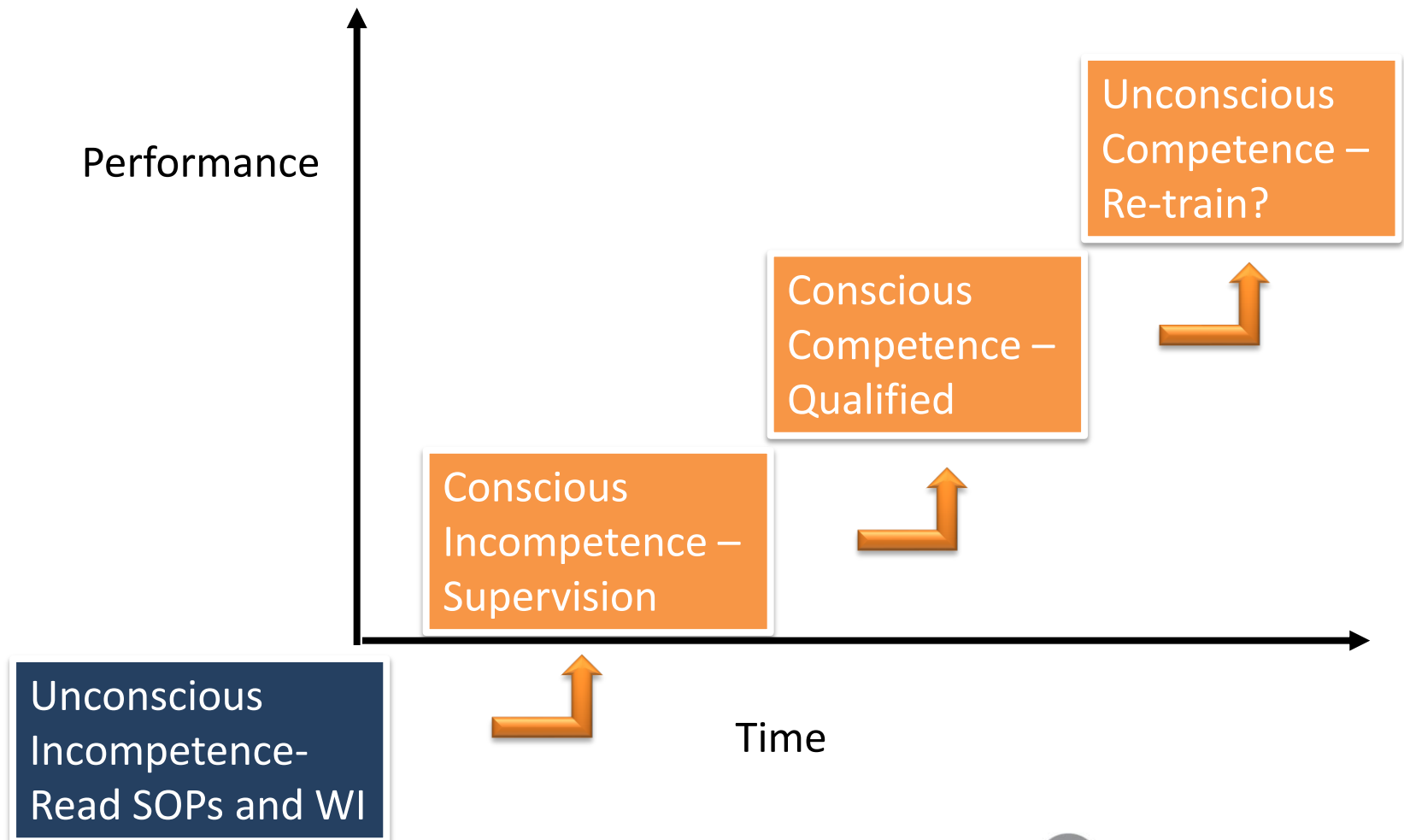
Dall'Alba and Sandberg, 2006

Problem-based Learning

- Increase the use of deep approaches
- Improve the retention of information
- Develop student independence and motivation
 - (Ramsden, 1992).
- Training addresses a gap in knowledge and skills
 - Knowledge from principles and theory
 - **Skills from practice (real-life scenario workshops)**



Stages of Learning



Regulatory Focus: Performance

- FDA inspections to focus to performance over compliance
- Qualifying employees = Final Performance Demonstration documented as a Qualification Event
 - PDA Letter, 2015
- **Practice-oriented learning addresses Performance at the Training stage...before qualification.**

Once Trained the Real Work Begins

- **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

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

How Many Es Now?

- FRE^ED IS A PRODUCTION OP^ERATOR. FRE^ED IS FE^EARFUL THAT HE^E MIGHT ER^ER IN HIS FI^ELD OF WORK, AND SUBSE^EQU^ENTLY FE^EEL THE^E IRE^E OF QA FOR HIS FAILUR^EE TO HIS DUTY OF CAR^EE. FRE^ED WORKS FOR A DE^EPARTM^EENT THAT MUST CARRY THE^E BURDEN^E FOR HIS ER^EROR. TODAY WE^E HOLD INDIVIDUALS ACCOUNTABLE^E FOR THE^EIR ER^ERORS BE^ECAUSE^E WE^E SHOULD EXPE^ECT NOTHING LE^ESS THAN FLAWLE^ESS PER^EFORMANCE^E FROM A HIGHLY TRAINED^E AND E^EDUCATED^E OP^ERATOR.

Why Do We Make Errors?

- Many reasons, some being:
 - Communication failure
 - Lack of effective training
 - Memory lapse
 - Inattention
 - Poorly designed equipment
 - Exhaustion, fatigue
 - Noisy, distracting working conditions

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!*

Other Considerations

- **Active errors** occur at the *sharp end* of the process – committed by people close to the product.
- **Latent errors** occur at the *blunt end*. These are decisions and influences made away from the action itself by management, administration, process & equipment designers, internal regulators etc. Examples;
 - Equipment design flaws that make the human-machine interface difficult
 - Document design flaws, where a procedure is hard to follow
 - System design flaws, where a quality system may be overly bureaucratic, forcing people to take shortcuts or operate outside the system
 - Organisational flaws, such as understaffing

Which Way?



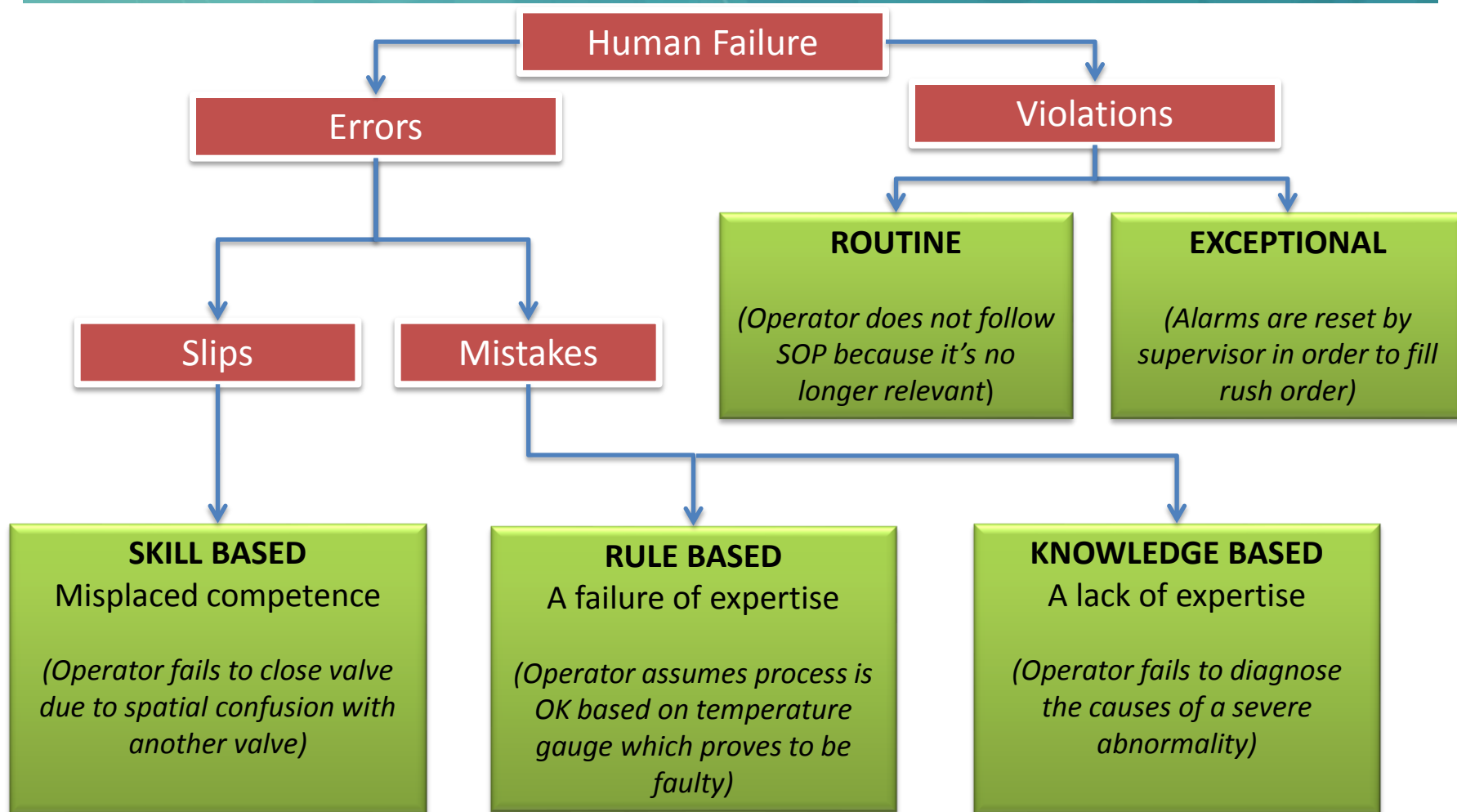
Left or Right?



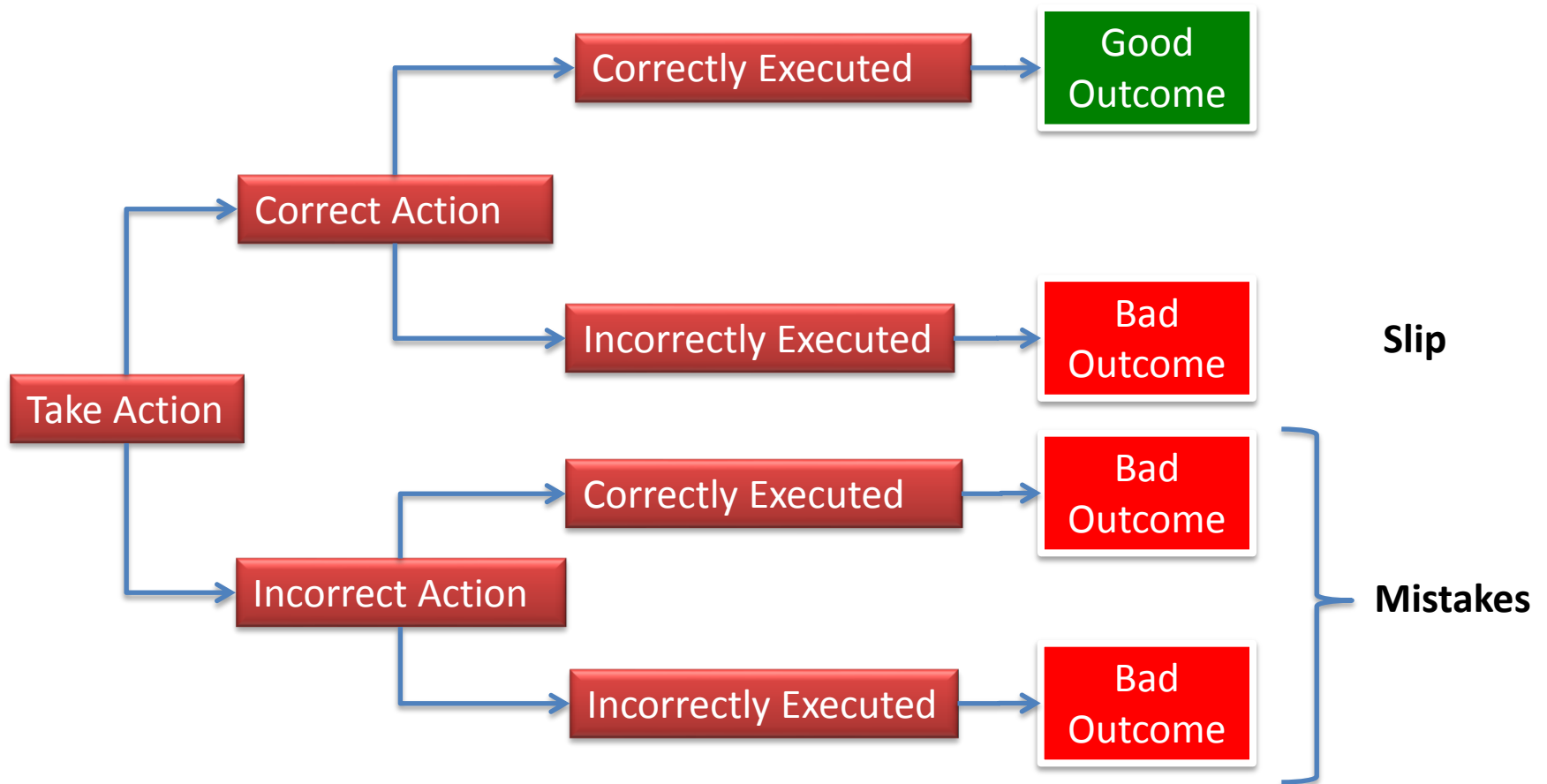
Human Performance 'Failure' Types

- **Slips:** Errors of execution
 - Doing the right thing incorrectly
- **Mistakes:** Errors of intention
 - Doing the wrong thing
- **Violations:** Deliberately doing the wrong thing
 - May be routine
 - May be extraordinary
 - GMPs allow for violations with prior approval

Human Performance 'Failure' Types



Slips versus Mistakes



Ref: MD+DI May 1997

Training for Slips and Mistakes

- Slips
 - Retraining not useful if staff are already skilled
 - Need to look at other things e.g. human factors, latent errors
- Mistakes
 - Retraining may be useful

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

Case Study

- Deviation No: 080400 –Hand Lotion with Aloe
- All lotions were backordered and the packaging operators were under pressure to produce 5 lotion lots within a 1 week period.
- The supervisor instructed operators to follow the necessary packaging instructions but to complete the paperwork after the fact, and not to waste time chasing signatures.
- The supervisor also ordered a minor clean after the previous product (Vit E cream), rather than a full clean required for a product changeover. To see if there had been contamination because of the reduced cleaning, 1 tube of lotion that was packed within the 1st hour of the batch was selected and a Vit E assay performed. No Vit E was detected.
- The operators also said that they were instructed to dispense the next batch into the filling tank/hopper prior to drying it. Micro is not checked on every batch.

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.

Take Home Messages

- Training is an asset, invest it getting it right first time
- Don't rely solely on training to avoid errors
- When human errors occur, investigate further to identify and address the root cause
- Create a just and fair culture to facilitate continuous improvement

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Thank You for Participating

Any Questions?

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