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FUTURE IN PHARMACEUTICALS

HUMAN ERROR

26 February 2014

Session Content

- Human Error – Context
- What Factors are Likely to Trigger Human Error?
- Human Error Risk Management – A Prospective Approach
- Organisational Strategy

mcgee pharma INTERNATIONAL

- Pharmaceutical Training, Compliance & Technical specialists
- Established 2004; based in Dublin, Ireland
- 14 Staff & 25 Associates
- International client base

WINNER OF THE ENTERPRISE IRELAND WMB FEMALE ENTREPRENEUR AWARD 2012

SFA National Small Business Awards 2013 WINNER

SFA National Small Business Awards 2012 FINALIST

Fingal Business Excellence Awards 2011

- **GLP** Good Laboratory Practice
- **GCP** Good Clinical Practice
- **GMP** Good Manufacturing Practice including Good Practice for Tissues and Cells (GPTC) and Good Engineering Practice (GEP)
- **GDP** Good Distribution Practice
- **MAH** Market Authorisation Holder compliance
- **GPvP** Good Pharmacovigilance Practice
- **GBP** Good Behavioural Practice
- **GPP** Good Pharmacy Practice

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Drug Development
- Preclinical Studies
- IMP Manufacture
- Clinical Trials

Approval
- Facility Design & Build
- Manufacturing License
- Product Authorisation

Manufacture
- Validation
- Manufacture & Testing
- QP Disposition
- Distribution

Post Marketing
- Pharmacovigilance
- Stability Monitoring
- Commercial Activity
- Complaints, Defects, Recalls
- Withdrawal

- 2012 was a Leap Year !
- Complimentary desk calendar had to be reprinted and resent to all clients

Implications of Human Error?

- **How drastic is a 1% error?**
  Assuring quality each production day, each dose, for each patient?
- *'It turns out that even a 1% error can add up to a lot of mistakes pretty fast.*
- *Getting it right 99% of the time is the equivalent of 20,000 lost articles of mail every hour.*
- *It's 5,000 botched surgical procedures every week.*
- *It's four accidents per day at major airports...*

If you can answer when, where and how often the defects occur… you have what you need [to start to address the problem]...

But don't just focus on the symptoms of the problem. Find the root causes'.

Chowdury, 2001

Human Error – Irish Medicines Board (IMB) Findings

- 25% of all Quality Defects such as deviations, lab errors, complaints are attributed to human error e.g.
  - Failing to follow procedures correctly
  - Using technical dossiers to support batch release that do not correctly reflect the contents of the Marketing Authorisation (MA)
  - Poor line clearance resulting in rogues being left on the line

- Quality defects are often attributed to human error <u>without justification</u>

  "We usually do not see this defined in any procedures and staff can be unclear on what comes within the meaning of 'human error' "

What Factors are Likely to Trigger Human Error?

- Risk Influencing Factors (RIFs) are

"adverse influences or Risk Influencing Factors (RIF's) trigger vulnerabilities or amplify their effects"

John Evans - Managing Director, HEB

- There are 2 main types of RIF's
  - *Stressor RIF's (Pressure causing a feeling of stress)*
  - *Structural RIF's (Inherent weakness in activity)*
  - RIFs can be grouped into 'families' of issues that might affect the risk of human error *Structural: Process, Information, Resource, Competence, Organisation, (PIRCO)*
  - *Stressor*

The Cumulative Effect

- A combination of factors can contribute to human error
- Certain factors can trigger other factors leading to a chain reaction and cumulative effect

Human Error Risk Management
Prospective Risk Identification

- Identify How & Where in the process 'Human Error' is likely to occur through the use of a scientific multidisciplinary team approach
  - Review process flow and information flow
  - Identify the RIFs
  - Identify the issues with which RIFs are commonly associated (PIRCOS)
  - Plan your processes to minimise & control these risks

- Consider the level of the RIF effect:
  1. Individual
  2. Local/Team
  3. Generic
     - e.g. mis-read table in a doc used widely in the company

1. Risk Assess

- Evaluate the risks for Human Errors or 'Hazards' identified in a process using a Quality Risk Management tool such as:
  - FMEA
  - HACCP
- Estimate the Risk in terms of:
  - Severity of Occurrence
  - Probability of Occurrence
  - Likelihood of Detection
- Identify actions to reduce unacceptable risks
  - Prioritise those Risks likely to have a serious impact on the product/patient

2. Risk Control: Error Prevention in Pharma

- Quality by Design (QbD)
  - Design Human Error potential out of the process
- Good Manufacturing Practice
  - Good Behavioural Practice (e.g. dress code, aseptic technique)
  - Clear unambiguous documents/records - designed to prevent Human Error
  - In Process Monitoring and Testing such as SPC, IPC……
- Environmental conditions
  - Lighting, noise, spacial limitations…..
  - Appropriate flow of activities

- Robust Training Approach
  - Gap analysis
  - Practical training should include
    - Physical examples of good and bad quality
    - What can go wrong in the process (learn from mistakes!)
  - Verify effectiveness of training or competency
  - Periodic Refresher training

Sustaining Error Reduction

3. Risk Review

- Planning changes to minimise potential for human error
- Monitoring effectiveness of change to eliminate / prevent / reduce Human Errors
- Reoccurrence analysis
- A rolling programme in place for identification, assessment and elimination/prevention/reduction of Human Errors

4. Risk Communication

- Development of a system for personnel to report potential opportunities for Human Error to occur & near misses
- Regular communication of Human Errors & associated risks – metrics
- GMP (refresher) training

Organisational Strategy Designing & Managing with Human Error in Mind

- Understand Human Error & contributory factors
- Create understanding of Risks in your organisation
- Analyse your processes & understand your error risks - QRM approach
- Develop tracking & evaluation of metrics routinely
- Realistic demands on employees - work overload / concurrent conduct of tasks leads to mistakes
- Motivation through recognition & support
- Empower personnel to address own RIF's
- Continuous Improvement process
- Atmosphere of accountability by displacement of blame

In Summary

- Be clear as to what constitutes Human Error
- Using a risk-based approach, identify the RIFs for your critical processes & design to minimise human error potential
- Apply a QRM approach to sustaining low levels of human error
- Promote a working environment that supports a proactive approach to minimising the potential for human error to occur & addresses error events holistically

Questions?