Investigating Human Error in Pharmaceutical Manufacturing
Lecture which took place at ILMAC Lausanne, Forum on October 4, 2017

By Dr. Carsten Wangnick, Head Quality Assurance at CARBOGEN AMCIS

On average, almost 30% of quality defects were attributed to human error and investigations into these root causes are generally poor and superficial. There were often no sustainable CAPAs (corrective and preventive actions) defined, and the corrective action was mainly just re-training. So what is the best way to deal with deviations and incidences which seem to be caused by human error?

This is a common topic of discussion in the GMP environment, especially during audits as many regulatory authorities no longer accept human error as a justifiable cause of deviation incidents in production of APIs and drug products. Some companies even strictly ban human error from the list of “root causes” for an incident as there are always other contributing factors which provoke the human error.

The most common approach to correcting this is re-training, however it often fails to produce the desired result, and training is only responsible for about 10% of the human errors that occur. This is because it only takes care of issues related to lack of knowledge, skill or ability. If the error didn't occur because of one of these factors than training can be futile. This can lead to less trust amongst employees to bring up issues, which results in management being less aware of system weaknesses, and does not help both parties. Some human error is inevitable, however putting a proper system in place will help us to detect, prevent it from reoccurring and to correct it. This will not only help us to be more productive but also fair-minded to those who go to work with good intentions, but become victims of weak systems.

Truth Behind Human Errors

Human error is an inherent part of human nature, and is always unintentional (if not it must be assumed as sabotage). It can be reduced but more investigation needs to be done on understanding the root cause of it. They are more often than not forced by the circumstances of the situation.

Human Errors Can Usually Indicate

- Potential deficiencies in the process (robustness)
- Potential deficiencies in the procedures (complexity)
- Potential deficiencies in the training (effectiveness/frequency)
- Potential deficiencies of the equipment (ergonomics)
- Potential resource bottleneck (stress, lack of time)
Our Approach to Reducing Human Error

1. A human error task force team was created and implemented
2. Conducted initial training of key stakeholders in the mainly affected departments (Production, QC)
3. Our focus was not to identify weaknesses in the involved processes or to blame people
4. We also set up a human error database for tracking and evaluation
5. We put together a questionnaire as a guidance and framework for the human error interviews
6. Investigations were reviewed by the human error task force team and to ensure a homogeneous quality level of investigations

Achievements
After one year of implementing this system we had a significant reduction of deviations with root causes to human error. We also improved our awareness on how to deal with so called human errors causing deviations. Performed more thorough root cause analysis which often identified multiple contributing factors. Created sustainable CAPAs which focused on the real contributing factors instead of retraining only. We also conducted more frequent use of effectiveness checks to prove the sustainability of the system.

Top 10 Takeaways When Investigating Human Error
1. Conduct interviews shortly after the incidence occurs, otherwise important information may be forgotten or it becomes too biased.
2. Create an open-minded atmosphere for the interview, so no finger pointing and try to avoid quick judgements.
3. Ask open-ended questions to encourage people to provide a full, meaningful answer in their own words coming from their knowledge and feelings about the situation.
4. During the interview, make sure to write down all the details even if it does not seem important for later analysis. This is to make sure you don’t miss any key information.
5. Remember! Most root causes are multifactorial.
6. Use post-it notes for later grouping and sorting of the factors.
7. Analyze the information with the interviewed colleagues.
8. Let the interviewed colleagues draw the conclusions and to define CAPAs. It will be a smoother process to except the new system if they have created it themselves, and if they come to the conclusion it creates an atmosphere of accountability and promotes greater learning.
9. Put together consequent CAPA follow-ups including effectiveness checks to avoid recurrence of the issue.
10. Once the root cause is established and a new effective procedure is in place, communicate the successful investigations and CAPAs!
Author

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*Full PPT presentation is available in the next pages
Investigation & Reduction of “Human Errors” in API Manufacturing

Dr. Carsten Wangnick, Head Quality Assurance, CARBOGEN AMCIS
Overview

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II.  Starting Point
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About CARBOGEN AMCIS

- > 30 years experience in API development/production
- Global presence – manufacturing sites
  - 4 x Switzerland
  - 1 x United Kingdom
  - 1 x France
  - 1 x Shanghai
  - 1 x India
- 500 employees in Switzerland
- > 250 chemists, with > 40% Ph.D.
- > 150 complex projects per annum
- 17 commercial products (custom manufacturing)
- Highly successful audit history
  - FDA in September 2017 → again no observations
WHAT MADE US ACT?

In 2015 for almost 30% of all deviations the assigned root cause was “human error”

The root cause investigations of these deviations very often were poor and superficial
(“oh it’s just a single event human error”, “this can happen”, “what can I do about it?”)

No sustainable CAPAs were defined (mainly just “re-training”)
Human Weaknesses

- It takes us long to automate a sequence of activities (playing an instrument)
- Performing numerous tasks in parallel may easily fail
- Conditioned behaviour is very difficult to reprogram
- Witness recall is notoriously inaccurate
- We see what we want to see
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According to a study of the University of Cambridge the sequence of characters in a word is not important. It is only vital that the first and last character remain in the right place. All other characters can be completely msesed-up. You are neevrtehsles albe to uderntsand it.
About Human Errors

- Human Errors are an inherent part of human nature
- Human Errors will happen if humans are part of a production process
- Human Errors are always unintentional (if not it must be assumed sabotage!)
- Human Errors can be reduced but not completely avoided (some companies think they can)
- Human Errors are the symptom but not the root cause
- Human Errors are forced by the circumstances of the situation

THE “NEW VIEW” OF HUMAN ERROR

<table>
<thead>
<tr>
<th>The old view</th>
<th>The new view</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human error is the cause of accidents</td>
<td>Human error is a symptom of trouble deeper inside a system</td>
</tr>
<tr>
<td>Systems are inherently safe and people introduce errors</td>
<td>Systems are inherently unsafe and people usually keep them running well</td>
</tr>
<tr>
<td>Bad things happen to bad people</td>
<td>All humans are fallible</td>
</tr>
</tbody>
</table>
Truth Behind Human Errors

What do “human errors” indicate?

- Potential deficiencies in the process (robustness)
- Potential deficiencies in the procedures (complexity)
- Potential deficiencies in the training (effectiveness/frequency)
- Potential deficiencies of the equipment (ergonomics)
- Potential resource bottleneck (stress, lack of time)
Our approach...

- Implementing a human error task force team
- Initial training of the important stakeholders in the mainly affected departments (Production, QC)
- **IMPORTANT:** the project intention is to identify weaknesses in the involved processes and not to blame people
- Setting up a human error database for tracking/evaluation
- Create a questionnaire as guidance and framework for the human error interviews
- Review of performed investigations by task force & feedback → assure a homogeneous quality level of investigations

**Finding the Root Cause**

- Define the Problem
- Any temporary measures?
- Inquiry
- Real Causes
- Definitive Solution
- Tackle the Root Cause
- Not the Symptom
- Improve Plans
- Application and Monitoring

Describe and understand the situation

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What is vital for a successful human error investigation?

- **GOYA:** Get Off Your Ass !!!
- Be quick with the interview! Otherwise important information may get lost/biased
- Create an open-minded interview atmosphere – no finger pointing, no quick judgements
- Ask “open-ended” questions to encourage a full, meaningful answer in their own words
- Write down all details independent if they seem to be important or not for later analysis
- Remember! Most “Root Causes” are multifactorial
- Use post-its to be flexible for later grouping/sorting of the factors
- Analyze the information together with the interviewed colleagues
- Preferentially let the interviewed colleagues draw the conclusions & define CAPAs for more acceptance
- Do consequent CAPA follow-up including effectiveness check to avoid recurrence of the issue
- Communicate successful investigations/CAPAs!
Case Study

“Human error”: not released Argon used in QC Lab

- A lab technician used a non released Argon cylinder
- General rule: check release status of all material before use not followed
  → human error on first sight, but...
- Two qualities exist: “GMP” & “non-GMP”- Argon
- But both from same supplier, same quality!
- Warehouse delivered wrong quality to the lab
- Lab technician thought only one (GMP) quality exists
- **Solution**: complexity reduced having only GMP quality available & invalidate the other article number
Results After 1.5 Years

Achievements

- Improved awareness on how to deal with so called “human errors” causing deviations
- Perform more thorough root cause analysis often identifying multiple “contributing factors”
- Sustainable CAPAs focussing on the real “contributing factors” instead of retraining only
- More frequent use of effectiveness checks to prove sustainability
- Significant reduction of deviations with root cause to “human error”
Thank you!

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