Investigation & Reduction of “Human Errors” in API Manufacturing

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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

Starting Point

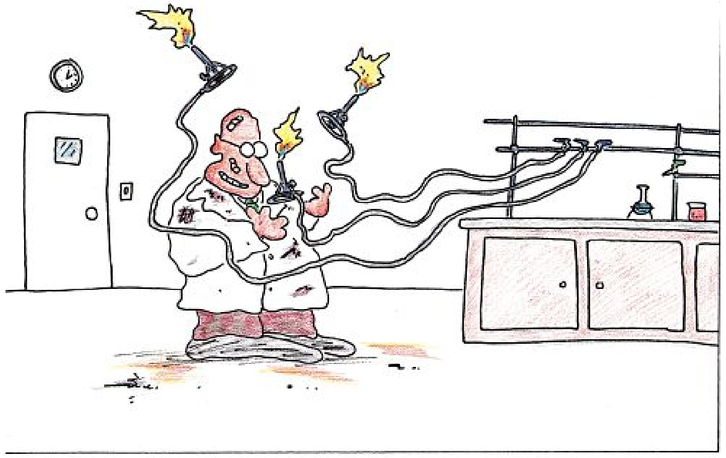
- WHAT MADE US ACT?
- In 2015 for almost 30% of all deviations the assigned root cause was “human error”
- The root cause investigations of these deviations very often were poor and superficial

  (“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 task in parallel may easily fail
- Conditioned behaviour is very difficult to reprogram
- Witness recall is notoriously inaccurate
- We see what we want to see

"How expensive would it be to just skip practice and get right to perfect?"



The secretive art of Bunsen Burner juggling

A Brief Experiment

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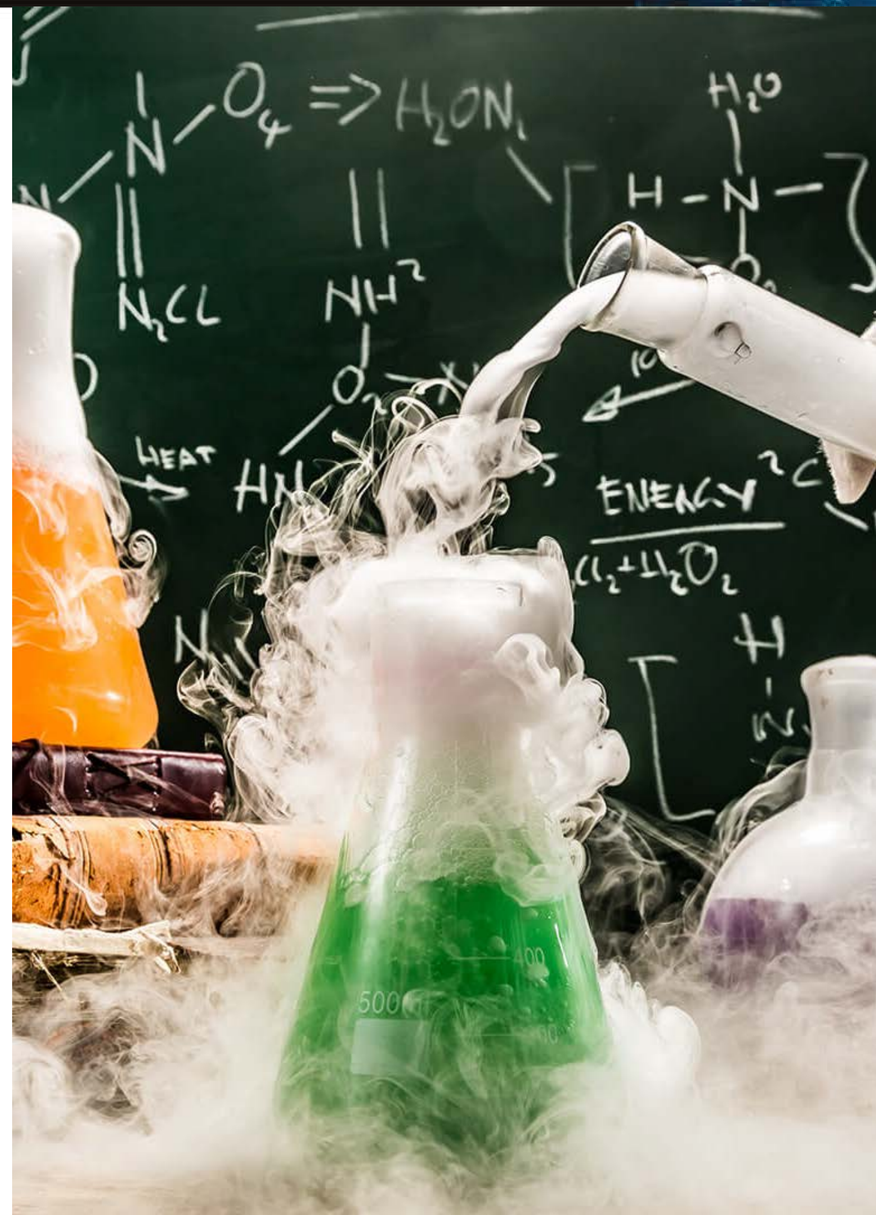


About Human Errors

- 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

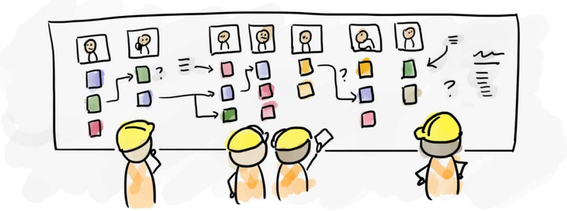
THE "NEW VIEW" OF HUMAN ERROR

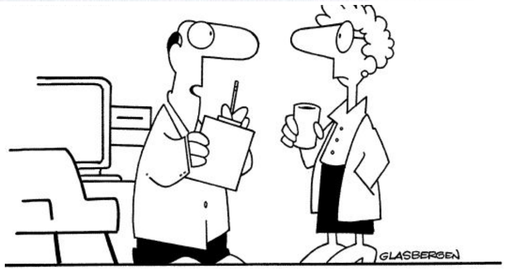
The old view	The new view
Human error is the cause of accidents	Human error is a symptom of trouble deeper inside a system
Systems are inherently safe and people introduce errors	Systems are inherently unsafe and people usually keep them running well
Bad things happen to bad people	All humans are fallible

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)



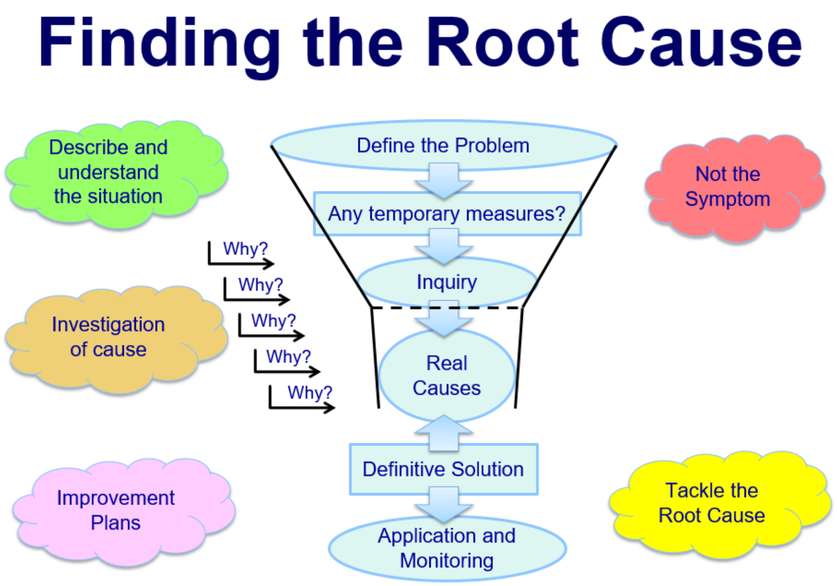


“According to the latest research,the average human body is 20% water and 80% stress.”

Human Error Reduction Project

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



Investigation of Human Errors

What is vital for a successful human error investigation?

- GOYA: **G**et **O**ff **Y**our **A**ss !!!
- 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

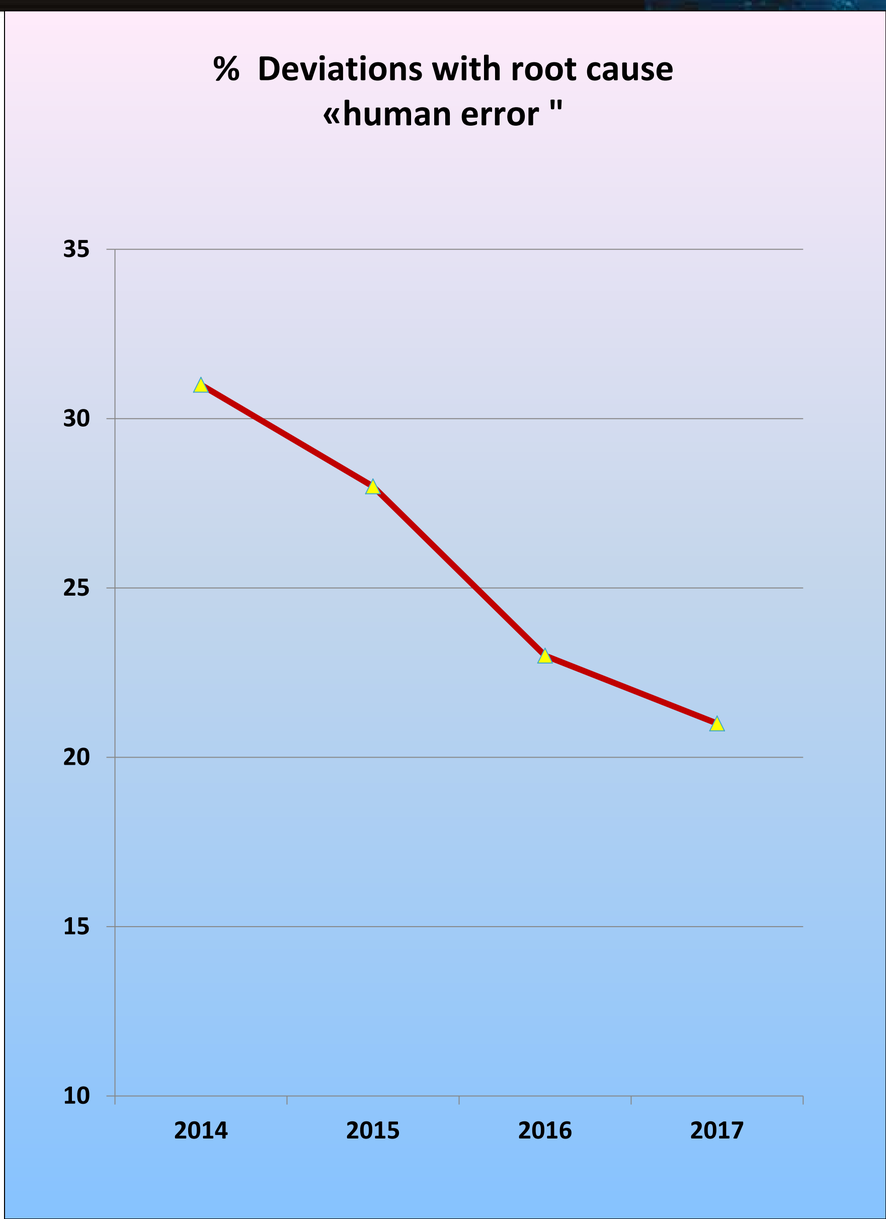
- A lab technician used a non released Argon cylinder
- General rule: check release status of all material before use not followed

  → 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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