# Sneak Peek

## *GMP Investigations and Problem Solving*

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TRAINING

# GMP Investigations MHRA Comments

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- A strong principle of GMP is operating in a state of control. The PQS is the foundation which helps companies achieve this state. During inspection, we will look for evidence that the investigation and Corrective and Preventive Action (CAPA) system is operating in a state of control. There are some symptoms if it is not, these can include:

- investigations being raised long after the event occurred or taking an unreasonable time to complete

- root cause analysis being raised as a CAPA to enable premature deviation closeout

- a large proportion of CAPAs being overdue or being extended

- human error being listed as a frequent root cause.

# GMP Investigations MHRA Comments



- Human error should only be cited as root cause when all other system and process related variables have been ruled out. It is plausible that, where human error is a potential root cause, the true root cause could be deficiencies in the training system, an overly complex or difficult to follow procedure, or perhaps other factors such as inappropriate multi-tasking and distraction. It is unlikely that ‘remind/re-train the operator’ will ever be an effective CAPA in such circumstances.

# GMP Investigations MHRA Comments
# Effective investigations

- Investigations should be launched from the outset with the intention of establishing true root cause and identifying appropriate CAPAs. It is not only a mechanism to protect patient safety, but a way to improve the efficiency of an organisation's operations.

- Investigators should consider beyond the initial probable root cause of an incident and confirm or rule out other plausible potential root causes. This should include speaking to relevant colleagues involved in the incident and best practice would include visiting the areas involved. A review of previous incidents is important to identify if this is a recurring issue within that area, on a specific piece of equipment, or a process.

# GMP Investigations MHRA Comments
# Root cause analysis

- There are several approaches to root cause analysis that are well known and recommended, however we do not always see them used even when there are clear advantages or ‘true root cause could not be identified’ has been recorded in the report.
- Such approaches include:
- Ishikawa fishbone diagrams
- the ‘5 whys’
- thinking wider and considering PQS trend data and any potential links.
- For example, while a seal failure on manufacturing equipment is the direct cause of oil leakage and equipment seizing, the root cause could be that:
- the wrong seals were fitted during planned maintenance
- the supplier has changed their specifications
- the seal had worn out, indicating the planned maintenance schedule was ineffective, potentially due to an increase of equipment utilisation.

# GMP Investigations
# Problem areas



- Areas of the PQS which require improvements in the type and thoroughness of investigations:
  - Deviations,
  - Complaints
  - Return
  - Recalls
  - Out of Specification Investigations OOS
  - Sterility test failures
  - Aseptic Process Simulation failures
  - Environmental monitoring failures and adverse trends

# Registration

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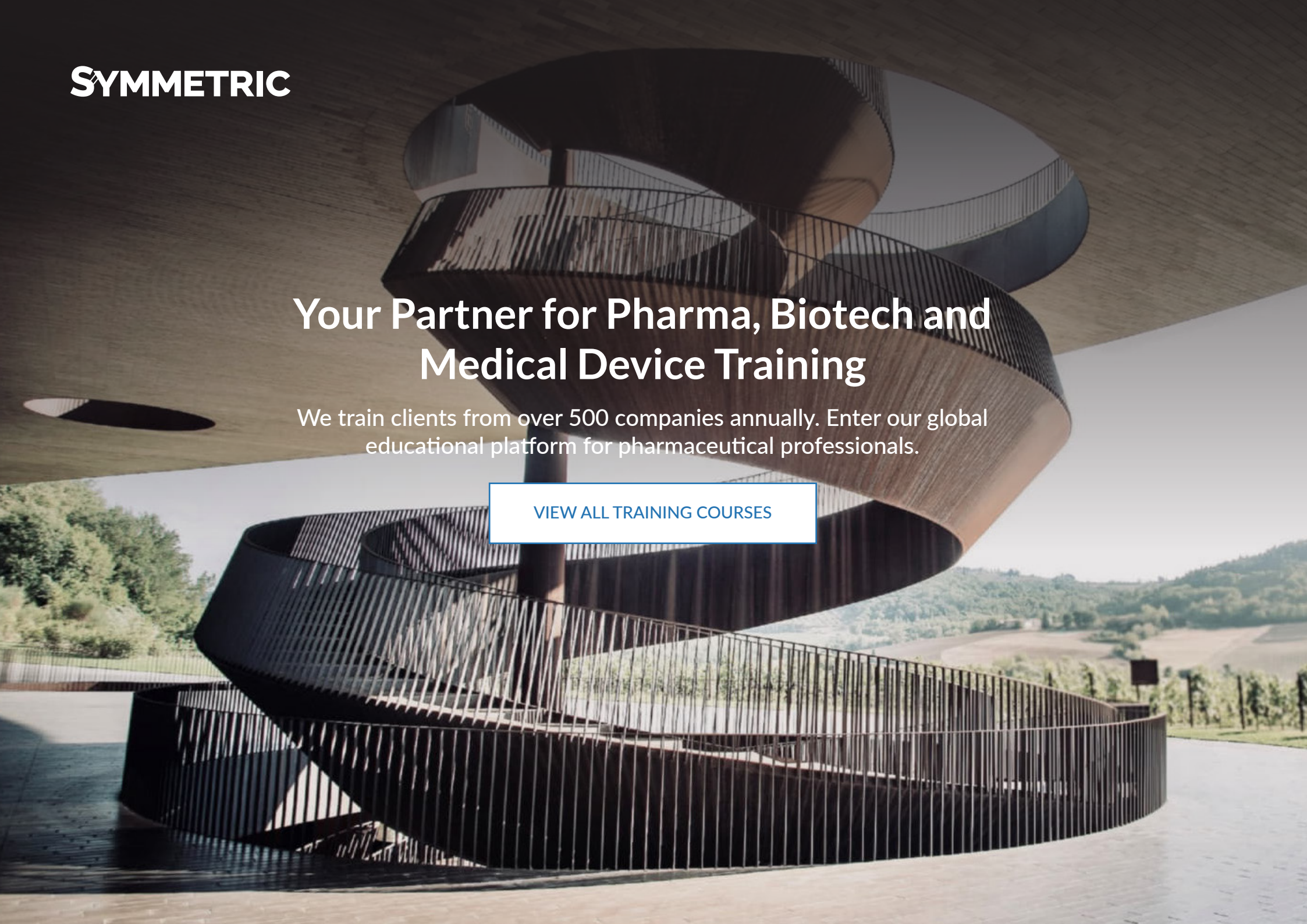
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