



# YOUR CAPA EFFECTIVENESS LADDER

by Martin Lush

## HOW FAR UP ARE YOU?

Your investigations and CAPA system is vital, having a business critical impact. It protects your patients, drives continuous improvement and helps manage your risks and company reputation. What could be more important?

However, despite being a high profile issue for many years, not all firms have got the message yet. Where does your firm stand?

Regulators continue to find that firms do not have effective CAPA systems, as evident from repeat incidents, often occurring time and again, despite an investigation report closed in the mythical "30 days". With regulators criticizing firms for repeat incidents, it's clear that some CAPA systems are not fit-for-purpose. Their CAPA "effectiveness ladders" are broken.

Your Task: Start at the bottom of the ladder. The first step. If you check all the criteria, move onto the next step. How far up the CAPA Effectiveness Ladder do you get? If you don't get to the top, you are putting your business at risk.

## WHY IS YOUR INVESTIGATION AND CAPA SYSTEM SO VITAL?

- > Allows you to assess the risk associated with every deviation incident
- > Helps you to learn from your mistakes...so they never happen again
- > Acts as a catalyst for driving continuous improvement
- > Tells the regulators a lot about your attitude to quality and risk, your leaders and your culture
  - Lots of repeat incidents = "They don't care."
  - Low numbers of deviations (incidents hidden?) = "Can they be trusted?"
  - Human error common root cause = "They don't understand."
- > Protects your company legacy and reputation



## 1. CULTURE AND LEADERSHIP BEHAVIOR

- > Open, transparent and blame-free culture
- > Incidents seen as fuel for continuous improvement
- > Metrics focus on driving down repeat incidents, not total number
- > Investigations seen as organizational priority, not inconvenience
- > Culture of quality, not compliance
- > Obsession with prevention and improvement, not firefighting
- > Investigations done by process experts, not only QA
- > Attitude that deviations are an opportunity to improve, not bad
- > Mistakes seen as learning opportunities!
- > No such thing as human error as the main bucket of root cause
- > No "close in 30 days" focus for all investigations

## 2. PROCESS KNOWLEDGE AND EXPERTISE

Fact: You can't fix problems unless you understand your processes.

- > You must have an institutional understanding of:
  - Product "key quality attributes"
  - Process critical control points
  - Basic GMPs
  - What can happen when things go wrong
- > People understand the "whys" and what questions to ask

## 3. A SIMPLE INCIDENT REPORTING SYSTEM

- > Deviation reporting form 2-3 pages max
- > Reporting system accessible to all
- > Incident report raised immediately
- > Investigation started immediately
- > Investigations at the scene, never from behind a desk

## 4. INCIDENTS ARE "RISK RANKED"

- > Incidents investigated proportionate to risk – firstly to patient
- > Objective criteria used to risk rank incidents
- > Failure mode effect analysis a key tool

## 5. TRAINED (CERTIFIED) DEVIATION INVESTIGATORS

- > Investigators trained in quality risk management and problem solving tools and techniques
- > Simple methods used (such as Ishikawa, 5 Whys, brain storming, Six Thinking Hats)
- > Have high levels of emotional intelligence and questioning skills
- > Focus on data-driven decisions, not emotion or bias
- > Always look for multiple causes, never a single root cause
- > Always ensure the investigation is not done in isolation and consider the bigger picture

## 6. FOCUS ON STRONG CAPAS

- > Quality of CAPAs from an investigation is more important than quantity
- > Corrective actions have clear, realistic measures of success and timing



- > Focus on moving toward a preventive action system that predicts issues and prevents their occurrence in the first place
- > Ensure CAPAs are shared / extended to other sites / systems / products where a similar issue could occur
- > It's about prevention, not reaction

## 7. INCIDENT REPORT THAT "TELLS IT ALL"

- > Reports allow the incident to be clearly understood years later by someone with no prior knowledge. Reports tell the whole story
- > Never written just for the inspector or auditor

## 8. EFFECTIVENESS CHECK AND FOLLOW UP

- > CAPAs reviewed and checked for effectiveness before final closure
- > Learning shared across enterprise

## 9. INTELLIGENT TRENDING AND KNOWLEDGE MANAGEMENT

- > Critical, major and minor findings all trended
- > Incidents grouped and investigated as one
- > Fast escalation processes
- > Sharing of knowledge company wide
- > Focus = Predicting future failures and continuous improvement

## HOW FAR UP THE LADDER ARE YOU?

- > If you got to the top, well done. Your company is well led and has a bright future
- > If you're at or near the top, work hard to stay there. Complacency can kill
- > Stuck in the middle? Look at what you have to do and act quickly. Being in the middle isn't good enough
- > Stuck on the first step? Help your leaders to understand what is expected of them before it's too late. If only on Step One = firefighting and crisis management
- > **If you don't act, the regulators will act for you (and with justification)**

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## ABOUT THE AUTHOR



Martin Lush has over 30 years' experience in the pharmaceutical and healthcare industry. He has held senior management positions in QA, manufacturing, QC and supply chain auditing and has conducted audits and education programs for many hundreds of companies in over 25 countries.

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