

# Audits and Inspections: From Chaos to Control

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# Learning Objectives

- \* **Recognize** the pitfalls of being excluded during the creation of a response to audit and/or inspection findings.
- \* **Summarize** how one company addressed one of its key challenges: securing early involvement in inspection response teams.
- \* **Identify** actions that may be taken to create your own audit and inspection guidance.

# The Story



- \* Interview between Audette Inspeccion and Candie Barre on the “Chochodur Case.”



# Impact

- \* **Timeframe involved:**

- \* November → March 31

- \* Holidays fell in time frame, yet when responding to CAPA, holiday were not considered.

- \* **People involved:**

- \* ~ 10 Business Leaders

- \* ~ 40 Business SME

- \* 12 Learning & Development individuals

- \* 1350 hours (1.5 FTEs) in 5 months from L&D alone



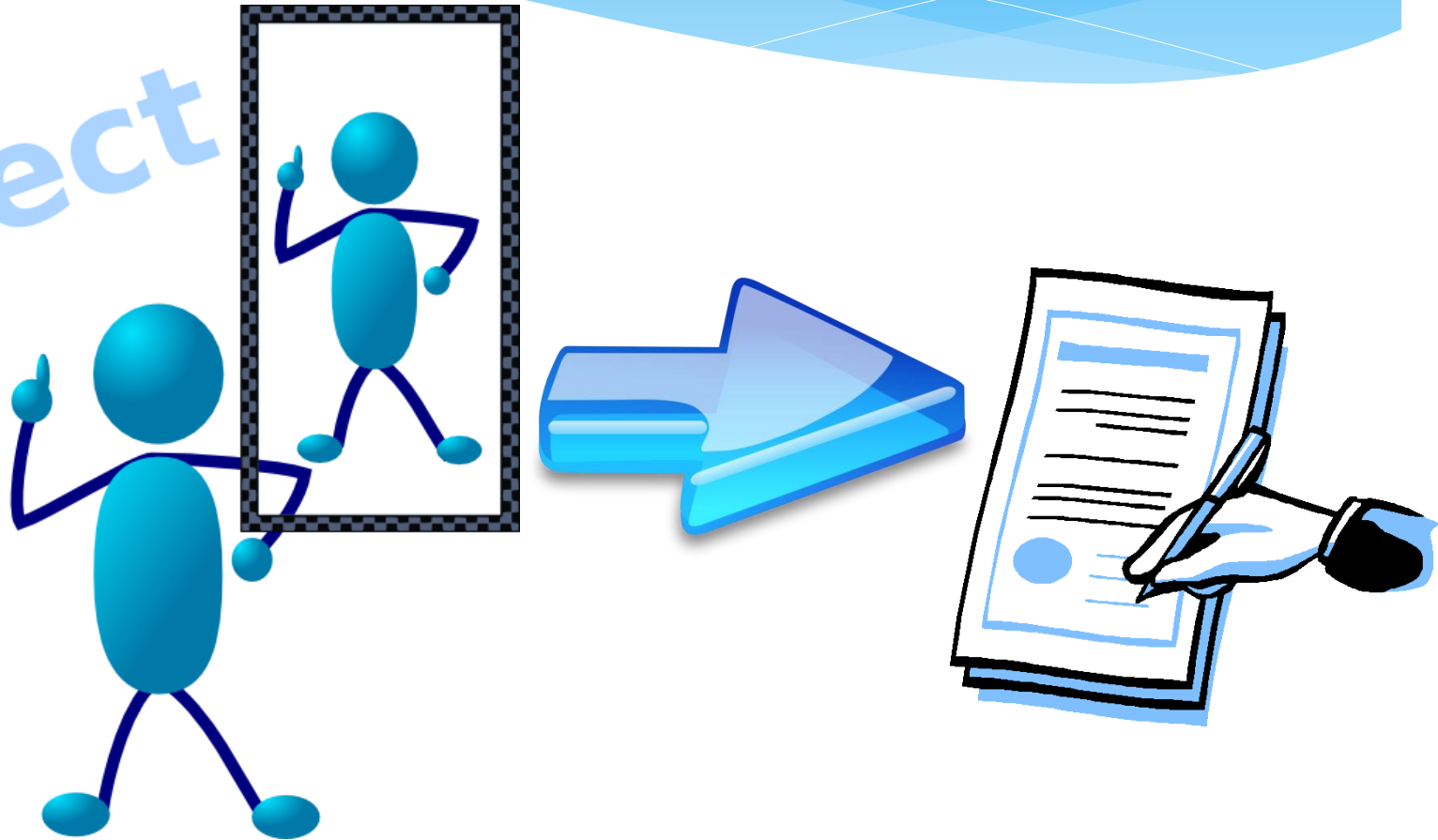
# Impact

- \* Sessions supported:
  - \* 13 sessions in March
- \* Completions Managed:
  - \* 5,088 training
- \* Reports Required:
  - \* 38 different reports run to track compliance?
- \* Opportunity Costs:
  - \* 1.5 FTEs that were “dedicated” to this effort
  - \* Business resources necessary to deliver



# Lessons Learned

Reflect



**TAKE ACTION**



# Taking Action: Step 1

- \* Formed Audits & Inspections team in MPI





# Taking Action: Step 2

- \* Created a guidance document with review and input from clients

## MRL Polytechnic Institute (MPI) Guidance

### **Purpose:**

To provide guidelines and best practices on the end-to-end processes for audit & inspection readiness and response planning specific to the design, delivery, and reporting of training related to Corrective and Preventive Actions (CAPAs). To provide standards for the generation of audit & inspection report requests.

### **Scope:**

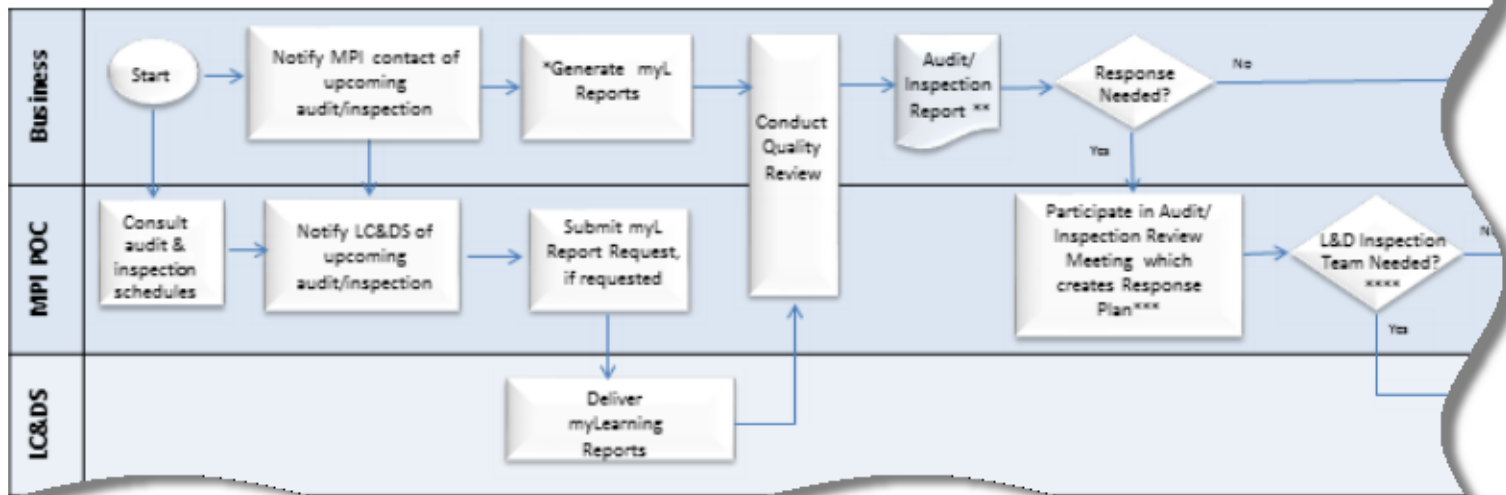
This document applies to GxP internal audit and external inspections. It captures tips, examples and 'lessons learned' to help future teams plan appropriately regarding timelines and the types of resources needed in order to minimize the chance of errors as well as the need for "fire drills" during inspection response activities. It is critical that MPI participates both in the initial review of audit / inspection findings and in the writing of the Inspection Response Plan (IRP) or Corrective and Preventative Action plan (CAPA). Involvement at this stage allows MPI to conduct a gap analysis, needs assessment, remedial assessment and evaluation strategy to ensure appropriate training solutions are recommended and to that timelines are realistic. Each L&D inspection team will need to agree upon roles and responsibilities within their own team.

# Taking Action: Step 3

- \* Created a process map

## MPI Audit & Inspection Readiness and Response Process Flow – 1

29-Jan-2016 v1.00



# Taking Action: Step 4

- \* Shared with clients



# Taking Action: Step 5

- \* Established a seat at the table!



# Discussion

The Case for Change!

# Instructions

- \* How might you create the “case for change” in your company?
  - \* Reflect upon what MPI did...
    - \* Think about similar situation in your own company
    - \* Would the steps that MPI took work in your company?
    - \* Why / why not?
- \* REPORT OUT

# Activity

Your team is called... Now what?  
How will you help?

# Instructions

- \* Evaluate an Inspection Report
- \* Review the situation and information provided
- \* Discuss the possible root causes
- \* Based upon your understanding of the findings, should training be a part of the corrective action/preventative action?
- \* REPORT OUT



# The Story – Part 2

- \* What happened when we established a seat at the table?

# Question & Answer



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# Contact Information

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