



# Investigation Report Assessment

## Course description

The Investigation Report Assessment course is designed to provide medical device industry professionals with the skills necessary to effectively and accurately complete CAPA investigation reports. From introduction to the key elements of an investigation report to analysis and action planning, this course provides a guide to developing reports that are critical to continuous improvement and product safety in the medical device industry.

## At the end of the course you will be able to:

- Understand the fundamentals of an investigation report and its importance in the medical device industry.
- Follow an established process flow for research reporting.
- Identify and describe the key elements of a research report, including impact assessment, research analysis and conclusions.
- Conduct an initial impact assessment and apply techniques such as bracketing, risk assessment, and containment actions.
- Conduct a historical review to contextualize the problem and improve understanding of its origin.
- Analyze data collected during the investigation to identify significant trends and patterns.
- Conduct a final evaluation of the impact of actions taken and propose corrective and preventive action plans.
- Develop an effectiveness plan to monitor the implementation of corrective and preventive actions.
- Use an investigation checklist to ensure completeness and consistency in the report writing process.


## Main topics

- 1 Introduction to Investigation Reporting
  - 2 Process Flow
  - 3 Key Report Elements and Purpose
    - Description
    - Impact Assessment
      - Bracketing
      - Risk Assessment
      - Containment Actions
    - Historical Review
- Investigation
    - Investigation Analysis
    - Investigation Findings
  - Final Impact Assessment
  - Actions Planning
    - Corrective Action
    - Preventive Action
  - Effectiveness Plan
  - Investigation Checklist

## Contact

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## Course features

Instructor Led 

Duration: 12 hours 

Tools and templates 

Applied learning 

Course certificate 