



# Audits and Failures to the Quality System

## Course description

“Audits and Failures to the Quality System” is a critical course tailored for operators in the medical devices industry, providing comprehensive insights into the purpose and implications of audits within the quality system. The course covers the objectives of audits, distinguishing between internal and external audit processes. Participants will gain proficiency in conducting internal audits to evaluate and improve their quality systems, as well as understanding the dynamics of external audits. The course also explores the significant consequences associated with failures in the quality system, emphasizing the importance of diligence and compliance in maintaining product quality and regulatory standards.

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

- Understand the purpose and methodology of audits, becoming proficient in conducting both internal and external audits within the medical device manufacturing context.
- Be prepared to deal with effective internal audits, assessing and improving your organization’s quality systems to ensure compliance with standards and regulations.
- Comprehend the dynamics of external audits, allowing them to collaborate seamlessly with external auditors and showcase the robustness of their quality systems.
- Be aware of the significant consequences associated with failures in the quality system, emphasizing the importance of proactively addressing issues to maintain product quality and regulatory compliance.

## Main topics

- 1 Purpose of audits
- 2 Internal audit
- 3 External audit
- 4 Consequences of failing to the Quality System

## Contact

 [www.smdlearning.com](http://www.smdlearning.com)

 [info@smdlearning.com](mailto:info@smdlearning.com)

 +506 8544 7000

 Costa Rica

## Course features

- Instructor Led 
- Duration: 2 hours 
- Tools and templates 
- Simulated learning 
- Course certification 