

23C - ISO 13485 Auditing & Improvement

Presenter

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Session Summary

This session has been designed to help you understand the requirements for auditing to ISO 13485. Understand the requirements of the auditing process; planning, conducting audits, auditing reporting and follow up. Learn how to conduct system and process audits. Do you know how to conduct a value added audit?

The presentation will cover:

Understanding the auditing process

Understanding ISO 13485 requirements and audit evidences needed

How to conduct system, process and product audits

Don't miss this opportunity to hone your skills vital to achieving your personal and business objectives.

About the Presenter – Jay Patel

Jay Patel is CEO of Quality & Productivity Solutions, an international consulting and training firm specializing in Six Sigma, Quality Systems, Lean, Project Management, Supply Chain and Business Improvements. He has more than 25 years of experience in management and quality and has held wide-ranging positions including Plant Manager and Corporate Director of Quality, Program Manager besides a consulting assignments at many reputed companies. Jay has 10 ASQ certifications including Certified Six Sigma Black Belt, Quality Auditor and Engineer. He has taught Black Belt, Master Black Belt, and Design for Six Sigma, Lean Certifications, all different ISO Auditor Certifications, He has Bachelor and Master Degrees in Engineering and an MBA. Jay is a RAB-Quality System Lead Assessor. Mr. Patel served at local and regional levels for the Project Management Institute, Institute of Industrial Engineers and American Society for Quality besides recipient of many awards. He is an ASQ fellow and has been ASQ Worcester Section Chair. Jay is Chairman of North East Quality Council (NEQC) and Conference Vice Chair besides NEQC's prestigious R. Shaw award recipient.