

Full Day work Shop on FDA cGMPs from A-Z by Lean Compliance partners

Course Objectives:

Provide participants with understanding of the FDA's Quality System Regulations (current Good Manufacturing Practices, 21CFR820), and how it applies to their everyday activities. Focus is on business processes starting with Supplier Controls and Receiving Inspection through to Packaging and Shipping. From the start, participants partake in hands-on exercises that are carried through the entire workshop, illustrating real-world impact cGMPs have on every part of an FDA-regulated business.

Contents Overview:

- Overview of the US Food and Drug Administration (FDA) & Quality System Regulations (QSR)
- General provisions of current Good Manufacturing Practice
- Management Responsibility
- Record-Keeping and Good Documentation Practices (GDPs)
- Supplier Controls
- Identification and traceability
- Acceptance activities for materials
- Quality Control
- Audits
- How to manage production and process changes
- Non-conforming products: how to address them
- Corrective and Preventive Actions (CAPA)
- Labeling, storage, distribution and installation

Benefits of Training:

Through this 1-day hands-on workshop, participants will work through exercises to demonstrate how cGMPs, following FDA 21 CFR Part 820, apply to all aspects of their business. Upon completion, participants will be able to understand the requirements of a quality system and how to identify potential gaps within one.

Workshop Exercises:

- Exercise - Quality Basics: Mix & Match of quality terms and examples in GMP environment.
- Exercise - Spot the GDP Errors: Attendees will identify GDP errors and correct them independently, followed by in-class review and Q&A.
- Exercise - Receiving Inspection: Exercise completed in pairs where attendees will simulate receiving inspection process in a non-GMP environment. Attendees will identify the errors in the process and recommend corrections.
- Exercise - Audit Receiving Inspection: Group discussion on audit checklist questions for a controlled process, using receiving inspection as an example.
- Exercise - Quality Car manufacturing controls: Simulation assembling quality cars in a non-GMP environment. Attendees will identify the errors in the process and recommend corrections.
- Exercise - Quality Car Design Inputs & Outputs, Design Verification: Group exercise to define design inputs and outputs, and applicable design verification testing for these.
- Exercise - Quality Car Manufacturing Validation Requirements: Group exercises to identify processes in quality car manufacturing that require validation or not, and why.

Who Should Attend

This 1-day workshop will provide valuable assistance to FDA regulated companies, such as:

Start-Ups and established companies in Medical Devices or Pharma

Companies looking to expand sales to the USA

Companies with external audit concerns/findings

Medical Equipment service providers & distributors

Anyone looking to identify potential gaps in their quality system

Management or Personnel representatives from:

- Executive Management
- Quality and Compliance
- Manufacturing and Operations personnel
- Any employee involved in regulatory audits



International Conference on

QA, QC & Validation

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About the Trainers/Speakers:

Cynthia Juncosa and Myriam Ochart are co-founders of Lean Compliance Partners, a consulting firm dedicated to working with FDA-regulated start-ups, growing and established business to their growth and competitiveness in local and global markets.

Cynthia's extensive training and practical experience in lean six sigma, operations management, social media and quality initiatives, and over 14 years of experience in the FDA-regulated industry gives her an appreciation for the challenges facing businesses today. Cynthia is passionate about employee training and development – it is the foundation for success of any business. Cynthia is a PMI certified project management (PMP) and ASQ certified Six Sigma Black Belt (CSSBB). She serves on the board of the Florida Speakers Association (FSA) for 2012-2013, and is an active member of the American Society for Quality (ASQ), Project Management Institute (PMI) and American Society for Training & Development.

Myriam has been consulting since 2007 providing consulting, process improvement, ISO implementation and Training. Myriam was one of six Six Sigma Black Belts working for global bank: ABN AMRO. Her extensive training and practical experience in transactional six sigma, lean six sigma, operations management and quality initiatives and acquired experience in multiple industries provides her in-depth knowledge of the challenges facing businesses today. Myriam is an ASQ certified Six Sigma Black Belt (CSSBB) and certified Manager of Quality/Organizational Excellence (CMQ/OE). She has been on the ASQ national Voice of the Customer Committee for the last 5 years and currently chairs the ASQ Community Outreach Committee. She is an active member of the American Society for Quality (ASQ) and American Society for Training & Development