

TRAINING COURSE OVERVIEW

Topic:

ISO 15378:2017 System Overview Training Agenda

Course Description:

This course is intended to introduce those working with primary packaging materials for medicinal products an overview of the ISO 15378 Primary packaging materials for medicinal products — Particular requirements for the application of ISO 9001:2015, with reference to good manufacturing practice (GMP) International Standard. This course can be used to formally document training to the ISO 15378 International Standard for internal auditors and external (supplier) auditors.

Course Topics:

- Discuss the history of ISO Standards
- Describe the ISO 9000 series of standards
- Evaluate the Seven Quality Management Principles
- Understand the process approach
- Understand risk-based thinking
- Identify and discuss common risk management tools
- Evaluate Good Manufacturing Practice (GMP) principles
- Identify and discuss the ISO 15378 clauses including best practices

Duration:

1 Day (8 hours)

Location:

TBD

Audience:

Internal Auditors
External Auditors
Directors
Managers
Supervisors
Engineers
Technicians
Inspectors

Other:

Participants will be administered a pre-test proficiency assessment as well as a post-test knowledge assessment.

A certificate of completion will be issued for each course participant.

Quality Systems Compliance L.L.C.

Your compliance partner...

Contact:



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Quality Systems Compliance LLC

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