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Webinar on

Manufacturing Quality Agreements- Qualifying Suppliers and Managing Quality in FDA-Regulated Industries

Learning Objectives

- *Identify FDA regulations and new guidance regarding quality agreements*
- *Utilize tips to help you manage quality agreements effectively*
- *Review the pitfalls to avoid when developing your program*
- *Organize stakeholders, develop a comprehensive document, and initiate*
- *Implement oversight steps that keep you compliant and on track towards continuous improvement*

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Areas Covered

- *Regulatory requirements for supplier qualification*
- *Responsibilities of manufacturers and suppliers*
- *The who and what of a good Quality Agreement*
- *What a Quality Agreement is - and is not*
- *What is meant by the title owner, contractor, adulterated drug, and the term manufacturing within the guidance?*
- *Responsibilities of the owner vs. contract facility*
- *GMP responsibilities*

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Quality agreements are an integral part of outsourced GMP manufacturing and testing.

PRESENTED BY:

Upon earning a degree in Zoology at North Carolina State University, Joy made her debut in the pharmaceutical industry in 1992 at Pharmacia & Upjohn performing Environmental Monitoring and Sterility Testing. Her hard work allowed her to move into a supervisory role at Abbott Laboratories where she oversaw their Quality Control Lab.

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On-Demand Webinar

Duration : 90 Minutes

Price: $200

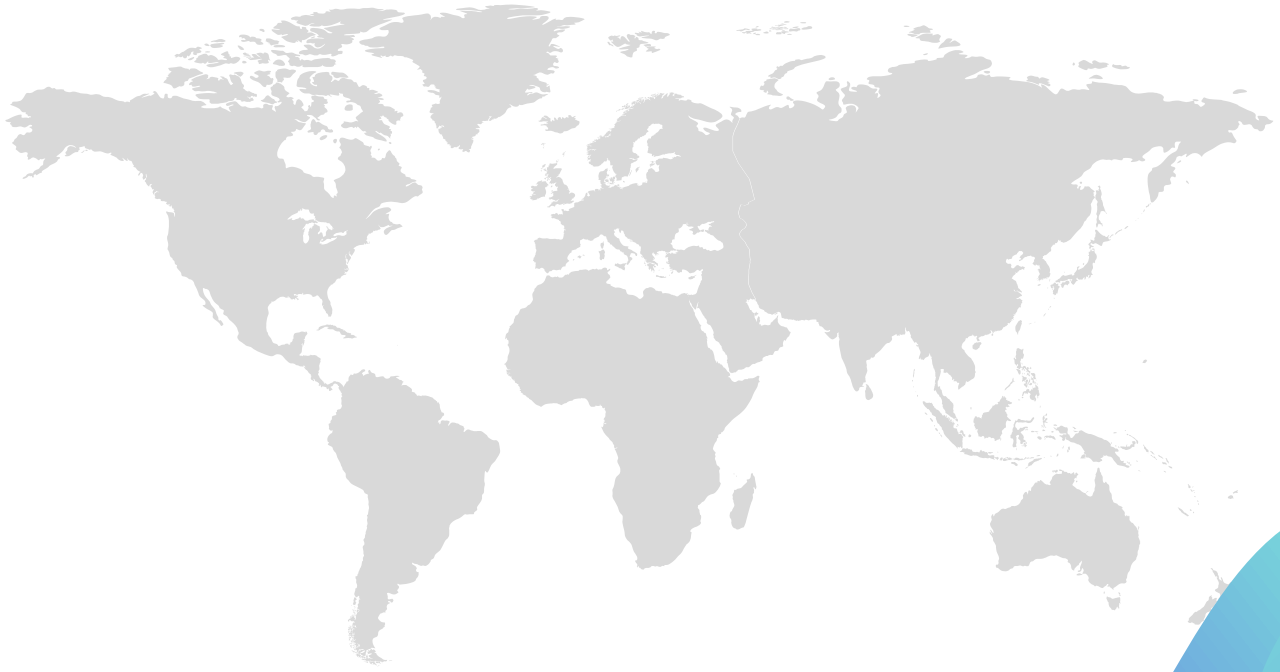
Webinar Description

Quality agreements are an integral part of outsourced GMP manufacturing and testing. They define the framework for quality expectations between you and your vendors and the responsibilities necessary to demonstrate drug quality, safety, and efficacy. In 2016, the FDA issued dozens of 483 observations relating to topics governed by the quality agreement system. Furthermore, in November 2016, the FDA finalized the “Contract Manufacturing Arrangements for Drugs: Quality Agreements Guidance for Industry” document.

Due to this new guidance, you can be sure that your firm’s quality agreement will receive increased scrutiny, leaving you vulnerable to the risk of non-compliant GMP products and services if your agreements aren’t clear and enforced.

Who Should Attend ?

Quality Assurance
External Manufacturing / Outsourcing
Quality Auditing
Technology Transfer
Regulatory Affairs / Compliance
Supply Chain
Purchasing
Risk Management
Managers and QA personnel from Contract Manufacturing Organizations (CMOs)



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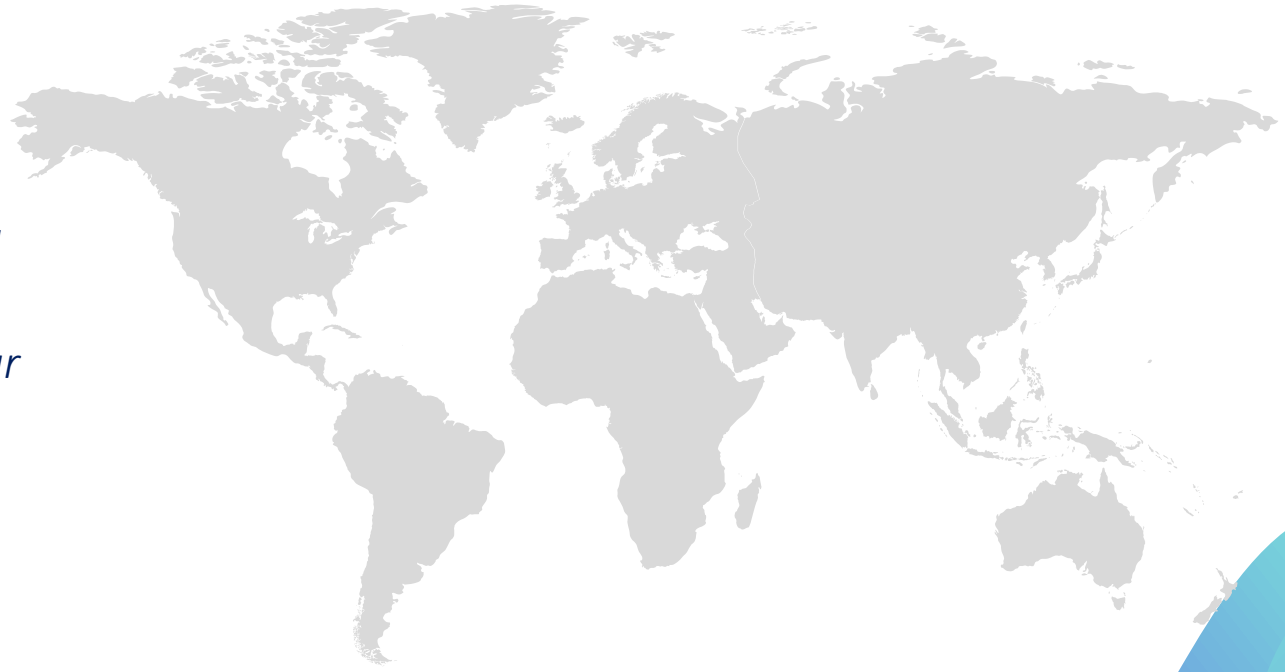
Why Should Attend ?

In this session, industry expert Joy McElroy will provide a fundamental overview of what an effective quality agreement program looks like and how to manage it. Joy will guide you through a quality agreement framework that may fit into your organization's vendor/supplier qualification program. This webinar will provide a thorough understanding of the content that is expected in Quality Agreements from a regulatory perspective. Each proposed section of a Quality Agreement is fully analyzed and suggested content is written with the new guidelines taken into consideration.



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