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Webinar on

CMO Supplier Quality Agreements - How to Comply with new FDA and EU Guidelines for Contract Drug Manufacture

Learning Objectives

- *The Who and What of a good Quality Agreement*
- *What a Quality Agreement is - and is not*
- *Responsibilities of the owner vs. contract facility*
- *GMP responsibilities*
- *A comparison of the new guidelines from the FDA and the EU*

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This Webinar presentation will provide a thorough understanding of the content that is expected in Quality Agreements from a regulatory perspective.

PRESENTED BY:

Roger Cowan is the founder and owner of R Cowan Consulting Services LLC, a consulting company specializing primarily in the area of pharmaceutical contract manufacturing. He has 37 years of experience in pharmaceutical quality assurance and manufacturing.

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On-Demand Webinar

Duration : 60 Minutes

Price: $200

Webinar Description

A Quality Agreement is a contract between a pharmaceutical firm and a GMP Contract Manufacturer detailing the responsibilities of each party in assuring the quality, safety, and efficacy of the manufactured drug.

Recently, the EU and the FDA issued regulatory guidance to bring some clarity and consistency to these quality contracts:

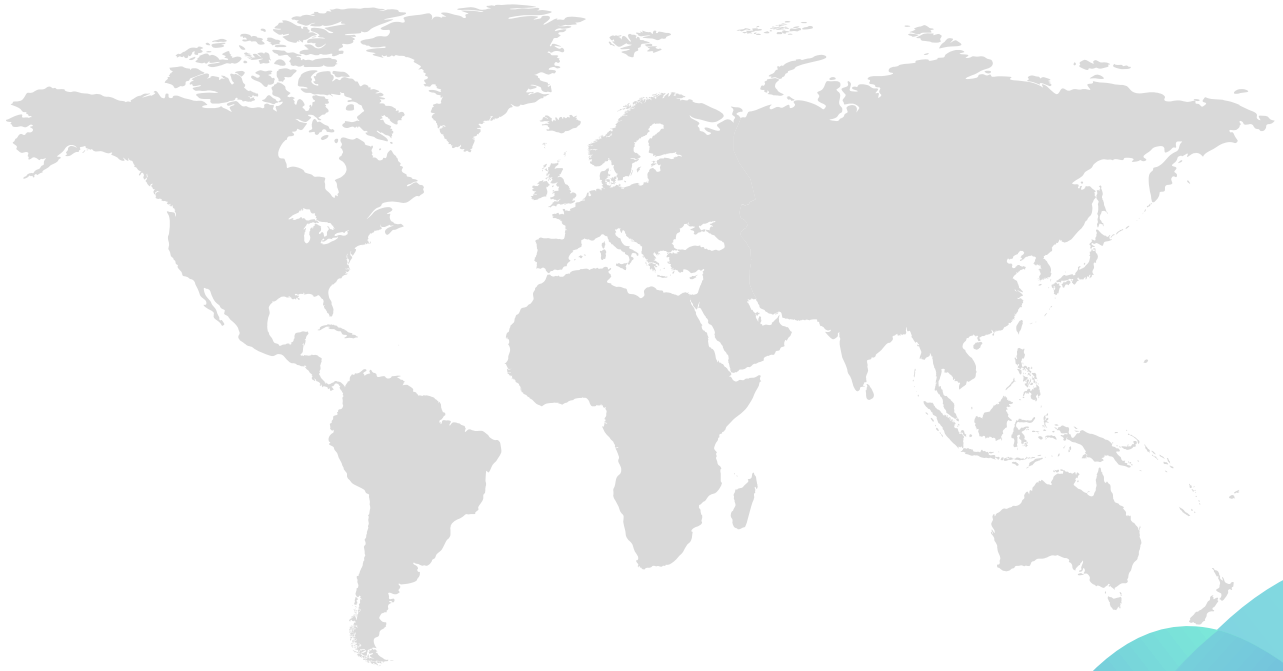
- EU GMP Chapter 7 "Outsourced Activities" January 2013
- Guidance for Industry - "Contract Manufacturing Arrangements for Drugs: Quality Agreements" November 2016

In 2010, the global CMO market was estimated at $26 billion dollars. Year on year growth has been 10.7% since 2008. The increasing use of outsourcing in the pharmaceutical industry along with recent well-publicized quality issues with CMOs, make it a necessity to have excellent quality oversight of external manufacturers to provide assurance of GMP compliance. A Quality Agreement is one tool used to accomplish this objective.

This Webinar presentation will provide a thorough understanding of the content that is expected in Quality Agreements from a regulatory perspective. Control of suppliers such as Contract Manufacturing Organizations has always been a requirement of the FDA and EU. With the issuance of these new regulatory documents; the expectation is that there will be a written documentation of this control. Proof of this control can be presented to FDA / EU inspectors in the form of a Quality Agreement which is specific to a particular CMO.

Each proposed section of a Quality Agreement is fully analyzed and suggested content is written with the new guidelines taken into consideration. Comparison of the two regulatory documents is presented with differences highlighted and discussed. A detailed discussion of Quality Agreement topics such as change control, documentation, facilities, and equipment, lab controls, sub-contracting, etc. is covered. The final FDA guidance is discussed and a review of comments from industry is included.

Who Should Attend ?



This webinar will provide valuable assistance to all personnel in

- *Quality Assurance*
- *External Manufacturing/Outsourcing*
- *Quality Auditing*
- *Technology Transfer*
- *Regulatory Affairs/Compliance*
- *Supply Chain*
- *Purchasing*
- *Risk Management*

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