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Webinar on

Batch Record Review And Product Release

Learning Objectives

- *Recognize regulatory requirements for batch records and batch record review*
- *Discover the essentials of batch record reviewer qualifications and training*
- *Establish a working relationship between production and quality reviewers*
- *What to do when a batch fails to meet specifications (discrepancies and deviations)*

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Areas Covered

- *Regulatory requirements for batch record review*
- *What to look for while reviewing batch records, i.e., good documentation practices, compliance with critical quality attributes and critical processing parameters*
- *Skills and responsibilities of an effective batch record reviewer*
- *Tools for effective batch record review*
- *Ensuring Production and Quality reviewers coincide with their reviews*
- *Extensive Training plan for batch record reviewers and when they can be considered "qualified" to review a record*

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This webinar attendees will learn the fundamentals for reviewing batch records in a pharmaceutical environment and they will learn how to react to discrepancies found in these records.

PRESENTED BY:

Danielle DeLucy, MS, is currently an Independent Consultant to the Biologics and Pharmaceutical Industries specializing in the areas of Quality Assurance and Quality Systems.Danielle began her QA career as a Quality Control Pharmaceutical Microbiologist at Lancaster Laboratories, a contract laboratory where she performed various tests for their clients.

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On-Demand Webinar

Duration : 60 Minutes

Price: $200

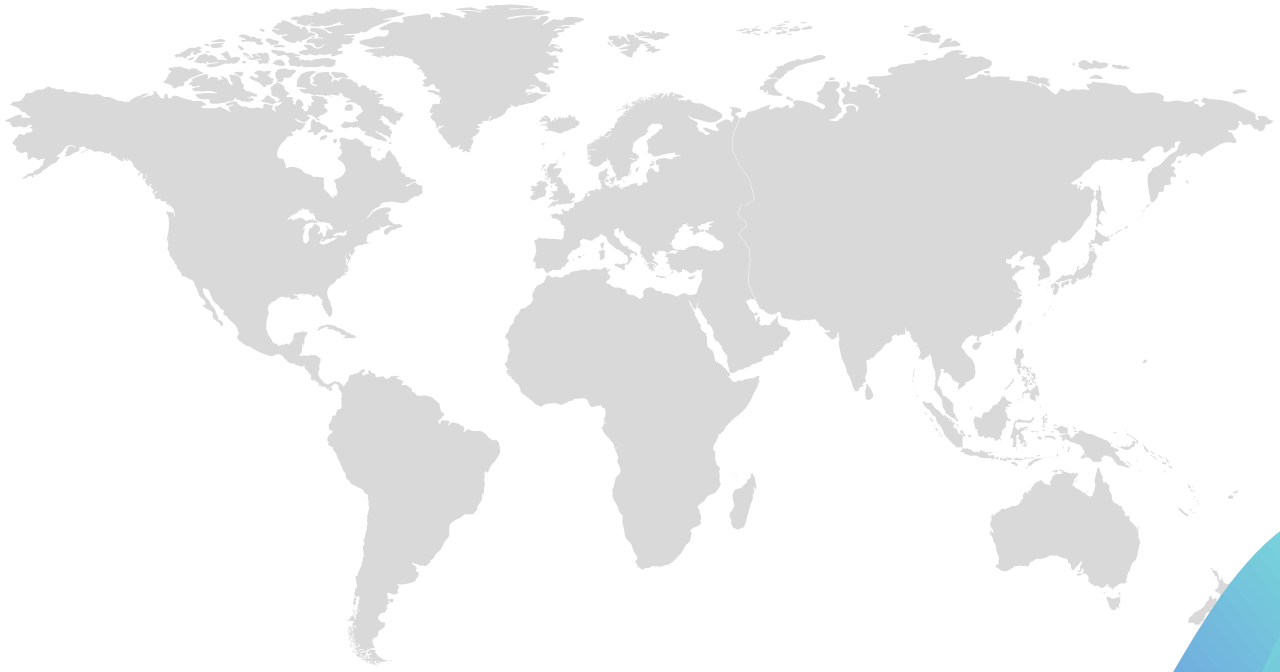
Webinar Description

This webinar will analyze each of these necessary elements of the batch record review process.

Most Regulatory Agencies require firms to have written procedures in place to document production and process controls, better known as batch records. Additionally, there must be written procedures for a batch record review process that demonstrate compliance. A strong batch record review system is essential in order to properly document all critical processing parameters that go along with the production and manufacture of pharmaceuticals, biologics, medical devices, etc.

Who Should Attend ?

Production personnel and Production Managers who review batch records and Quality Assurance batch record reviewers.



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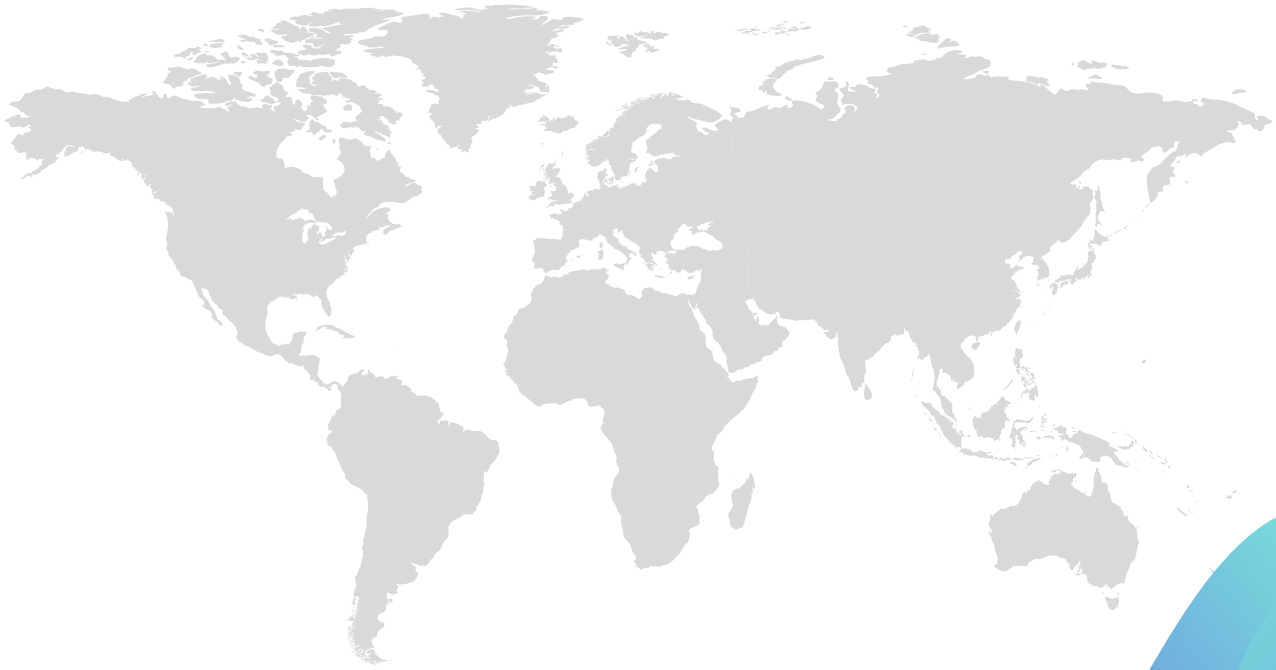
Why Should Attend ?

Upon completion of this session, attendees will learn the fundamentals for reviewing batch records in a pharmaceutical environment. They will hear about the proper training that must be demonstrated before one is considered a suitable reviewer of these critical documents and they will learn how to react to discrepancies found in these records.



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