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Webinar on

Implementation and Management of GMP Data Integrity

Learning Objectives

- *Understand the current regulatory position on data integrity*
- *Discover the criteria for data integrity*
- *Recognize what needs to be addressed to ensure data integrity within a regulated GXP laboratory*
- *Learn about approaches to improve data integrity in a laboratory environment*
- *Part 11 compliance*
- *FDA citations related to data integrity issues*

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Data integrity is the assurance that data records are accurate, complete, intact and maintained within their original context, including their relationship to other data records.

PRESENTED BY:

In recent years, FDA has increasingly observed CGMP violations involving data integrity during CGMP inspections.

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On-Demand Webinar

Duration : 60 Minutes

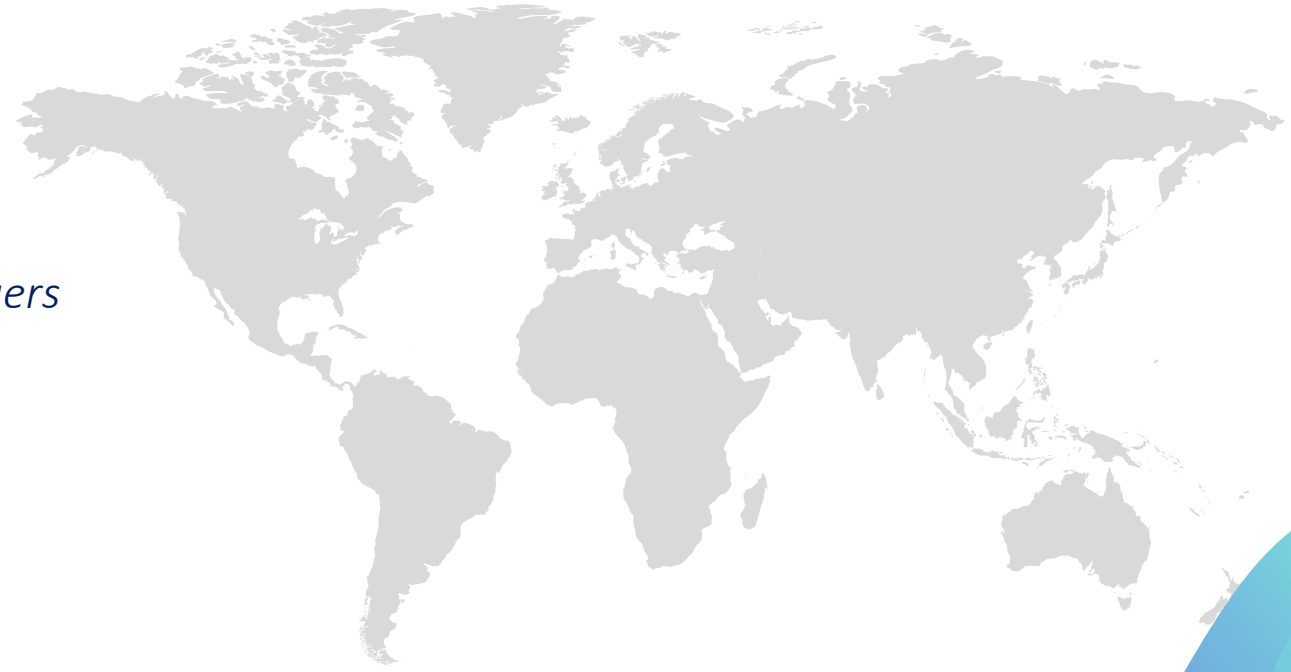
Price: $200

Webinar Description

Data integrity is the assurance that data records are accurate, complete, intact and maintained within their original context, including their relationship to other data records. This definition applies to data recorded in electronic and paper formats or a hybrid of both. To assure the quality of raw materials, in-process materials and finished goods, laboratory data integrity is assuming greater importance in current Good Manufacturing Practices (CGMP) for the US Food and Drug Administration (FDA)-regulated industry. Data integrity and security infractions are not only 21 Code of Federal Regulations (CFR) Part 11 issues but also severe CGMP violations. The reasoning behind this complex issue is quite simple: if the integrity of laboratory data is compromised, batches of finished goods may not comply with regulatory authorization terms and, consequently, will not be released for sale.

Who Should Attend ?

Site Quality Operations Managers
Quality Assurance personnel
Plant Managers and Supervisors
Manufacturing Superintendents and Managers
Regulatory Affairs Managers



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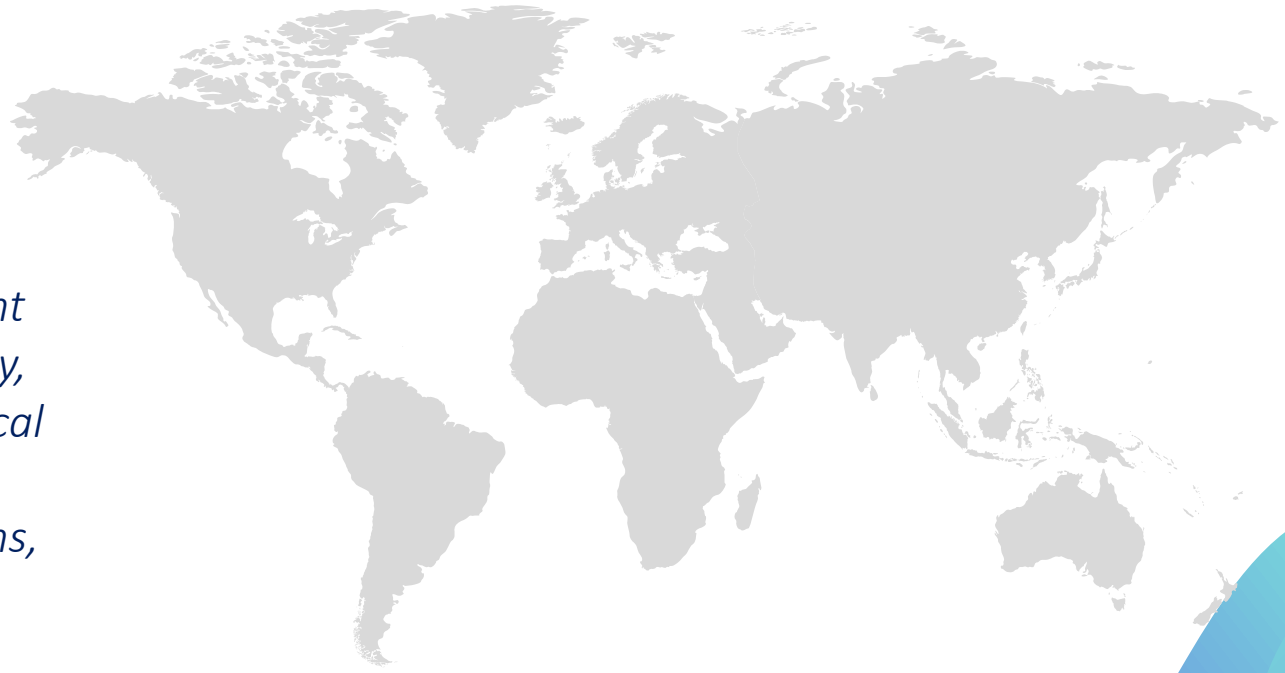
Why Should Attend ?

In recent years, FDA has increasingly observed CGMP violations involving data integrity during CGMP inspections. This is troubling because ensuring data integrity is an important component of the industry's responsibility to ensure the safety, efficacy, and quality of drugs, biologics and medical devices. These data integrity-related CGMP violations have led to numerous regulatory actions, including warning letters, import alerts, and consent decrees. Attendees will obtain an understanding of the Regulatory expectations for Data Integrity. The information provided at the webinar will enable the attendees to review practices at their own site and identify gaps in their own practices.



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www.grceducators.com
support@grceducators.com
740 870 0321