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Webinar on

Good Documentation Practice and Record Keeping Regulations (FDA & EMA)

Learning Objectives

Following the completion of this webinar you will gain a basic to moderate knowledge of definition, purpose, importance of GDP, General rules of GDP, GDP as applies to laboratory notebook documentation, US Pharmacopeia General Chapter <1029> introduction "Good Documentation Guidelines", A very brief introduction to European Union (EU) GDP, and finally its enforcement along with some observation samples from FDA.

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This 60-min Webinar covers the essentials of GDP, its definition, purpose, and importance.

PRESENTED BY:

Dr. Afsaneh Motamed Khorasani, PhD, is a Medical and scientific Affairs expert and a Senior Scientist with a strong background in biomedical science and clinical trial/research.

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On-Demand Webinar

Duration : 60 Minutes

Price: $200

Webinar Description

Good Documentation Practices (GDP) is an essential factor that needs to be closely followed by the personnel in any regulated environment as a process for successful project completion including observations of unanticipated responses that are required to be accurately recorded and verified. This 60-min Webinar covers the essentials of GDP, its definition, purpose, and importance. Then expands on general rules and principles of GDP (US & EU), General tips for Laboratory Notebook documentation and finally discussing GDP enforcement by regulatory bodies in different countries with some examples of FDA citations.

Who Should Attend ?

Anybody who works in a regulated environment

Engineering / Manufacturing & Production Personnel / Managers

Research and Development Personnel (R&D) / Managers

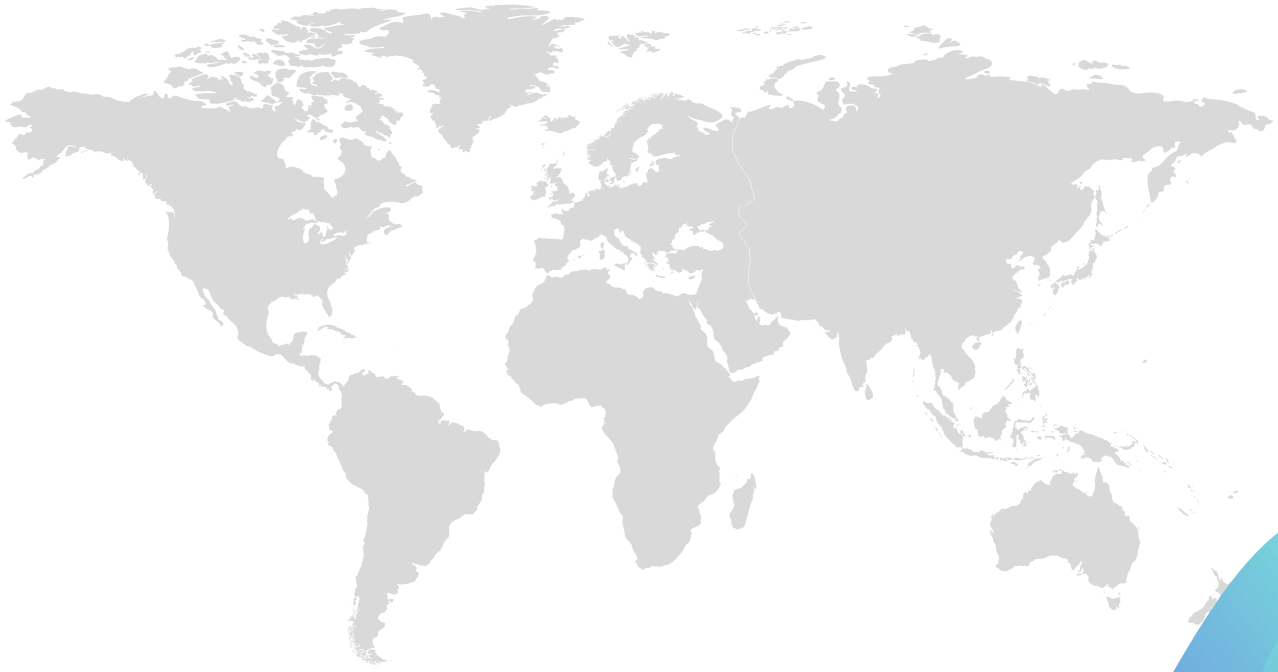
Quality Assurance & Quality Control Personnel / Managers

Laboratory Personnel / Managers

Validation Specialists

Clinical trial personnel

Project Managers



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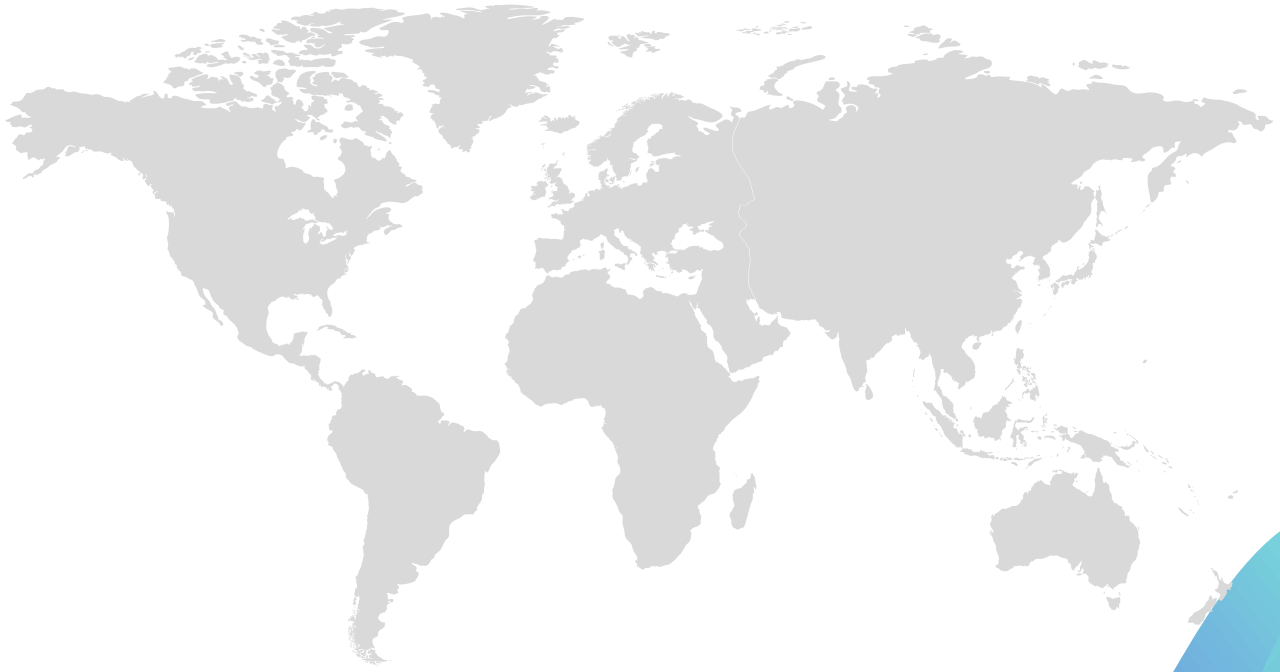
Why Should Attend ?

If you are involved in any product manufacturing, knowing GDP regulations is a must for you. It prevents a lot of errors and minimizes the chance of being spotted by the regulatory bodies in their audits.



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