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Webinar on

SOPs For GXP Compliance

Date : 18 March 2019

Areas Covered

- *Understand why we need written SOP procedures*
- *Gain insight into expectations for an effective written documentation*
- *Understand Regulatory requirements for the creation, compliance, and maintenance of SOPs*
- *Gain techniques for creating effective SOPs and other written documents to minimize costly revisions*
- *Understand roles and responsibilities for the review and approval of written documents consistent with compliance requirements*
- *Learn how training and implementation of SOPs should be carried out to meet inspectors expectations*
- *Ensure you have effective control, archival and disposal of SOPs*

This webinar will help to learn how to write SOPs to comply with inspection requirements.

PRESENTED BY:

Dr Laura Brown, PhD, MBA, Diploma Clinical Sciences, is an independent QA and Training Consultant in the Pharmaceutical Industry as Managing Director LB Training and Development Ltd., Course Director for the MSc in Clinical Research, School of Pharmacy at the University of Cardiff, and Course Director MSC Regulatory Affairs, TOPRA.

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Date : 18 March 2019

Time : 01 : 00 PM EST

Duration : 60 Minutes

Price: $179

Webinar Description

This webinar will help Sponsors, CROs in the US, EU and internationally; understand how to write SOPs to comply with inspection requirements.

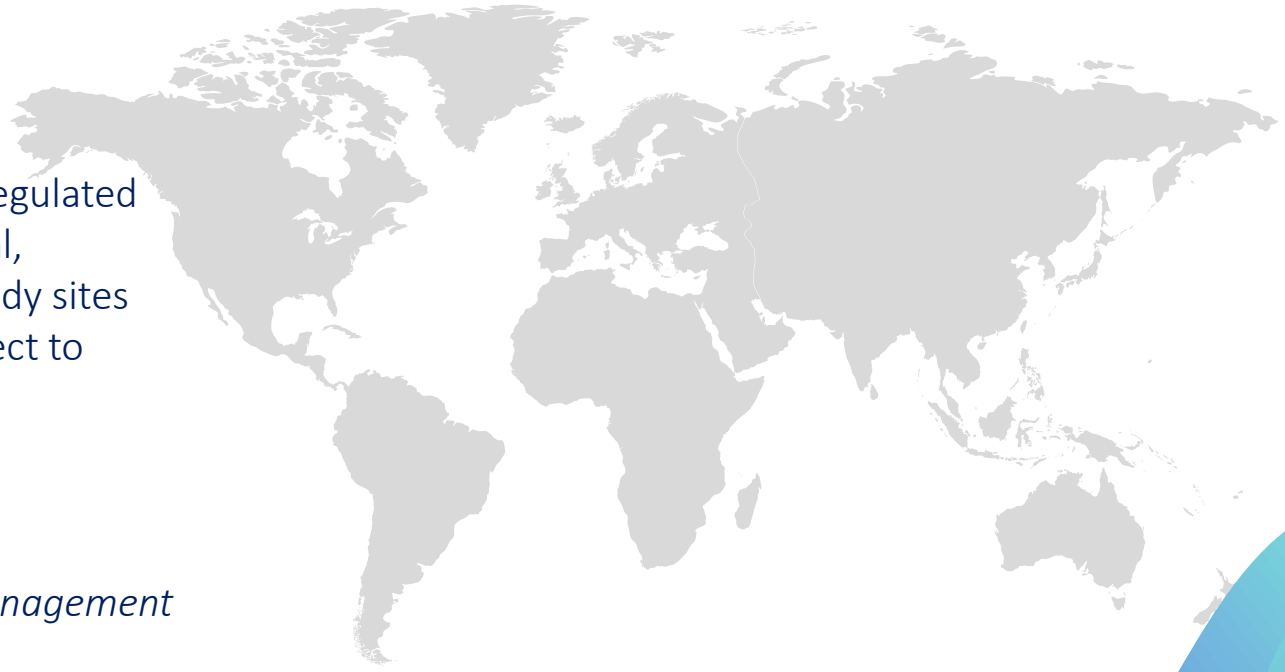
The lack of or inadequate standard operating procedures (SOPs) continue to dominate the FDA's and other regulatory inspector’s inspection observations. This is often caused by poor writing and management and control of SOPs.

SOPs need to be easily understood by all those who have to follow them. Well written and effective SOPs are not only regulatory requirements, but they also make good business sense. Too often employees fail to follow SOPs because they can't understand them, and too many times we've seen procedures being constantly revised. This leads to lengthy and expensive investigations and costly revisions.

The webinar has been specifically designed to learn how to create and review SOPs, and generate a system for training and implementation of effective and compliant written procedures. This webinar will assist you to prepare for inspection of SOPs, particularly since such inspection readiness of SOPs are taking considerable time to prepare for. Inspections of SOPs of critical activities that impact business success on several levels. Therefore, preparation and management of the inspection and audit process of SOPs is an important business activity, not just a distraction from day to day routine.

Potential adverse consequences to the company if an inspection of SOPs does not go well range from time-consuming responses to regulatory observations, to publicly available Warning Letters, delayed product approvals, and the specter of civil or even criminal litigation by the FDA. These consequences are preventable with good preparation and management of SOPs.

Who Should Attend ?



This webinar will provide critical assistance to FDA regulated companies including professionals in pharmaceutical, biotechnology, CRO, SMO, vendor companies, or study sites including investigator-initiated studies that are subject to inspection or audit of their GXP SOPs.

It will also be of interest personnel such as:

Clinical Research archiving and document management personnel,
Quality assurance managers and auditors

Clinical Development managers and personnel, Clinical research associates

Drug Research and Development managers and personnel, Manufacturing, Document management

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Pharmacovigilance, Laboratories, CROs, Consultants

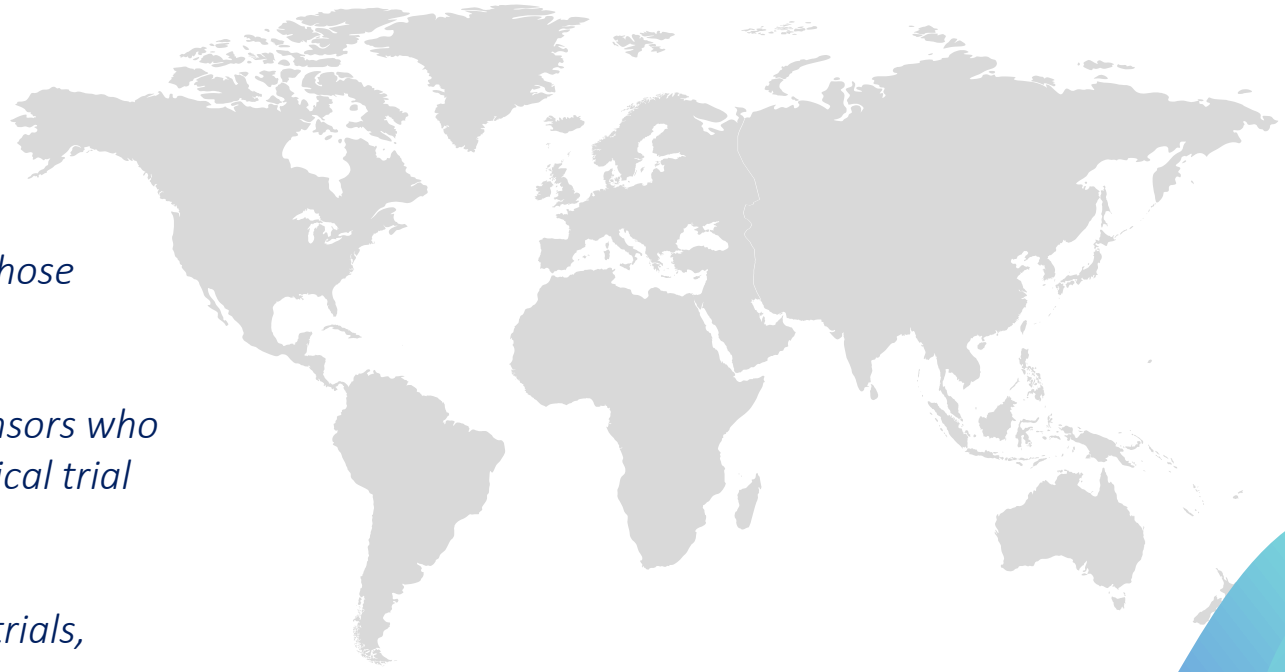
Regulatory Affairs, Project Management, To those departments who have SOPs

Sponsors and non-commercial sponsors, Sponsors who have their own laboratories for analyzing clinical trial samples

Laboratories analyzing samples from clinical trials, Clinical trial supply

To those departments who have SOPs

Legal, regulatory authorities and all other professionals who want to know more about inspection of SOPs



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