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Quality system controls for clinical trial development and conduct

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Clinical studies continue to fail to meet the minimum regulatory requirements as shown by worldwide regulatory citations that are issued on a fairly consistent basis. What is even more concerning is that these areas remain year after year and include inadequacy in; study oversight, protocol compliance, investigational product accountability, training, and ethical committee oversight. With all the emphasis on training that many sponsors and investigators put their staff through, the guidance documents issued by the regulatory authorities, continued negative inspections and resulting citations, which in turn result in negative publicity, why does this continue to happen in this day and age? Applying a quality system approach, including the conduct of risk management techniques, will help ensure that industry and their partners, such as third party vendors and site personnel, are better prepared to identify and plan for potential risk areas, plus deal with issues as they arise.

This session will introduce the concepts and application of a quality system approach to study management for regulated clinical trials to ensure adequate risk assessment, evaluation and application for superior performance. It will provide direction on a practical approach to incorporating it into the practice of daily clinical research activities. The session is geared towards intermediate participants at both the site and sponsor level who already have a good understanding in the requirements of clinical research, but are seeking further direction in how to execute clinical research from a quality systems approach.

Objectives: Upon completion of this program participants will be able to:

1. Relate the concepts of a quality system approach to the conduct of clinical trials
2. Define risk management principals
3. Identify how corrective and preventative action plans apply to a clinical quality system approach

Biography

Lee Truax-Bellows is a founder, president and CEO of Norwich Clinical Research Associates Ltd. (NCRA). NCRA is a full service clinical contract research organization (CRO) based in upstate NY. Lee has an extensive background in the pharmaceutical and medical device industries, having worked for both industry and a CRO as a Monitor, Medical Communications Associate, Project Manager, Senior Quality Auditor, Senior Trainer, and Regulatory and SOP Consultant. Lee has been involved in regulated research for 20 plus years and currently specializes in product development, GCP auditing, SOP development and training on regulated research and Good Clinical Practice. Lee is an active member of the Association of Clinical Research Professionals (ACRP), New York State MedTech Association and Society of Quality Assurance (SQA). Lee is ACRP certified as a Certified Clinical Research Associate (CCRA) and registered through SQA as a Registered Quality Assurance Professional in Good Clinical Practices (RQAP-GCP).

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