

# International Conference on Clinical Trials

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### The future of clinical trial conduct demands a quality system approach: Are you ready?

The latest emphasis from regulatory authorities within clinical study conduct is to design, develop and execute clinical studies using a Quality System Approach. While both the FDA and EU emphasize this approach, regulatory agencies provide little direction on how this can be achieved. The latest example of such an approach can be found within the FDA's guidance on conducting a risk-based approach to monitoring. Risk management is an integral component of a quality system approach. As with a Quality System Approach many researchers do not have the knowledge or experience to conduct clinical trial risk management. This workshop will apply practical approaches and demonstrate associated tools and skills to assist the participant in using a Quality System Approach within the clinical trial arena.

#### 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. She 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, GCP Trainer, and Regulatory and SOP Consultant. She has been involved in regulated research for the past 25 years and currently specializes in product development, GCP auditing, and SOP development and training on regulated research and Good Clinical Practice. She is an active member of the Association of Clinical Research Professionals (ACRP), New York State MedTech Association and Society of Quality Assurance (SQA). She 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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