Lee Truax-Bellows, J Clin Trials 2015, 5:3
http://dx.doi.org/10.4172/2167-0870.S1.006

OMICS International
conferenceseries.com

International Conference on

Clinical Trials

July 27-29, 2015 Orlando-FL, USA

Lee Truax-Bellows

Norwich Clinical Research Associates Ltd. (NCRA), USA

The impact of a quality system approach on outsourcing and conduct of clinical research trials

Learning Objectives:

1. Summarize current trends in clinical trial outsourcing
2. List a minimum of 3 potential problem areas for the conduct of clinical research trials
3. Describe a minimum of 3 reasons why quality system management has become an integral requirement for the conduct of clinical trial research

As anyone in the business can attest to, the conduct of regulated clinical research continues to evolve. Several reasons for this evolution are based on 1) lessons learned over the years, 2) a continuing shift of clinical trial expectations from a regulatory perspective and 3) the advent and progression of electronic communication and documentation. With this evolution come both old and new issues that arise during the conduct of the trials. This session will focus on the impact of this evolution on the preparation, management and conduct of clinical research trials and provide an overview of why developing and using a robust Quality System Management approach has become a necessity for the conduct of regulated clinical trials.

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 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).

ltb@ncra.com

Notes: