Aware of the Similarities and Differences in the files

Date : Jan 31, 2018 - 10:00 AM

Event URL : http://www.BostonEventsList.com/events/aware-of-the-similarities-and-differences-in-the-files-jan-2018

Organizer : Netzealous LLC DBA - Compliance4All

Venue : online

Location : 161 Mission Falls Lane, Suite 216,,
Fremont, California, United States, ZIP: 94539
Phone: 8004479407

Ticket Price: One Dial-in One Attendee Price: $150.00
Overview:
It will also consider the European Union's MDD TF/DD requirements, and evaluate the documents' differing purposes / goals, as well as the two different device classification schemes.

Why should you Attend:
companies go global, they must meet different product design documentation. The cGMPs mandate Design Control and the Design History File (DHF). In order to sell globally, the EU's CE-marking documentation is a requirement - the Technical File or Design Dossier.

Areas Covered in the Session:
DHF "Typical" Contents and Deliverables
The DMR and DHR / Lot / Batch Record
TF / DD Required Contents
Parallel Approaches to Documentation - Teams
FDA and NB Audit Focus

Who Will Benefit:
QA
RA
R&D
Engineering

Production
Operations
Marketing

Speaker Profile:
John E. Lincoln is a medical device and regulatory affairs consultant. He has helped companies to implement or modify their GMP systems and procedures, product risk management, U.S. FDA responses. In addition, he has successfully designed.

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Event Categories :