Mastering DHF, DMR, and DHR: Essential Documentation in Medical Device Manufacturing Webcast

Duration: 4 hours

Course Description

Medical device manufacturing is not an easy process. If anything goes wrong, the entire batch of products is at stake. Is there any solution to it? DHF, DMR, and DHR are the three Ds of medical device that needs to be managed carefully.
Even though these files serve different purposes, it is essential to understand how they are mutually inclusive for effective technical documentation. This seminar offers a deeper insight into the documentation part of medical device manufacturing. Moreover, the seminar will cover the latest requirements proposed by FDA and European Union.

Learning Objectives

Below are the topics discussed in the seminar:
Session 1

- Introduction
- Design Control Under 21 CFR 820.30
- Design and Development Planning under ISO 13485:2016 7.3
- The U.S. FDA's DHF
- The EU MDR's D&DPF
- MDR's "General Safety and Performance Requirements"
- Device Classification - U.S. FDA vs. EU MDD
- Design Files' "Typical" Contents
- The DMR and DHR / Lot / Batch Record TD Expected Contents

Session 2

- Risk Management / File Under ISO 14971
- Narrative
- Hazzard Analysis
- FTA
- D-, P-, and U-FMECA's
- Report

Session 3

- Human Factors / Use Engineering Under IEC 62366-1:2015
- The User Interface
- The 9 Stages
- The HF / UE File
- Session 4
- Putting It All Together
- Design Control
- The Team
- Concurrent Compilation of the Three Files
- Derivative Documents Development
- Completion
- FDA and NB Audit Focus
- Final Q & A

Who will Benefit

- Quality and Research Analyst
- R&D Professionals
- Engineering
- Production
- Marketing

Faculty John E. Lincoln

John E. Lincoln, is Principal of J. E. Lincoln and Associates LLC, a consulting company with over 36 years experience in U.S. FDA-regulated industries, 22 of which are as an independent consultant. John has worked with companies from start-up to Fortune 100, in the U.S., Mexico, Canada, France, Germany

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