

## 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.

**Contact Detail:**

Compliance4All DBA NetZealous,

Phone: +1-800-447-9407

Email: [support@compliance4All.com](mailto:support@compliance4All.com)

**Event Categories :**