FDAnews Announces: Medical Device Risk Management, June 27-28, 2017, Arlington, VA

FDAnews and Ombu Enterprises present a two-day workshop designed to untangle every mystery of risk management and put manufacturers on the path to compliance.

Medical Device Risk Management Workshop, June 27-28, 2017

FALLS CHURCH, VA, UNITED STATES, May 19, 2017 /EINPresswire.com/ -- Medical Device Risk Management: Batten Down the Hatches – Rough Seas Ahead
Presented by FDAnews and Ombu Enterprises
June 27-28, 2017 – Arlington, VA
www.fdanews.com/mdriskmanagement

Say “risk management” to a medical device manufacturer and watch his or her face.

Sighs. Frowns. Groans.

Risk management is just plain hard, complicated, conflicted and confusing. Yet few topics spread tentacles into so many aspects of an operation or draw so many warning letters.

It’s time to batten down the hatches and come to terms with the rough seas of risk management.

FDAnews and Ombu Enterprises are here to help, with a two-day workshop.

These intense skull sessions are designed to untangle every mystery of risk management and put manufacturers on a path to full compliance. Attendees will discover:

• Fundamental concepts of risk management
• Regulatory structures of the U.S., Canada, and the EU
• Warning letters analysis — avoiding pitfalls that bring others down
• The process flow in the international standard ISO 14971:2007
• Relationship between the Risk Management System and ISO 13485:2016
• The EU variant, EN ISO 14971:2012 and how to implement it
• Role of production and post-production information including linkage to the EU’s Requirements for Clinical Evaluation
• And much more!

Plus three new sessions have been added for 2017:

• The EU Regulations including the Medical Device Regulation (MDR) and the In Vitro Diagnostic Medical Device Regulation (IVDR)
• The Draft Guidance Documents for 510(k) Changes and risk management considerations
• Cybersecurity focusing on the FDA-CDRH Premarket Cybersecurity and Postmarket Cybersecurity guidances

The workshop starts with ISO 14971:2007 as the base process standard. The first day focuses on the risk management process, using EN ISO 14971:2012, the de facto global standard. The workshop points out differences with the MDR and anticipates the European version of the standard.

The second day focuses on the processes with a base in ISO 14971:2007. Many of these processes, defined in standards or guidance documents include specific, subject oriented, requirements.

Dan O'Leary, a favorite presenter at dozens of FDAnews-sponsored workshops, provides the understanding and practical tools to join the disparate pieces into a coherent whole and create a solid foundation for the coming changes. Mr. O'Leary boasts 30+ years' experience in quality, operations and program management in regulated industries including aviation, defense, medical devices and clinical labs.

Risk management affects nearly every aspect of medical device manufacture. Yet many devicemakers lag behind the curve, courting warning letters or worse. Get up to speed quickly and easily.

Who Will Benefit:
Here are just a few of the many executives who will benefit:

• Project managers involved in design and development
• Design engineers
• Quality engineers
• Manufacturing engineers
• Quality auditors
• Production managers
• Scientists involved in device research and development
• Medical staff evaluating risk, safety or effectiveness
• Quality or regulatory staff assigned to complaint, CAPA or MDR management
• Training personnel
• General/corporate counsel

Conference Details:
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Batten Down the Hatches – Rough Seas Ahead
Presented by FDAnews and Ombu Enterprises
June 27-28, 2017 – Arlington, VA
www.fdanews.com/mdriskmanagementDay1

Tuition:
Early Bird Pricing (through May 26): $1,597
After May 26: $1,797
Significant team discounts are available.

Easy Ways to Register:
Online: www.fdanews.com/mdriskmanagementRegister
By phone: 888-838-5578 or 703-538-7600

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