FDAnews Announces — Medical Device Complaint Management: Escape the Labyrinth March 20-21, 2019 Arlington, VA

Warning letters — and worse — await device/diagnostics firms that neglect QMS and complaint management. Here’s what to do.

FALLS CHURCH, Va. (PRWEB) January 25, 2019 -- Medical Device Complaint Management Escape the Labyrinth

**An interactive workshop from FDAnews and Ombu Enterprises**
March 20-21, 2019
Arlington, VA
https://www.fdanews.com/ meddevicecomplaints

Device and diagnostics makers face a jumble of QMS regulations in the U.S., Canada and the EU. They’re maddeningly complex and can even conflict with each other and violations often trigger warning letters and other sanctions.

The stakes are high. It’s worth two full days of time to get things straight.

FDAnews has called on a top-rated presenter, Dan O’Leary of OMBU Enterprises LLC. Using actual warning letters, case studies, hands-on exercises and real-world examples, this interactive two-day workshop will arm one for every complaint management challenge that key regulatory agencies come up with, and help one integrate a complaint management program into a comprehensive QMS.

Plan on coming home with a deep understanding of:

- The regulators: The FDA, Canada, the EU current state and the EU future state … how they’re similar, how they differ
- The role of QSR, ISO 13485:2016, ISO 14971:2007, and national and regional variants
- The many definitions of complaints: And their implications
- Warning letters: What they teach
- Process flow and decision points for U.S., EU and Canadian regulators
- Adverse event reporting: Decisions and timelines
- Trend reporting to regulators: Understanding the systems
- Field actions and associated regulatory reports: How to spot the triggers
- Design changes that trigger the need for updated submissions
- QSR and the MDSAP Audit Model: How regulators use them
- And MUCH more!

Get ready to roll up your sleeves. Attendee’s will be working from course materials that include slides from PowerPoint presentations, copies of relevant guidances and regulations, and worksheets from 10 interactive exercises that Mr. O’Leary has prepared especially for this workshop.

QMS changes constantly. Take new requirements from the EU-MDR, with particular emphasis on post-market surveillance. It’s one of the most complicated parts of a regulation rife with interlocking systems of plans and reports … and just one example of the headaches involved in getting QMS right. But getting QMS right is — or
Meet the Presenter:
Dan O’Leary is President of Ombu Enterprises LLC, offering training and execution in Operational Excellence that focuses on analytic skills and a systems approach to operations management. Mr. O’Leary boasts 30+ years’ experience in quality, operations, and program management in regulated industries including medical devices, clinical labs, aviation and defense. He is an ASQ certified Biomedical Auditor, Quality Auditor, Quality Engineer, Reliability Engineer, and Six Sigma Black Belt; and is certified by APICS in Resource Management.

Who Will Benefit:
- Quality management
- Regulatory affairs
- Quality engineering
- Design engineering
- Design/development
- Complaint specialists
- Corrective-action specialists
- Recall coordinators
- Medical staff evaluating risk, safety, or effectiveness
- General/corporate counsel

Webinar Details:
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Tuition:
Early Bird Pricing: $1,597 (available until Feb. 20, 2019)
Regular Pricing: $1,797 (after Feb. 20, 2019)
Significant team discounts are available.

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

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