

# Medical Device Supplier Quality and Management

Practical Approaches to Cost Effective  
Implementation

March 2017





# Your Presenters

This workshop has two presenters

– **John Avellanet** from Cerulean Associates LLC

[www.Ceruleanllc.com](http://www.Ceruleanllc.com)

– **Dan O’Leary** from Ombu Enterprises, LLC

[www.OmbuEnterprises.com](http://www.OmbuEnterprises.com)

Each developed portions of the material


We will tag team in the presentation

# Disclaimer

This is not legal advice. Information in this presentation draws upon a variety of sources, including published FDA warning letters, FDA and EU regulations, GHTF and other regulatory guidance documents, personal experiences, interviews and research, all or any of which may or may not have been prepared or conducted by the presenters. Presenters do not provide a warranty concerning the accuracy of the information contained in this presentation. The contents of this presentation are intended for general information only and should not be construed as legal advice. Presenters assume no liability for actions taken or not taken as a result of the information in this presentation.

This presentation is copyrighted 2017 by Cerulean Associates LLC and Ombu Enterprises, LLC. All rights reserved.

# Participant Introduction

- Your Name
- Your company 

You might have a competitor or a supplier in the room
- Your job title
- Something about the supplier quality management issues you face in your company

# Our Class

- Our approach is casual
- Turn off (or silence) your cell phones for the workshop
- Ask lots of questions
- Bring examples from your experience
- Participate
- Have fun!

# Our Approach

- Learning can come studying the mistakes of others!
  - We use FDA Warning Letters and FDA-483 excerpts to illustrate some issues.
- We also employ simple questions to help check understanding
- Structured interactive exercises throughout

# Picture Credits

Photos, images and clip art that appear on these slides have been used to enhance this presentation and may NOT be used for commercial or promotional purposes without permission from copyright holders.  
Do not remove or copy from this presentation.

Contact:

Microsoft Corporation

FDAnews

Ombu Enterprises, LLC

Cerulean Associates LLC