

## 23E - Medical Device Production, Excel Spreadsheets, and Part 11 Compliance

### Presenter

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### Session Summary

FDA regulations require that manufacturers must validate software used for production or the QMS. One of the most common applications is Excel 2003. This presentation gives Quality Engineers the tools to perform the validation.

We discuss the following issues:

- The pitfalls of using Excel without a good regulatory plan
- How to recognize when you are using software in production or the quality system
- The use of Excel tools to help ensure spreadsheets are built correctly
- The FDA's requirements and expectation for production and quality system software
- The reason for Part 11 and some of the implications
- The requirements of Part 11 for electronic records and the current guidance document

Topic Outline:

- Overview of the regulations
- Excel Validation
- Using the Excel Convert Function
- Excel Formula Auditing
- Excel Protection
- Track Changes
- Understanding automated process
- Electronic records

### About the Presenter – Dan O'Leary

**Dan O'Leary**, President, Ombu Enterprises has more than 30 years experience in quality, operations, and program management in regulated industries including aviation, defense, medical devices, and clinical labs. He has a Masters Degree in Mathematics, focusing on logic and number theory. His professional experience relates to quality, reliability, and operations management. Dan is the President of Ombu Enterprises, LLC, a company offering training and execution in Operational Excellence. Ombu helps companies achieve efficient and effective processes and regulatory compliance.

Dan is a regular speaker at international conferences including ASQ, ISM, and RAMS. Dan teaches courses in reliability methods, medical device regulations and practices, statistical methods, management systems (ISO 9001 & ISO 14001), and project management. Dan is a member of the American Mathematical Society, American Statistical Association, Society of Industrial and Applied Mathematicians, Institute for Supply Management, Project Management Institute, APICS, and is a Senior Member of the American Society for Quality and has held leadership positions in ASQ sections. He is an ASQ Certified Biomedical Auditor, Quality Auditor, Quality Engineer, Reliability Engineer, and Six Sigma Black Belt; and is also certified by APICS in Resource Management.