Leverage New Tools for Device CAPA Compliance
AGENDA

10:00 a.m. - 10:15 a.m. **Introduction to the Virtual Conference**

10:15 a.m. – 11:15 a.m. **The CAPA Procedures You Need to Survive in 2014 — Device Compliance Guru Reveals What Will Make the Difference Next Year**

CAPA gets more complex each year. In this roll up your sleeves session, industry expert **Dan O'Leary** pops the hood and shows you how the CAPA engine should run. You'll learn how to create a CAPA compliance program that works, bolstered by strong procedures for quality audit reports, quality records, service records and complaints. Plus, you'll come away understanding how to employ the FDA's requirements for statistical methodology.

Attendees will learn how to:

- Create procedures to drive effective CAPA compliance
- Analyze processes, work operations, concessions to assure that are integrated into and support CAPA programs
- Develop strong procedures for quality audit reports, quality records, service records, complaints
- Employ required statistical methodology — a key focus of FDA's recent inspections

Dan O'Leary, President, Ombu Enterprises

11:15 a.m. – 11:30 a.m. **Break**

11:30 a.m. – 12:30 p.m. **Cut the CAPA: the Bottom-Line Value of Prevention — Understanding the Role Effective CAPA Management Can Play in Increased Efficiency and Profitability**

An effective CAPA program can improve the bottom line. In this session, long-time industry analyst **Jason Spiegel** uses case studies and specific scenarios to demonstrate how a preventative approach to CAPA has saved time and money for regulated entities – and how it can do the same for you.

Attendees will learn:

- The benefits of a preventative CAPA program
- What are the smart investments to make?
- Case studies: The benefits of preventive programs
- How to leverage CAPA beyond compliance

Jason Spiegler, Director, Strategic Market Development, Camstar Systems; Chair, ASQ North Carolina Chapter

12:30 p.m. – 1:30 p.m. **Lunch**

1:30 p.m. – 2:30 p.m. **CAPA on the Front Lines: Lessons Learned at Abbott**

Theory is good. Theory is helpful. But real-life examples are better. In this session, **Sherry Schiller**, Abbott Diagnostic's CAPA point person for more than six years, takes you inside a major industry player to see how it shored up its CAPA program, plugged the most vexing holes and saw clear benefits to getting CAPA right.

Attendees will learn:

- How (and why) Abbott changed its CAPA compliance philosophy
- How to spot potential CAPA problems — and fix them fast
- An insider's views on compliance realities — and how to tackle them step-by-step
- The clear benefits of a rejuvenated CAPA program

Sherry Schiller, CAPA Consultant; former Associate CAPA Specialist, Abbott Diagnostics

2:30 p.m. – 2:45 p.m. **Break**

2:45 p.m. – 3:45 p.m. **Here Comes the FDA Investigator — You Can Read the QSIT Manual All You Want, But What Are Investigators Really Looking For?**

You've learned from the best practices, and worst mistakes, of other companies' programs. You've developed what you believe to be a robust CAPA program. Guess what? It won't matter much if you can't demonstrate it to an FDA inspector. In this session, **Ken Miles** brings his more than 28-year inspection experience at FDA to give you valuable insights into the mind of an FDA inspector.

Attendees will learn:

- What any FDA investigator — young, old, newbie or veteran — are thinking when they walk into your plant
- How to anticipate any potential red flags that can send an inspection south – fast.
- How to work with an FDA inspector before, during and after the inspection.
- How other companies' bad CAPA compliance programs can be a learning tool

	Ken Miles, Principal, Alpha Quality Assurance; formerly a senior FDA medical device investigator for 28 years
3:45 p.m. – 4:00 p.m.	**Closing Comments and Adjournment**