

## 13E –FDA’s QUALITY SYSTEM FOR PHARMACEUTICAL MANUFACTURERS GUIDANCE

### *Presenter*

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### *Session Summary*

As part of its *21st Century Initiative*, FDA is expecting the same ever-increasing level of quality systems already demanded of Medical Device firms at drug companies as well. While theoretically "optional," FDA's quality system guidance defines practical expectations that are already required under ICH Q10 and 21 CFR 820.1(b), which directly affect drug firms. Many FDA District Offices are conducting site inspections under the Quality System Inspection Technique, which this guidance mirrors.

In addition, FDA is currently considering a new set of quality system regulations for Combination Product manufacturers, and an understanding of the differences and synergies between the Medical Device and Pharmaceutical Quality Standards will be essential to effectively implementing the new 21 CFR Part 4.

### *About the Presenter – Jeff Boatman*

**Jeff Boatman** is a Quality System Senior Subject Matter Expert at QPharma, a validation and compliance-consulting firm in Morristown, New Jersey. Jeff has spent 21 years in the drug and device industries and is an expert in regulatory requirements. He has held nearly every technical position in the Medical Device field, from manufacturing technician to lab supervisor, R&D engineer to Quality Consultant, Compliance Manager to Director of Quality. Jeff is an ASQ Certified Quality Auditor and the developer of ASQ's course on the Quality System Regulation.