

Date: August 9-10, 2016

Time: 8:30am-4:30pm

Ohlone College
Newark Center Campus
Room 1100

UNDERSTANDING QUALITY SYSTEM REGULATIONS—MEDICAL DEVICES

Life Sciences/Biotechnology Workshops

THE WORKSHOP

This two-day class focuses on understanding regulations and standards with illustrative examples of how to correctly implement them. Participants will conduct real-life situation evaluations. Documents discussed: the “Good Manufacturing” (GMP / QSR) regulation required by the US FDA (21 CFR820), the California FDB, the EN ISO 13485:2016 standard required by the European Commission and Health Canada, changes to the MDD and ISO guidelines including the latest ISO 14971 Risk Management:2012. After finishing the workshop, participants will improve their:

- Auditing techniques
- Procedural writing skills and
- Ability to manage external auditors.

The workshop does not require prior regulatory training. This workshop provides 1.4 recertification units for those seeking or renewing ASQ CQA, CBA or CQM or similar certifications.



THE INSTRUCTOR

David Awbery has been in the medical device/in-vitro diagnostic device industry since 1974. Seventeen of those years were spent working in industry for multinational companies that included eight years with two startups. He has been a contract medical device auditor for KEMA and TNO, and presently performs medical device/IVD audits on a contract basis for DEKRA. He does occasional in-house internal auditor training and performs internal audits as needed for companies in the Bay Area. He has a master’s degree in biological sciences and a secondary teaching credential.

Registration: Enrollment fee is \$150.

<http://www.ohlone.edu/org/commed/register.html>

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Questions?
Contact
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