May 31 – June 1, 2017 • Costa Rica Marriott Hotel San Jose
La Ribera de Belen • Heredia, Costa Rica

The ASQ Biomedical Division Proudly Presents

PROCESS VALIDATION AND INTEGRATING RISK MANAGEMENT

Early-bird pricing of only $499 if you register before April 15; $599 afterward.

ASQ Biomedical Division
The Global Voice of Quality®

Improper or ineffective process validations have resulted in a significant number of warning letters. End-of-the-line production testing alone is not enough to ensure quality of your manufacturing processes. Validation planning is now expected to include the integration of risk management.

Process validation has always been a challenge for medical device manufacturers. You're not alone; help is on its way. Look at our planned topics:

- FDA perspective on process validation
- Key elements and overview of process validation, e.g., MVP, IQ, OQ, PQ
- Best practices for process validation, e.g., sterilization, clean rooms, cleaning
- Software validation: equipment and manufacturing support (i.e., MES, documentation systems)
- Process validation interactions with MDSAP audit program
- Introduction to PFMEA and connecting the DFMEA to the PFMEA
- Best practices using statistics with validation
- Changes to the European Medical Device Regulation
- Risk management integration into the business
- How suppliers affect your validation and best practices to reduce variations
- Advanced process risk management tools, e.g., process hazard analysis, hazard analysis, and HACCP

FDA keynote speaker Captain Kimberly Lewandowski-Walker has been invited!

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MORE DETAILS AND REGISTRATION AT eventbrite.com/e/process-validation-and-integrating-risk-management-tickets-31386229056
OR tinyurl.com/ASQbiomed-PV

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