



Biomedical
Division
The Global Voice of Quality™

Call for Speakers



Costa Rica Marriott Hotel San Jose

May 31 – June 1, 2017, San Jose, Costa Rica

Process Validation and Integrating Risk Management

Interested in speaking? Need your response by January 31st....

For the 2017 seminar, we are looking for presentations that provide **interaction and active learning**. Attendees should leave each session with tools they can use immediately for Process Validation or Risk Management.

For the right presentation we will extend the normal 45 minute session to an hour or more. Areas of interest include:

- 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 (ie. 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 (need tools and hands on examples)
- 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

Speakers that are interested:

Speakers that can offer more than one presentation are encouraged.

One (1) complimentary conference registration will be awarded per speaker.

ASQ Biomedical Division appreciates your volunteerism in speaking at this high-quality educational event. As such, we will help cover travel expenses if your company does not wish to reimburse. Please contact the program co-chairs if there are questions about our policy on travel expenses. More information will follow once you are signed up as a speaker.

Interested in speaking?

Then send an email to the co-Chairs:

Jim Shore, gunnyshore@gmail.com

Edwin Garro, edwin@pxsglobal.com

Timing of the process:

1/31 – Speakers notify the co-Chairs that they will speak at the conference

2/28 – Speakers complete Submission Form for review, including abstract and bio

3/14 – Speakers are vetted by Committee

5/1 – Speakers submit their presentations to the Committee for review

Submission Form:

Please use the attached “Technical Presentation Submission” form to submit your session proposals. Ensure you complete the form in its entirety. If something is N/A; please put N/A.) All accepted speakers will be notified no later than March 30, 2017.

**Process Validation and Integrating Risk Management Seminar
Technical Presentation Submission Form
Due: February 28, 2017**

Presentation / Tutorial Title:

Presenter(s) (individual(s) who will attend the conference and present – please note that there is ONE complimentary registration per accepted presentation):

Summary (50-150 words to be used in the conference brochure / website, newsletters, etc.):

Abstract (200-500 words, must provide more detail than the Summary):

Expected Takeaways (please provide three):

Contact Information (duplicate this section for each presenter)

Principal Contact Name	
Organization/Affiliation	
Email Address	
Postal Mailing Address	
City, State, Zip Code	
Country	
Work Phone	
Home Phone	
Fax Number	
Biography (<100 words)	
Will your company pay for your travel expenses?	

Do you have a second presentation? If so, provide the following information:

Summary (50-150 words to be used in the conference brochure / website, newsletters, etc.):

Abstract (200-500 words, must provide more detail than the Summary):

Please email this completed form to: gunnyshore@gmail.com

Questions? Please contact the co-Chairs:

Jim Shore, gunnyshore@gmail.com

Edwin Garro, edwin@pxsglobal.com