

Invitation from ASQ Inland Empire August 19, 2020 Virtual Meeting

DATE:

Wednesday,
August 19, 2020

Corrective and Preventive Action (CAPA) Insights: Lessons Learned from FDA Inspections

This is a virtual/online meeting. Meeting information and instruction for how to join the meeting will be provided 24 hours before the event.

Time:

6:00 PM – 7:00 PM PDT

Cost: Free for ASQ members and non-members

To register for this online/virtual meeting, click [here](#).

Attendance at this meeting earns 0.5 RUs toward ASQ recertification.

NOTE: Be sure to use the same email address to join the virtual meeting as you use when registering in order to receive the RUs. You must register for the event and join virtually to receive RUs.

For more information about the Inland Empire ASQ Section, click [here](#).

For more information about our local Columbia Basin ASQ section and future upcoming events: www.asq614.org/



Toni Lucero-Aurelio

Director, Regulatory Affairs and Quality System Compliance
ASQ Certified Reliability Engineer and Quality Engineer

Over the past ten years, the US FDA has given increasing scrutiny to how medical device manufacturers manage their CAPA programs.

This presentation will discuss:

- Common difficulties encountered
- Recommended practical approaches to identifying actions needed
- Analysis and collection of data
- Verification of effectiveness

Toni will address these items and more. This is a great opportunity to learn more about the implications for our future professional – and personal – lives.

About the speaker: Toni Lucero-Aurelio attended the Transportation Design program at Art Center College of Design in Pasadena. She studied Global Enterprise Management at Ecole Supérieure de Commerce de Rouen and at University of Oxford, and received her Masters in Business Administration from Pepperdine University.

Toni has 15 years of experience in medical devices ranging from endovascular and drug-eluting stents, respiratory diagnostics and ventilators, to Class III active implantable devices, as her background progressed from R&D Engineering to Quality and Regulatory Affairs. In her current role as Director Regulatory Affairs and Quality System Compliance at Applied Medical in Rancho Santa Margarita, she oversees the Internal Audit and CAPA programs.

Toni is a member of Regulatory Affairs Professionals Society and is ASQ Certified Reliability Engineer, Quality Engineer and Six Sigma Black Belt.