



**Title Sharing Experiences for Creation of Sufficient Clinical Data**

**Date Tuesday, 08 September 2020 (9:00 AM) - Wednesday, 09 September 2020 (2:00 PM) Eastern Time (US & Canada)**

**Facilitators:**

- Julien Senac, PhD with TÜV-SÜD
- Ibim Tariah, PhD, formerly with BSI for over 20 years, now with R&Q Consulting
- Krishna Medasani, MD with Natus Medical Devices
- Catalina Suarez-Cuervo, MD with Conmed Devices
- Richard Holborow, MD, with BSI
- David R Rutledge, Pharm.D., Global Strategic Solutions and Workshop Leader

**Agenda:**

<b>9:00 AM EST</b>	<b>Start of day 1 workshop</b>
<b>9:00 - 10:30 AM EST</b>	<b>Welcome and Workshop Introduction. Six panel members state the problem from their perspective, set expectations, and comment on why we are here today. A review of Likert Survey development and analysis is provided. TÜV-SÜD and BSI, the two largest notified bodies with full designations for MDR and IVDR, share their perspectives. Manufacturer employees and consultant panelist provide practical solutions.</b>
<b>10:30 - 10:45 AM EST</b>	<b>15-minute break</b>
<b>10:45 AM - 12 PM EST</b>	<b>Speaker presentations: Interactive breakout sessions work on cases to present to panel. Identify targets to develop surveys for.</b>
<b>12:00 - 12:45 PM EST</b>	<b>Lunch</b>
<b>12:45 - 2:00 PM EST</b>	<b>Speaker presentations: Present cases back to panel members who comment on each approach to increase the probability of a successful application. End with a Q&amp;A session. Cases will represent Low Risk IVDs, MD Class 1r, Orthopedic Implants, CV/Peripheral Guidewires, Monitors, Implantable Valves, High Risk IVDs, and a humorous case for Star Wars fans to showcase principles.</b>
<b>2:15 PM EST</b>	<b>End of Day 1 Meeting</b>

<b>9:00 AM EST</b>	<b>Start of day 2 workshop</b>
<b>9:00 - 10:30 AM EST</b>	<b>Speaker presentations: Welcome and Workshop Introduction. Six panel members state the problem from their perspective, set expectations, and comment on why we are here today. A review of Big Data Hospital Networks is provided. TÜV-SÜD and BSI, the two largest notified bodies with full designations for MDR and IVDR, share their perspectives. Manufacturer employees and consultant panelist also provide practical solutions.</b>
<b>10:30 - 10:45 AM EST</b>	<b>15-minute break</b>

<b>10:45 AM - 12 PM EST</b>	<b>Speaker presentations: Interactive breakout sessions work on cases to present to panel. Identify targets to develop hospital network strategies.</b>
<b>12:00 - 12:45 PM EST</b>	<b>Lunch</b>
<b>12:45 - 2:00 PM EST</b>	<b>Speaker presentations: Present cases back to panel members who comment on each approach to increase the probability of a successful application. End with a Q&amp;A session.</b>
<b>2:15 PM EST</b>	<b>End of Day 2 Meeting</b>