WEDNESDAY, JULY 23, 2026, 1:30 PM-5:30 PM

SOCIETY OF ROBOTIC SURGERY – MEDICAL DEVICE REGULATION
Location:

Survey Notes:

1) Current pain points
2) 2026 challenges
3) Federal and Global Coordination

1:30pm Welcome:
ALL SESSION MODERATORS

1:35-1:55pm SESSION 1

1:35-1:55pm Guest Speaker: Assessing the Health of a RASD Regulatory Filing in 2026
Speaker:

Basic Tutorial on Process for RASD in 2026

Specific topics:
Paper on credentialing in the hospital: Vendor Neutral
Governance around Black Box to use as a learning system
DeNovo vs. Traditional 510K
Grid on Common vs. Different aspects to filing RASD device across markets

Telesurgery: Understanding the Regulatory Framework and Additional Requirements to Utilize (eg FDA/FCC/NTIA/OTSP)
Telecom: need for a globally understood framework in telesurgery (eg first responder example)

Panel on:
- USA
- EU
- Japan
- S.Korea
- China
- India
- Other?

Case Study on telesurgery: Courtesy of MedBot leadership Example of Questions

Case Studies
Present that case at a specific moment of decision:

New Bot: Human Factors Testing Moment of Decision

New Indication External RWE in Literature vs. IDE Study in different space Moment of Decision

New Instrument Testing Moment of Decision: Bench/Human Factors vs. Clinical Evidence

New Digital Capability: pick an example such of a software-based iteration: tool tracking or "invite a friend" moment of decision on global coordination/black box governance…..

New Frontiers Discussion:
Humanoids….
Automation… (eg. APRA-H program Omar mentioned)
Real AI in surgery…

1:55-2:45pm Global RASD and Digital Surgery Global Regulatory Review
On Regulatory And Market Access In The Following Countries:

- US FDA Update:
- EU CE Mark:
- EU CE Mark:
- Greater China:
- Brazil:
- Chile:

2:45-3:15pm SESSION 2: Clinical Data, Testing and Indications for Use in RASD
Surgeon / Hosp Admin Panel:
Medical Device Company Panel:

1. Clinical Data Requirements
   - What evidence thresholds are evolving for complex devices like robotic systems? How do regulators view RWE in complementing traditional clinical data?
   - Questions offered by Clinician / Industry Panel

2. Usability Testing
   - Emphasis on human factors engineering and surgeon training validation.
   - Questions offered by Clinician / Industry Panel

3. Post-Market Surveillance (PMS)
   - PMS integration with AI monitoring and digital feedback loops; proactive risk management (PRM).
   - Questions offered by Clinician / Industry Panel

4. Indications for Use (IFU)

- Aligning IFU evolution with new procedural evidence and AI enhancements, discussion of umbrella procedures and similar procedures, use of RWE for indication expansion
- Questions offered by Clinician / Industry Panel

3:15pm BREAK

3:30-4:15pm SESSION 3: Emerging Technology Focus
Surgeon / Hosp Admin Panel:
Medical Device Company Panel:

1. Telesurgery Developments
   - Regulatory Frameworks for Remote Proctoring vs. Full Telesurgery: Key safety and liability considerations that regulators foresee for cross-border telesurgery applications.
   - Questions offered by Clinician / Industry Panel

2. AI/ML in Robotic Platforms
   - Integration of Adaptive AI, Explainability, Validation, and GMLP (Good Machine Learning Practice): Discuss expectations for validating AI algorithms in robotic systems, particularly regarding continuous learning models.
   - Questions offered by Clinician / Industry Panel

3. Predetermined Change Control Plans (PCCP)
   - Adoption of FDA's AI Action Plan and PCCP Frameworks for Algorithm Updates: Discuss collaboration to define acceptable PCCPs that balance safety with innovation.
   - Questions offered by Clinician / Industry Panel

4:15-5:00pm SESSION 4: Global Regulatory Considerations
Surgeon / Hosp Admin Panel:
Medical Device Company Panel:
Panel:

1. EU Expert Panels (MDR)
   - Understanding their influence on high-risk (Class III) device approvals and clinical evaluation reports (CERs). Discuss how to better prepare for EU expert panel review, especially for novel robotic systems?
   - Questions offered by Clinician / Industry Panel

2. Presubmission Pathways (US FDA Q-Sub)
   - Maximizing value from pre-sub interactions for RASD and AI-driven systems. Discuss common pitfalls seen in Q-Submissions for robotic systems, and how to optimize early engagement.
   - Questions offered by Clinician / Industry Panel

3. IMDRF & Regulatory Harmonization
- Alignment across FDA, EU MDR, PMDA (Japan), NMPA (China) for AI/ML and robotic surgery. Discuss collaborative opportunities exist through IMDRF for harmonizing evidence requirements for robotic systems globally.
- Questions offered by Clinician / Industry Panel

5:00-5:30pm SESSION 5: Training and Security

Surgeon / Hosp Admin Panel:
Medical Device Company Panel:
Panel:

1. Cybersecurity and Data Privacy in Robotic Platforms
- Safeguarding sensitive patient and procedural data in connected surgical environments. How do regulators assess cybersecurity preparedness, and what emerging standards should manufacturers align with (e.g., ISO 27001, NIST)?
- Questions offered by Clinician / Industry Panel

2. Regulatory Sandbox Initiatives
- Participation in sandbox pilots (e.g., FDA's Digital Health Center of Excellence, MHRA's AI Airlock). How manufacturers may participate in regulatory sandbox initiatives for emerging technologies like AI and telesurgery.
- Questions offered by Clinician / Industry Panel

3. Training & Credentialing Requirements
- Regulatory expectations for training validation, proctoring, and competency tracking. How regulators view the role of simulation and AI-driven training in ensuring consistent operator performance.
- Questions offered by Clinician / Industry Panel

5:30pm Closing Remarks