

Regulatory Boundaries and Emerging Frameworks in Robotic, Incisionless, and Distributed Surgery

Hosted by: Society for Robotic Surgery (SRS)

Date: July 23, 2026

Time: 7:30AM - Noon

Session Objective

To review current international regulatory approaches to robotic, incisionless, automated, and distributed surgical systems; identify areas where regulatory boundaries remain unsettled; and define priority areas where the Society for Robotic Surgery can contribute technical, non-promotional input to regulatory science.

7:30 – 7:40AM

Opening Remarks: Why Regulatory Boundaries Matter Now

Moderators: Mohan Nathan and Binita Ashar

7:40 – 8:30 AM

Global Regulatory Updates: U.S., EU, China, Southeast Asia, and Latin America

Moderators: Binita Ashar and Mohan Nathan

TBD speakers with panel discussion

Core questions

- What categories of robotic, incisionless, or digitally enabled surgical systems are most active in your region?
- What regulatory questions are becoming more common or more difficult?
- Where are current frameworks working well?
- Where are the boundaries becoming less clear?

8:30 – 9:25 AM

Boundary Cases in Surgical Regulation: Automation, Incisionless Therapies, and Specialty-Specific Edge Cases

Moderators: Mohan Nathan and Binita Ashar

TBD speakers with panel discussion

Core questions

- When does automation change the regulatory question rather than simply add features?

- How should device manufacturers think about systems that combine imaging, targeting, navigation, and therapy delivery?
- How do specialty-specific applications stress existing frameworks?
- What can specialty-specific areas such as ophthalmology and neuro-intervention teach us about where current frameworks translate well and where they begin to strain?
- Where do current pathways remain predictable, and where do they become less predictable?

9:25 – 9:40 AM

Break

9:40 – 10:35 AM

Telerobotic and Distributed Surgical Care: What Falls Within Device Regulation and What Falls Outside It?

Moderators: Binita Ashar and Mohan Nathan

Framing remarks: Binita Ashar – *A Readiness Framework for Tele-Robotic Surgery Deployment*

Speakers and Moderated Discussion with Invited Regulatory Participants

- **Vipul Patel** — *Distributed Surgical Care: The Clinical Vision and the Regulatory Reality*
- **Marcio Moschovas** — *Training, Safety, and Clinical Readiness in Distributed Surgical Care*
- **Shadi Saikali** — *Building Safe Distributed Surgical Systems: Infrastructure, Oversight, and Evidence Needs*
- **TBD**– *What Rural Hospitals Would Need Before Saying Yes to Tele-Robotic Surgery*

Core questions

- Which aspects of telesurgery are device issues versus infrastructure, licensure, reimbursement, liability, or credentialing issues?
- What evidence is needed to support safety across a networked environment?
- How should latency, connectivity, cybersecurity, and fail-safe transition be addressed?
- What technical standards or collaborative science would be most useful?

10:35 – 11:20 AM

Cross-Cutting Evidence Expectations and the Most Unsettled Regulatory Boundaries

Moderators: Mohan Nathan and Binita Ashar

TBD Panel

Core questions

- What evidence models will be needed for evolving platforms rather than static products?
- How should regulators think about operator dependence, training, and learning curve?
- Where is international alignment realistic?
- What regulatory science gaps are most appropriate for SRS to help address?

11:20AM – Noon

Closing Discussion: Priority Areas for SRS Engagement

Moderators: Binita Ashar and Mohan Nathan