FDA 2024: REGULATOR SESSION

SRS 2024

FRIDAY, JUNE 21 • ACACIA BALLROOM 3-5

PROGRAM MODERATORS: Vipul Patel and Mohan Nathan

FDA COURSE DIRECTOR AND SPEAKER: Binita Ashar (FDA Center for Device and Radiologic Health)

FDA PARTICIPANTS: Binita Ashar– Director, Office of Surgical and Infection Control Devices
Mark Trumbore – Assistant Director, Robotically-Assisted Surgical Devices Team

3:00pm	**Opening by Vipul Patel: Purpose and Unique Opportunity in Today's Session**
3:05pm - 3:20pm	**FDA 2024 Update Lecture** *Binita Ashar*
3:20pm - 4:15pm	**Session 1: Alternate Questions Between Clinical and Industry Panel** **Clinicians Focus on Clinical Data and Evidence** **Industry Focus on Pathway and Testing** **Clinical Leaders:** *Inderbir Gill (Dean of Innovation USC), Chris Thompson (Harvard), Sharona Ross (President SRS), Adnan Siddiqui (Jacobs Institute), Ralph Clayman (Dean – Emeritus/Distinguished Professor UCI School of Medicine)* • **R. Clayman:** Certain procedures have very similar task loads… how do we ensure that surgeons are using the latest technology on label while also not burdening companies with onerous and repetitive data requirements? • **I Gill:** Increasingly algorithms and AI technology will offer enhancements to overlay insights such as no fly zones, anatomical enhancement, and decision support tools, many of these enhancements may utilize continuous learning technology which are difficult to utilize a gated regulatory pathway. How should surgeons & companies think about this evolving area? • **Adnan Siddiqui:** What are important considerations to have Non-US clinical data considered in the submission? • **C. Thompson:** Real world evidence (RWE) has been used for many years to support clearances. What key factors should companies consider when planning to use RWE data for to successfully support clearance/authorization of premarket RASD submissions? What challenges can you share? • **S. Ross:** How should surgeons & companies think about indications for use and the concept of umbrella procedures? **Industry Leaders Panel:** *Fred Moll, Ian Purdy, (Intuitive Surgical Regulatory), Todd Wilson (Endoquest), Beth Stephen (Medtronic Regulatory), Ying Mao (Ronovo), Marc Edgar (NVIDIA), John VanVleet (MMI)* • **M. Edgar:** With AI's ongoing expansion in surgical robotics, what challenges and opportunities does the FDA anticipate in regulating this field, and how is the agency addressing automation and AI in robotic systems? • **F. Moll:** What key lessons and themes has FDA has learned from reviews of RASD DeNovos that could be valuable for companies to know when preparing future submissions? • **I. Purdy:** Has FDA considered application of predetermined change control plans for RASDs? and if so where does the FDA envision opportunities for their use to support the evolution of RASDs? • **B. Stephen:** FDA introduced the term "premarket clinical performance validation test" in a recent DeNovo approval. What is FDA's definition for this term and what general considerations does FDA have for manufacturers designing a "premarket clinical validation test"? • **Y. Mao:** FDA has required training programs as Special Controls for RASD DeNovos with recent authorizations. What has FDA been learning from the training programs in context of safety and effectiveness in review? • **T. Wilson:** When should a company consider a Pre sub meeting and when should they not?

4:15pm - 5:00pm	**Session 2: Alternate Questions Between Clinical and Industry Panel** **Clinicians Focus on Evolution of Data and Next Gen Capabilities** **Industry Focus on Evolution Pathways of New Technology** **Clinical Leaders:** *Ajit Sachdeva (Head of Education, ACS), Rick Satava (U of Washington), Martin Martino (SRS Past President),S Horgan (UCSD)* • **S. Horgan:** At USCD we have a developed Multidisplinary Center for the Future of Surgery: How does and should the FDA partner with practicing surgeons in evaluating and accelerating innovation? • **A. Sachdeva:** How should companies go about validating their training? How should companies try to demonstrate usability or human factors testing and how can they determine the best setting for such testing to take place? • **R. Satava:** Evidence based medicine requires evidence based education. Simulation is rapidly advancing as a tool to trial and demonstrate capabilities without going through human cases. How is the agency viewing simulation as a means of evidence generation? • **M. Martino:** Can you share insights gained from establishing the Digital Health Center of Excellence and how these experiences are shaping the FDA's regulation of robotics? **Industry Leaders Panel:** *Mischa Dohler (Ericsson Telecom), Jonathan Chen (Microport), Joy Sacmar (Johnson & Johnson Regulatory), Mark Toland (MMI), Jayaweera Sudharman (NSF)* • **J. Sacmar:** As companies increasingly seek to develop software enhancements to existing robotic platforms, how is the FDA expecting to adapt to allow a pathway for iteration via software capabilities? • **M. Dohler:** Robotic devices can increasingly be networked and remotely controlled through advances in spectrum. How has the FDA approached regulation and requirements for telesurgery? • **J. Chen:** Does the FDA Guidance on Balancing Premarket and Postmarket clinical data from 2015 still reflect FDA's current thinking on this topic? (If not, in what ways have FDA's positions changed?) Does FDA have best-practice considerations for Industry preparing evidence plans using a balanced pre-/post-market approach? Is FDA's evaluation impacted if the premarket data are RWD or non-US data? • **M. Toland:** What is the FDA's perspective on utilizing post-market registry data to expand indications? Could you provide an example where this approach has been or could be successful? • **J. Sudharman:** As a participant in the International Medical Device Regulators Forum (IMDRF), is FDA involved in efforts to harmonize the regulation of surgical robotics internationally, or is there a perceived need for such efforts?
5:00pm - 5:20pm	**Open Q&A**
5:20pm - 5:30pm	**Final Closing Remarks** *Binita Ashar and Vipul Patel*