AdvaMed
Advanced Medical Technology Association
Events & Education

510(k) and De Novo Submissions Workshop

Virtual
February 9 – 10, 2027

Feb 9, 2027

9:00 – 9:05 am **Welcome and Introductions**

9:05 – 10:30 am **The Law and Regulations**
Sally Maher, Regulatory Consultant, Sally Maher Consulting

- 510(k) definition
- 510 and 513 FDCA
- Guidance for 510(k): general & product specific
  - How to find it
  - How to use it
- Different types of 510(k)s; which to use
- Review of bundling 510(k)s
- FDA Product Codes – Activity

10:30 – 10:45 am **Break**

10:45 pm – 12:00 pm **510(k) Strategy and Planning**
Tony Blank, Senior Director of Regulatory Affairs, AtriCure

- Staff involved
- Role of each function
- RA responsibilities
- Use of guidance
- Global considerations
- Pre-submissions
- Predicates
- Breakthrough Devices Program
- Safer Technologies Program

12:00 – 1:00 pm **Lunch Break**

1:00 – 2:15 pm **Preparing the Submission**
Jemin Jay Dedania, Senior Director of Regulatory Affairs and Compliance at the National Evaluation System for health Technology, MDIC
Melissa Hall, Founder and Principal Consultant, Statera Regulatory Consulting

- General information including how to select a predicate device
- Assembling the 510(k)
- eSTAR

2:15 – 2:30 pm **Break**

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Important Notice
The information provided in this course represents the personal opinions of the instructors and does not necessarily represent the opinions of AdvaMed staff. Companies relying on the information do so at their own risk and assume the risk of any subsequent liability that results from relying on the information. The information does not constitute legal advice.

2:30 – 3:15 pm **The FDA Review Process**

Sapana Patel, Policy Analyst, FDA

- How it works at FDA
- FDA/industry interactions
- Refuse to Accept
- Submission Issue meetings
- FDA holds
- Interactive review
- Least Burdensome flag
- Current pilots

3:30 – 4:00 pm **CDRH Ombudsman Program**

Ken Skodacek, CDRH Deputy Ombudsman, FDA

- Confidential, independent, impartial resource for resolving disputes
- Formal appeals process (21 CFR 10.75)

Feb 10, 2027

9:00 – 10:15 am **Clearance: Launch and After**

Tony Blank, Senior Director of Regulatory Affairs, AtriCure

- What clearance does and does not mean
- Promotional practices for 510(k) devices
  - FDA
  - FTC
- Complaint Handling and MDRs
- When to File a New 510(k) for Device Modifications
- Catch-up 510(k)s

10:15 – 10:30 am **Break**

10:30 – 11:00 am **De Novo**

McKenzie Cato, Senior Associate, King & Spalding

- Definition of a De Novo
- Final Rule on De Novo
- When De Novo is used
- Differentiation from 510(k)

11:00 – 11:30 am **Regulatory Strategy for De Novo**

Speaker TBA

- Key eligibility criteria
- Benefit-risk analysis

11:30 am – 12:00 pm **Preparing the De Novo Submission**

Speaker TBA

- Content
- Assembling the submission

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12:00 – 1:00 pm **Lunch Break**

1:00 – 1:30 pm **FDA Review Process for De Novo**
McKenzie Cato, Senior Associate, King & Spalding

- Use of Pre-Submission meeting
- Rationale for De Novo
- Clinical Protocols
- Special Controls
- Benefit-Risk Considerations

1:30 – 2:00 pm **Maintenance of a Granted De Novo**
Peter Yang, De Novo Program Lead, FDA

- Post-market requirements
- Classification Order
- De Novo database, granting order, decision summary
- Use as a predicate
- Making changes to granted De Novo device

2:00 – 2:15 pm **Break**

2:15 – 3:15 pm **Open Forum Q&A with the Experts**
Led by: ***Tony Blank, Senior Director of Regulatory Affairs, AtriCure***

Attendees have the opportunity to engage directly with the available regulatory experts in a secure, open forum format. Participants are encouraged to ask detailed, real-world questions related to their own submission challenges, FDA interactions, and regulatory strategy considerations.

3:15 pm **Adjournment**

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