AdvaMed
Advanced Medical Technology Association
Events & Education

510(k) Submissions Workshop

AdvaMed Office
1301 Pennsylvania Ave. N.W. Suite 400 Washington, D.C.
February 3 – 4, 2025

Feb 3, 2025

8:30 – 9:00 am **Registration Check-In and Continental Breakfast**

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 am – 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 **Networking Lunch**

1:00 – 2:15 pm **Preparing the Submission**
Jemin Jay Dedania, Director of Regulatory Affairs, Global Regulatory, Hogan Lovells
Melissa Hall, Founder and Principal Consultant, Statera Regulatory Consulting

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

AdvaMed
Advanced Medical Technology Association
Events & Education

2:15 – 2:30 pm **Break**

2:30 – 3:15 pm **The FDA Review Process**
Angela DeMarco, Biomedical Engineer, Center for Devices and Radiological Health, FDA

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

3:15 – 3:30 pm **Break**

3:30 – 4:00 pm **CDRH Ombudsman's Office**
Ken Skodacek, Center for Devices and Radiological Health, Deputy Ombudsman, FDA

- Roles & Responsibilities
- Appeals Process

Feb 4, 2025

8:30 – 9:00 am **Continental Breakfast**

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**
Elaine Tseng, Counsel, King & Spaulding

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

AdvaMed
Advanced Medical Technology Association
Events & Education

11:00 – 11:30 am **Regulatory Strategy for De Novo**
Ginny Hu, Director, Regulatory Affairs, Dexcom
- Key eligibility criteria
- Benefit-risk analysis

11:30 am – 12:00 pm **Preparing the De Novo Submission**
Bryan Osborne, Senior Director, Regulatory Affairs, Dexcom
- Content
- Assembling the submission

12:00 – 1:00 pm **Networking Lunch**

1:00 – 1:30 pm **FDA Review Process for De Novo**
Pooja Panigrahi, Policy Analyst, FDA
Peter Yang, De Novo Program Lead, Office of Regulatory Programs, Office of Product Evaluation, Center for Devices and Radiological Health, FDA
- 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, Office of Regulatory Programs, Office of Product Evaluation, Center for Devices and Radiological Health, 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 – 4:15 pm **Applied Learning and Breakout Discussions**
**In person participants, only*
- 510(k) & De Novo Recap
- Facilitated Breakout Group Deep Dive - Hypothetical Case Studies & Key Takeaways
- Regroup for Q&A

4:15 pm **Adjournment**