

# 510(k) and De Novo Submissions Workshop

Virtual Event

February 8 - 10, 2022

*\*Schedule Reflected in Eastern Time*

## February 8, 2022

- 11:00 am – 11:05 am**     **Welcome and Introductions**
- 11:05 am – 11:50 am**     **The Law and Regulations**  
*Sally Maher, 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
- 11:50 am – 12:35 pm**     **510(k) Strategy and Planning**  
*Sally Maher, Sally Maher Consulting*
- Staff involved
  - Role of each function
  - RA responsibilities
  - Use of guidance
  - Global considerations
  - Pre-submissions
  - Predicates
  - Breakthrough Devices Program
  - Safer Technologies Program
- 12:35 pm – 12:50 pm**     **Group Q&A**
- 12:50 pm – 1:05 pm**     **Break**
- 1:05 pm – 2:20 pm**     **Preparing the Submission**  
*Wil Henderson, Hogan Lovells*
- General information including how to select a predicate device
  - Assembling the 510(k)
  - eCopy
- 2:20 pm – 2:35 pm**     **Break**

### **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.



**AdvaMed**

Advanced Medical Technology Association  
Events & Education

**2:35 pm – 3:50 pm**

**The FDA Review Process**

*Angela DeMarco, FDA*

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

**3:50 pm – 4:20 pm**

**CDRH Ombudsman's Office**

*Ken Skodacek, FDA*

- Roles & Responsibilities
- Appeals Process

**4:20 pm – 4:35 pm**

**Group Q&A**

**February 9, 2022**

**11:00 am – 11:01 am**

**Welcome**

**11:01 am – 12:20 pm**

**Clearance: Launch and After**

*Tony Blank, 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

**12:20 pm – 12:30 pm**

**Group Q&A**

**12:30 pm – 12:45 pm**

**Break**

**12:45 pm – 1:15 pm**

**De Novo**

*Quynh Hoang, King & Spalding*

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

**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.



**AdvaMed**

Advanced Medical Technology Association  
Events & Education

- 1:15 pm – 1:45 pm**      **Regulatory Strategy for De Novo**  
*Holly Drake, Dexcom*  
*Michelle Monroe, Dexcom*
- Key eligibility criteria
  - Benefit-risk analysis
- 1:45 pm – 2:15 pm**      **Preparing the De Novo Submission**  
*Holly Drake, Dexcom*  
*Michelle Monroe, Dexcom*
- Content
  - Assembling the submission
- 2:15 pm – 2:30 pm**      **Group Q&A**
- 2:30 pm – 2:45 pm**      **Break**
- 2:45 pm – 3:15 pm**      **FDA Review Process for De Novo**  
*Peter Yang, FDA*
- Use of Pre-Submission meeting
  - User Fee
- 3:15 pm – 3:45 pm**      **Maintenance of a Granted De Novo**  
*Peter Yang, FDA*
- Post-market requirements
  - Classification Order
  - De Novo database, granting order, decision summary
  - Use as a predicate
- 3:45 pm – 4:00 pm**      **Group Q&A**
- 4:00 pm**                      **Closing Remarks and Adjourn**

**February 10, 2022**

- 12:00 pm – 1:15 pm**      **Applied Learning and Discussion**
- Hypothetical Case Study Review
  - Facilitated Breakout Group Deep Dive
  - Key Takeaways
  - Final Program Q&A

**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.