AdvaMed
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510(k) Submissions Workshop

Virtual Event
February 22 - 23, 2021
**Schedule Reflected in Eastern Time*

Feb 22, 2021

11:00 – 11:05 am **Welcome and Introductions**

11:05 am – 12:20 pm **The Law and Regulations**
Sally Maher, Maher Consulting Group

- 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
- CDRH organizational structure
- FDA Product Codes - activity

12:20 – 12:25 pm **Break**

12:25 – 1:40 pm **510(k) Strategy and Planning**
Sally Maher, Maher Consulting Group

- Staff involved
- Role of each function
- RA responsibilities
- Use of guidance
- Global considerations
- Pre-submissions
- Predicates

1:40 – 1:50 pm **Break**

1:50 – 3:20 pm **Preparing the Submission**
Wil Henderson, Hogan Lovells

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

3:20 – 3:25 pm **Break**

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3:25 – 4:55 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

Feb 23, 2021

11:00 – 12:30 pm **Clearance: Launch and After**
Tony Blank, Infinity Biomedical Group
- What clearance does and does not mean
- Promotional practices for 510(k) devices
  - FDA
  - FTC
- Complaint Handling and MDRs

12:30 – 12:35 pm **Break**

12:35 – 1:05 pm **When to File a New 510(k) for Device Modifications**
Tony Blank, Infinity Biomedical Group
- Catch-up 510(k)s

1:05 – 1:25 pm **510(k) Post-Clearance Exercise**
Quynh Hoang, King & Spalding

1:25 – 1:35 pm **Break**

1:35 – 2:35 pm **De Novo**
Peter Yang, FDA
- Definition of a De Novo
- When De Novo is used
- Differentiation from 510(k)
- Format
- Use of pre-sub
- Post market requirements
- Use as a predicate

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2:35 – 2:40 pm **Break**

2:40 – 3:25 pm **Regulatory Strategy for De Novo**
Holly Drake, Dexcom

- Key eligibility criteria
- Benefit-risk analysis
- Case example

3:25 – 4:10 pm **CDRH Ombudsman's Office – Roles & Responsibilities and the Appeals Process**
Ken Skodacek, FDA

4:10 – 4:15 pm **Closing Remarks and Adjourn**