510(k) Submissions Workshop
AdvaMed Office
701 Pennsylvania Ave. N.W. Suite 800 Washington, D.C.
October 7-8, 2019

Oct 7, 2019

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
- 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

10:30 – 10:45 am Break

10:45 – 12:15 pm 510(k) Strategy and Planning
    Fatemeh Razjouyana, BD
- Staff involved
- Role of each function
- RA responsibilities
- Use of guidance
- Global considerations
- Pre-submissions
- Predicates

12:15 – 1:30 pm Networking Lunch

1:30 – 3:15 pm Preparing the Submission
    Linda Chatwin, Emergo
- General information including how to select a predicate device
- Assembling the 510(k)
- eCopy

3:15 – 3:30 pm Break

Important Notice
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3:30 – 4:00 pm  
30 min exercise on 510(k)  
*Fatemeh Razjouyan, BD*

4:00 – 5:00 pm  
Networkig Reception

**Oct 8, 2019**

8:30 – 9:00 am  
Continental Breakfast

9:00 – 10:45 am  
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

10:45 – 11:00 am  
Break

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 – 1:30 pm  
Networking Lunch

1:30 – 2:00 pm  
When to File a New 510(k) for Device Modifications  
*Tony Blank, Infinity Biomedical Group*
- Catch-up 510(k)s

2:00 – 2:30 pm  
Post-Clearance Exercise  
*Linda Chatwin, Emergo*

2:30 – 2:45 pm  
Break
2:45 – 3:45 pm  De Novo
Sergio M. de del Castillo, 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

3:45 – 4:15 pm  Q&A

4:15 pm  Adjournment

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