510(k) Submissions Workshop
Courtyard Irvine Spectrum
Irvine, CA
February 24 – 25, 2020

Feb 24, 2020

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, 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

10:30 – 10:45 am  Break

10:45 – 12:15 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

12:15 – 1:30 pm  Networking Lunch

1:30 – 3:15 pm  Preparing the Submission
Wil Henderson, Hogan Lovells
- 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)  
Wil Henderson, Hogan Lovells

4:00 – 5:00 pm  
Networking Reception

Feb 25, 2020

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  
  o FDA  
  o 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  
510(k) Post-Clearance Exercise  
Quynh Hoang, King & Spalding

2:30 – 2:45 pm  
Break
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2:45 – 3:45 pm  De Novo
Sergio 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 – 4:30 pm  Regulatory Strategy for De Novo
Holly Drake, Dexcom
- Key eligibility criteria
- Benefit-risk analysis
- Case example

4:30 pm  Adjournment