



AdvaMed

Advanced Medical Technology Association
Events & Education

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
Kristin Davenport, Covington & Burling LLP

- 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 Razjouyan, 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

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.



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- 3:15 – 3:30 pm** **Break**
- 3:30 – 4:00 pm** **30 min exercise on 510(k)**
Fatemeh Razjouyan, BD
- 4:00 – 5:00 pm** **Networking 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

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2:00 – 2:30 pm	Post-Clearance Exercise <i>Linda Chatwin, Emergo</i>
2:30 – 2:45 pm	Break
2:45 – 3:45 pm	De Novo <i>Sergio M. de del Castillo, FDA</i> <ul style="list-style-type: none">• 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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