



510(k) Submissions “The Course” for Beginning RA Professionals for Preparing a 510(k)

Washington, DC
October 26 – 27, 2009

Monday, October 26th

8:30 – 9:00

REGISTRATION AND CONTINENTAL BREAKFAST

9:00 – 9:05

Welcome

Thomas Maeder, Executive Director, MTLI, AdvaMed

9:05 – 10:25

The Law and Regulations

Heather Rosecrans, Director, 510(k) Staff, FDA/CDRH

Michael Santalucia, Vice President, RA, Global Scientific Affairs, Bausch & Lomb

- The legal basis for a 510(k): The potential consequences of not submitting a 510(k)
- Different types of 510(k)s
- How to determine if a 510(k) is needed
- How to select the appropriate type of 510(k)s
- Review of bundling 510(k)s

10:25 – 10:50

BREAK

10:50– 12:20

Assembling the 510(k)

Sheri Hall, Vice President, Regulatory Affairs, BD

- How to select a predicate device
- How to collect and organize the data and actually prepare the 510(k)
- Standards Data Report - Form 3654

12:30 – 1:30

LUNCH

- 1:30 – 3:30** **Assembling the 510(k) Exercise**
Sheri Hall, Vice President, Regulatory Affairs, BD
- 3:30 – 3:50** **BREAK**
- 3:50 – 4:40** **513(g) Requests for Information and Requests for Designation**
Lawrence “Jake” Romanell, Office of the Center Director, FDA/CDRH
- 4:40 – 5:00** **QUESTIONS & ANSWERS**
- 5:00** **ADJOURNMENT**

Tuesday, October 27th

- 8:30 – 9:00** **CONTINENTAL BREAKFAST**
- 9:00 – 10:30** **Strategy and Planning**
Michael Santalucia, Vice President, RA, Global Scientific Affairs, Bausch & Lomb
- Factors to consider when developing a strategic and regulatory plan
 - How to define the role of the regulatory professional
 - How to use FDA guidance when planning and organizing the 510(k)
 - General vs specific use
- 10:30 – 10:50** **BREAK**
- 10:50 – 12:00** **The FDA Review Process**
Sheri Hall, Vice President, Regulatory Affairs, BD
Marjorie Shulman, Consumer Safety Officer, Pre-market Notification Staff, FDA/CDRH
- The review process for traditional 510(k)s
 - Interacting with FDA before and during the review process
 - The role of the regulatory professional in resolving disputes
 - How the FDA “holds” process work
- 12:00 – 1:00** **Lunch Presentation: Ombudsman, Office of the Center Director, CDRH/FDA**
Les Weinstein, Ombudsman, FDA
- 1:00 – 2:00** **Interactive Exercise**
- 2:00 – 2:20** **BREAK**
- 2:20 – 3:00** **510(k) Post-Clearance Process**
All Faculty
- Deciding when to submit a new 510(k) for a device modification

- Obtaining information about another company's devices
- Modifications
- Life cycle considerations
- Promotional practices

3:00 – 3:50	510(k) Post-Clearance Process Exercise <i>All Faculty</i>
3:50 – 5:00	QUESTIONS & ANSWERS <i>All Faculty</i>
5:00	ADJOURNMENT

Important Notice

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