



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

Las Vegas, NV
February 22 – 23, 2010

Monday, February 22nd

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| 8:30 – 9:00 | REGISTRATION AND CONTINENTAL BREAKFAST |
| 9:00 – 9:05 | Welcome
<i>Thomas Maeder, Executive Director, MTLI, AdvaMed</i> |
| 9:05 – 10:25 | The Law and Regulations
<i>Heather Rosecrans, Director, 510(k) Staff, FDA/CDRH</i>
<i>Michael Santalucia, Vice President, RA, Global Scientific Affairs, Bausch & Lomb</i> <ul style="list-style-type: none">• 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)
<i>Connie Finch, Vice President, Regulatory Affairs, BD</i>
<i>Sheri Hall, Vice President, Regulatory Affairs, BD</i> <ul style="list-style-type: none">• 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
<i>Connie Finch, Vice President, Regulatory Affairs, BD</i> |

3:30 – 3:50	BREAK
3:50 – 4:40	513(g) Requests for Information and Requests for Designation <i>Lawrence “Jake” Romanell, Office of the Center Director, FDA/CDRH</i>
4:40 – 5:00	QUESTIONS & ANSWERS
5:00	ADJOURNMENT
5:00 – 6:00	RECEPTION

Tuesday, February 23rd

8:30 – 9:00	CONTINENTAL BREAKFAST
9:00 – 10:30	Strategy and Planning <i>Michael Santalucia, Vice President, RA, Global Scientific Affairs, Bausch & Lomb</i> <ul style="list-style-type: none">• 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 <i>Connie Finch, Vice President, Regulatory Affairs, BD</i> <i>Marjorie Shulman, Consumer Safety Officer, Pre-market Notification Staff, FDA/CDRH</i> <ul style="list-style-type: none">• 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 <i>Les Weinstein, Ombudsman, FDA</i>
1:00 – 2:00	Interactive Exercise
2:00 – 2:20	BREAK
2:20 – 3:00	510(k) Post-Clearance Process <i>All Faculty</i> <ul style="list-style-type: none">• 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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