

## Amsterdam 510(k) Workshop

The Amsterdam 510(k) Workshop is a 2-day event. Presentations will be in English and seating is limited to 100 attendees. The opening remarks for the workshop will begin at 9am (09:00) on October 11 and we expect to end the day around 5pm (17:00). Snacks will be provided a 10am (10:00) and 3pm (15:00) each day. Lunch will be provided in the City Cafe at the hotel around Noon (12:00) each day. Attendees are on their own for breakfast and dinner each day. However, I expect that many of us will go out to dinner as a group to continue the networking activities. You could also ask any of the speakers to meet you for breakfast if you wanted to speak with them privately.

Travel expenses and the hotel rooms are the responsibility of attendees and not included in the registration.

### Hotel Info

Here is the hotel information in order to make reservations:

DoubleTree by Hilton Amsterdam Centraal Station  
Oosterdoksstraat 4, 1011DK, Amsterdam  
Telephone: [+31 \(0\)20 530 0800](tel:+31205300800)  
Email: [AMSCS.Events@hilton.com](mailto:AMSCS.Events@hilton.com)  
[Amsterdam.doubletree.com](http://Amsterdam.doubletree.com)



The location was selected so you can also easily take a train and walk next door to the hotel.

The cost of rooms, not including taxes or parking, is as follows:

- Twin Guest Room = €224
- Queen Executive Room = €269
- Queen Jr. Suite = €305
- Executive Suite w/ View = €314
- King Master Suite w/ Terrace = €422



### Workshop Details

During the workshop there will be multiple speakers presenting on specific technical requirements for the various sections of a 510(k) submission. Therefore, I expect some topics will not be applicable to the products that you might be working on while others may be very timely. During entire workshop there will be a breakout area in the hallway outside the London conference rooms on the 1st floor. There will be beverages available to attendees throughout the day, and you are encouraged to network with other attendees and speakers. There will also be



Q&A sessions after each speaker during the two days. We will even be conducting a few exercises to give attendees practice in navigating the FDA databases and creating some of the documents required for your next submission.

The following speakers are scheduled to speak at the workshop:

- Niels van Tienen (clinical study expert)
- Leo Eisner (electrical safety expert)
- Adam Shames (human factors testing)
- Wolfgang Huber (software validation and IEC 62304)
- Rob Packard (FDA eCopy, Pre-Sub Meetings & Predicate Selection)
- Mary Vater (Implementing Design Controls & Risk Management)
- Biocompatibility - Speaker TBD

Most of the presentations will be approximately 45 minutes in length to give people time to ask questions and so we can have frequent breaks. As other speakers are confirmed, I will add their name to the landing page on the website and include a link to their company or LinkedIn profiles. We are working on a draft agenda in parallel, but until the speaker list is finalized the agenda will not be released.

### **Free Webinars & Homework Prior to the Workshop**

We will also be offering a few free webinars during the next few months on these topics to promote the event, but also so people can learn a little about the topics before the workshop. Hopefully, this will eliminate the need for me to explain "What is a 510(k)?"

### **Pricing**

The current cost of registration is \$1,195. This reduced pricing ends August 10. The price increases \$200/month after that:

- \$1,395 from August 11-September 10
- \$1,595 from September 11-October 10

Send me an email if you prefer to be invoiced instead of paying via PayPal.

### **What's in the "SWAG bag"?**

Yes, we will have a bag for each attendee that includes promised information and marketing materials. Here's the current list of promised items:

- A physical copy of my book "[How to prepare your 510\(k\) in 100 days.](#)"
- A flash drive with my 510(k) templates in PDF and Word format - includes pre-sub and De Novo templates
- A flash drive with presentation slide decks for each of the speakers
- Business cards and marketing material for the sponsors--currently Medical Device Academy, Inc. and [Factory-CRO](#)

### **Bring your laptop and a power adapter**

There will be free WiFi for attendees and the layout will be a classroom setting with tables. Therefore, we encourage you to bring your computer to take notes and so you can visit websites that are described as resources by the speakers. You can also open the templates and slide decks for each of the speakers in order to take notes electronically. You can even send emails. Power outlets will be provided, but not adapters to European style outlets.

In order to register for the event, you can pay the early bird price via PayPal directly on the website. Alternatively, I can invoice you by email with payment instructions for a wire transfer. I'm open to other payment arrangements if you have suggestions. Here's the registration webpage link:

<http://medicaldeviceacademy.com/amsterdam-510k-workshop/>

### **Learn how to say 4 things in Dutch**

A friend of mine from my local Toastmaster's group is a worldly traveler. She recommends that you learn how to say 4 things in a native language when you travel: 1) Hello, 2) Thank you, 3) What is your name? and 4) Where is the bathroom? Therefore, I am going to try learning a little Dutch from my Pimsleur CDs over the next 3 months. I hope to speak well enough to order meals and drinks in the evening, and to greet everyone at the conference in poorly spoken Dutch instead of English--my native language. Hopefully, I will also be able to find the bathroom.

