Las Vegas 510(k) Workshop

The Las Vegas 510(k) Workshop is a 2-day event. Presentations will be in English and seating is limited to 60 attendees. The opening remarks for the workshop will begin at 9:00 am on March 21 and we expect to end the day around 6:00 pm. Snacks will be provided a 10:45 am and 2:45 pm each day. Lunch will be provided at the hotel around Noon 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.

Pricing

The cost of registration is $995. Send me an email if you prefer to be invoiced instead of paying via PayPal or if you want to pay by credit card through https://squareup.com/.

Hotel Info

Travel expenses and the hotel rooms are the responsibility of attendees and not included in the registration. The cost of rooms, not including taxes or parking, is $149 for single occupancy and $169 for double occupancy. Here is the hotel information in order to make reservations: http://embassysuites3.hilton.com/en/hotels/nevada/embassy-suites-by-hilton-las-vegas-LASESES/index.html

Embassy Suites by Hilton Las Vegas
4315 Swenson Street
Las Vegas, NV 89119 USA
Tel: +1.702.795.2800

Workshop Details

The speaking room for this event will be the Flamingo Ballroom. 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. Attendees can also network with other attendees and speakers throughout the workshop. 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.

Event Speakers
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)
- Thor Rollins (biocompatibility expert)

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.

Tentative Agenda Day 1

Time	Speaker	Topic
8:00		
8:30	N/A	Registration & Networking
9:00		Welcoming remarks, 510(k) Process & Predicate Selection
9:30	Rob Packard	Indications for Use, Vol 4 Doc 1 & 2
10:00	Mary Vater	510(k) Design & Risk Requirements
10:45	N/A	Morning Break & Networking
11:00	Wolfgang Huber	Traceability Matrices & Agile Product Development
11:30		
12:00	N/A	Lunch & Networking
12:30		
13:00	Mary Vater	Creating a Testing Plan
13:30	Leo Eisner	Intro to 510(k) process for Section 17 & IEC 60601
14:00		Standards Update
14:30	Rob Packard	Cover letter, Vol 3 Doc 3 & Form 3514, Vol 3 Doc 1 and 2
14:45	N/A	Afternoon Break & Networking
15:00	Niels van Tienen	Section 20 - When are clinical studies required? and What are the requirements for approving a study?
15:30		Considerations. OUS data for 510k - US data for EU.
16:00	Adam Shames	How to pass human factors testing
16:30		
17:00	Thor Rollins	Explaining the differences between the FDA guidance of
17:30		application of ISO 109931-1 and the actual standard

Tentative Agenda Day 2

Time	Speaker	Topic
8:00	Rob Packard	Pre-submission requests
8:30		Table of Contents, Vol 2 Doc 1 & Project Management
9:00	Mary Vater	Biocompatibility Summary, Vol 15 Doc 1
9:30		
10:00	Thor Rollins	The impact of adding or changing a colorant to a medical device
10:45	N/A	Morning Break & Networking
11:00	Leo Eisner	Recent FDA issues for Section 17
11:30		
12:00	N/A	Lunch & Networking
12:30		
13:00	Rob Packard	Validation Requirements - Benchtop, Animal Studies & Human Clinicals
13:30	Niels van Tienen	Major steps in starting a clinical study. Control mechanisms in clinical trials.
14:00		
14:30	Mary Vater	Secton 18
14:45	N/A	Afternoon Break & Networking
15:00	Adam Shames	Integrating HF into Design Controls
15:30		
16:00	Wolfgang Huber	Section 16 - Software Validation requirements
16:30		

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)?"

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 3-ring binder containing the following:
    - Hard copy the book "How to prepare your 510(k) in 100 days"
    - Notes pages for each of the presenters' slide decks
    - Hard copies of the 510(k) templates for you to take notes on
- A flash drive with my 510(k) templates in PDF and Word format - includes pre-subs and De Novo templates
- A flash drive with presentation slide decks for each of the speakers

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 outlet adapters for attendees from outside the USA).

In order to register for the event, you can pay via PayPal directly on the website. Alternatively, I can invoice you by email with payment instructions for a wire transfer or credit card payment through https://squareup.com/. I'm open to other payment arrangements if you have suggestions. Here's the registration webpage link:

http://medicaldeviceacademy.com/las-vegas-510k-workshop/