Global CompliancePanel

Netzealous
Knowledge, a Way Forward…

2-day In-person Seminar:

FDA's Software Monsters: Cybersecurity, Interoperability, Mobile Apps and Home Use

SFO, CA

September 7th & 8th, 2017

9:00 AM to 4:30 PM

Price

Price: **$1,295.00**

(Seminar for One Delegate)

Register now and save $200. (Early Bird)

Register for 5 attendees

Price: **$3,885.00** You Save: $2,590.0 (40%)*

~~$6,475.00~~

ENROLL

***Please note the registration will be closed 2 days (48 Hours) prior to the date of the seminar.*

Casper Uldriks

ex-FDA Expert and former Associate Center Director of CDRH

Casper (Cap) Uldriks through his firm "Encore Insight LLC," brings over 32 years of experience from the FDA. He specialized in the FDA's medical device program as a field investigator, served as a senior manager in the Office of Compliance and an Associate Center Director for the Center for Devices and Radiological Health. He developed enforcement actions and participated in the implementation of new statutory requirements. His comments are candid, straightforward and of practical value. He understands how FDA thinks, how it operates and where it is headed. Based on his exceptionally broad experience and knowledge, he can synthesize FDA's domestic and international operational programs, institutional policy and thicket of legal variables into a coherent picture.

Overview :

Software's level of complexity and use is expanding at exponential levels. Likewise, the potential risks to health follow suit. Ransomeware attacks hold your software hostage until you pay hundreds or thousands of dollars. Life supporting and life sustaining healthcare grinds to a halt. Extracting personal healthcare information is another plague that has a huge financial incentive for hackers. Your software is running on thin ice.

Agenda:

Day One

9:00 am - 10:15 am

Lecture 1: FDA authority and regulatory program

- Types of Software are devices
- Regulatory strategy
- Risk classification
- Office of the National Coordinator (ONC) for Health Information Protection
- Software regulatory applications
- FDA Guidance
  - Premarket submissions
  - Paradigms: aeronautics

10:15am - 10:30am **Break**

10:30 am - 12:00 am

- Quality System Regulation (QSR)
  - Design verification and validation
  - Voluntary standards
  - Corrective and Prevent Action Plans
- Voluntary standards
- Recalls:
  - Service / maintenance / recall.
  - Implementation strategy
- Corrections and Removals reporting
- Updates: FDA vs. non-FDA
- Predictive analytics

12:00 PM - 1:00 PM Lunch

1:00 PM - 2:30 PM

Lecture 2: Interoperability

- Compatibility by design
  - Hardware
  - Software
- Labeling
  - Precautions
  - Instructions for use
- Use of Voluntary Standards

2:30 PM - 2:45 PM **Break**

- Proprietary information
- Failure management / follow up
- User's vs. manufacturer's legal responsibility
  - System configuration
  - Customization
  - Environment of use
  - Professional

Day Two

9:00 AM - 10:15 AM

Lecture 1: Cybersecurity

- Device vulnerabilities: malfunction and failure
- Pre-emptive design and evolution
- Hackers' malware/virus strategy

10:30 AM - 10:45 am **Break**

10:45 am - 12:00 pm

- Post-event management
  - Corrective and preventive action for software
  - Disclosure to users
  - Reports to the FDA waiver
- National Institute of Standards and Technology Reports

12:00 PM - 1:00 PM **Lunch**

1:00 PM - 2:30 PM

Lecture 2: Medical Mobile Applications (mobile apps)Post-event management

- Mobile apps defined as a device
- FDA regulatory strategy and guidance
- National Institute of Science and Technology Report and Collaboration
- Updates (FDA vs. non-FDA updates)
  - Criteria for corrective and preventive action deemed recalls
  - Reports of Corrections and Removals
  - Reports of adverse events

2:30 PM - 2:45 PM **Break**

2:45 PM - 4:30 PM

Lecture 3: Professional vs. lay use / home use

- Labeling: instructions for use and precautions
- Environment of use
- FDA regulation of accessories
- Federal Communications Commission (FCC) regulation

Global CompliancePanel

2-day In-person Seminar:
FDA's Software Monsters: Cybersecurity, Interoperability, Mobile Apps and Home Use

Group Participation

10%	2 Attendees to get offer
20%	3 to 6 Attendees to get offer
25%	7 to 10 Attendees to get offer
30%	10+ Attendees to get offer

Payment Option

1. Credit Card: Use the Link to make Payment by Visa/Master/American Express card click on the register now link
2. Check: Kindly make the check payable to NetZealous DBA GlobalCompliancePanel and mailed to 161 Mission Falls Lane, Suite 216, Fremont, CA 94539, USA
3. PO: Please drop an email to support@globalcompliancepanel.com or call the our toll free +1-800-447-9407 for the invoice and you may fax the PO to 302 288 6884
4. Wire Transfer: Please drop an email to support@globalcompliancepanel.com or call our toll free +1-800-447-9407 for the wire transfer information

What You will get

1. Learning Objectives
2. Participation certificates
3. Interactive sessions with the US expert
4. Post event email assistance to your queries.
5. Special price on future purchase of web based trainings.
6. Special price on future consulting or expertise services.
7. Special price on future seminars by GlobalCompliancePanel.
8. Seminar Kit – includes presentation handout, ID card, brochure, trainings catalog, notepad and pen.
9. Networking with industry's top notch professionals

Contact Information: Event Coordinator

NetZealous LLC, DBA GlobalCompliancePanel
161 Mission Falls Lane, Suite 216,
Fremont, CA 94539, USA
Toll free: +1-800-447-9407
Fax: 302 288 6884
Email: support@globalcompliancepanel.com

www.globalcompliancepanel.com

Kindly get in touch with us for any help or information.

Look forward to meeting you at the seminar

GlobalCompliancePanel