Global CompliancePanel

Netzealous
Knowledge, a Way Forward…

2-day In-person Seminar:

The Value of a Human Factors Program

Los Angeles, CA

February 22nd & 23rd, 2018

9:00 AM to 6:00 PM

Price

Price: **$1,495.00**

(Seminar for One Delegate)

Register for 5 attendees

Price: **$4,485.00** You Save: $2,990.0 (40%)*

~~$7,475.00~~

Register for 10 attendees

Price: **$8,222.00** You Save: $6,728.0 (45%)*

~~$14,950.00~~

ENROLL

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

Thomas Bento

Sr. Vice President of Regulatory & Quality Assurance , Nihon Kohden America

Thomas is a student of Quality and Regulatory Compliance and has been supporting the design, development and compliance of Medical Device Manufacturing for over 15 years. He started his career training in Software engineering and shortly moved into Commercial Software Quality. After many years of working for companies like Mitek Systems and Hewlett Packard, the decision was made to work in the regulated space of Medical Device Manufacturing, working at Edwards, Pulmonetic Systems and as a regulatory consultant for small, medium and large Medical device manufactures.

He is currently the Sr. Vice President of Quality & Regulatory Assurance at Nihon kohden America, manufacturers of Patient Monitors

Overview :

This seminar will explain the implementation of ISO 62366 and the regulatory expectations discussed in the 2016 FDA Guidance for a compliant human factors/ usability program.

The ISO 62366 is an "Consensus" Standard, making it a gold standard for regulatory submissions. We will look at other reference points regarding HF, like AAMI/ANSI HE75:2009

Agenda:

Day One

This session will demystify the regulatory expectations discussed in the 2016 FDA Guidance for a compliant human factors/ usability program and the implementation of ISO 62366 Standard

Lecture 1: Definitions, requirements and approaches for Human Factor Engineering using ISO 62366

- Definition of Human Factor Engineering
- The importance of HFE for public health
- Main reasons for non-compliance
- Available HFE resources
- FDA's inspection and enforcement strategy for HFE
- Lessons from FDA Warning Letters and how to avoid them

Lecture 2: Introduction to FDAs Guidance for Human Factor Engineering

- Regulatory Expectations for HFE
- Requirements for HFE
- Implementation for of HFE from FDAs Guidance
- Developing a gap analysis
- Steps for implementation a Defensible HFE program

Lecture 3: Strategies to detect and avoid HFE issues

- Recruit, train and retain employees who will be responsible for ensuring HFE
- Preventing issues related to Human Factors
- Changing the quality culture
- Understand high risks in HFE
- Learning from internal audits and FDA inspections

Day Two

This session will introduce you to ANSI/AAMI HE75:2009(R)2013 Human Factors Engineering-Design Specifications as they relate to medical devices and medical related software. You will walk away with a better understanding of the impact these requirements have on your product lifecycle and related product release schedule.

Lecture 4: Definitions, requirements and approaches for Human Factor Engineering using HE-75

- User Capabilities
- Real World Demand
- Managing the Risk of Use Error
- Environmental Considerations

Lecture 5: HFE Usability Testing

- Overview of the Standard
- User Input
- Design Priorities
- Types of Usability Testing
- Logistics
- Protocol Related Activities

Lecture 6: HFE Labeling

- Introduction to Labeling, Symbols and Markings
- Design Guidelines

Lecture 7: HFE Design

- Alarm Design
- Design Elements - Connectors and Connections
- Controls
- Visual Displays
- Use of Automation
- Software User Interface
- Integrated Solutions

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The Value of a Human Factors Program

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
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What You will get

1. Learning Objectives
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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

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