




2-day In-person Seminar:

Human Factors and Predicate Combination Products

-  Washington, DC
-  July 20th & 21st, 2017
-  9:00 AM to 6:00 PM



Virginia A. Lang

Principal and Founder HirLan,
Inc. and HirLan International SA

Virginia started in the medical research field as a Coordinator of Research at the Clinical Research Unit Kennedy Institute of Johns Hopkins Medical Center. She was responsible for the initiation, coordination, and management and/or analysis of research projects in the Clinical Research Unit. These projects were funded by various Federal Government Agencies. Subsequent to Johns Hopkins Medical Center, Virginia entered the field of Human Factors through the doctoral program at SUNY Binghamton. Virginia held a fellowship at the Aeromedical Research Laboratory of the United States Air Force at Wright-Patterson AFB, Dayton, Ohio and a fellowship at NASA. Her research dealt with cognitive factors that differentially affect the characteristics of visual displays.

Overview :

The FDA has placed significant emphasis on the role of Human Factors in the approval of devices used for medical purposes. There are several current guidance documents and new proposed Draft Guidance documents. This seminar will compare these Guidance documents. Additionally, strategic recommendations will be presented on how to implement these requirements into the medical device design, development and approval processes. Finally, Human Factors methods and best practices will be covered that the FDA is requiring.

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~~

ENROLL

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



Agenda:

Day One

Lecture 1: Overview of Human Factors and the FDA perspective

Lecture 2: Human Factors Methods and Device Product Life Cycle

Lecture 3: Human Factors and Risk Analysis & Management

Lecture 4: Human Factors: What Devices Require Human Factors Evaluation and Validation?

Day Two

Lecture 1: Human Factors and Combination Products (Part 1)

Lecture 2: Human Factors and Combination Products (Part 2)

Lecture 3: Human Factors and Combination Products Submitted in an ANDA (Part 1)

Lecture 4: Human Factors and Combination Products Submitted in an ANDA (Part 2)



Areas Covered in the Session:

- Overview of Human Factors and the FDA perspective
 - Human Factors Methods and Device Product Life Cycle
 - Human Factors and Risk Analysis & Management
 - Human Factors: What Devices Require Human Factors Evaluation and Validation?
 - Human Factors and Combination Products
 - Human Factors and Combination Products Submitted in an ANDA
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Who will benefit:

- Quality Assurance
 - Regulatory Affairs
 - Device Engineers
 - Device Manufacturers
 - Pharma / Medical Device
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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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- 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

GlobalCompliancePanel