

3RD

HUMAN FACTORS ENGINEERING & USABILITY STUDIES

SUMMIT

Designing Medical Devices, Combination Products, and IFUs That Satisfy Regulators, Eliminate Errors, and Improve the User Experience



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SANOFI



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PROTEUS DIGITAL HEALTH



Gia Rozells
Director, User Experience,
BECTON DICKINSON



Bob Nesbitt
Director, Human-Centered
Design and Human Factors,
ABBVIE



“Very engaging and important content.”
—Senior Engineer, **EDWARDS LIFE SCIENCES**

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IN-DEPTH STRATEGIES FOR YOUR GREATEST USABILITY CHALLENGES!

- ✓ Creating and Submitting Regulatory Document Templates
- ✓ Prioritizing Accessibility for Patients With Functional Limitations
- ✓ Targeting Device Software and Apps Toward User Needs
- ✓ Embracing Holistic Design Methodologies for an Improved User Experience
- ✓ Refining the Statistical Framework for Human Factors Analysis
- ✓ Updating Risk Management Protocols to Anticipate Product Misuse

3RD

HUMAN FACTORS ENGINEERING & USABILITY STUDIES SUMMIT

Dear Colleague,

Biopharma companies producing combination products and medical devices face a very steep learning curve in order to meet regulatory requirements for human factors testing. The FDA has issued multiple new sets of guidelines in just the last four years, with the most recent having a particularly significant impact on the pipeline of any company working with biosimilars. And even if you have perfect regulatory clarity, it would still be challenging to identify, gather, and work with all of the necessary user groups during usability testing.

ExL's **3rd Human Factors Engineering & Usability Studies Summit** is your can't-miss conference focusing on the most important strategies for validation testing protocols, IFU design, managing outsourcing partners, and optimizing the user experience. Based directly on requests from our audience, this year's program will offer unprecedented detail on how to:

- **Recruit ideal user groups** while meeting budgets and deadlines
- Use **risk management methodologies** to anticipate product errors
- Improve the validation testing and user interface of **medical device software**
- Create and submit templates necessary to **document regulatory compliance**
- Ensure devices have been validated for **users with special needs**

With 15 in-depth, educational sessions and over four hours of networking, no other event goes into as much detail on these challenges while also being conveniently located for West Coast audiences!

I look forward to seeing you in San Francisco this February for a unique learning and networking event.

Sincerely,

Matt Greenbaum

Matt Greenbaum
Production Team Leader
ExL Events

WHO SHOULD ATTEND

Medical device, biotech, and pharma professionals responsible for:

- ✓ Human Factors / Human Factors Engineer
- ✓ Usability / User Experience / User Interface / UX / UI
- ✓ Combination Products / Combo Products
- ✓ Medical Device / Device Design / Device Development / Device Technology
- ✓ Design Assurance Engineer
- ✓ Product Development
- ✓ Handheld
- ✓ Wearable
- ✓ Pharmaceutical Development Operations
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- ✓ Instrumentation
- ✓ Quality / Quality Control / Quality Assurance / Quality Engineer
- ✓ Regulatory Affairs / Regulatory CMC
- ✓ Risk Management
- ✓ Pharmacovigilance
- ✓ Software Engineering / Software Management / Software Development
- ✓ Marketing / Brand Management
- ✓ Clinical Affairs / Clinical Research / Clinical Development
- ✓ Pharmaceuticals
- ✓ Brand Manager

This event is also of interest to:

- ✓ Human Factors Specialists
- ✓ Medical Device / Combination Product Design and Engineering Specialists
- ✓ CROs / Regulatory Specialists

VENUE THE ARGONAUT

495 Jefferson Street
San Francisco, CA 94109

To make reservations, please call 877-622-5387 and request the negotiated rate for ExL's February Meetings. You may also make reservations online at <http://bit.ly/2wWD0e0>. The group rate is available until **January 22, 2018**. Please book your room early, as rooms available at this rate are limited.

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MONDAY, FEBRUARY 12, 2018: DAY ONE

8:00 Registration and Continental Breakfast

8:45 Chairperson's Opening Remarks

Nick Allen, *Global Director, Design and User Experience*,
GE HEALTHCARE

ADAPTING TO NEW REGULATIONS

9:00 Craft the Proper Industry Response to Draft HF Guidelines on Biosimilar Interchangeability

The 2017 draft guidelines on biosimilars are misguided, focusing too much on non-inferiority studies. It is important for the industry to recognize the flaws of these guidelines and keep a united voice in giving comments and feedback.

- Review problem areas such as IP, patent protection, and disincentives for improvement
- Emphasize the severity of errors over the number of errors
- Establish clear lines of communication with regulators about HF training

Ed Israelski, *Technical Advisor, Human Factors*, **ABBVIE**

9:45 Create the Ideal Templates to Show Compliance With Engineering Expectations

The key deliverables requested under current guidelines can best be documented through creating templates. Though some sections are always required for it, there is more room for success or failure based on the verbiage of instructional wording and recommended wording. What you say is just as important as how you say it!

- Detail the templates needed for test plans, test reports, project plans, known use errors reports, hazard analysis, and others
- Create sufficiency and better organize information
- Streamline communications with regulators

Tressa Daniels, *Manager, User Experience*, **BECTON DICKINSON**

10:30 Networking Break

11:00 Update on the Progress and Priorities of the Combination Product Coalition HF Working Group

2017's new draft guidelines on biosimilars and supplemental NDAs demand a considered, collective response from the industry. The Combination Product Coalition HF Working Group is continuing to examine the most important topics while helping to maintain firm standards within the industry.

- Analyze feedback concerning the interchangeability of biosimilar combination products with their reference products
- Envision the next steps for comparative analysis of combination products in an ANDA
- Explore new methods of providing IFUs

Bob Nesbitt, *Director, Human-Centered Design and Human Factors*, **ABBVIE**

11:45 Key Human Factors Considerations From an Interview With CDRH at FDA

Requests for human factors data continue to gain momentum within FDA and other international regulatory bodies, especially in the premarket submission process. The Center for Devices and Radiological Health (CDRH) has published several guidance documents to assist manufacturers with HFE premarket submissions, but challenges about best practices still exist.

- Learn insights from an interview with the team lead of CDRH's Human Factors Premarket Evaluation Team
- Discover key HFE considerations to successfully meet regulatory expectations to bring safe, effective and usable medical devices to market
- Understand strategies to minimize business related risks

Melissa Lemke, *Director, Human Factors Engineering*, **AGILIS CONSULTING**

12:30 Luncheon

SELECTING AND WORKING WITH USER GROUPS

1:30 Map the Full Range of Errors for Combination Products in At-Home Use

Even if the device elements work properly, patients using a combination product on themselves may be confused by drug viscosity, clarity, opacity, and other features. If failure to take a complete dose is a critical use error, then this must be reviewed within your HF evaluations in a manner different from standard device risk analysis.

- Support HF results with extra clinical-use and actual-use testing for home-use products
- Predict the aspects of self-administered combination product use that may be most confusing
- Recognize where this differs from device risk analysis

2:15 Enhance Medical Device Usability for Patients With Functional Limitations

Several U.S. and international standards are available to support manufacturers to produce medical devices that can be used well by patients with disabilities. For example, one section (4203) of the PPACA mandated the development of standards for accessible medical instrumentation, which were issued in January 2017. Another standard that supports the development of more accessible medical devices is ISO 11608-7:2016, needle-based injection systems for medical use – Part 7: Accessibility for persons with visual impairment. In addition, ISO/IEC Guide 71:2014, guide for addressing accessibility in standards, is an international document that provides guidance on how to incorporate the needs of users with various disabilities into any standard.

- Learn about standards that provide guidance on maximizing medical device accessibility
- Grasp the basic requirements of the key standards
- Understand the responsibilities of healthcare providers and the opportunities for manufacturers

Molly Story, *Head, Global Usability Engineering and Risk Management, Medical Device Development*, **SANOFI**

3:00 Networking Break

3:30 Drive Device Usability and Procurement Decisions With Healthcare Provider Involvement

To thoroughly assess the usability of medical devices, involving the end users is critical. This is applicable not only during the device development process, but also when healthcare systems are faced with procurement decisions for already-marketed products. However, it can be difficult to gain access to these users and conduct usability activities in an optimal manner.

- Going beyond user testing to collect data from end users early in development
- Techniques for evaluating products for procurement and how to incorporate user feedback
- Interacting with clinicians in a meaningful way to optimize usability input

Natalie Abts, *Program Manager, Usability Services*, **NATIONAL CENTER FOR HUMAN FACTORS IN HEALTHCARE**

4:15 Update Your Risk Management Protocols to Better Anticipate Product Misuse

The industry lacks long-term expertise on combination products, making it much harder to anticipate the ways users might misuse products – or to adapt to misuse that wasn't anticipated. Gathering and updating expertise from dedicated risk management professionals can improve your HF verification methods.

- Plan and stratify responses for all possible user group backgrounds
- Specify the types of human interactions you are measuring
- Test devices under traveling conditions

Barbara Young, *Quality Engineer*, **SIEMENS HEALTHCARE**

5:00 Day One Concludes

“Clear, easily followed presentations on real-life examples. It was great to talk about best practices for making reports and testing work.”

—Senior Quality Engineer, **ABBOTT VASCULAR**

TUESDAY, FEBRUARY 13, 2018: DAY TWO

8:00 Continental Breakfast

8:45 Chairperson's Recap of Day One

Nick Allen, *Global Director, Design and User Experience*, **GE HEALTHCARE**

UPDATING YOUR TEST DESIGNS

9:00 Re-Evaluate the Statistical Underpinning of HF Analysis

The statistical tests preferred by the FDA have reliability challenges and may produce false positives for devices that are not completely safe. Changing the number of users tested could give better assurances about usability and potential for harm.

- Interrogate whether standards and goals for HF testing are actually safe
- Instill a deeper grounding in statistical analysis
- Make sure that any mistakes that do happen are harmless

Jacques Ginestet, *Head, Wearables Development*, **PROTEUS DIGITAL HEALTH**

9:45 Embrace Holistic Design Methodologies for Breakthroughs in User Experience

If you wanted to design a medical device for your best friend to use, how would you change it from the status quo? By envisioning the full user experience, and prioritizing the removal of their fears, you can build a device that everyone uses as intended.

- Review the most important lessons of key design schools
- Adapt the holistic exposure for design methods
- Quantify a reduction in patient fears and anxieties

Nick Allen, *Global Director, Design and User Experience*, **GE HEALTHCARE**

10:30 Networking Break

11:00 Keep Design Validation Centered in Your HF Studies

Collecting HF data is pointless if you can't properly interpret it and draw conclusions from it. Design validation is a legal requirement, but practitioners often do HF studies without mentioning that aspect – even though it could change the requirements and acceptance criteria.

- Recognize when data can and cannot be interchanged between design validation and HF tests
- Analyze differences in acceptance criteria
- Select the best techniques for data interpretation

Ling Lu, *Senior Principal Scientist, Combination Product Design Control Group Lead*, **PFIZER**

11:45 Quantify the ROI of Human-Centered Design

Iterative and early investment in design requirements, along with an active risk management system, can yield a drop in product complaints and improved product reliability and credibility. A review of relevant literature can clarify the testing requirements and investment priorities that produce the best outcomes.

- Apply lessons early in order to save money in the development phase
- Remain flexible in design requirements to end up with a better product that users like and use more
- Meet product performance and user acceptance standards before you meet your deadlines

Gia Rozells, *Director, User Experience Design*, **BECTON DICKINSON**

12:30 Luncheon

1:30 Properly Sequence All of the Validation Tests for Device Software

It is often unclear how the many engineering tests behind medical device software should be combined at the end of the development life cycle. Naturally, you want to minimize the risk of demanding further changes to the device or software, but in some cases, this may be unavoidable as it would be revealed either by engineering or validation tests.

- Run late formative tests that mirror validation tests
- Map out the risks that will arise, forcing new runs of both engineering and HF tests
- Determine the optimal test order and time frame

Jonathan Avedikian, *Human Factors Engineer*, **ABBOTT**

2:15 Maximize Output and Minimize Time and Cost When Recruiting Human Factors Study Participants

HF study participant recruitment can be challenging, costly, and time-consuming, but the recruitment of appropriate subjects is critical for use error identification, hazard mitigation, and test success. Taking advantage of social media for recruitment allows the most appropriate study subjects to be recruited from a wide geographic region. Performing HF testing with a well-designed user group results in the safer use of products and fewer post-market complaints.

- Develop robust subject recruitment requirements based on understanding the relevant characteristics of intended users (capabilities, experience, specialty, ability to use technology, etc.)
- Understand practice-level and geographic differences in intended users to ensure broad representation during testing
- Recruit using social media to target selected users while minimizing recruitment time and cost

Kristen Stebbins, *Clinical Researcher*, **WELCH ALLYN**

3:00 Conference Concludes



"Content was very relevant and novel to me. A pleasure to hear from such experts!"

—*Human Factors Engineer*, **GENENTECH**



"Gained insights and tips for submitting studies to FDA."

—*Senior Software Engineer*, **ELEKTA**

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to register [CLICK HERE](#) or

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Registration Fees for Attending ExL's 3rd Human Factors Engineering & Usability Studies Summit

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