4TH

HUMAN FACTORS ENGINEERING & USABILITY STUDIES SUMMIT

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

February 4–5, 2019
Hyatt Centric Fisherman's Wharf | San Francisco, CA

ALL-NEW INSIGHTS ON THE GREATEST REGULATORY, TECHNICAL, AND OPERATIONAL CHALLENGES FACING USABILITY PROFESSIONALS:

- Update on the Post-Brexit Outlook for Human Factors Standards
- Set Usability Priorities for Start-Ups
- Design Around Challenges for Device Interoperability
- Properly Situate Human Factors Testing Within the R&D Life Cycle
- Explore the Potential of Multimedia IFUs
- Rely on Human Factors Engineering to Prevent Recalls and Reputational Damage

Ryan Clukey
Senior Manager, System Validation and Human Factors Engineering
PHILLIPS

Darin Oppenheimer
Executive Director, Head, Drug Device Center of Excellence
MERCK

Marc Stern
Director, Product Management
CERUS CORPORATION

Tina Rees
Associate Director, Human Factors
FERRING

Sami Durrani
Senior Manager, Human Factors
FRESENIUS MEDICAL CARE

Ed Israelski
Technical Advisor, Human Factors
ABBVIE

John Kruse
Senior Human Factors Specialist
3M

"The quality of the speakers was excellent and the topic was represented well by diverse perspectives."
–Senior Director, User Experience, **ILLUMINA**

"Valuable, real examples of human factors work and how problems can be addressed."
–Senior Manager, Risk Management and Human Factors, **ABBVIE**

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4TH HUMAN FACTORS ENGINEERING & USABILITY STUDIES SUMMIT

Dear Colleague,

As combination products grow both more commonplace and more complicated, the regulations governing them change as well, and so does best practice in designing and validating IFUs. Yet one of the most important strategic questions for device designers and engineers still needs to be further explored: How to elevate human factors engineering from a mentality of regulatory compliance to one of improving the user experience and gaining a marketplace advantage.

The **4th Human Factors Engineering & Usability Studies Summit** (February 4–5, San Francisco) provides in-depth insight on working with multiple user groups, improving the user interface of medical device software, and properly siting human factors engineering into device life cycles in order to avoid wasted time, money, and reputational damage. Our all-new agenda focuses on how you can:

- Adapt to **new domestic and international human factors regulations** in a post-Brexit marketplace
- Provide a **better sensory experience** to users
- Improve device **interoperability**
- Communicate the **ROI of human factors testing** to project management
- Shift into **multimedia IFUs** for better user outcomes

I look forward to seeing you in San Francisco in February!

Sincerely,

Matt Greenbaum

Matt Greenbaum
Production Team Leader
ExL Events

WHO SHOULD ATTEND

Biopharma and medical device professionals responsible for:

- Human Factors / Human Factors Engineer
- Usability
- User Experience / User Interface / UX / UI
- Combination Products / Combo Products
- Device Development / Device Technology
- Design Assurance Engineer
- Product Development / New Product Development
- Medical Device
- Device Development / Technology / Design
- Industrial Design
- Design Controls
- Handheld / Wearable
- Patient Experience
- Pharmaceutical Development Operations
- Technology / CTO
- R&D / R&D Engineer
- Customer Experience
- Engineering / Device Engineering / Clinical Engineering
- Architect / Design Architect / Solutions Architect
- Validation
- Packaging / Labeling
- Instrumentation
- Mobility
- Quality / Quality Control / Quality Assurance / Quality Engineer
- Regulatory Affairs / Regulatory CMC
- Risk Management
- Pharmacovigilance
- Software Engineering / Software Management / Software Development
- Clinical Affairs / Clinical Research / Clinical Development
- Pharmaceutics
- Brand Manager
- Formulation / Formulation Development

This event is also of interest to:

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

VENUE

HYATT CENTRIC FISHERMAN'S WHARF

555 North Point St.
San Francisco, CA 94133

To make reservations, please call 402-592-6464 and request the negotiated rate for **ExL's 4th Human Factors Summit**. You may also make reservations online at **https://bit.ly/2Mrzg7U**. The group rate is available until **January 14, 2019.** Please book your room early, as rooms available at this rate are limited.

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To Register: 201 871 0474 Click Here

DAY ONE | MONDAY, FEBRUARY 4, 2019

8:00 Registration and Continental Breakfast

8:45 CHAIRPERSON'S INTRODUCTION

Darin Oppenheimer, *Executive Director, Head, Drug Device Center of Excellence,* **MERCK**

UPDATE ON DOMESTIC AND INTERNATIONAL REGULATORY STANDARDS

9:00 POST-BREXIT UPDATE ON INTERNATIONAL STANDARDS AND HARMONIZATION

International Usability Standards will be releasing new amendments in 2019 that will further harmonize terminology agreements between FDA and international regulators. After long delays, new updates on test report forms will be forthcoming for gauging compliance in international standards will now help inform your compliance strategy. In addition, MHRA recently issued its final guidance on human factors, though just how far its reach extends in a post-Brexit landscape has not yet been tested.

- Address pre-existing gaps between domestic and international regulations
- Pinpoint the regulators and Notified Bodies that require compliance with older IEC 62366:2007
- Recognize that other regulators will say that newer standards, even if unrecognized by EU, are state of the art and should take precedence
- Examine the value of gaining regulatory approval in the split-off UK

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

9:45 PANDORA'S BOX IS A LEGACY PRODUCT: WORKING WITH ADD-ONS TO OLDER DEVICES

Developing a new add-on for an older product can be highly challenging, since before 2009 most devices likely did not have to go through human factors testing to be approved in the first place. If you need to make a modification or add a new part that must be validated, does that trigger a requirement to validate the entire system — perhaps for the first time?

- Establish the circumstances where you can validate product additions and where full device validation is necessary
- Navigate the challenges of legacy products assembled under earlier regulatory expectations
- Gather regulatory feedback and real-world cases

Janet Lowe, *Senior Manager, Device Development, Medical Affairs,* **ICU MEDICAL**

10:30 Networking Break

11:00 GRASP THE LIFE CYCLE CHALLENGES FOR DIGITAL THERAPIES AND HEALTH SOLUTIONS

As medical devices grow more interconnected, how can they adapt to a consumer culture accustomed to deleting apps that are awkward or not frequently used? The risk profile for digital device applications is unlike anything the industry has faced before, and most of these challenges are being outsourced to software providers under very light regulatory oversight.

- Clarify relationships and responsibilities among outsourced software providers
- Adapt risk management, usability, and supply chain skill sets towards the digital area
- Tackle challenges in backward-compatibility, platform access, wifi reliability, and security

Suraj Ramachandran, *Director, Regulatory Affairs, Drug-Device Center of Excellence,* **MERCK**

11:45 SELECT THE IDEAL SCENARIOS FOR RISK ASSESSMENT

Only a small amount of your clinical trials will be devoted to mimicking the device use process, and you must make sure to include human factors and all scenarios that would be used in normal circumstances. Depending on how you interpret risk assessments, you may face more of a struggle in representing real scenarios.

- Clarify how to present experiments and evaluations
- Ensure your product is completely aligned with guidance documents
- Determine the models best suited for mimicking cases

Wenjing Wang, *Regulatory Affairs Manager,* **DENTSPLY SIRONA**

12:30 Luncheon

PROPERLY UNDERSTAND YOUR USERS IN TESTS AND THE CLINIC

1:30 WHEN "COMPLIANT" IS THE ENEMY OF "GOOD": A NEW PERSPECTIVE ON USER EXPERIENCE

Usability requirements are very basic and focused entirely on user safety. Device manufacturers may follow these guidelines well, and thus fulfill minimum requirements while missing the bigger picture of user experience, to the detriment of user satisfaction and market success. For some, meeting usability requirements means checking the box in a late formative or a summative; however, this approach misses nuances about the user or the context of use that could have resulted in meaningful design changes during the development process.

- Walk through the evolution of a device from one that is simply safe and error-free to one that additionally offered a superior user experience
- Understand how to increase user adherence to treatment by identifying how a device can fit into daily life (allow for discretion when needed, exceed aesthetic expectations, enable mobility when needed, and motivate users)
- Review a device which met a safety requirement on one level and actually created a hazardous scenario on another level

Susan McDonald, *Senior Human Factors Engineer,* **XIMEDICA**

DAY ONE | MONDAY, FEBRUARY 4, 2019

2:15 **PRIORITIZE PATIENT NEEDS AND FEARS TO PRODUCE A BETTER SENSORY EXPERIENCE**

There are no regulatory requirements for medical devices to provide anything better for patients than biosafety, let alone paying attention to their feelings. Particularly for devices that are administered by HCPs in a clinical setting, a new approach that respects patients' psychological needs and responses can help to create a more pleasant experience during what is typically a time of discomfort or fear.

- Build off PPACA questionnaires concerning how patients feel about their treatments
- Acknowledge patient fears and reorient the device environment around comfort
- Adapt from feedback from architectural professionals and experimental psychology

James Kleiss, *Sensory Quality and Emotional Design Specialist,* **GE HEALTHCARE**

3:00 **Networking Break**

3:30 **PUSH FOR IMPROVED ERGONOMIC SENSORS IN MEDICAL DEVICES IN AN MHEALTH CONTEXT**

When designing sensors related to user interface software, you must account for not only how the user will touch the sensor but also their overall body posture. By adapting the shape and features of the sensor, you can overcome some common mistakes from past designs.

- Monitor sample users for full body positioning
- Reorient user testing to account for their feelings on colors and textures
- Revolutionize the ergonomics of sensors
- Handle "white coat syndrome" through gamification

Didier Clerc, *UX Designer,* **LEMAN MICRO DEVICES**

4:15 **AVOID REGULATORY INTERVENTIONS BY PROPERLY SITUATING HUMAN FACTORS TESTING WITHIN THE R&D LIFE CYCLE**

Past approaches to human factors saw engineers brought in at late stages and with low budgets and a set number of iterations to work with; this led to problems being discovered in the field and more scrutiny from FDA. A risk-based product team, featuring a broad cross-section of expertise, can assess major risks and uncertainties early.

- Acknowledge the likelihood that FDA will dig deeper for flaws if it seems usability testing was left for later stages
- Document that you made simple tests early and made changes in a longitudinal manner
- Preselect the human factors team roles best for getting regulatory submissions through more easily

John Rovnan, *Product Manager,* **ZOLL MEDICAL CORPORATION**

5:00 **FLAG THE WARNING SIGNS OF SELF-EDITED, MISLEADING USER FEEDBACK**

Getting an accurate record from simulated use can be surprisingly hard. If users experience difficulty, they may grow defensive, reactive, and embarrassed, blaming the IFUs or even denying that anything went wrong. Making participants feel comfortable in the honest sharing of opinions is a challenge, but a worthwhile one.

- Recognize that user groups may not want to be confrontational or critical
- Work around common avoidance tactics for embarrassing or negative feedback
- Rely on prior experience in conducting studies

Sami Durrani, *Senior Manager, Human Factors,* **FRESENIUS MEDICAL CARE**

5:45 **Day One Concludes**

DAY TWO | TUESDAY, FEBRUARY 5, 2019

8:00 **Registration and Continental Breakfast**

8:45 **CHAIRPERSON'S RECAP OF DAY ONE**

Darin Oppenheimer, *Executive Director, Head, Drug Device Center of Excellence,* **MERCK**

BEST PRACTICES IN USABILITY TEST PROTOCOL DESIGN

9:00 **DESIGN AROUND CHALLENGES FOR DEVICE INTEROPERABILITY**

When patients are using multiple devices at once, what standards should be used to prioritize data and readouts among them? And what incentives are there for different companies to cooperate?

- Explore the likelihood of integrating data from multiple devices — both within and between companies
- Analyze how to prioritize alerts and problem resolution among multiple devices
- Discuss applications for combining multiple reports at central data stations

Darin Oppenheimer, *Executive Director, Head, Drug Device Center of Excellence,* **MERCK**

DAY TWO | TUESDAY, FEBRUARY 5, 2019

9:45 **USE PERCEPTION-COGNITION-ACTION ANALYSIS EFFECTIVELY**

The Perception-Cognition-Action analysis is a framework to evaluate the usability of designs. It has some similarities to cognitive walkthrough methods, which are used for early evaluation of software designs. It is important to review and compare these methods, and understand how they analyze use-related risk.

- Structure use scenarios for user testing
- Extend PCA analysis to improve the overall user experience
- Help usability practitioners add business value to products while avoiding perceptions of "scope creep" from management

John Kruse, *Senior Human Factors Specialist,* **3M**

10:30 **Networking Break**

11:00 **AGREE ON THE BEST TIMEFRAMES WHEN OUTSOURCING TO DESIGN FIRMS AND CONSULTANTS**

Human factors consultants may be of the most help in the early stages of a project — but that is where you have the least budget to expend on them. Particularly for smaller companies, it may be difficult to gather the input of human factors consultants early in the development process when they could have had the most influence on product design.

- Confront the "box-checking" view of summative studies
- Share mindsets between sponsors and outsourcing partners concerning the best timeframe for applying human factors studies
- Make budgeting and outsourcing decisions based on the size and maturity of both the sponsor and the design or consulting firm

Marc Stern, *Director, Product Management,* **CERUS CORPORATION**

11:45 **MEASURE THE BENEFITS OF REPLACING TRADITIONAL IFUS WITH A "QUICK START" GUIDE**

Videos and verbal cues may be much more helpful to patients than printed IFUs with elaborately detailed wording. Design and media changes to IFUs can result in quantifiable improvements for daily company operations.

- Compare and contrast levels of device errors and helpdesk calls once Quick Start guides are introduced
- Allow for development of devices with greater ease of mechanical assembly
- Link up instruction illustrations with improved performance

12:30 **Luncheon**

OPTIMIZE DESIGN TEAM DYNAMICS, COMMUNICATION, AND LEADERSHIP

1:30 **HELP PROJECT MANAGERS SEE THE BUSINESS OPPORTUNITIES RESULTING FROM IMPROVED USABILITY**

Project managers may sometimes see usability testing only as another painstaking procedure to be fit into schedules and budgets. But the sooner you can identify and implement user preferences into your design, the more you can turn it into a business play and acquire extra market share.

- Convey the opportunities for business success based on performance and aesthetic aspects
- Quantify the potential for growth represented by better customer experiences
- Make a clear case for business-end benefits after reductions in user complaints

Ryan Clukey, *Senior Manager, System Validation and Human Factors Engineering,* **PHILLIPS**

2:15 **MANAGE PROJECT TIMELINES AND WORK WITH AN EYE ON DATA FREEZES**

The biggest issue with medical device development during usability testing is ultimately not costs but timelines. Every day not at market is a day with no sales revenue and increasing R&D costs. Facing these tight timelines, managers may sequence usability tests in ways they think are logical but actually do not give sufficient time to analyze and respond to data changes.

- Aim to get all input into the system so it can be coded before design freezes
- Troubleshoot false assumptions in the earliest stages
- Fully convey the scope of human factors work and the meaningful time intervals between tests

Tina Rees, *Associate Director, Human Factors,* **FERRING PHARMACEUTICALS**

3:00 **CONFRONT THE CHALLENGES AND FALSE ASSUMPTIONS OF HUMAN FACTORS IN START-UPS**

Start-up device companies face a high learning curve for usability testing, not only concerning regulatory compliance and team skill but also business development and selecting outsourcing partners. There can also be ideological, generational hurdles to overcome: many companies may reflexively build technologies suited for younger, more "connected" users, when their actual user groups will likely be older, less tech-savvy, and facing visual, cognitive, or mobility challenges.

- Pinpoint areas of unmet need or failures of engagement in the current device market
- Know when to involve human factors expertise, either insourced or outsourced
- Learn why some devices go unused in order to improve device adherence
- Involve business-critical stakeholders from early stages

Sathya Elumalai, *CEO,* **MULTISENSOR DIAGNOSTICS**

3:45 **Conference Concludes**

HOW TO REGISTER:

Phone: 201 871 0474

Online: Click Here

Email: register@pmaconference.com

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