2ND ANNUAL

MEDICAL DEVICE HUMAN FACTORS & USABILITY

OCTOBER 23-24, 2018 | ARLINGTON, VA

Developing User-Centered Medical Devices which Maintain Compliance with Regulatory Requirements through Proactive Discovery and Testing of End-User Needs, Deployment of Comprehensive Product Risk Assessment Operations & Execution of Robust Design & Human Factors Validation

DISTINGUISHED PRESENTERS INCLUDE:

Jonathan Avedikian
Human Factors Engineer
ABBOTT

Tina Rees
Associate Director, Human Factors
FERRING PHARMACEUTICALS

Tressa Daniels
Manager of User Experience, Infusion Division
BECTON DICKINSON (BD)

Executive Pending
Biomechanical Engineer
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Chan Lee
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Jason Wise
Staff Human Factors Engineer
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Joanne Jaime
Senior Manager, Product Labeling
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Samuel Psota
Senior Usability Engineer
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ATTENDEE PROFILE:

Organizations currently researching and developing the next generation of medical technologies with a risk-based approach that ensures quality and regulatory certainty will find this meeting of particular interest. With a speaker platform which integrates hundreds of years of combined industry experience and expertise, presenters will deliver on educational scenarios based in real-life situations impacting device manufacturers on a global scale.

VPs, Directors and Executives incorporating the following job functions will find this meeting of the greatest interest:

- Human Factors
- Usability Testing
- User Experience
- Industrial Design
- Design Assurance

SPONSORSHIP OPPORTUNITIES

Supplier partners to the medical device industry looking to further relationships with human factors and usability executives will find this meeting of particular interest. Products and services currently being sought by industry executives include:

- Summative evaluations
- Formative & usability testing
- Validation of human factors
- Industrial design
- Product R&D
- Regulatory guidance

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DAY ONE | TUESDAY, OCTOBER 23

8:00 REGISTRATION & WELCOME COFFEE

8:50 Chairperson's Opening Remarks & Program Welcome

9:00 FIRESIDE CHAT: SHOWCASING THE VALUE OF HUMAN-CENTERED DESIGN TO INTERNAL EXECUTIVE TEAMS

Human factors engineering and usability testing offers a wide array of benefits for medical device corporations in the design, development, and future iterations of medical technologies, ensuring products created meet the needs of users in a manner which is safe and effective. However, at times executive leadership can be unaware of the bottom-line benefits that this research provides, restricting the budget and resources devoted to this critical design and development group. Through an interview-style format, participants will hear from human factors executive leaders who are translating the need for human factors engineering and driving home the benefits of this function.

- Creation of a value proposition showcasing HF team's impact
- Highlight positive product changes executed from usability studies
- Conveying deficiencies mitigated through HF operations

MODERATOR: Jonathan Dalton, *Co-Founder & CEO,* **THRIVE**

INTERVIEWEE

Jonathan Avedikian, *Human Factors Engineer*
ABBOTT

9:45 EMPLOYING HEURISTIC EVALUATION FOR EARLY USER RISK DETECTION

Medical device usability teams are seeking strategies to enhance usability studies without the logistical undertaking of user recruitment, and have found significant value in heuristic analysis as a tactic to reduce user related issues both pre and post market. A fundamental avenue to assess the usability of a device during early development is through the process of heuristic evaluation, which allows for a variety of experts to examine and determine risk on a device based on an established assessment baseline. The preemptive discovery of user errors prior to formative and summative studies allows HF teams to mitigate risk by enhancing device design prior to user recruitment, creating a standard for device usability and will ultimately promote human factors compliance.

- Overview of heuristic evaluation in device usability
- Developing criteria to create an applicable heuristic approach
- Creating expert consensus after heuristic evaluation

Steve Vargas, *Staff Human Factors Engineer*
ABBOTT

10:30 COFFEE & NETWORKING BREAK

11:00 IMPLEMENTING A FORMALIZED HUMAN FACTORS & USABILITY PROCEDURE

- Analyze knowledge gaps regarding current usability studies
- Determine resource and manpower requirements
- Creation of team expectations & implementation timelines
- Integrating HF engineers into design team procedures

Samuel Psota, *Senior Usability Engineer,* **ROCHE**

11:45 MASTERCLASS: TAILORING TASK ANALYSIS BASED ON SPECIFIC DEVICE DESIGNS

Implementing an efficient task analysis is crucial for a robust usability risk mitigation strategy as it is a method of determining user error potential within the context of a specific device and a valuable tool to identify potential safety hazards. While human factors teams recognize the importance of task analysis, uncertainty occurs when engineers attempt to define and individualize tasks' level of risk. Proficiently conducting task analysis is instrumental in assessing usability risk and possessing the ability to discern a task's risk potential within the context of a device will ensure the safety of a medical product.

- Identifying device specific critical tasks
- Associating task with correct level of risk
- Review commonly utilized analysis procedures

Deepti Surabattula, *Principal Human Factors Engineer,* **FUJIFILM**

12:30 LUNCHEON FOR ALL PARTICIPANTS

1:45 MASTERING USABILITY RECRUITMENT IN HUMAN FACTORS

FDA requirements mandate that a minimum of fifteen users participate in a medical device usability study to be considered compliant with current human factors regulations, and logistical execution of recruitment for summative studies can be particularly challenging for HF teams. Recruitment of study end-users is a significant hurdle for many usability executives as certain study specifications are extremely defined, narrowing the number of available study participants. To ensure the compliance and validity of usability studies, human factors teams can implement practical tactics of expanding the defining criteria for end users, partnering with existing establishments to locate potential users, and distributing internal resources to increase end user participation.

- Strategies for sourcing applicable end users
  - › Specific diseases populations
  - › Appropriately credentialed users
- Incentivizing end users for human factors studies
- Streamlining internal logistics of user recruitment

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

2:30 ENSURING ROBUST REGULATORY COMPLIANCE ON INSTRUCTIONS FOR USE

Regulatory bodies have significantly increased oversight around medical device usability, and recent requirements have amplified scrutiny around usability expectations regarding Instructions For Use (IFU). A recent clause in EU MDR labeling has required IFU's to be comprehensible and legible, which has led to HF teams seeking clarity in methods to adequately measure and demonstrate the usability of instructions. UX experts are also seeking to ensure IFU methodologies are within the parameters of the standards of IEC 62366, regulatory perspectives will provide essential insights into expectations of IFU's from varying notified bodies and regulatory agencies, along with best practices to ensure usability of IFU's.

- Accurately validating instructions for use
- Methodologies to test for IFU in HF
- Assuring IFU are legible & comprehensible

Joanne Jaime, *Senior Manager, Product Labeling,* **DEXCOM**

3:15 COFFEE & NETWORKING BREAK

3:45 WORKSHOP: MODERATING HUMAN FACTORS STUDIES FOR OPTIMAL USABILITY INSIGHTS

Moderators are essential components of usability studies, and seasoned leaders are able to obtain valuable human factors insights without bias during user participated human factors studies, but many obstacles in a real world usability study often prevents UX teams from collecting objective data. Human factors teams can improve facilitation skills by clearly setting expectations for roles, robustly checking for understanding of participant and observing behavior rather than soliciting opinions. An interactive skill building opportunity will provide insights into common missteps of moderators as well as build take home skills for usability teams.

- Ensuring questions are non-leading
- Avoiding explain device design to users
- Discovering root cause user error
  - › Probing for true usability errors
  - › Cognition vs perception determination
- Difference between interviewing & testing

Russell J. Branaghan, *Professor,* **ARIZONA STATE UNIVERSITY**

5:00 CLOSING REMARKS & DAY ONE CONCLUSION

6:30 FACILITATED GROUP NETWORKING DINNERS

In order to foster networking opportunities and increase attendee engagement, Q1 has arranged for a group reservations at a nearby restaurant, located a short walk from the hotel. This dinner is not sponsored by Q1 or any supplier partner and is open to any participant looking to have an evening out with other attendees. Please let a staff member know if you'd like more information or to join the group.

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DAY TWO | WEDNESDAY, OCTOBER 24

8:30 Registration & Welcome Coffee

9:00 HUMAN FACTORS REGULATORY PERSPECTIVE: FIRESIDE CHAT WITH THE FDA

In an effort to ensure compliance with FDA human factors requirements, executives are constantly seeking opportunities to interact directly with the FDA. Through a question and answer format, attendees will get the chance to participate in a dialogue with FDA in an educational environment. Following the presentation, an FDA representative will answer previously submitted questions on the following topics:

- Preparing UX data for summative studies
- Guidelines for human factors specific validation
- Class specific HF regulatory expectations

MODERATOR:

Chan Lee, *Director of Regulatory Sciences*
HOGAN LOVELLS

PARTICIPANTS:

Executive Pending, *Biomechanical Engineer*
FDA, CDRH

Executive Pending, *Human Factors Reviewer*
FDA, CDRH

9:45 WORKSHOP: OPTIMIZATION REGULATORY DOSSIER DEVELOPMENT PROCESSES

A product's regulatory submission dossier is a critical component in the continue approval for medical devices and the increased demand for transparency regarding human factors and usability data has many HF executives debating how to best package this information and what level of information is required within submission packages. In an interactive workshop setting, the facilitator will provide small groups with specific scenarios regarding the inclusion of human factors data during the development phase of regulatory submission dossiers and time will allow for each group to collaboratively discuss best practices and practical solutions for each scenario. Groups will share experiences and learn how industry colleagues have managed similar situations in the past.

Chan Lee, *Director of Regulatory Sciences*
HOGAN LOVELLS

10:30 COFFEE & NETWORKING BREAK

11:00 PANEL: DESIGN VALIDATION VS. HUMAN FACTORS VALIDATION

Human factors teams are constantly striving towards improving device designs to promote ergonomics and ease of use, but a lack of consensus regarding which usability and design changes require formal validation testing has led to roadblocks in improving the usability of a device. Formalized validation studies can be both time consuming and costly; and differentiating between usability feature that effects the safety and efficacy of a device as opposed to a usability feature that will improve the user experience but not modify safety or efficacy is a point of ambiguity for human factors team. Clarity into regulatory expectations regarding human factors as well as discussion around industry consensus of when design revalidation is required will enhance a manufactures ability to justify human centered device design without unneeded validation retesting.

- Validating user safety vs. user needs
- Parameters for revalidation in usability
- Efficacy of device vs customer preference

MODERATOR:

Sean Hagen, *Principal*
BLACKHAGEN DESIGN

PANELISTS:

Tressa Daniels, *Manager of User Experience, Infusion Division*
BECTON DICKINSON (BD)

Christina Reinhart, *Manager, User Experience and Human Factors Engineering*
ILLUMINA

11:45 CASE STUDY: DEVELOPING HUMAN FACTORS PROCESS FOR VARYING DEVICE TYPES

Defining a starting point for usability procedures on varying devices can be challenging, as a variety of avenues exists in order to successfully assess usability. Establishing a usability process for a new device concept can be especially challenging, and HF teams are often unsure of a starting point in usability for products with specific and unknown user requirements. An overview of an organization's development and implementation of new usability procedures will service as a valuable framework for crafting human factors operations for varying and newly developed devices.

- Type & class specific usability procedures
- Expanding beyond formative & summative studies
- Identifying appropriate formative testing parameters

Trent Kahute, *Co-Founder & COO,* **THRIVE**

Jonathan Dalton, *Co-Founder & CEO,* **THRIVE**

12:30 LUNCHEON FOR ALL PARTICIPANTS

1:30 PANEL DISCUSSION: BEST PRACTICES FOR SUMMATIVE STUDIES

Ensuring the accurate collection and documentation of usability data for compliant summative studies is a top tier concern for medical device usability teams. While many areas of FDA'S human factors regulations require further clarification, a particular area of challenge is centered on the correct process for submitting user experience data in summative studies. Discerning task failures, defining critical versus non critical tasks, and mitigating the FDA's request for additional information are areas in which human factors teams are seeking additional insights. Varying industry procedures on scoring task completion, demonstrating use error rectifications, and appropriately grouping tasks for summative studies can provide valuable clarity support HF teams in ensuring compliant usability testing documentation.

- Scoring tasks in summative studies
- Varyin sample size in submissions
- Root cause analysis in summative

PANELISTS:

Russell J. Branaghan, *Professor,* **ARIZONA STATE UNIVERSITY**

Deepti Surabattula, *Principal Human Factors Engineer,* **FUJIFILM**

2:15 CASE STUDY: STRATEGIES TO ENHANCE POSTMARKET USABILITY PROCESSES

A majority of medical device human factors teams lack a robust process for evaluating the usability of a product once FDA approval is received, which creates a significant risk as postmarket usability incidents can lead to costly product recalls or increased regulatory scrutiny. Usability teams are striving to create a harmonized process for obtaining postmarket user data and analyzing documented complaints to detect inherent device usability flaws to proactively mitigate risk. Monitoring potential compliance issues with postmarket usability studies and developing a process to analyze user experience on marketed devices is critical for maintaining both optimal user experience as well as ensuring the continued safety of the device.

- Utilizing linguistic tools to analyze device complaints
- Probing newly reported complaints to identify usability
- Strategies for collecting additional user experience data
- Impending regulatory requirements for postmarket HF

Jason Wise, *Staff Human Factors Engineer,* **SIEMENS**

3:00 CASE STUDY: DETERMINING NECESSARY DESIGN CHANGES TO MITIGATE USE ERRORS

Following the detection of use errors, HF teams are tasked with determining if a design change is required and if the error remedy requires a minor design modification or a complete redesign. Product change recommendations require comprehensive usability study data to justify a design update, and additional challenges exist in creating a consensus around the minimum amount of use error incidents to merit a design update. Delving into creating a baseline criteria to recommend a design update, best practices for identifying the specific mechanisms causing user failures, and avenues to collaborate with design teams for overall safety will ensure robust usability and compliance.

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

3:45 CLOSING REMARKS & PROGRAM CONCLUSION