dge DYNAMIC GLOBAL EVENTS

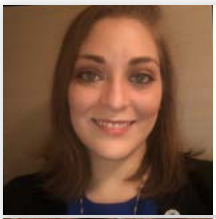
ONLINE LIVESTREAM
DECEMBER 5-6, 2022

3RD HUMAN FACTORS ENGINEERING & USABILITY STUDIES CONGRESS

Improving User Experience and Regulatory Success through Innovative Designs of Medical Devices, Combination Products, and IFUs

FEATURED SPEAKERS

Regina Atim
Founder, **CLINICIANS TOUCH HEALTHCARE SOLUTIONS**; Technical Operations, Human Factors, **OTSUKA**



Nicole Bette
Senior Human Factors Engineer

EMBECTA

Paul Blowers
Director, Human Factors, Drug Delivery Solutions

ABBVIE

Joe Cesa
Manager, Human Factors Engineering, Surgical Robotics

MEDTRONIC

James Duhig
Director, Patient Integration, Pharmacovigilance and Patient Safety

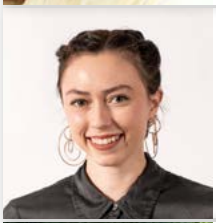
ABBVIE

Valerie Fenster
Director, Packaging and Human Factors Engineering

AKERO THERAPEUTICS

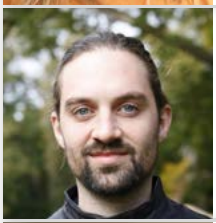
Ed Israelski
Member of Board on Human Systems Integration

NATIONAL ACADEMY OF SCIENCES



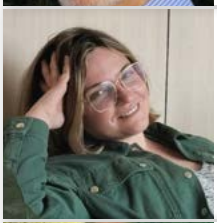
Kai Johnson
Usability Engineer 1

MINNETRONIX



Christian Karlsmose
Senior Usability Engineer

LEO PHARMA

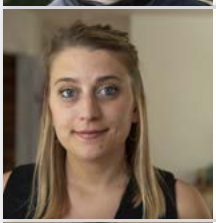


Julie Pronzac
Senior UX Designer

VARIAN MEDICAL SYSTEMS

Joseph Purpura
Associate VP, Executive Director, Head of Medical Device Safety

ABBVIE / ALLERGAN AESTHETICS



Kay Sim
Human Factors Engineer

TELEFLEX

Dan Sloat
Director, User Experience

FRESENIUS MEDICAL CARE

Kelly Sum
User Researcher

INTUITIVE SURGICAL

Leah Swanson
Senior Principal Engineer, Human Factors

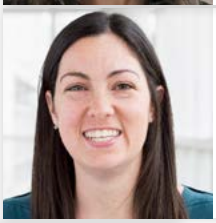
BAXTER

Anneliis Tosine
UX Research Manager

VARIAN MEDICAL SYSTEMS

Medha Tyagi
Design Quality & Human Factors Staff Engineer

STRYKER

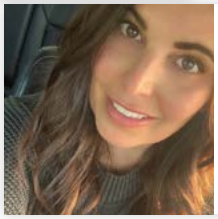


Tiffany Warner
Staff Human Factors Engineer

ETHICON

Anthony Watson
VP, Regulatory Affairs

PEAR THERAPEUTICS



Denise Ziemann
Application Engineer, Human Factors & Usability Engineering

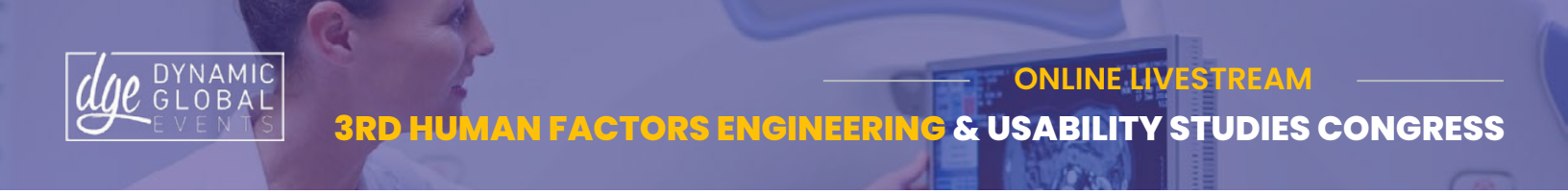
3M

> **All the speakers were terrific!**
>
> ASSOCIATE DIRECTOR, PRODUCT DEVELOPMENT, CERUS CORPORATION

> **I really enjoyed the presentations; they were relevant and applicable to my current role and experiences.**
>
> HUMAN FACTORS ENGINEER, BAXTER

IN-DEPTH ANALYSIS:

- Identifying the optimal amount of TRAINING DECAY
- Learning the right lessons from SELF-CORRECTED USER ERRORS
- Understanding the level of realism and detail expected for SIMULATED USE ENVIRONMENTS
- Overcoming the unique challenges of TESTING FOR HOME-USE
- Properly integrating human factors input throughout the DEVELOPMENT LIFE CYCLE



DYNAMIC GLOBAL EVENTS

ONLINE LIVESTREAM

3RD HUMAN FACTORS ENGINEERING & USABILITY STUDIES CONGRESS

Facing higher team turnover rates, unclear regulatory expectations, and the logistical and scheduling challenges of remote work environments, human factors and usability testing has become more difficult and unpredictable than ever. DGE invites you to learn and network with an incomparable global team of experts at the **3RD HUMAN FACTORS ENGINEERING & USABILITY STUDIES CONGRESS**, streaming **online December 5-6.**

NO OTHER EVENT GOES INTO AS MUCH DETAIL ON THESE CRUCIAL TOPICS YOUR TEAMS NEED!

- Finding the right lessons from short-lived, self-corrected user errors
- Focusing on the amount of simulated training decay regulators expect to see in your protocols
- Targeting the optimal levels of realism and detail in simulated use environments
- Overcoming the challenges of test design for the home-use environment
- Ensuring that human factors design input is properly integrated throughout the product life cycle

WHO SHOULD ATTEND

- Human Factors / Human Factors Engineer
- Usability
- User Experience / User Interface / UX / UI
- Combination Products / Combo Products
- Device Development / Device Technology
- Design Assurance Engineer
- Engineering / Mechanical Engineering
- Product Development / New Product Development
- Device Development
- Device Technology
- Device Design
- Industrial Design
- Design Controls
- Quality / Product Quality
- Regulatory Affairs
- Handheld
- Wearable / Wearables
- Patient Experience
- Risk / Risk Management
- Pharmaceutical Development Operations
- Technology / CTO
- Technical Support
- R&D / R&D Engineer
- Customer Experience
- Engineering / Device Engineering / Clinical Engineering
- Architect / Design Architect / Solutions Architect
- Validation
- Packaging
- Labeling
- Instrumentation
- Mobility

REGISTER

DAY ONE

Monday, December 5th, 2022

ALL TIMES ARE IN EST

8:00 AM	**Registration & Log In**
8:45 AM	**Chairperson's Opening Remarks** Joseph Purpura, Associate VP, Executive Director, Head of Medical Device Safety, **ABBVIE / ALLERGAN AESTHETICS**

BEST PRACTICE IN FINDING, GATHERING, AND LEARNING FROM USER GROUPS

9:00 AM	**Balance the Need for Usage Data Access while Maintaining Patient Privacy**

If designers had easier access to patient usage data, they could produce a better, safer user experience. Greater data flexibility can make designers more attentive to patient needs that may not always be evident to clinicians – but at all steps, you must take care to keep data safe and anonymized.

- Give designers more keys and insights to produce better designs and UX
- Enable designers to analyze patient insights
- Empower patients to be more active in their own care

Julie Pronzac, Senior UX Designer, **VARIAN MEDICAL SYSTEMS**

9:45 AM	**PANEL: Correct for Subjective Bias when Observing Short-Lived or Self-Corrected Errors**

What does it mean if a user came close to an error, but stopped themselves just beforehand – or was able to quickly reacquire correct device use? Do you need to account for and differentiate these in your results?

- Outline the most common dilemmas about subjective observations
- Fine-tune your thresholds for identifying errors and pre-error steps that are "close enough"
- Understand the differing voices on this issue

Kai Johnson, Usability Engineer 1, **MINNETRONIX**
Regina Atim, Founder, **CLINICIANS TOUCH HEALTHCARE SOLUTIONS**; Technical Operations, Human Factors, **OTSUKA**
James Duhig, Director, Patient Integration, Pharmacovigilance and Patient Safety, **ABBVIE**

10:30AM	**Break**
10:45 AM	**Turn User Frustrations into Learning Opportunities**

If a user is struggling with your product and seems to be getting frustrated, you could step in and solve it for them… which would fail the study. If they stick it out and keep trying, you could salvage the results. How do you know when to intervene, and what are the best tools and phrasing to use in such circumstances?

- Pre-plan open-ended questions that encourage users to think through their frustrations
- Coach them to step back and re-evaluate while still maintaining normal use behavior
- Find the best language for describing training scenarios or IFUs

Kay Sim, Human Factors Engineer, **TELEFLEX**

11:30 AM	**Integrate Feelings and Emotions into UX Research**

Focusing too much on traditional cognitive dimensions of usability testing can lead to a limited caricature of what your user is actually like. Often, users aware they are being observed will become "people-pleasers" and not admit frustration or failure, which can impact both your results and the overall product experience. The dynamic of their emotional landscape is a key part of the user experience and should be included in your data sets – but this is hard to define, or to consistently capture. By finding the appropriate measure of a user's changing emotional state, you can more clearly capture the patient journey and shape better outcomes.

- Use 1-on-1 interviews to construct taxonomies of emotions
- Look beyond mechanical error to reveal what users articulate as troubling to them
- Acknowledge the role emotion plays in allowing users to absorb what they hear

Dan Sloat, Director, User Experience, **FRESENIUS MEDICAL CARE**

12:15 PM	**Lunch**
1:15 PM	**Explore Recent Regulatory Trends on Design and Validation of IFU's.**

We have seen the US FDA and EU regulatory authorities increase scrutiny as well as evolving their preferences for both design details and validation evaluation methods for medical product IFUs. The FDA has published new Guidance: Instructions for Use — Patient Labeling for Human Prescription Drug and Biological Products — Content and Format. This session will review those guidances, and also describe how sponsors responded to recent regulatory observations from actual product submissions.

- No use of white text on color backgrounds
- No highlighting of important text in color (e.g. red)
- Emphasized concern about "color blind" users, which in some cases is misinformed.
- Preferences for non-standard symbols
- Specific preferences for certain types of graphical illustrations not supported by usability test data
- IFU Layout option preferences including numbering and organizing schemes
- IFU Validation should be separate from User Interface validation
- IFU test participants should not be instructed to find information in the IFU materials while being asked Knowledge Task Questions.

Ed Israelski, Member of Board on Human Systems Integration, **NATIONAL ACADEMY OF SCIENCES**

CONSTRUCT INNOVATIVE TEST PROTOCOLS

2:00 PM	**Reinvent Usability Testing to Confront the Complexity Challenges of Surgical Robotics**

Surgical robotics are among the most complex of all medical devices – a "system of systems," with multi-layered user interfaces. The sheer number of steps required to manage such complexity can itself be a source of error. What are the most important steps your teams must bear in mind to keep robotics manageable and testable while still meeting timelines?

- Clearly envision the architecture of a multi-layered system
- Ensure users know how to prioritize alarms
- Confront circumstances where robotic features themselves may surprise or confuse surgical users – such as whether brief armature collisions trigger alarms

Joe Cesa, Manager, Human Factors Engineering, Surgical Robotics, **MEDTRONIC**

2:45 PM	**Break**
3:00 PM	**Determine Ideal Levels of Realism and Detail for Simulated Use Environments**

Even in early stage research, device technicians are pressed to keep their testing areas matching real life circumstances as much as possible. But this can raise challenges when the fidelity of the use environment is not in itself critical. How much representation is really required, and how much is just an "extra"? Is there such a thing as too much detail?

- Highlight circumstances when asking users to pretend would lead to unnatural behaviors and inhibit produce use
- Avoid risking your budgets and timelines by representing all fine detail in an environment
- Find a middle ground on the realism spectrum

Christian Karlsmose, Senior Usability Engineer, **LEO PHARMA**

3:45 PM	**Standardize Simulated Training Decay Periods for Usability Validation Testing**

There is no firm consensus on the amount of training decay that realistically represents final device use. What is the ideal amount that you should aim for in order to meet regulatory expectations and keep users safe from errors? And does the length and severity of training decay differ based upon task type?

- Review results of a pilot study and extrapolate next steps
- Highlight the differences in training decay for perceptual, cognitive, and motile tasks
- Refine methods for categorizing task types

Kelly Sum, User Researcher, **INTUITIVE SURGICAL**

Day 1 Concludes

DAY TWO

Tuesday, December 6th, 2022

ALL TIMES ARE IN EST

8:00 AM — **Registration & Log In**

8:45 AM — **Chairperson's Recap of Day One**
Joseph Purpura, Associate VP, Executive Director, Head of Medical Device Safety, **ABBVIE / ALLERGAN AESTHETICS**

MAINTAIN COMPLIANCE DURING REGULATORY UNCERTAINTY

9:00 AM — **PANEL: Technically Assess Usability from a Home-Use Perspective**

Guidance documents for testing home-use devices leave many questions unanswered; in practice, FDA typically reviews study design on a case-by-case basis. What new steps must you take for testing devices that are primarily initiated, used, and discarded specifically in the home?

- Confront a lack of infrastructure as compared to more general-use devices that could be meant for hospitals
- Understand regulatory requirements and flexibility
- Clearly distinguish between devices that can be used in a home and those designed specifically for that

MODERATOR: Joseph Purpura, Associate VP, Executive Director, Head of Medical Device Safety, **ABBVIE / ALLERGAN AESTHETICS**
Anthony Watson, VP, Regulatory Affairs, **PEAR THERAPEUTICS**
Paul Blowers, Director, Human Factors, Drug Delivery Solutions, **ABBVIE**

9:45 AM — **Anticipate and Meet FDA Expectations for Use Error Analysis**

FDA reviewers expect you to clearly present use-related risks for critical tasks, with extensive detail on the stages where they occurred and the mitigations you have planned. Whenever you make a product change that involves revalidation, you will need to provide a clear and strong rationale.

- Paint the clearest picture of what Use Errors look like
- Recognize that task analysis is the foundation for Use Error Analysis
- Learn the clearest lessons from past enforcement

Valerie Fenster, Director, Packaging and Human Factors Engineering, **AKERO THERAPEUTICS**

10:30 AM — **Take a Practical View into Inclusive Device Design Methodologies**

Regardless of your position, there are small changes you could make starting today to better incorporate inclusive design into your company and your product development. These seemingly small changes can have big impacts down the line that you might not have foreseen.

- Define concepts – what is inclusive design, and what isn't
- Analyze the connection between workplace inclusion and device design inclusion
- Spotlight inclusive design tools you can begin incorporating into every phase of the product development life cycle

Nicole Bette, Senior Human Factors Engineer, **EMBECTA**

11:15 AM — **Break**

LEAD DIVERSE TEAMS TOWARDS DESIGN SUCCESS

11:30 AM — **Build a Cross-Disciplinary Team to Execute Summative Tests**

A well-executed summative test requires input from many disciplines, including risk management, product management, quality assurance, device development, training, and others – not all of which will have usability expertise. Team members from these other disciplines may not fully understand just how invested they need to be in the test, from the early stages, for your device to be a success.

- Set expectations regarding internal stakeholders needed in each test phase
- Scope your test to evaluate a comprehensive set of risk controls
- Know when to start recruiting and scheduling participants
- Create an accurate test environment for more accurate test results
- Disposition findings efficiently

MODERATOR: Tiffany Warner, Staff Human Factors Engineer, **ETHICON**
Anneliis Tosine, UX Research Manager, **VARIAN MEDICAL SYSTEMS**
Denise Ziemann, Application Engineer, Human Factors & Usability Engineering, **3M**

12:15 PM — **Evaluate Whether Users can Accurately Hypothesize the Causes of Error**

Traditionally, test users would be interviewed shortly after observed task completion to determine what led them into error. But it may be that if a user has had a few minutes since touching a product, they have lost the ability to truly recall what was going through their minds during the error. Based on what your users tell you, can you accurately grasp what potential errors could be – or do you need to restage with a larger sample size?

- Recognize when users are hypothesizing a what-if scenario for errors they cannot otherwise explain
- Gauge the likelihood that a test user is extrapolating for multiple errors they believe they encountered
- Open doors to new testing methodologies

1:00 PM — **Lunch**

2:00 PM — **Better Integrate Human Factors Engineering Throughout the Product Life Cycle**

Too often, human factors are only discussed in a few product phases, aiming towards product evaluation – when so much more could have been achieved if key studies had started earlier. With better-planned routine involvement, HF engineers can act as a differentiator among competitors, gain deeper understanding of end-users, design more customer-centric products, and ultimately save on costs.

- Facilitate individual research and customer interaction
- Justify HF involvement in all stages, including post-market evaluation
- Engage earlier in order to guide the design of a more effective, user-friendly product
- Cultivate deeper awareness of HF among other teams to minimize inter-departmental disagreements

Medha Tyagi, Design Quality & Human Factors Staff Engineer, **STRYKER**

2:45 PM — **Select Technologies that Enable Global Cross-Team Collaboration**

Getting HF involved sufficiently early in the design process to allow for collaboration and meaningfully impact product development can require working with diverse and widely-dispersed teams, across different time zones, functions, countries, and cultures. What technologies are best for guaranteeing accessible and understandable information for all team members, and how quickly and efficiently can you leverage them for better partnerships?

- Train regional project managers to "follow the sun" with briefings and data transfers across time zones
- Maintain shared secure data archives for ready use
- Grasp that expectations for timeframes may differ regionally

Leah Swanson, Senior Principal Engineer, Human Factors, **BAXTER**

Conference Concludes

ONLINE LIVESTREAM

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