DYNAMIC GLOBAL EVENTS

MAY 15-16, 2025

WYNDHAM PHILADELPHIA HISTORIC DISTRICT | PHILADELPHIA, PA

6TH HUMAN FACTORS ENGINEERING & USABILITY STUDIES CONGRESS

Maintaining Regulatory Compliance and Cross-Functional Team Expertise while Designing and Testing Devices that Ensure Market Dominance and Minimize Use Errors

Improve your Communication Methods with Users to Get Clearer Feedback

Ellie Rundell
Usability Leader
SANOFI

Mark Destefano
Director, Combination Products and Devices R&D, Advanced Technology R&D
TEVA

Emily McClellan
Human Factors Engineering Specialist
MERCK

Leverage In-House Expertise to Drive HFE Success

Mary Pat Cottengim
Senior Principal Usability Engineer
BAUSCH & LOMB

Focus on the Impact of Human Factors in Early Stage Device Selection

Bidisha Nandi
Human Factors Engineer
REGENERON

Darian James
Senior Scientist, Device Development
MERCK

Ease Human Factors Recruitment for Rare Disease Populations

Sibi Ramachandran
Human Factors Engineer, Device Development
ALEXION

Learn Key UX Lessons for Artificial Intelligence in Healthcare

Vera Shuman
Advanced Software Development Specialist
SOLVENTUM

Navigate the Overlap Between HFE Formative Work and Traditional UX Design Work

Patrick Lukasak
Principal Designer
MEDTRONIC

> **Excellent topics and speakers!**
>
> –Human Factors Engineer, **INNOVENN**

> **All talks have been very high quality!**
>
> –Manager, **KINNEIR DUFORT**

6TH HUMAN FACTORS ENGINEERING & USABILITY STUDIES CONGRESS

Designing the next generation of medical devices and combination products requires smoothly navigating regulatory and technological changes while also gathering the needed data from every user group; but now you face the new challenges of working with AI and designing IFUs that most users will see on their smartphones.

DGE invites you to its **6th Human Factors Engineering & Usability Studies Congress** – the industry's most trusted and in-depth meeting on the technical, regulatory, and teamwork skills that your product pipeline needs! This year's all-new agenda features detailed insights on:

- Learning key UX lessons for AI in healthcare
- Navigating regulatory requirements in Japan
- Using HF to guide early stage device selection
- Minimizing the impact of observers on usability testing
- Improving communication methods with user groups to get clearer feedback
- Ensuring test protocols reflect real-world conditions

.....and much more! **Join us May 15-16** in Philadelphia for answers to all your crucial usability questions!

WHO ATTENDS

- Medical Device
- 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

> **The conference was very well organized, the venue was nice, the speaker topics had a good variety and were all well-put together.**
>
> -Senior Human Factors Engineer, **OUTSET MEDICAL**

> **Very informative and relevant to our work.**
>
> -Device Engineer, **TEVA**

DYNAMIC GLOBAL EVENTS

6TH HUMAN FACTORS ENGINEERING & USABILITY STUDIES CONGRESS

FEATURED SPEAKERS

Ken Catchpole
Chair, Clinical Practice and Human Factors

MEDICAL UNIVERSITY OF SOUTH CAROLINA

Megan Conrad
Associate Professor

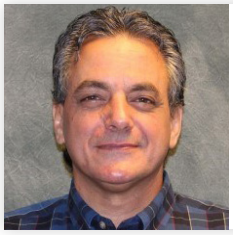
UNIVERSITY OF DETROIT MERCY

Mary Pat Cottengim
Senior Principal Usability Engineer

BAUSCH & LOMB

Siddharth Desai
Chief Technology Officer

PRISTINE SURGICAL



Mark Destefano
Director, Combination Products and Devices R&D, Advanced Technology R&D

TEVA

Anastasia Diamond
Principal, Regulatory Affairs & Human Factors

WEST PHARMA

Valerie Fenster
Director, Packaging and Human Factors Engineering

AKERO THERAPEUTICS

Martijn Gommeren
Principal Human Factors Engineer

CONVATEC

Ed Israelski
Co-Convener, **ISO/IEC Joint Working Groups For Usability Engineering Medical Device Standards,** Technical Advisor, Human Factors

ABBVIE

Darian James
Senior Scientist, Device Development

MERCK

John Li
Associate Director, Human Factors

MERCK

Patrick Lukasak
Principal Designer

MEDTRONIC

Emily McClellan
Human Factors Engineering Specialist

MERCK

Bidisha Nandi
Human Factors Engineer

REGENERON

Sibi Ramachandran
Human Factors Engineer, Device Development

ALEXION

Ellie Rundell
Usability Leader

SANOFI

Drew Seils
Senior Manager, Human Factors & Usability Engineering

MEDTRONIC

Vera Shuman
Advanced Software Development Specialist

SOLVENTUM

Aishwarya Suresh
UX Manager, Customer Centered Design

MEDTRONIC

REGISTER

DAY ONE

Thursday, May 15th, 2025

ALL TIMES ARE IN EST

8:00 AM	**Registration & Networking Breakfast**
8:45 AM	**Chairperson's Opening Remarks**

KEEP UP WITH NEW REGULATIONS AND TECHNICAL DEVELOPMENTS

9:00 AM	**Navigate Human Factors in Japan: Regulatory Insights and Design Considerations for Combination Products**

- Review new regulatory standards and requirements for combination products, packaging, IFUs, and adverse event reporting in Japan
- Understand the role of HCPs in Japan and their impact on combination product design and development
- Adapt to cultural and linguistic differences in product design and labeling

John Li, Associate Director, Human Factors, **MERCK**

9:45 AM	**Learn Key UX Lessons for Artificial Intelligence in Healthcare**

As healthcare solutions increasingly feature AI, this brings new challenges to usability research. AI outputs can have a broad range of quality and noticeably "weird" errors – so how can you confidently assess risks and validate products? AI also significantly changes user workflows, making it more important to ensure working on the right problems.

- Plan a good workflow fit when user workflows are changing
- Develop and validate automatic metrics required for AI model optimization based on user feedback
- Increase your skill set to include data wrangling and quantitative analysis skills

Vera Shuman, Advanced Software Development Specialist, **SOLVENTUM**

10:30AM	**Networking Break**
11:00 AM	**Focus on the Impact of Human Factors in Early Stage Device Selection**

- Utilize HF in formative studies to narrow down multiple device options
- Evaluate user needs and requirements in early stages
- Recognize how patient characteristics can impact device function in unexpected ways

Bidisha Nandi, Human Factors Engineer, **REGENERON**
Darian James, Senior Scientist, Device Development, **MERCK**

11:45 AM	**Pinpoint Usability Challenges of Lyophilized Drug Products**

Old-fashioned methods for reconstituting lyophilized drug products placed a heavy burden on lay users, who often struggled to mix and inject them properly. Dual-chambered devices can take some of these challenges away, but introduce new ones – so how can you strike the best balance in your designs?

- Review market progress of dual-chambered syringes and auto-injectors
- Outline the new challenges of dual-chambered devices
- Adapt device design around drug formulations that users must be allowed to self-administer

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

12:30 PM	**Lunch**

1:45 PM	**CASE STUDY: Human Factors in Single Use Medical Devices and Integrated H/W and S/W**

Single-use endoscopy products must integrate input from both users, use environment, and the user interface. When designing a single-use product with associated software component, aimed for use by surgical team members, teams must prioritize a thorough hazard analysis.

- Recap the HF and system architecture of a single-use endoscopy device
- Evaluate the impact of single-use vs reusable devices
- Trace development through actual and simulated study environments

Siddharth Desai, Chief Technology Officer, **PRISTINE SURGICAL**

GATHER THE MOST USEFUL FEEDBACK FROM USERS AND TEAM MEMBERS

2:30 PM	**Minimize Impact of Observers on Usability Testing**

How would you feel walking into a room of 12-15 people all eager to watch you potentially fumble through using a tool you've never seen before? As researchers responsible for organizing such studies, we need to be able to lead without authority when planning user studies and set clear boundaries for attendees. This can be harder to do when starting in a new role or early in one's career before gaining confidence to ensure that even business leaders know their place when attending usability testing.

- Understanding potential impact and biases induced by attendees
- Setting boundaries with project teams
- Considerations for space and facility planning for research

Drew Seils, Senior Manager, Human Factors & Usability Engineering, **MEDTRONIC**

3:15 PM	**Networking Break**
3:45 PM	**PANEL: Improve your Communication Methods with Users to Get Clearer Feedback**

It is too easy to get into a mental frame of conducting research when what you really need to do is hold conversations. Treating test users like a performance for you to view will yield far worse results than understanding their mental models and motivations – and this will require convincing them that you are on their side, not judging them.

- Frame their involvement as helping you with a project, not assessing their abilities
- Position yourself as a "safe" outside opinion with whom they can share confidential critiques
- Modify your approach as needed to gather feedback about internal tools

Ellie Rundell, Usability Leader, **SANOFI**
Mark Destefano, Director, Combination Products and Devices R&D, Advanced Technology R&D, **TEVA**
Emily McClellan, Human Factors Engineering Specialist, **MERCK**

4:30 PM	**Find the Best Way to Add Root Cause Analysis to User Research**

Typically, user research does not require root cause analysis of how use errors are detected and analyzed for risk and root cause. With no specific guidance from regulators, companies can approach user research in highly different manners.

- Adapt best practice around your scope and creative style
- Debate the number of formative tests you should perform, and how you know when to stop
- Acknowledge why some companies may actually want to avoid best practice recommendations on root cause analysis

Anastasia Diamond, Principal, Regulatory Affairs & Human Factors, **WEST PHARMA**

5:15 PM	**Navigate the Overlap Between HFE Formative Work and Traditional UX Design Work**

- Recognize the value of designers partnering closely with HF teams
- Focus on UX tools that designers leverage
- Analyze similarities and differences of the two teams

Patrick Lukasak, Principal Designer, **MEDTRONIC**

Day One Concludes

DYNAMIC GLOBAL EVENTS

DAY TWO

Friday, May 16th, 2025

ALL TIMES ARE IN EST

8:00 AM	**Registration & Networking Breakfast**
8:45 AM	**Chairperson's Recap of Day One**
9:00 AM	**Ease Human Factors Recruitment for Rare Disease Populations**

Recruitment for a full Human Factors summative study is especially difficult when working in the realm of rare disease. Is there a better, more structured way to approach recruitment that can yield better results and ease the stress of a human factors summative study?

- Work with internal resources to start creating a panel of interested patients
- Build a surrogate justification that can overcome FDA scrutiny
- Collaborate with vendors to help ease the burden of recruitment

Sibi Ramachandran, Human Factors Engineer, Device Development, **ALEXION**

9:45 AM	**Test for Medical Device Usability In Real-World Conditions**

Integration of technologies into regular everyday work systems benefits from human factors considerations. Medical devices are not always designed around the complex, messy and unpredictable situations in which they are used. Using direct observations of clinical work, systems analysis approaches, human factors integration frameworks, and incident reports, you can continue to bridge the gap between "work as imagined" and "work as done" for device design and implementation.

Ken Catchpole, Chair, Clinical Practice and Human Factors, **MEDICAL UNIVERSITY OF SOUTH CAROLINA**

10:30 AM	**Networking Break**
11:00 AM	**Plan a Business Strategy to Get the Funding your Projects Require**

It can still be difficult to get upper management to understand the value of HFE/UI, and this can be an obstacle to funding key projects. It is crucial to prepare for 1-on-1 advocacy and to spread a grassroots personal management understanding of your work so other teams know how and when to approach you.

- Assess how frequently your own projects don't get funded due to what are perceived as higher priorities
- Confront head-on the reputational challenges you face in a field that lacks clear meanings and metrics and that may be seen as less important than systems, safety, or software
- Home in on the value proposition
- Show ROI Rate of Return for investments in HFE/UE with mini-business cases

Ed Israelski, Co-Convener, ISO / **IEC JOINT WORKING GROUPS FOR USABILITY ENGINEERING MEDICAL DEVICE STANDARDS**; Technical Advisor, Human Factors, **ABBVIE**

11:45 AM	**Leverage In-House Diverse Expertise to Drive Human Factors Engineering Success**

What are the best strategies for building and advocating for diverse, cross-functional teams? By learning to harness the full potential of HFE, you can bring your team and organization to new levels of success.

- Convey the benefits of in-house usability research
- Cultivate cross-functional teams with diverse expertise and interest in HFE
- Recruit from varied backgrounds and experience to enrich team capabilities and testing outcomes
- Utilize insights from psychology and education to streamline user training and enhance usability

Mary Pat Cottengim, Senior Principal Usability Engineer, **BAUSCH & LOMB**

12:30 PM	**Lunch**
1:45 PM	**Cater to Different Instruction Styles by Developing and Validating Quick Reference Guides and QR Codes**

IFUs are required to carry so much safety information that they may be more intimidating than educational. Users often rely more on previous experience, on instructions from HCPs or other promotional support resources, or even social media. These can be more digestible – but have different risk and regulatory considerations.

- Highlight success rates of instructional materials, including risk mitigations and user adherence of the UI experience.
- Review conflicting feedback from health authorities on whether quick reference guides and QR codes are acceptable – and how this varies across markets and regions.
- Keep user preferences and capabilities in mind throughout IFU design.

Martijn Gommeren, Principal Human Factors Engineer, **CONVATEC**

2:30 PM	**Translate Input from Biostatisticians for HFE Team Members**

Comparative use guidelines for generics can cause confusion for your team, as they were written with a biostatistics perspective that focuses on clinical trial design, not HF studies. Each sector lacks understanding of the other, and this can get in the way of proper comparative analysis and leveraging data.

Megan Conrad, Associate Professor, **UNIVERSITY OF DETROIT MERCY**

3:15 PM	**Building a Better UIDD: A Framework for Collaboration and Risk Mitigation**

The User Interface Design Description is a critical document within the Design Control process, yet it has historically been challenging to read and navigate. The key question is: how can we transform the UIDD into a more effective, user-friendly tool that serves as a valuable resource for all stakeholders, particularly the HFE team?

- Simplify the UIDD: Streamline the document's structure and present workflows in a clear, intuitive manner, making it easier for all stakeholders to understand and utilize.
- Collaborate with HFE early: Engage the HFE team in early discussions to walk through the system workflows, enabling the identification and mitigation of potential risks at the outset of the project.
- Evolve the UIDD over time: Continuously refine and update the UIDD as the project progresses, ensuring that it accurately reflects the evolving design and remains a relevant tool for decision-making and risk management.

Aishwarya Suresh, UX Manager, Customer Centered Design, **MEDTRONIC**

Conference Concludes

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PRICING

SUPER EARLY BIRD
$1,896
Register by February 21

EARLY BIRD
$2,096
Register by March 21

STANDARD
$2,296
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$2,496
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