ALL-NEW SESSIONS AND BEST PRACTICES FOR:

- Building User Expectations into Medical Device Software Design
- Empowering Project Leaders to Meet Device Testing Deadlines
- Gathering Input from KOLs to Improve Usability Concepts
- Recruiting the Right User Populations for Challenging Validation Studies
- Modifying Your Training Syllabus for Human Factors Tests

Content was very relevant and novel to me. A pleasure to hear from such experts!
—Human Factors Engineer, GENENTECH

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MEDICAL DEVICE
USABILITY

To Register: 866-207-6528
www.exlevents.com/humanfactors
Dear Colleague,

Medical devices and combination products are under tighter regulatory scrutiny than ever to ensure the safety and efficacy of the user experience. The past year has seen a number of new guidelines delivered by the FDA and MHRA, yielding many new questions about the best ways to maintain compliance around identifying risk and selecting proper user groups. This can be particularly challenging for traditional pharmaceutical companies that are now attempting to design combination products but may lack long-term experience in human factors engineering.

ExL’s 2nd Human Factors Engineering & Usability Studies Summit provides you with an unprecedented depth of understanding regarding the technical and regulatory requirements for designing a successful combination product. No other event offers more up-to-date analysis of domestic and international regulatory guidelines while also guiding best practice toward improving the device user experience. Join us to learn how to:

- Ensure compliance with the latest regulatory guidelines on human factors
- Improve your outreach and training methods for diverse user populations
- Optimize your validation testing methodologies
- Upgrade the user experience for medical device software and apps
- Lead teams to a better understanding of human factors engineering needs

I look forward to welcoming you to Burlingame this February!

Sincerely,

Matt Greenbaum

Matt Greenbaum
Production Team Leader

WHO SHOULD ATTEND:
This conference is designed for pharmaceutical, biotech and medical device professionals responsible for:

- Human Factors/Human Factors Engineering
- Usability
- Combination Products
- Device Development/Device Design/Device Technology
- Product Development
- Device/Patient Safety Pharmaceutical Development Operations
- Technology
- Research & Development
- User Experience
- Customer Experience
- Engineering/Device Engineering/Clinical Engineering
- Design Controls
- Industrial Design
- Validation
- Packaging
- Quality/Quality Control/Quality Assurance/Quality Engineering
- Regulatory Affairs/Regulatory CMC
- Risk Management
- Pharmacovigilance
- Software Engineering/Software Management/Software Development
- Marketing
- Clinical Affairs/Clinical Research/Clinical Development

This event is also of interest to:

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

VENUE
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9:00 Develop the Best Response to EU Requirements for Time-Centric User Tests
EU regulators are now requiring medical device developers to undergo a unique user test, which significantly differs from the US validation standards. These new tests focus on the label reading comprehension and timed speed of sample users who do not share the disease indication of intended users. What is the best way to move forward with this new challenge?
   ➤ Differentiate between reading comprehension and in-hand device use success
   ➤ Make the case to EU regulators that timed use is not realistic
   ➤ Learn best practice for modifying user test methodologies
Valerie Fenster, Senior Manager, Human Factors Engineering, AMGEN

9:40 Clarify when No Further Submissions of Protocols to the FDA Are Possible
It typically takes four months for the FDA to review your protocol submissions – and at some point, your development timelines will no longer allow you to delay a product launch. You will eventually reach a point where the benefit of the latest FDA feedback no longer outweighs the risk of them having a problem with your final report.
   ➤ Benchmark how many submissions and how much feedback will be considered adequate
   ➤ Prioritize meeting development timelines over multiple redundant submissions
   ➤ Grasp the potential risk factors and most likely questions should a problem arise later
Willy Liou, Senior Manager, Regulatory Affairs, AMGEN

10:20 Assemble Your Best Efforts at Testing “Production Equivalent” Usability
Due to the time requirements for detailed usability studies, you will rarely have your production process completely finalized or ready-to-self devices. You need to get as close to final as possible during your testing, but this opens up a wide range of definitions.
   ➤ Pinpoint the likelihood of using verified lines with processes similar to the final manufacturing environment
   ➤ Determine the magnitude of change still likely before final production
   ➤ Gather perspectives from multiple companies and international regulators
Maxim Budyansky, Chief Technology Officer, AVITUS ORTHOPAEDICS

11:00 CombiningUSERías

11:30 Scale Usability Engineering Efforts Based on the Situation – Including New Product Development, Line Extension, Technical Change and Remediation
How do you design your usability engineering procedures and documentation to effectively assess, document and pass the scrutiny of regulatory agencies (e.g., the FDA and EU)? Some of these devices may have already been used by clinicians for decades. If you’re making noncritical changes to a product, must you still devote as much effort as you would for a product being newly developed?
   ➤ Discuss how and why you should develop your usability procedure to allow for the various situations that medical device manufacturers run into during product development. Avoid the ‘one size fits all’ approach
   ➤ Leverage user interfaces of unknown provenance effectively
   ➤ Use QMS subprocesses (e.g. risk management and postmarket surveillance) to guide, assess and demonstrate the effectiveness of use error controls
   ➤ Use usability testing (both formative and summative) based on the changes made to the product’s user interface
Jeremy Hansen, Design Assurance Engineer, Product Development, ULTRADENT

12:10 Persuade Budget Holders to Release Funds for Early Stage Testing
With budgets tight and the demands on funds high, it is tempting for senior managers to push back on early stage formative testing and release funds only for what appears to be essential – the validation study. However, this is a false economy: early stage testing gives an opportunity to make small (inexpensive) decisions early rather than being forced to make big decisions later. Other stakeholders, such as the commercial and marketing functions, can help to support your case if you show them how they will benefit too. Budget holders understand cost benefit, so presenting your case from the budget holder’s perspective makes you more persuasive.
   ➤ Present a cost benefit case for early stage testing
   ➤ Persuade senior managers to release funds earlier
   ➤ Enlist other stakeholders to help your case
Richard Featherstone, Managing Director, MEDICAL DEVICE USABILITY

12:50 PANEL: Judge the Dispensation of Results After Errors Arise in Final Simulated Use Studies
Both CDER and CDRH require simulated use studies that must be examined as closely as postmarket studies. If these final simulated use studies reveal errors, how can combination product sponsors tell when they have leeway to advocate for device approval – or when they should admit the need for a late-stage change?
   ➤ Learn to position products as worthy of approval despite errors
   ➤ Recognize the implications of late-stage corrective action steps
   ➤ Examine the best methods for convincing FDA reviewers of your perspective
MODERATOR: Bob North, Owner, HUMAN CENTERED STRATEGIES
Ed Israelski, Technical Advisor, Human Factors, ABBVIE
Jaifying Shen, Director, Device Development – Human Factors, Design Control and Risk Management, MERCK

1:30 Networking Break

2:30 Modify Training Syllabus for Human Factors Tests
The FDA requires an untrained arm of almost every study though it is possible for companies to justify exceptions, such as situations where the audience would be professionals with experience using similar products. The guidelines can be confusing, as they allow waivers for training if it is demanded within the product label, but they also require that device sponsors specify every possible risk – including those resulting from errors among untrained users.
   ➤ Specify when moderators or the shadowing of other users will be recommended
   ➤ Avoid any seeming mandate for practice on a training device
   ➤ Differentiate between training meant for device trainers and that meant for end users
Tresa Daniels, Manager, User Experience, BECTON DICKINSON
Protai Tala, Lead Verification and Validation Engineer, CAS MEDICAL SYSTEMS

3:10 Ensure Adequate Populations for Human Factors Validation Studies
Validation studies require at least 15 participants in each distinct user group, which can be challenging – particularly when dealing with rare indications or equipment used by very specialized personnel. A variety of tactics can be employed to complete validation work in the face of a challenging population.
   ➤ Rely on literature to help define distinct user groups
   ➤ Identify target users through multiple recruitment tactics
   ➤ Determine when surrogates are appropriate and reasonable to use in place of hard-to-find users
Tina Rees, Senior Research Scientist, Human Factors, ELI LILLY

3:50 Networking Break

4:20 Clarify Focus on Combination Product Customers
If a pharma company is too internally focused it will Not clearly understand the viewpoint of its own customers. A better grasp of the needs of end users, especially healthcare practitioners, is essential.
   ➤ Recognize when changes to mechanism, packaging and labeling affect user behavior
   ➤ Separate screening study error reduction from human factors studies
   ➤ Eliminate overconfidence and misconceptions about customer needs
Siddharth Desai, Director, Device Development, HERON THERAPEUTICS

5:00 Fully Integrate Visual Design with Usability Considerations
Human factors considerations can sometimes take a backseat to the visual design of a device’s shape and colors — but the two cannot truly be separated. Visual design has a strong impact on the user experience, and design teams must take this into account.
   ➤ Clarify the risks of visual design decisions that do not account for user needs
   ➤ Encourage close cooperation between visual designers and usability experts
   ➤ Proactively convince businesses of the value of usability engineering
Duy Le, Usability Engineer, PHILLIPS HEALTH SYSTEMS

5:40 Day One Concludes
Overcome old attitudes toward customer identity and needs
Modernize what had been a market-focused approach
Maintain the integrity of combination product validation data
Garner feedback on combination product features for end users and
Document all formative studies and their outcomes as needed for reference
Deploy device apps that can be used for orders, refills or drugs that may need
Recognize widespread smartphone access regardless of economic strata
Incorporate software engineers and analytical techniques into your work
Make document updates in a way that doesn’t jeopardize timetables
Gather input and approvals from a project leader; a patient representative;
Change industry attitudes and philosophy around the material and procedural
Rely on KOLs for delivery of multiple concepts and improved productivity
Manage the schedules of multiple team members as well as the product
Avoid changing global rules or other aspects of the user interface
Identify common mistakes by study sponsors
Pinpoint the do’s and don’ts of postmarket research phrasing
Recognize when process changes are necessary for reporting adverse events
Ensure that outcomes of evaluations are properly fed back to all stakeholders
Avoid the most serious errors among consultants

12:30 Break Silos When Sharing Human Factors Expertise
What may come as second nature to classically trained human factors professionals will be more of a challenge for other R&D team members. This is particularly important when sequencing human factors testing within the context of broader clinical tests. The priorities of users, regulators and business needs must all be clarified and addressed during formative evaluations
Convince R&D team and business members that early evaluation of preliminary prototypes does make a difference
Ensure that outcomes of evaluations are properly fed back to all stakeholders and incorporated and traced into other R&D processes
Stand firm in the use of qualitative evaluation methods and resist the pressure to come up with quantitative figures afterward
Document all formative studies and their outcomes as needed for reference in the usability engineering file

Sonja Foerster, Team Leader, Human Interaction Design, Instrument Usability Engineering, ROCHE

MANAGEMENT AND TEAMWORK FOR HUMAN FACTORS SUCCESS

1:00 Luncheon

2:00 Manage Multi-Disciplinary Review Teams to Address Risk and Usability Challenges in Device Design
Late-stage design changes require rapid input from a cross-functional team to ensure that usability problems have been analyzed and resolved. All stakeholders, from regulatory, engineering, quality medical, risk management and other teams, must agree on mitigation steps and the proposed changes must be cost-effective. But how can these committees best be managed—especially when all of the participants may be managing several issues that impact schedules and already have their own deadlines?
Keep a risk-based, quality-oriented focus on meetings with marketing, commercial and regulatory colleagues
Gauge the impact of late-stage changes from a cost and schedule perspective with input from engineering teams
Manage the schedules of multiple team members as well as the product

Edward Halpern, Principal Research Engineer, ABBVIE

2:30 Empower Project Leaders to Meet Device Testing Deadlines
When working on formative tests, all documentation must be approved before you can run a study. It requires significant advance planning to make sure to complete the documents weeks ahead of time so they can go through the necessary review and approval processes.
Gather input and approvals from a project leader, a patient representative, and QA, risk management and regulatory affairs professionals, among others
Recognize when process changes are necessary for reporting adverse events
Make document updates in a way that doesn’t jeopardize timetables

Tatyana Budantsev, Project Manager, PROFUSA

3:00 Teach Your Teams when Usability Research Is No Longer Appropriate
Combination product sponsors put themselves at risk if they fail to understand the difference between market research and the usability testing of a device that is under design control. Postmarket surveillance is always important, but an investigation of why certain devices are more favored than others or what the user experience is like runs the risk of invalidating the research the sponsor has already performed.
Clearly communicate the usability research cycle with commercial and market research colleagues
Pinpoint the do’s and don’ts of postmarket research phrasing
Maintain the integrity of combination product validation data

Valerie Fenster, Senior Manager, Human Factors Engineering, AMGEN

3:30 Conference Concludes

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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
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Complying with the Latest Regulatory Guidelines, Updating the Design and Validation Testing Protocols for Medical Devices and Combination Products, and Optimizing the User Experience

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