We bring together specialists in Human Factors, Industrial Design, Rapid Prototyping and Simulation, Visual Communications and Information Design, Risk Management/Safety, Product Design and Quality/Regulatory Compliance for a comprehensive approach to HCD. Our track record of successful FDA submissions and improved user safety and acceptance speaks for itself. Maybe that’s why 90% of our HCD business comes from satisfied former clients.

**COMPLETE REGULATORY REQUIREMENTS**

Expedite required regulatory testing and move your products to market quickly and efficiently. We deliver objective, easy-to-understand data and analysis that fully meets submission requirements for FDA and other regulatory/notified bodies.

- Run rigorous HCD programs under ISO 13485-certified and FDA-registered Quality Systems.
- Fold HCD activities seamlessly into the Design History File for regulatory submission.

**STREAMLINE DEVICE DEVELOPMENT**

Maximize the value of HCD by building it into the design process right from the start. We can help you condense development timelines and reduce costs and risks by incorporating HCD at all stages of development, from initial concept to pre-market testing.

We deliver integrated design solutions where users, technologies and the operating environments are appropriately matched for optimal, safe and effective use and performance of your medical device. Our systematic approach saves time and money by uncovering potential issues earlier in the design process and discovering hidden insights to help you meet needs your users can’t yet define.

- Conduct high-fidelity in-home or surgical suite studies, low-fidelity simulations, and everything in between—including studies with minors and minors with parents.
- Complete rigorous usability studies, focus groups and simulations in our specialized facilities in Columbus, Baltimore, St. Louis, Boston and Minneapolis.
- Condense development timelines through use of Battelle’s own Institutional Review Board (IRB).

**Our Capabilities**

- Task/Function Analysis
- Heuristic Evaluation
- Formative and Summative/Validation Testing
- Contextual Inquiry/User Research
- Statistical Analysis
- Human Performance Assessment

**Our Markets**

- Drug Delivery
- Surgical Devices
- mHealth
- Home Healthcare
**Evaluating Safety Risks Prior to Market Launch**

A large device manufacturer had developed a surgical tool kit that combined two steps in the established procedure into a single step, changing the workflow. The client perceived this as an efficiency for the procedure and an advantage over existing products. The client came to Battelle late in the development process for a summative study, driven by a letter received from FDA requesting a human factors validation study within a short time period. Lacking a defined Use Failure Modes and Effects Analysis (uFMEA), risk analyses, or any prior formative assessments, we convinced the client to do a formative study prior to the full validation study in order to gain some quick insights at lower cost before engaging in the full study. During the formative research, we identified a significant usability risk that resulted in the procedure taking longer due to the change in workflow. This could be unsafe for patients as the specific procedure was time sensitive. Subjective feedback indicated that surgeons did not like the change in workflow, which could impact adoption. Ultimately, the client decided not to proceed with summative research and halted the launch of the product. Completing the formative research saved substantial cost and prevented the launch of a product with significant liability risks.

**Presenting Complex Medical Information in an Easy-to-Understand IFU**

A large pharmaceutical client came to Battelle for evaluation of their Instructions For Use (IFU) for an injection device. The client had been working with a design firm to develop the IFU and had added a large number of images, believing they would make the IFU easier to understand. However, we discovered that as the client added more images, the actual outcome was an increase in failures when patients tried to use the revised IFU. We researched the procedure and created a single graphic that visually walked the patient through the steps required for use. The IFU provided an effective translation of what the manufacturer believed needed to be communicated into a format that the patient could understand, presented in a visually compelling design.

**Saving Unnecessary Costs on an FDA Revalidation Request**

A pharmaceutical client added a sound suppressor to its auto injector to quiet the device. The FDA thought that this fundamentally changed the device by removing an auditory signal of injection completion and wanted revalidation of the new design for usability. By reviewing the existing risk analyses and past usability test results along with academic literature citations on behavioral principles, Battelle determined that the “auditory cue” did not impact injection behavior because of the speed of the injection process. Human reflexes are not fast enough to stop the process in time to avoid a full injection, with or without an auditory cue. We wrote a white paper to justify not doing a new user study and were able to convince the FDA that the device did not require revalidation. This saved the client the time and money required to do a full summative study of three user groups that would have resulted in a four to five month delay of their product launch.

**Communicating the Hospital Environment**

Battelle was contracted to conduct contextual research in a series of hospitals to better understand the process of dispensing daily medication to patients. We observed hospital environments with different procedures and equipment in place, and created a report highlighting the operational differences. To communicate the significance of our findings, we created a visual process map showing the core steps relating to both types of dispensing procedures, the occupation responsible for each step, as well as key observations. Using color-coding, we were able to visually show the distinct differences in dispensing responsibility, along with potential risks, potential for additional cost/waste, and the amount of time/efficiency required for each step. Using these visual graphics, we were able to evaluate each step of the process and give the client a visual snapshot of the current efficacy and potential opportunity areas.

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**CONTEXTUAL RESEARCH**

“In particular I wanted to commend your team on several best practices including the very well done research summary report — You have built a great foundation for Innovation.”

- **Director, Innovation Programs**
  - Major Pharmaceutical Distributor and Health Information Technology Company

“It is incredible how you were able to take so much complex information and boil it down into a simple, elegant solution.”

- **General Manager, Infection Prevention**
  - Large Biotechnology Company

**CONCEPT DEVELOPMENT**

“The product concepts Battelle created have received the most positive customer feedback we have ever seen!”

- **Global Technology Leader**
  - Large Medical Product Provider

**HUMAN FACTORS**

“I am extremely pleased with how the study is being conducted. It is refreshing to see how well organized everything is. The team is performing extremely well.”

- **Group Head, Human Factors Engineering**
  - Major Pharmaceutical Company

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Every day, the people of Battelle apply science and technology to solving what matters most. At major technology centers and national laboratories around the world. Battelle conducts research and development, designs and manufactures products, and delivers critical services for government and commercial customers. Headquartered in Columbus, Ohio since its founding in 1929, Battelle serves the national security, health and life sciences, and energy and environmental industries. For more information, visit www.battelle.org.

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