



# Battelle Medical Device Solutions

From the initial insight and discovery phase to post-launch, Battelle integrates a deep knowledge base and a device agnostic approach throughout the medical device development process. Our medical product research and development capabilities facilitates the creation of rapid response solutions to solve problems that were previously unsolvable. At Battelle, we can help you seamlessly navigate the pitfalls of the medical device valley of death, enabling your products to get to market and stay in market.

## LET THESE STATS SINK IN

**41%** of R&D leaders say they are ineffective at surfacing new ideas for transformational innovation

The average time for concept development and proof of concept work for a subset of medical device companies is **20** months.

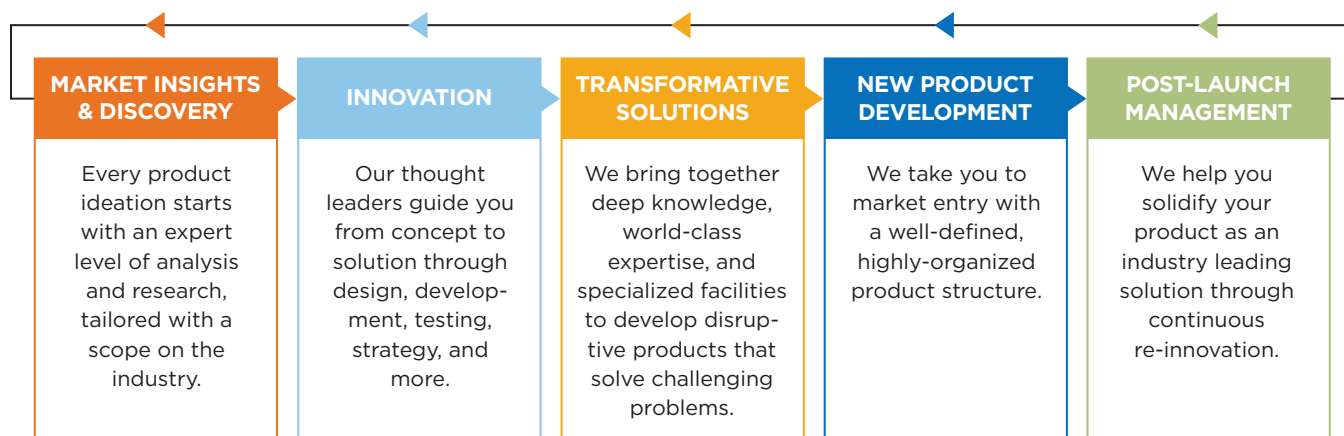
The average total cost for companies to bring a low- to moderate-risk 510(k) product from concept to clearance is approximately **\$31** million.

High risk (PMA) average is **\$94** million.

More than **80** percent of medical technology companies have fewer than **50** employees.

Battelle's Medical Device Solutions are uniquely positioned to impact all five of these stats and create a meaningful time to market advantage for our clients.

## Comprehensive Medical Device Development



**BATTELLE**



## MARKET INSIGHTS & DISCOVERY

Every product ideation starts with an expert level of analysis and research, tailored with a scope on the industry.

### Market Research & Competitive Analysis

- Competitive Product Features & Benefits
- Competitive Teardown & Assessment
- Contextual Inquiries
- Market Feedback Research

### Technical & Regulatory Research

- Initial Regulatory & Standards Reviews
- Requirements Gathering
- Technical Due Diligence
- Technical Landscape Survey
- Technology Advancement Activities
- Technology Feasibility Research

### User Research

- Anthropometric Assessment
- Contextual Inquiries
- Ethnographic Research
- Focus Groups
- User Needs
- Task Analysis





## INNOVATION

Our thought leaders guide you from concept to solution through design, development, testing, strategy, and more.

### Concept

- Concept Generation
- Co-Created Concepts
- Concept Development
- Design Inputs
- Industrial Design
- Materials Innovation
- Multidisciplinary SME Approach

### Feasibility

- Engineering Testing
- Focused Works-Like Modeling
- Intellectual Property Development & Protection
- Material Compatibility
- Technology Assessment

### Definition

- Key Performance Indicators
- Looks-Like Modeling
- Technology Strategy & Road mapping

### Additional Services

- Platform Expansion
- Proof of Concept
- Rapid Prototype - 3D Modeling
- Risk Reduction Prioritization
- Structured Selection Process
- Technical Risk Reduction



## TRANSFORMATIVE SOLUTIONS

We bring together deep knowledge, world-class expertise, and specialized facilities to develop disruptive products that solve challenging problems.



### NeuroLife<sup>®</sup> Technology

For the first time ever, this wearable sleeve enables you to take real-time, high-resolution measurements of the nerves and muscles of the forearm. This technology is used in targeted stimulation interventions that recreate dexterous hand movements.



### Drug Delivery Technology

We enable you to solve seemingly impossible drug delivery challenges through drug delivery innovative solutions. Examples include our core annular flow (CAF) and controllable-force autoinjector (CFAI) technology which provide faster, better delivery of viscous drugs, and our ChemEngine technology that drives injections at a tunable speed while being adaptable.

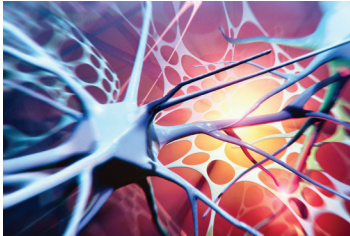




### **Intraocular Lens**

Our adjustable intraocular lens technology replaces the eye's natural lens that is removed during cataract surgery. It allows the surgeon to fine tune the lens after implantation, correcting vision abnormalities that can't be treated with a conventional lens due to its slight shift in position during healing.

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### **Non-Viral Gene Delivery (NVGD)**

Our NVGD platform helps you solve the most substantial hurdle to realizing gene editing therapies: delivery. It uses nanoparticles capable of loading at least ten times the five kilobase limit of virus vectors. By combining a robust yet versatile synthesis platform with in vivo tracking and machine learning directed design, it addressed the throughput and challenge, unlocking high-throughput parallel in vitro and in vivo screening of thousands of nanoparticles.

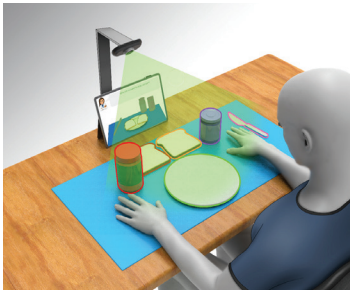
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### **Bioelectronic Medicine (BEM)**

BEM uses devices that connect to the brain or nervous system to monitor, stimulate, or modulate the electronic signals that enable communication between the brain and all body systems. Battelle's BEM program is focused on creating technologies that replace pills with electricity using reactive nerve stimulation to treat disease and dysfunction.

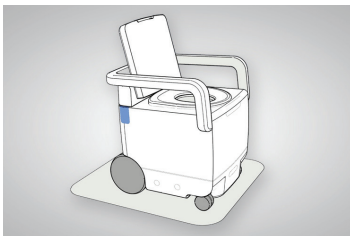
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### **Activity Assistant™**

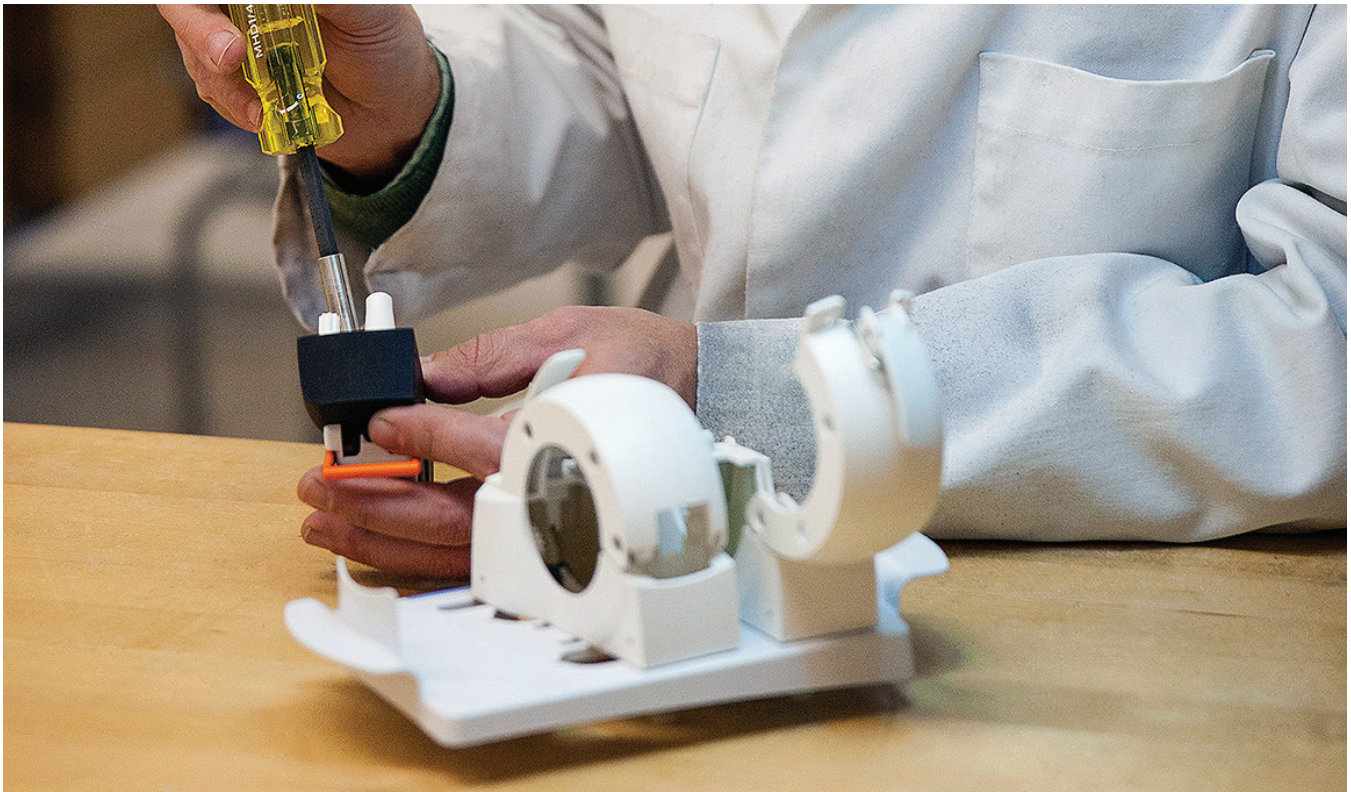
Our Activity Assistant™ rehabilitative technology is a wearable recognition platform for people recovering from traumatic acquired brain injury (ABI) that introduces a revolutionary approach to assessing, monitoring and treating cognitive impairment. It is a portable, autonomous biofeedback system that provides real-time feedback while patients perform functional activities using real objects. Activity Assistant™ monitors progress across time that can be viewed by patients, caregivers, occupational therapists and physicians, requires minimal supervision, and can be used in both the clinic and home environment.

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### **GoBot Toilet**

A bathroom visit for a person with limited mobility can be challenging. Our GoBot Smart Restroom Toilet is an all-in-one system that automatically navigates to the user in need, then to the bathroom for disposal, providing patients with dignity by maintaining their independence. It extends time at home for patients facing future transition to managed care and improves quality of life for both the patient and caregiver in both home and assisted living conditions.



## NEW PRODUCT DEVELOPMENT

Battelle takes you to market entry with a well-defined, highly-organized product structure.

### Product Development Capabilities

- Algorithms
- Artificial Intelligence & Machine Learning
- Design for Automated Assembly
- Bill of Materials
- Clinical Builds
- Design for X
- Design for Manufacturing
- Design History File / Design Master File
- Design Verification Testing
- Device Function / Robustness Enhancement
- Drop Testing / Impact Simulation
- FEA (static, dynamic, impact)
- IFU / Labeling /Packaging
- Molds
- Preclinical Testing
- Process Validation
- Prototype Build & Test
- Safety Risk Management (FMEA, Hazards Analysis, etc.)
- Simulation Analyses
- Software Development
- Tolerance Analysis / Six Sigma
- Total Product or Component Redesign
- Usability Studies (summative & formative)
- Verification Testing
- Fluidics Design & Modeling
- Reliability Analysis and Warranty Cost Prediction





## POST-LAUNCH MANAGEMENT

We help you solidify your product as an industry leading solution through continuous re-innovation.

- Development for Mitigations
- Failure Analysis
- FDA Recall Resolution/Notice Letters
- Innovation for Mitigations
- Product Redesign
- Root Cause Investigation
- Threat & Risk Assessment

Connect with a Battelle expert today.

800.201.2011 | [solutions@battelle.org](mailto:solutions@battelle.org) | [www.battelle.org](http://www.battelle.org)

### Battelle Delivers

**65+**

years of medical device design and development experience.

**250+**

companies as their medical device research and development partner.

**100%**

success rate for FDA submissions with Battelle human centric design work.

**40+**

granted medical technology patents and 100+ patents pending.

**BATTELLE**

It can be done