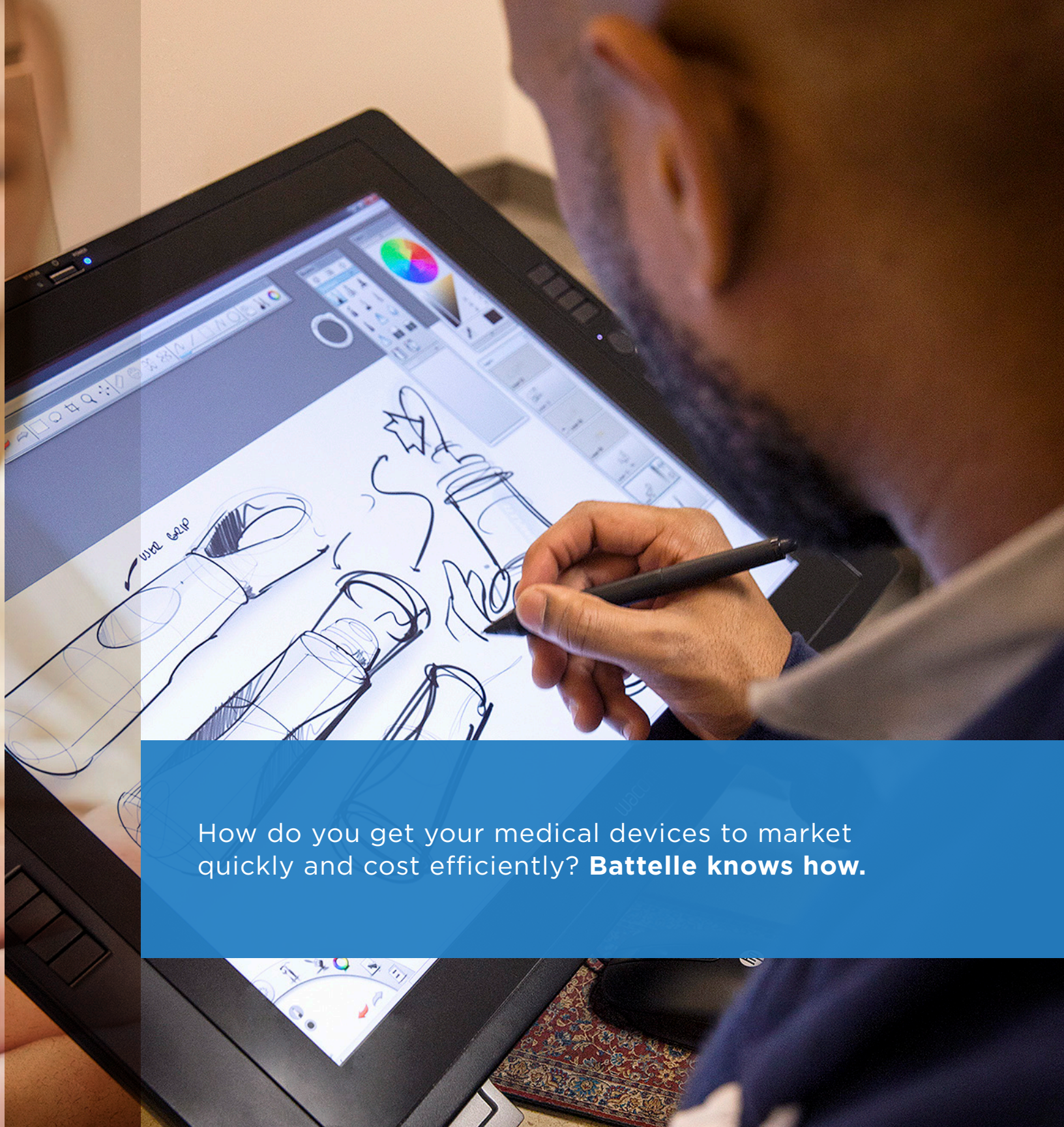




Battelle Medical Devices

# FROM CONCEPT TO MARKET WITH CONFIDENCE

**BATTELLE**



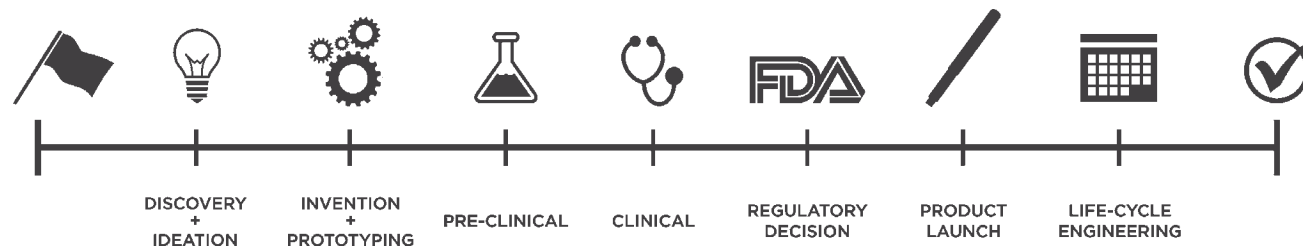
How do you get your medical devices to market quickly and cost efficiently? **Battelle knows how.**

# An Integrated Approach to Medical Device Development

Find a smoother path to market and maintain a clear competitive advantage with Battelle's proven, integrated approach to medical device design, development and validation. Our medical device team brings together unmatched experience in life sciences, device engineering, optics, analytics, human centric design and more to translate today's discoveries into tomorrow's must-have medical devices.

## We can help you:

- Condense development timelines
- Accelerate regulatory approval
- Minimize risks and costs



## Did you know?

Battelle can help you develop original intellectual property to keep you ahead of the competition.

**Call us to find out how.**





# Your Problems, Solved

From human factors to cybersecurity, we're solving some of the biggest design and development challenges in the industry. No other organization brings together a broader range of experts under one roof to smooth your way to commercialization.

We've been at the forefront of discovery in drug delivery, neurotechnology and in vitro diagnostics...to name just a few. In the following pages, we'll explore some examples.

# From Ideation to Commercialization

We can help you at every stage of the product development cycle, from concept generation to feasibility, design and development, and translation to manufacturing. We use an integrated, cross-functional approach to help clear the path to regulatory approval and a successful market launch.



## APPLIED RESEARCH

### Product Strategy

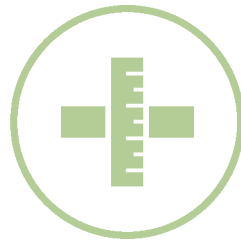
- Research methods built upon voices of consumers, competition and business
- Prioritization of product requirements ensuring right features embodied in products

### Technical Feasibility

- Engineering and life sciences expertise to understand technical performance and feasibility
- Early determination of technical flaws to limit development risk

### Technology Resources

- Access to cross-industry expertise and novel technologies at Battelle and the national laboratories we manage or co-manage



## DEVICE DEVELOPMENT

### Systems Engineering

- Safety Risk Management
- Requirements Development

### Detailed Design

- Industrial Design
- Human Factors Analysis
- Concept Studies
- Proof of Concept
- Systems Architecture
- Engineering Prototyping
- Device Development
- DHF Documentation

### Verification & Validation

- Test Planning
- Test Script Creation
- Verification Units Assembly
- Assembly of Clinical Trial Units
- Verification Execution
- Validation Execution
- V&V Results Reports



## MANUFACTURING

### Manufacturing Services

- DFMA & Prototype Builds
- Clinical Trial Device Production
- Pilot Manufacturing
- Limited Run Manufacturing
- Volume Production
- Training & Field Service Test



## LIFE-CYCLE ENGINEERING

### Cost Reduction

- Manufacturing Process Review
- Materials Review
- DFMA Analysis

### Device Enhancement

- Independent Design Reviews
- New Technology Insertion
- Verification & Validation Testing
- Replacement Part Identification

### CAPA Management

- Root Cause Analysis
- Design of Experiments & Testing
- Design Improvement
- Verification & Validation



# DRUG DELIVERY

Accelerate your R&D pipeline and meet market demands with our integrated design, development and testing services for drug and biologic delivery systems.



## Battelle is partnered with

Zogenix to develop DosePro®,  
a needle-free, instant injection  
technology for delivering  
biologic drugs.

We combine experience in formulation,  
medical device development and human  
factors engineering to deliver market-  
ready products designed with usability  
and efficacy in mind.

- Novel injection devices
- Contrast-media injectors
- Patch pumps
- Infusion pumps
- Skin permeation delivery systems



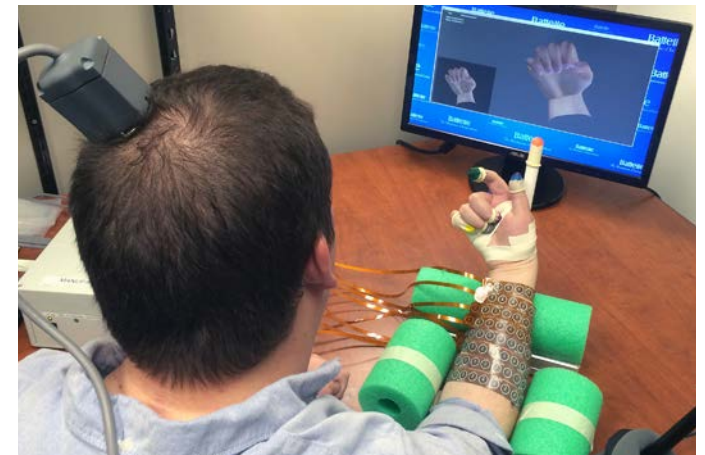


# NEUROTECHNOLOGY

Push the boundaries of the possible with innovative solutions to address brain and spinal cord injury.

Battelle pushes the boundaries of science and technology to create innovative solutions in neurotechnology. And Battelle NeuroLife™ neural bypass technology is one example. Our technology bypasses damaged areas of the nervous system so the brain can communicate directly with the muscles, thereby empowering paralyzed patients to regain conscious control of their fingers, hand and wrist.

- Neurorehab & Battelle NeuroLife Neural Bypass Technology
- Neural Signal Processing & Data Analysis (Battelle EluciData™)



We helped a paralyzed patient regain control of his hands and fingers with NeuroLife, an innovative neural bypass technology.

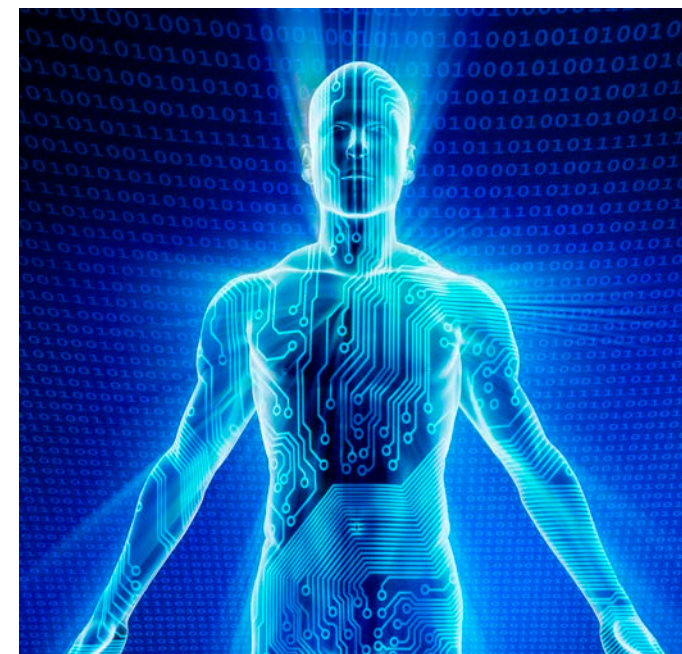


## IN VITRO DIAGNOSTICS

From small point-of-care devices to large clinical analyzers, Battelle's integrated engineering and product development services will help you move seamlessly from R&D to manufacturing.

We bring together deep experience in bioinformatics, biologics, chemistry and related fields to deliver innovative in vitro technologies.

- Assay development
- Bioinformatics
- Optics development and engineering



We're tapping into the promise of advanced analytics to create smart diagnostic devices powered by Battelle EluciData™.



# DEVICE CYBERSECURITY

Reduce your risks and meet emerging cybersecurity standards with Battelle DeviceSecure® Services.





Battelle DeviceSecure® Services experts identify cybersecurity vulnerabilities and provide a comprehensive approach to risk management and regulatory approval using software, hardware and embedded systems solutions for your medical device. Our experienced teams combine industry-leading expertise in cybersecurity, medical device design, hardware and software development.



#### **ARCHITECTURE & ADVISORY SERVICES**

##### **Safety & Security from the Start**

- Full life-cycle support from product definition through sustainment
- Vulnerability research and secure design
- Cyber risk-based process evaluation (14971/62304/13485)
- Online training and consulting



#### **VULNERABILITY ASSESSMENT**

##### **Shed Light on Existing and Emerging Risks**

- Medical device security analysis and assessment
- Specialized tools, software and hardware to support the full spectrum of cyber concerns
- Hardware/firmware/software reverse engineering
- Vulnerability assessment of existing and future medical device products
- Embedded and application-level engineering design and development



#### **ANTI-TAMPER & ANTI-COUNTERFEIT**

##### **Protect Valuable IP & Validate Critical Sourced Components**

- Tamper vulnerability analysis
  - Anti-tamper tools, techniques and solutions
- Hardware, software and chemical
- Anti-counterfeiting
  - Quality assurance of sourced components for risk assessment of medical devices



# HUMAN CENTRIC DESIGN

Develop products that meet regulatory requirements and fulfill the real needs of your end user population.

Our cross-disciplinary Human Centric Design (HCD) teams combine cognitive psychology, behavioral science, industrial design, user experience and device engineering to help you understand how human capabilities and limitations impact product safety, use and performance.

We integrate HCD principles into all of our medical device design services, so you can avoid costly surprises and delays and get your products to market faster.

- Rapid prototyping and simulation
- Visual communications
- Risk management/safety testing
- Task/function analysis
- Heuristic evaluation
- Validation testing
- Contextual inquiry/user research
- Statistical analysis
- Human performance testing
- Ergonomic measurement
- Simulated environment testing
- Regulatory compliance

#### **Clinical Services**

- Clinical study design and development
- Registered IRB for clinical trials
- Dedicated usability lab





# MAKE THE WORLD A HEALTHIER PLACE

Battelle is solving complex global health challenges that help save and improve millions of lives. We work with government and commercial clients around the world to answer critical issues in public health, develop and improve innovative medical devices, aid in the development of critical new drugs, and bring new therapies to market quickly and safely.

## **Who is Battelle?**

We are the world's largest independent research and development organization, operating at the forefront of scientific discovery. We bring together world-class scientists, engineers and technologies with a single mission: to translate discovery into market innovations that make the world better.



# What problems can we solve for you?

Start accelerating your development timelines today.  
Contact us for a free needs assessment.

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

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](http://www.battelle.org).

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It can be done