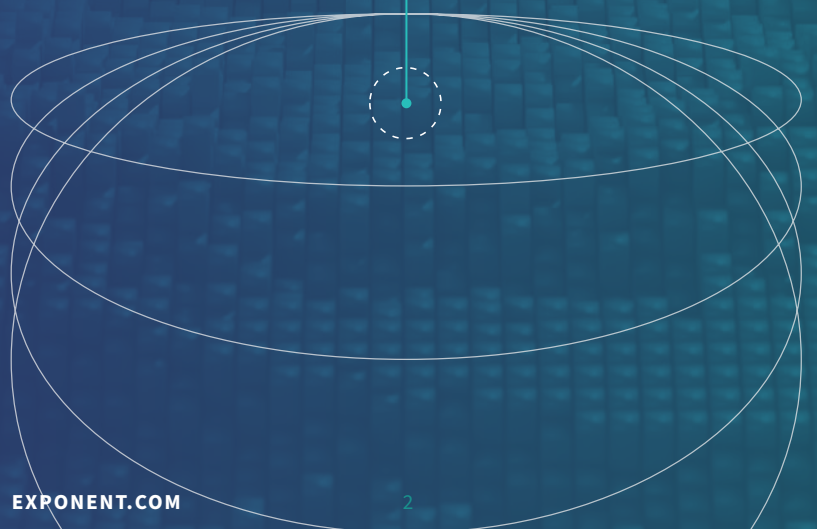# Exponent®

Life Sciences & Healthcare

TOTAL PRODUCT LIFECYCLE SUPPORT FOR MEDICAL INNOVATIONS

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Hard Questions.
Tough Challenges.
Bring It.

In an era of accelerating change, Exponent is the only premium engineering and scientific consulting firm with the depth and breadth of expertise to solve our clients' most profoundly unique, unprecedented, and urgent challenges.

Exponent's 950+ consultants help our clients navigate the increasing complexity of more than a dozen industries, connecting decades of pioneering work in failure analysis to develop solutions for a safer, healthier, more sustainable world.

Exponent by The Numbers

90+
Technical
Disciplines

30+
Offices Across North
America, Europe & Asia

1967
50+ Years of
Scientific Excellence

Transforming Science into Life-Changing Impact

With lives on the line, innovations that support healthcare demand the highest levels of scientific rigor. Whether you're developing a novel drug, a sturdier stent, or a faster flu test, you need clear answers to complex questions, quickly.

Exponent supports our life sciences clients across the total product lifecycle by solving critical design, regulatory, safety, and market access challenges. We can collaborate with you throughout your journey, helping you navigate risks and opportunities — and optimize outcomes — with science-based strategies and specialized expertise.

Pharmaceuticals

Providing science-based strategy and innovative research solutions across the full scope of clinical development, from preclinical studies to post-marketing surveillance; generating real-world evidence (RWE) for small-molecule, cell, and gene therapies; and prescription digital therapeutics.

Combination Products

Assisting with design review, evaluation, and regulatory strategy for products spanning tried and true injectables, leading-edge devices, and digital health innovations.
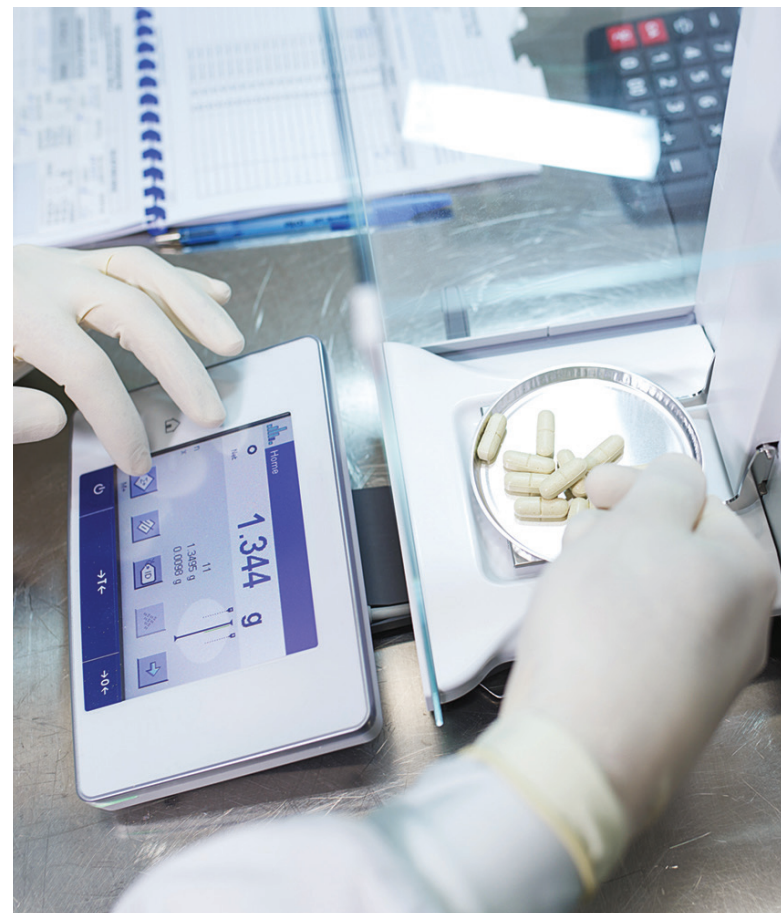
In Vitro Diagnostics

Supporting the full range of in vitro and companion diagnostics, including high-throughput clinical laboratories, point-of-care, and at-home testing products.

Over-the-Counter Drugs

Researching safety and efficacy evidence; identifying interactions; aiding regulatory approval; supporting manufacturing quality.

Medical Devices

Evaluating catheters, stents, artificial discs, joint replacements; analyzing cutting-edge electronic and radio-frequency devices, and innovative software-as-a-medical device products; and more.

Bridging the Gap Between Innovation, Regulation, Safety & Performance

From medical devices, pharmaceuticals, and supplements to digital health and wearables, we deliver rigorous science that quantifies impacts on human health.

Exponent helps you push the envelope on the development, deployment, safety, and effectiveness of cutting-edge drugs, devices, and diagnostics — concomitantly balancing benefits and risks. Count on our multidisciplinary, data-driven, evidence-based assessments to give you clarity on your most complex product needs and challenges

Health Sciences Innovation

Navigating FDA and global regulatory frameworks for novel medical devices, pharmaceuticals, and combination therapies; devising testing beyond standards; developing innovative delivery systems, acceptable usage, and dosage; demonstrating comparative effectiveness and economic value.

Government Sector

Evaluating benefits, risks, and value of authorized Medicare-reimbursed drugs, devices, and procedures; assisting with validation of diagnostics and health technology assessments.

Consumer Products

Evaluating biocompatibility of wearables; analyzing sensitizing materials, including plastics, metals, and composites; assessing exposure toxicity risks; determining levels and safety of magnetic and radiation emissions.

Food & Beverage

Validating health claims for supplements and food; evaluating next-gen formulations and additives; supporting navigation of global regulatory frameworks; and more.

Industrial & Manufacturing

Assessing whether employees or the public are at risk of long-term health issues; verifying product efficacy; evaluating exposures from manufacturing processes and fate and transport for byproducts.

Accident & Failure Investigation

Evaluating failures in medical devices, pharmaceuticals, and other healthcare equipment; pinpointing materials, electrical, software, and biomechanical engineering failures; supporting retrieval analysis, corrective and preventative actions (CAPA), and quality management systems.

Disputes

Evaluating product function for intellectual property and patent disputes; assessing product performance for contract disputes and acquisitions; providing root cause analyses for insurance claims and loss management disputes; conducting failure analysis for international arbitration and product liability, including mass tort.

Environment & Sustainability

Improving medical and hazardous waste management; analyzing chemical emissions; advising on toxicology studies; helping implement best practices for occupational health.

Industrial Operations & Technology

Supporting regulatory compliance for device manufacturers; guiding best practices for in vitro processes; improving sanitation strategies.

Product Analysis & Improvement

Recommending how to apply cutting-edge materials; solving radio frequency issues; testing MR compatibility of next-gen implants; supporting the development of novel combination products.

Product Safety & Recall

Testing for materials leaching; evaluating recalls for implanted devices; coordinating and supporting regulatory agency communications.

Regulatory & Compliance

Support and planning for global regulatory strategies—from design review to post-market surveillance—based on a product's unique characteristics.

Research Strategy & Implementation

Advancing materials research; designing novel testing methods for durability and safety of complex medical devices.

Risk Assessment & Mitigation

Objectively assessing procedural efficacy; analyzing real-world evidence (RWE); identifying medical device safety risks.

Technology, Data & Innovation

Acquiring data for clinical trials and pharmaceuticals; assessing causal inference, treatment safety, and effectiveness; improving public health; analyzing device and treatment value; advancing health equity.

Science-Based Strategies & Specialized Expertise

We thrive on bringing data-driven and evidence-based approaches to unstructured problems in health sciences and pushing the boundaries of what's possible. Across decades of work with life sciences and healthcare products, we've developed many specialized capabilities to address your most vital challenges.

Shaping the World of Digital Health

Are You Optimizing Your Wearable Technologies?

Exponent provides cutting-edge multidisciplinary support for all phases of the wearable product lifecycle, including innovative digitalization to help you effectively demonstrate clinical, experiential, and economic value.

Our unique approach integrates extensive expertise in biomechanics, human behavior, epidemiology, and data science with detailed knowledge of injury, disease, and state-of-the-art intervention modalities to select optimal wearable technologies for "fit for purpose" solutions that are scalable and replicable.

We also have broad experience in biocompatibility and other challenges associated with materials selection, design, and development of wearables. Some of our services include:

- Loading on the human body
- Physiological ground truth comparisons
- User-specific characterization (anthropometry, tissue properties)
- Large-scale participant studies
- Human body modeling (physical modeling, simulation, cadaver testing)
- Human injury potential evaluations

- Data acquisition, contextualization through data-driven insights
- Scalable research and analysis (processing and analysis tools)
- Validation in a box/real-world validation (remote validations)
- Methodologies for collecting data (tools)
- Biocompatibility assessments

Pushing the Boundaries of Real-World Data & Evidence

How Can Data-based Decisions Improve Healthcare?

Exponent helps medical manufacturers and healthcare professionals make data-informed decisions by identifying, cleaning, extracting, and translating real-world data (RWD) into real-world evidence (RWE), supporting clients in getting their products to market faster. And after medical products reach the market, our broad experience with public and commercial claims and medical records databases, registries, and surveillance data enables us to address questions of data quality and appropriateness. Some of our services include:

- Health economics and outcomes research

- Identification of high-quality RWD and RWE for specific needs

- Review of specific industry case studies where RWE has succeeded and failed

- Data analytics, including payer database and electronic health record analytics

- Scientific white paper development and peer-reviewed publications

- Market access and reimbursement strategies, including evidence generation and product value demonstration

- Portable modeling tools for one-on-one discussions with stakeholders

- Medical device outcomes assessments

TESTING & EVALUATIONS

Redefining What's Possible

We bring an unparalleled level of integrated expertise to every test and evaluation for pharmaceuticals, medical devices, diagnostics, digital therapeutics, and more. From basic drug formulations to combination and software-as-a-medical-device products, our testing helps you develop and bring products to market that perform better, last longer, and operate more safely.

Advancing Outcomes with Biomedical Evaluations

Medical device design requires knowing how a device will perform under a range of conditions when interacting with the human body. Because standard test methods may not be able to evaluate all characteristics related to product performance, our scientists and engineers know how to customize tests to help you understand the limits of device performance early in the design process helping you get ahead of risks, develop safer products, meet regulatory requirements, and accelerate time to market. Some of our services include:
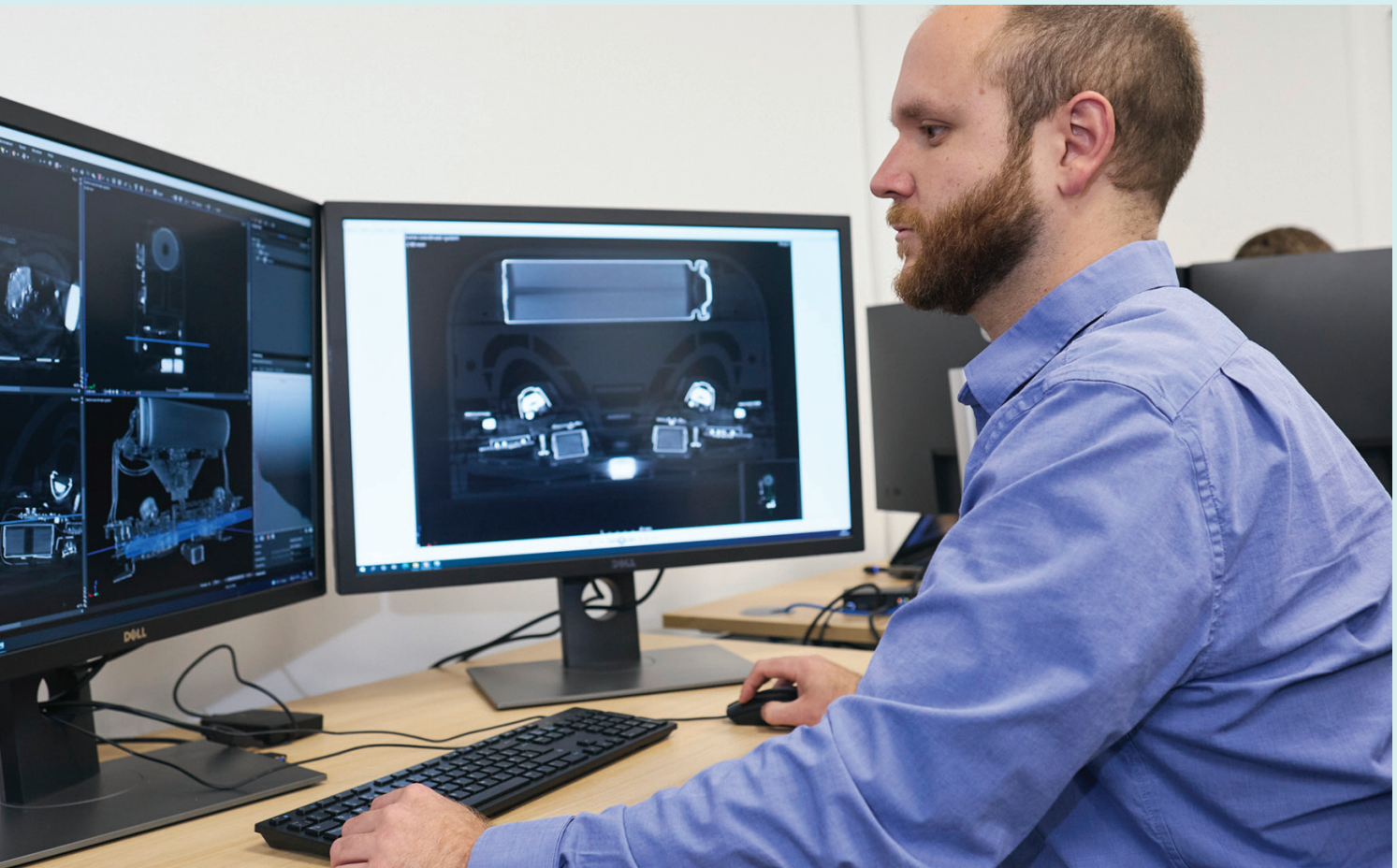
- Fatigue and corrosion testing to assist with product development, quality assurance, regulatory submissions, and post-market surveillance.
- Biomechanical analysis of product design and safety.

- MRI compatibility testing to mitigate risks and meet regulatory requirements.
- Software-as-a-medical-device product testing and risk analysis.
- Retrieved device and tissue analysis to support device development, clinical studies, and post-market surveillance.
- Biofluid dynamics analysis using state-of-the-art model definition and software for product development.
- Wear and biotribology testing to establish wear test programs and provide insights for achieving regulatory requirements.
- Finite element analysis (FEA), in combination with mechanical engineering, metallurgy, polymer science, and failure analysis, to address complex computational projects.
- Robust failure analysis.

Customized Battery Testing

Exponent provides mission-critical custom product safety, performance, and industry certification battery testing services for medical devices. We prioritize broad quality metrics in parallel with industry certification standards to help our clients create safe, high-performing products. Exponent's experience in failure analysis and design evaluation allows us to identify potential weaknesses and design custom battery testing to better understand how a product could fail during use or expected misuse. Some of our testing services include:

- Battery Risk Assessments & Corrective Action
- Battery Failure Analysis & Investigation
- Battery Design Review, Quality & Safety Assessments
- Battery Safety & Recall Support
- Battery Vendor Evaluation Services
- Battery Supply Chain Services

Redefining What's Possible

Find the level of scientific rigor your medical devices require, along with the regulatory experience you need to bring them to market in a timely manner. Drawing on the latest materials, methodologies, and technologies, our work helps you innovate without sacrificing safety or performance.
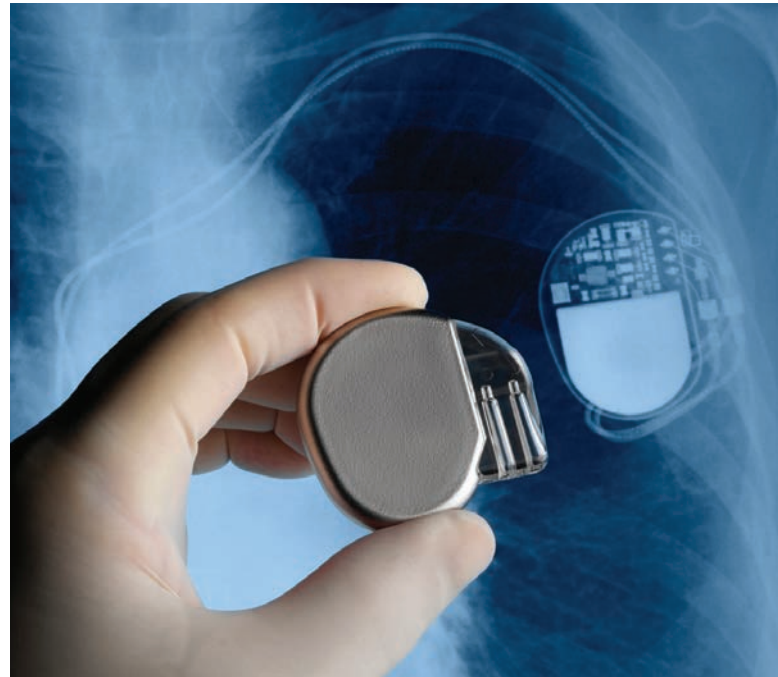
Shaping the World of Digital Health

Understand How Your Product's Mechanics and Materials Perform in the Real World

When it's critical to understand how your medical device, combination product, or other therapeutic will perform on or in contact with the human body, Exponent brings together the expertise and equipment needed to provide answers. We apply engineering intuition, materials acumen, and decades of experience to create custom test scenarios that uncover and explain critical weaknesses underlying your product's mechanics and materials.

Mechanical Evaluations That Push the Limits

Our team leverages Exponent's extensive testing capabilities to improve the reliability and performance of therapeutic products by:

- Recreating complex real-world scenarios to understand what happened (and whether it could happen again).

- Understanding product vulnerability to identify a range of use conditions, avoid other failures, and improve product safety.

- Going beyond providing test data by advising on changes to designs, materials, or manufacturing methods that can mitigate risks.

Advancing Innovation Through Materials Testing

Exponent helps you understand medical device materials and their interactions at the chemical, molecular, and atomic level. We thrive on uncovering the possibilities and perils of combined materials and engineering challenges for:

- Composite structures (carbon fiber, glass fibers, and more)
- Polymers
- Sandwich materials
- Metals and alloys
- Additive manufactured materials

What can we help you solve?

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E*x*ponent®