Exponent is a scientific and engineering consulting firm that provides solutions to complex technical problems. We provide the highest quality technical, regulatory, economic, risk management, epidemiological, and safety assessment services to assist our clients with issues throughout all stages of the medical device product development lifecycle. Our medical device clients face numerous challenges today to get products to market, including developing appropriate preclinical and clinical plans to evaluate safety and effectiveness, preparing compelling regulatory submissions, and understanding the market and reimbursement strategies for their products during development.

Our engineers and scientists assist clients with characterization of biomaterials, biological tissues, and medical devices, and their interactions. As a function of regulatory compliance, we can perform preclinical testing and formulate a related regulatory strategy, conduct design verification and validation, perform design and manufacturing failure analyses, manage recalls, and analyze medical device explants. In addition, our staff can analyze clinical outcomes for medical devices using administrative claims databases. Our expertise is also utilized in product liability and intellectual property litigation, technology acquisition, and due diligence.

Medical Device Development Services
- Preclinical regulatory strategy, analysis, and testing
- Biocompatibility and thromboresistance
- MRI compatibility testing and analysis
- Regulatory and quality assurance support
- Outcomes and economic assessment of medical devices
- Failure analysis
- Medical device regulatory compliance and product recalls
- Due diligence and intellectual property support
- Medical litigation support

Preclinical Regulatory Strategy
Our engineers and scientists have extensive expertise in the medical device product development process, including biomaterial selection and characterization, preclinical test method development and strategy, and experimental and analytical performance evaluations using either custom test methods or standard tests defined by the International Organization for Standardization (ISO) and the American Society for Testing and Materials (ASTM International). We perform mechanical and materials evaluation of implants and delivery instrumentation pertaining to patent evaluation and infringement issues, third-party design reviews, or for FDA or international regulatory submissions.
We can also evaluate novel medical device performance characteristics, to answer specific questions related to materials, biocompatibility and biocompatibility software (failure analysis, reliability and testing, interaction with hardware), and functionality (fracture, electronic circuit/component failure, functional surface coating integrity, tissue interaction, battery depletion, drug elution).

Device Performance Characterization Analysis and Testing

We also have extensive experience conducting biomechanical evaluations using cadaveric models and validated finite-element (FE) models. Our retrieval programs collect explanted devices, including orthopedic and spinal implants, neurostimulators, pulmonary devices, pacemakers, implantable cardioverter defibrillators (ICDs), and their leads, stents, filters, and heart valves. We have developed custom-made implant retrieval kits, which have enabled the creation of a repository of information to support assessment of the performance and failure modes of retrieved implants, and development of analytical and physical test methods and standards. Exponent supports the regulatory process at both the state and federal levels in the United States. Our scientists also have experience with international regulations, CE mark compliance, and EN/IEC/ISO standards compliance. We have broad experience in regulatory agency interactions for product submissions for class I, II (510(k)), and III (PMA) medical devices. Finally, we also assist our clients in quality systems implementation and improvement for compliance with FDA GMP/QSRs, ISO 14971, and ISO 13485.

Biocompatibility & Thromboresistance

Biomaterials (biostable and biodegradable) for use in the development of medical devices and drug delivery devices can be polymeric, biologic, metallic, ceramic or their composites, each presenting unique biocompatibility and thrombogenicity characteristics (if in blood contact). Biocompatibility testing is typically addressed in FDA guidance documents and ISO 10993 biocompatibility standards. The new generation of implantable and tissue engineered medical devices control biologic interactions by use of bioactive, therapeutic, smart, and nano-enabled materials to improve safety and efficacy. Exponent has a wide range of expertise in areas relating to biocompatibility testing, including assessment of corrosion (such as general, pitting [ASTM F2129], galvanic [ASTM G71] and fretting), degradation, toxicity of materials in long-term implants or particulates left in situ after surgical procedure, and measurement of metal release rate as a function of time (metal leaching rate) for long-term implants. We have extensive experience in biokinetie modeling of metal release from metallic implants, and toxicity and biocompatibility of a wide range of organic and inorganic compounds, metals, and biopolymers. We frequently assess the toxicity and biocompatibility of materials and residues on multiple-use units after reprocessing/resterilization. We regularly advise our clients on the toxicity and fate of nanomaterials and particulates, and device-related infection control strategies and associated regulatory support.

MRI Compatibility Testing and Analysis

Exponent performs compatibility testing and finite-element analysis of medical devices using magnetic resonance imaging (MRI). Through our A2LA-accredited laboratory, we assist medical device manufacturers in validating MRI safety and compatibility design requirements and regulatory labeling requirements. We have performed MRI testing on a variety of cardiovascular, orthopedic, pulmonary, neurologic, dental and spinal devices and provided analysis and guidance to clients with regard to FDA submission in the context of performance to standards. Exponent’s analytical techniques allow manufacturers to determine the risks associated with already-implanted devices and to formulate a strategy for serving the needs of users and patients. Exponent provides analysis and labeling guidelines for use in formulating a strategy for marketing the devices and to guide submissions to regulatory authorities. We have the capability—and are accredited to ISO 17025—to test at 1.5T and 3.0T with both wide-bore and conventional-bore configurations, in accordance with all applicable MRI ASTM standards (F2052, F2119, F2182, F2213 and F2503). Exponent also has arrangements with regional research institutions to conduct studies at high field strength, if needed.

Regulatory and Quality Assurance Support

Exponent has successful experience with regulatory agency interactions and communications with healthcare professionals in clinical development and manufacturing of novel devices. Exponent provides manufacturing operations support, manufacturing process analysis, troubleshooting and process failure modes and effects analysis (FMEA), as well as process verification, validation, and statistical process control support. We can help your firm devise, implement, and execute regulatory strategies.
for traditional and combination medical device product registrations in the U.S. and internationally, including technical File/Design Dossier Clinical Evaluation Reports (CERs). We also assist clients with regulatory non-conformity issues such as 483 and FDA warning letters and product recall situations.

Outcomes & Economic Assessment of Medical Devices

Exponent has expertise in outcomes studies, economic assessments, and clinical research for medical devices and other health-care interventions. We use modeling and simulation studies to evaluate the cost effectiveness of health-care interventions, and we use national medical hospitalization and claims data to evaluate the associated epidemiology. We provide market research to identify demographic and geographic trends in historical and projected market demands for a broad spectrum of health-care interventions. We help our clients evaluate the impact of pharmaceuticals, medical devices, biotechnology products, and diagnostics on treatment patterns, medical care resource utilization, and health-care costs. Exponent can assess the changes in health outcomes resulting from new medical technologies, including fewer complications, reduced disease cases or symptoms, improved quality of life, and improved patient satisfaction. We use cost-effectiveness models to quantify changes in health outcomes relative to their costs and to the costs of alternative health-care interventions, allowing determination of the appropriate value for these new medical technologies. We can examine costs from the payer (direct medical expenses), patient (lost wages, co-pays), and societal (lost productivity) perspectives. We can provide a complete medical and economic assessment, incorporating data from clinical trials, published literature, and national surveys to help payers, physicians, and industry understand the budgetary and medical impact of adopting specific technologies.

Failure Analysis and Risk Management

Exponent has experience in risk management and in performing design reviews using techniques such as fault-tree and failure modes and effects analysis (FMEA). Our biomedical, biomechanics, materials, mechanical, and electrical engineers have many years of direct experience evaluating medical device failures and improving product performance, including design and risk analysis and implantation/device deployment investigations. Exponent has broad experience across the medical device industry in conducting root-cause and risk analyses as part of Corrective and Preventive Action (CAPA) procedures. Our experienced medical staff can also evaluate the health and safety implications of device failures. Our experience includes product failure analysis, health hazard evaluations, root-cause analysis, and device history record reviews (DHRs) as part of CAPA programs, medical and scientific literature reviews, medical device reporting (MDR), and “recall readiness” planning.

Medical Device Regulatory Compliance & Product Recalls

How well a company manages a recall situation or deals with regulatory non-conformity is important. Issues identified in a 483 or FDA Warning Letter can affect not only the future viability of the product, the company’s liability, and financial loss, but also the company’s reputation and “brand equity.” Reaching a decision to recall a product, and conducting the recall, requires careful evaluation, including analysis of adverse-event reports, identification of the specific products or lots of products to be recalled, execution of a health hazard evaluation, and implementation of a Corrective and Preventive Action (CAPA) plan, including a root-cause analysis. Determining whether a device failure occurred and identifying and correcting its cause, are key to getting a product back on the market after a recall. Exponent’s staff has many years of experience in evaluating medical device failures and providing input to enhance product performance. We are well positioned to review your internal standard operating procedures for quality control, inspections, validation, qualification, investigations, root-cause analyses, and CAPA planning, and assessing the impact of the observations noted by FDA. With the participation of Exponent’s statisticians and data analysts, we can also evaluate the trending practices being used to track nonconformances, as well as to enhance the procedures to control and monitor non-conforming products. Exponent has extensive medical, engineering, scientific, and regulatory expertise to assist medical device companies in handling these situations.

Due Diligence and Intellectual Property

Exponent scientists and economists typically work with your business development team to assist you with development plan assessment, benchmarking, and competitive landscape assessment; indication assessment; commercialization assessment; and identification of key milestones. We can also assist
you with partner identification, intellectual property assessment, trade dress, trademarks and copyrights, trade secrets, and valuation of intellectual capital. We perform technical due diligence for investors or their representatives (e.g., venture capitalists or investment bankers) as they seek to determine the value of a target firm’s intellectual property. Such advice has been used by our clients during license negotiations and for purposes of corporate mergers and acquisitions. When a dispute arises over the utility or effectiveness of a claimed feature or improvement, Exponent scientists and engineers can develop and implement tests to assess differences in function or demonstrate whether utility is substantial. Resolution of a patent dispute often hinges on precise interpretation of the language used to claim the invention. Exponent's specialists can assist with claim interpretation in a number of ways: illustrating the meaning of a technical concept through comparative examples and visual demonstratives, clarifying the precise manner in which claimed features interact, and opining about the completeness and suitability of drawings and specifications. Our breadth of experience and our accomplished record as medical device consultants can be a potent supplement to a patent litigation team both in Markman hearings and at trial.

Medical Device Litigation Support

Our scientists and engineers are well versed in the technical and confidential issues surrounding product liability disputes. This knowledge base can be applied early on in product development to minimize costs associated with failures and litigation. Our engineers and scientists routinely conduct medical device failure analysis investigations for legal clients. These investigations range from analyses of relatively simple surgical tools to complicated drug delivery systems where we help determine the likely cause of adverse events that have resulted in litigation. Our state-of-the-art testing and engineering laboratories have been used on numerous occasions to prepare trial demonstratives. Our visual communications staff uses the latest videographic and 3D animation technologies to help describe a complex idea in simple terms, and these displays and demonstrations are often used in settlement conferences and at trial.