



Pharmaceutical Industry Services



Exponent is a scientific and engineering consulting firm that provides solutions to complex technical problems. We provide the highest quality technical, regulatory, economic, and safety assessment services to assist our clients with issues related to human and veterinary pharmaceutical and biotechnology products, including manufacturing, preclinical and clinical development, risk management, and regulatory support.

Pharmaceutical Development Services

- CMC – Drug Substance and Drug Product
- Preclinical Development
- Clinical Development
- Health Outcomes Research
- Epidemiology and Postmarketing Safety
- Regulatory and Quality Assurance Support
- Environmental Assessment
- Due Diligence and Intellectual Property Support

CMC – Drug Substance and Drug Product

Our CMC professionals provide experienced consultation in drug substance and drug product manufacture, formulation, delivery, analytical test methods development, and CMC regulatory issues. We can assist with your drug development needs from minimally qualified products for Phase 1 clinical studies to fully validated products for Phase 3 clinical trials. We also assist our clients in quality systems implementation and improvement for compliance with GLP, GMP, and ISO 9000.

Preclinical Development

Exponent's Health Sciences professionals have many years of successful hands-on technical and strategic experience in the design and completion of preclinical drug development programs, from simple to complex. Our diverse staff provides support to all phases of small molecule and biologics (e.g., vaccines, monoclonals) drug development from preclinical studies to post marketing safety assessment (Phase IV). Exponent scientists assist you in supporting your clinical trials and regulatory submissions in the U.S. and internationally. In the preclinical phase information on target indication, patient population, burden of disease, co-morbidities, risk factors and treatment patterns used in developing the target product profile, and in the design of early clinical trials is essential for a successful clinical development plan. Our staff has extensive experience in developing target product profiles for both drugs and vaccines.

Clinical Development

Exponent's Health Sciences professionals have successful experience in the design and completion of national and international clinical development programs for a wide variety of indications, ultimately bringing these new drugs and drug combinations to market. We help clients advance their products while containing costs, maintaining timelines and

minimizing risks. We develop a detailed strategic plan and budget analysis so your projects stay on track and your investors are well-informed. For every project, we identify critical issues to minimize delays and define the best strategic route to market.

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 agents. We help you devise, implement and execute regulatory strategies for small molecule drugs and biologics product registrations in the US and internationally, including orphan drug applications (ODA), pediatric implementation plans (PIP) and Risk Evaluation and Mitigation Strategies (REMS). We also assist clients with regulatory non-conformity issues such as 483 and FDA warning letters and product recall situations. Further, we provide advice and expertise to our clients to ensure compliance with FDA Good Laboratory Practices (GLPs), Good Clinical Practices (GCP), Good Manufacturing Practices (GMPs) and the ISO 9000 family of standards for quality management.

Health Outcomes

Understanding the natural history of the target indications as well as patients' perceptions of disease are important for the design of a clinical program and for product differentiation. Epidemiologists, biostatisticians, clinicians, economists and health outcomes scientists at Exponent describe and interpret patterns of disease occurrence in populations in order to characterize the disease population, their co-morbidities, survival and treatments and to predict market size for a given indication or suite of indications. We develop strategies to incorporate patient reported outcomes in clinical trials, including instrument development or selection, analysis, and interpretation. In addition, we evaluate the burden of disease in relation to cost-effectiveness or cost-utility associated with interventions.

Pharmaco-epidemiology and Postmarketing Safety

Epidemiologists at Exponent assist clients in developing strategies for the design, implementation, analyzing and reporting of "real-world" observational studies and registries to support clinical development and postmarketing safety. In such evaluations, elucidating patient and lifestyle factors associated with "real-world" use of a drug or vaccine is key to a thoughtful evaluation of potential safety events. This involves characterizing target indications, patients, potential adverse events and patterns of patient care. These types of studies are essential for developing a robust safety program to support the clinical development of novel agents.

Environmental Risk Assessment

Exponent's EcoSciences professionals have global expertise in all aspects of conducting environmental risk assessments including evaluating fate and transport properties, developing exposure scenarios, assessing ecological effects on non-target organisms, and determining risk quotients for all potentially affected environmental compartments. Our scientists are also involved in the global dialogue surrounding the detection of trace concentrations of pharmaceuticals in surface water and drinking water and the related issues of potential treatment, risk, regulation and product defense.

Due Diligence and Intellectual Property

Exponent scientists and economists typically work with your business development colleagues to assist you with development plan assessment and GAP analysis for CMC, preclinical, clinical, regulatory and environmental drug development programs; benchmarking and competitive landscape assessment; indication assessment; commercialization assessment and identification of key milestones. We can also assist you with partner identifications, intellectual property assessment, trade dress, trademarks and copyrights, trade secrets, and valuation of intellectual capital.



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