

# Pharmaceuticals

SOUND SCIENCE FOR IMPROVED DRUGS & RISK MANAGEMENT



Exponent®



# 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

# Pharmaceutical Industry Services

Our Health Sciences practice applies an unparalleled combination of industry-specific knowledge, specialized expertise, and an interdisciplinary approach to a broad range of scientific, regulatory, and business issues facing the pharmaceutical industry. Our scientists leverage decades of experience in pharmacoepidemiology, toxicology, industrial hygiene, health services research, health economics and outcomes research, regulatory sciences, statistics and data sciences, biomedical engineering, and other technical fields.

## Selected Capabilities

### Pharmacoepidemiology & Real-World Evidence

Our pharmacoepidemiology and RWE services include the following capabilities:

- Designing and conducting pre- and postmarketing safety and effectiveness studies
- Novel epidemiological designs and analytic methodologies
- Selection, quality assessment, and analysis of electronic health records (EHR) and healthcare claims data
- Scientific and regulatory consulting on emergent safety issues
- Evaluation and support of regulatory strategies across the full life cycle
- Signal detection, enhanced pharmacovigilance, and risk evaluation and mitigation strategies (REMS)
- Comparative effectiveness research (CER)
- Prescription to over-the-counter (Rx-to-OTC) switches
- Evaluating and implementing RWE strategies
- Estimating healthcare access, costs, and value
- Systematic review and meta-analysis
- Litigation support



## Health Economics & Outcomes Research

Our team designs and implements a variety of health economics & outcomes research (HEOR) engagements across the life sciences sector. Our HEOR work is often applied to market access strategies such as value-based pricing, health technology assessment (HTA) submissions, and value dossier input. HEOR provides the evidence framework for valuebased healthcare (VBHC) collaborations between pharma and other healthcare stakeholders including but not limited to value-based agreements such as pay-for-performance and warranty constructs.

**Representative project types include strategy, modeling, and research studies:**

<b>Strategy:</b>	Systematic Literature Reviews and Meta-analysis; Protocol Design; Therapeutic Area Reviews, and Asset HEOR Plans
<b>Modeling:</b>	Burden-of-Illness Assessment; Cost-Effectiveness Analysis; Budget Impact Analysis
<b>Research:</b>	Early- and Late-Phase Trial HEOR Input; Retrospective and Prospective HEOR Research; Scientific Conference Abstracts, Presentations, and Journal Manuscripts

## Market Access & Value-Based Healthcare

Our team helps life sciences companies differentiate their products by evaluating regulatory, human factors, or market adoption strategies intended to facilitate market adoption and accelerate return on investment (ROI). Building on technical assessments and scientific insights, Exponent also helps companies build strategies for reimbursement and to inform pricing negotiations via budget impact or cost-effectiveness models for healthcare payers.

**Representative project types include strategy, modeling, and research studies:**

<b>Strategy:</b>	Value Dossiers; Therapeutic Area Reviews, Asset Market Access Plans; Value-Based Agreement Scenario Planning; Digital Health Strategy
<b>Modeling:</b>	Value-Based Pricing; Value Framework & Health Technology Assessment Simulations; Value/Risk/Outcomes-Based Agreement Analysis
<b>Research:</b>	Value-Based Healthcare Collaborations between Pharma, Payers, Providers, Medical Associations and Technology Partners



## **Selected Capabilities** *(continued)*

### **Regulatory Sciences & Support**

Exponent offers regulatory advising and strategic consulting across the product life cycle.

- **Pre-Approval:** Even before a product is approved, Exponent can assist with the development of pre-approval study designs, preparation for regulatory advisory meetings, and creation of postapproval safety strategies.
- **Peri-Approval:** Exponent scientists work with sponsors to respond to regulatory queries, negotiate post-marketing requirements, and design protocols for enhanced pharmacovigilance, registries, REMS, and epidemiological studies.
- **Post-Approval:** Exponent supports regulatory milestones, including safety reports, enhanced pharmacovigilance, re-evaluation of regulatory requirements, and Rx-to-OTC switches.

### **Toxicology**

Our toxicologists assess potential health risks of reagents, excipients, degradants, and impurities in drug products and extractables in combination products through the following activities:

- Designing and performing chemical characterization studies
- Conducting toxicological assessments to derive permissible daily exposure levels
- Developing exposure limits for extractables for specific products that pertain to product quality and safety

### **Industrial Hygiene**

Our broad experience in conducting workplace evaluations and occupational risk assessments includes the following areas of expertise:

- Characterizing reproductive, developmental, and other hazards
- Evaluating inhalation and dermal exposures to active pharmaceutical ingredients
- Assisting in deriving occupational exposure limits, occupational exposure banding, and surrogate (containment) verification for various manufacturing

# Outsmart Your Toughest Challenges.

When you're stuck, when you're facing a never-before-seen issue, when everything's on the line, turn to Exponent.

Our consultants thrive on solving unstructured problems, leveraging multidisciplinary expertise and state-of-the-art testing so you can move ahead with confidence. Bring us your tough, your complex, your impossible challenges — and reap the advantages of 50+ years of data-backed industry insights and failure analysis learnings.

We're with you all the way.

**GET IN TOUCH**

**INFO@EXPONENT.COM | EXPONENT.COM**



What can we help you solve?

$x$



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