



The BlueRidge Life Sciences Family of Companies

We are a family of best-in-class companies offering integrated teams to solve the multifaceted problems and challenges faced by our life sciences clients, particularly in the drug development arena. We provide expert-managed services with a spirit of collaboration, a passion for advancing science, and unparalleled technical excellence. Scientific, technology, and regulatory solutions

ToxStrategies



EpidStrategies

HEORStrategies



Who we are.

Your pharmaceutical team of regulatory toxicology experts that support strategic planning and execution of toxicology programs for small molecules, biologics, and complex therapies.

Services include:

- Toxicology program design
- Evaluation / positioning of complex toxicology data
- Study placement and monitoring
- Preparation of nonclinical sections of regulatory documents (i.e., IBs, briefing books, module 2 summaries)
- Meetings with Health Authorities
- White papers and waivers
- Toxicology monographs
- QSAR modeling (i.e., ICH M7 assessments)
- Value proposition development/testing

When to call us.

When you need strategic advice or “boots on the ground” support for toxicology aspects of a nonclinical development program.



Marcie Wood, PhD
SVP
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Who we are.

Your clinical research advisory company that works with pharmaceutical & Biotech organizations to operationalize development and regulatory pathways for new treatments for CNS diseases. The CLINTREX team utilizes its experts with disease-specific knowledge, with a particular emphasis on neurodegenerative diseases (eg. AD, PD, HD, MS, epilepsy, and migraine, etc.) to help you design clinical trials and address regulatory issues.

Services include:

- Pre-clinical development
- Clinical development plan
- Clinical trial design and execution
- Regulatory support/strategy
- Medical writing with disease-specific expertise
- Investor due diligence support
- CMO (Chief Medical Officer) services

When to call us.

When you need an integrated team of internationally-renowned experts to work collaboratively with members of your organization in order to identify, clarify, and solve pre-clinical, clinical trial, biostatistical, and regulatory issues essential to product development and approval for CNS indications.



Cornelia Kamp, MBA
VP Operations
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EpidStrategies

A BlueRidge Life Sciences Company

Who we are.

Your consulting scientists with innovative and robust solutions for conducting, evaluating, and interpreting epidemiological studies in the pharmaceutical, medical device, nutritional product, and environmental chemical industries. Our research frequently results in peer-reviewed publications and presentations at scientific conferences and is also used in numerous regulatory documents in the US and Europe. Services include:

Services include:

- Study design / protocols
- Statistical analysis / plans
- Meta-analysis
- Publication development
- Evidence strategy
- Value proposition development / testing
- Feasibility studies
- Systematic literature reviews
- Clinical trial reporting
- Regulatory applications

When to call us.

When you need to evaluate the evidence for a small molecule, biologic, gene or cell therapy, nutritional product, medical device, or an environmental/occupational chemical effect, and want an external team who uses sound science and rigorous methodology to provide high-quality comprehensive solutions pre- and post-product launch.



Heidi Reichert, MA
Managing Statistician
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HEORStrategies

A BlueRidge Life Sciences Company

Who we are.

Your multidisciplinary Health Economics and Outcomes Research (HEOR) consulting team that develops innovative and actionable solutions to support the development and commercialization of pharmaceutical, biologic, and medical device products. Our experts work with clients to generate real-world evidence that demonstrates the value of life sciences products.

Services include:

- Health economics and strategy
- Economic models
- Evidence synthesis
- Network meta-analysis
- Epidemiology, health outcomes and observational studies
- Comparative effectiveness studies
- Patient-centered research

When to call us.

When pharmaceutical, biotechnology, and medical device companies need to develop and implement innovative approaches to strengthen the evidence for a small molecule, biologic, gene or cell therapy, or medical device product, and address the challenges faced as they bring these products to market.



Naomi Sacks, PhD
VP
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Scientific technology and
regulatory solutions

Epidemiological
studies solutions

Clinical and economic
valuation, development and
commercialization solutions

Biopharma cold chain
engineering solutions

Drug/biologic delivery system
development solutions



MODALITY SOLUTIONS

A BlueRidge Life Sciences Company

Who we are.

Your Biopharma cold chain engineering solutions partner with regulatory expertise and proven methodologies to accelerate your therapy approval, ensure product quality in transit, and provide time-critical responses to global regulatory inquiries.

- Validation engineering
- Regulatory guidance
- Advance testing
- Cold chain optimization
- 125+ therapies
- 250+ successful regulatory interactions
- 300+ thermal packing designs
- 30+ countries

When to call us.

When you need successful cold validation experts with relevant know-how on all modalities and temperature ranges to provide integrated solutions for shipping validation planning and execution through post-market design and optimization of resilient cold chain logistics network.



Rob Battista

Engineering Manager

rbattista@modality-solutions.com



Suttons Creek The Device Team for Pharma

A BlueRidge Life Sciences Company

Who we are.

Your outsourced team of experts that bridge the combination product gap, supporting from strategic planning through post-market activities. If it touches the device, we ensure reduced time to approval and increased ROI. Program planning/execution and corporate development services include:

- QMS Set Up
- Device/Vendor Selection
- Clinical Development
- Commercial Development
- Regulatory Approval
- Commercial Launch
- Postmarket Surveillance
- Combination Product Strategy
- Corporate Readiness/Change
- Education/Training
- Operations Development
- Executive CP Coaching

When to call us.

When you have a drug delivery device or software supporting your pharmaceutical product and need strategy support or outsourced team members for device development and regulatory submission.



Steve Badelt, PhD

EVP and Managing Partner

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Learn more at **blueridgelifesciences.com**