THE ToxStrategies family of companies

Scientific, technology, and regulatory solutions

Epidemiologial studies solutions

Clinical and economic valuation, development and commercialization solutions

Biopharma cold chain engineering solutions

Drug/biologic delivery system development solutions

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.

Innovative Solutions
Sound Science

Tox Strategies

Contact:
Marcie Wood, PhD
SVP, Pharmaceutical Practice
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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.

CLINTREX

Contact:
Cornelia Kamp, MBA
VP Operations
ckamp@clintrex.com

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.

- 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.

Innovative Solutions / Sound Science

MODALITY SOLUTIONS

Contact:
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Engineering Manager
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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 inquires.

- 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.

Suttons Creek
The Device Team for Pharma

Contact:
Craig Voellmicke
Director of Sales
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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.

EpidStrategies

Contact:
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Managing Statistician
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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:

- Study design / protocols
- Statistical analysis / plans
- Meta-analysis
- Publication development
- Evidence strategy
- Value proposition development / testing
- Feasability 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.

HEORStrategies

Contact:
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Vice President
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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.