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LIFE SCIENCE COMPLIANCE EDITION

Alethea Wieland,
President & Founder

CLINICAL RESEARCH STRATEGIES

AN END-TO-END APPROACH TO COMPLIANCE IN LIFE SCIENCES

$15

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TOP 10
LIFE SCIENCE COMPLIANCE
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CLINICAL RESEARCH STRATEGIES

AN END-TO-END APPROACH TO COMPLIANCE IN LIFE SCIENCES

Unforeseen accidents in the healthcare industry have often served as the impetus for a positive change. Back in 1991, the establishment of Poly Implant Prothese (PIP), a French-based company, had augmented breast implant therapies at scale. However, felonious efforts to reduce the manufacturing cost using industrial-grade silicone in 2001 put an end to the golden ages of the Life Sciences industry. With several harmful side effects, including inflammation and scarring, these implants—unapproved for medical applications—continued to raise questions over patients' safety in the long run. As such, the European Commission was obligated to embark on a complete overhaul of the regulations for medical devices to provide high levels of safety and restore public confidence.

The result was the European Medical Devices Regulation (MDR). In addition, the European Union radically changed its privacy policies with the introduction of the General Data Protection Regulation (GDPR). In contrast, the US government, having recognized the inadequacy of regulations to address the latest innovations, passed the 21st Century Cures Act which required the Food and Drug Administration (FDA) to release new guidance for the purpose of accelerating research methodology and improving time to market.

"While in the EU, these regulations are meant for ensuring patients' safety by adding more conformance requirements, they have severely compromised the Life Sciences industry's quest to push the boundaries of innovation," says Alethea Wieland, the President and Founder of Clinical Research Strategies.

Seconding her statement is a study published by Deloitte that says, "Globalization, alliances and

Alethea Wieland,
President & Founder

David Link,
MBA, Chief Quality and
Regulatory Officer and Founder

partnerships, heightened transparency expectations, increased emphasis on innovative technologies, and ever evolving needs for existing and emerging customers are driving them to re-examine their approach to compliance." As such, identifying, analyzing, and mitigating compliance risks have evolved into a fundamental prerequisite for Life Sciences companies in developing an effective strategy to help future-proof their business. However, keeping up the innovation pace with this regulatory landscape will no longer be an easy task, especially for startups and mid-sized organizations.

Established to help organizations navigate through the highly dynamic and complex regulatory frameworks is Clinical Research Strategies. This Pennsylvania-based contract research organization and executive management consultancy helps Life Sciences companies and digital healthcare entrepreneurs, especially with novel or first-in-class medical products, understand the costs and resources required to execute a successful clinical development plan and regulatory strategy. Although the firm primarily focuses on startup and mid-size companies, Clinical Research Strategies caters to a wide range of customers, including large clinical research, pharma, and medical device organizations. The company helps them fill short-term or long-term staffing solutions with high-performing teams.

> Our project-specific, fit-for-purpose staffing services enable clients to instill fiscal discipline and reduce risks in clinical development, quality assurance programs, and post-market activities at all stages of their clinical trials

A Passionate Duo Steering the Transformation

Clinical Research Strategies is a result of Alethea's and David Link's—who serves as the Chief Quality and Regulatory Officer, respectively—vision to offer an enterprise-wide view of compliance and fiscal

risks to help startups and mid-size companies successfully navigate through the regulatory framework. Alethea brings three decades of experience in the Life Sciences industry, working predominantly with pre-clinical and clinical affairs and regulatory submissions to various agencies. Link serves as an innovative and transformative leader who has over 30 years of experience in quality assurance and regulatory affairs, working in the aerospace, defense, manufacturing, and medical device industries. The tech-duo identified that compliance failures could be costly—both in terms of fines, remediation costs, and reputational damage—and many organizations lack in-house expertise and resources to meet their regulators' requirements.

Passionate to help Life Sciences companies, Alethea and Link decided to combine their longstanding experience to establish Clinical Research Strategies. "Backed by powerful executive-level management and an agile team of strategists and tactical experts, we are able to quickly identify the gaps within the Life Sciences space and roll up our sleeves to help clients address business deficiencies," mentions Alethea. To this end, the company designs and develops a comprehensive suite of services that helps the Life Sciences industry innovate and carve its way ahead.

All-Inclusive Service Portfolio

Clinical Research Strategies provides end-to-end services to Life Sciences organizations—from their inception to strategizing an effective approach go-to-market with their products—by helping comply with all regulatory requirements. "Our project-specific, fit-for-purpose staffing services enable clients to instill fiscal discipline and reduce risks in clinical development, quality assurance programs, and post-market activities at all stages of their clinical trials," says Alethea. A typical client engagement begins with Clinical Research Strategies assisting Life Sciences entrepreneurs to kick-start their business and establish value, beyond the idea, for investors. The company provides them with valuable insights, helping navigate through a series of requests for proposals (RFPs) to identify and collaborate with the right vendors. For clients that lack resources, the firm serves as an in-house team to help manage their vendors and build a strong foundation before they head toward discussions with regulators.

"We pride ourselves on being regulatory scientists with deep know-how who can help clients adapt to change and improve their business performance," says Alethea. This allows Clinical Research Strategies to interpret regulations, especially related to risk management, clinical evidence, post-market clinical follow-up studies, routine surveillance, and complaint handling, helping clients become inspection-ready. Clients can use its comprehensive service portfolio to remain compliant to regulations—like GDPR, EU MDR, UK post-Brexit regulation of medicines, and recommendations by FDA, Health Canada, Therapeutic Goods Administration (TGA), and more.

An Extra Edge Over the Competition

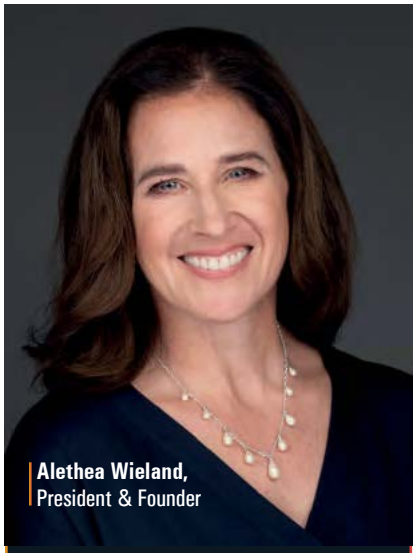
What makes Clinical Research Strategies unique is the personal responsibility to think both analytically and holistically to avoid unintended consequences of short-

sided decisions, and to enable clients to keep costs and timelines as low as possible, harness technology, and meet the regulator's needs, instead of pushing band aid methods. "Our teams are actively doing the work and facing investors, regulators, patients and other stakeholders, and these lessons learned are extremely valuable for sharing with our clients," mentions Alethea. The company deploys a dedicated team of industry experts to customize its clients' risk management and quality assurance programs, including building or repairing their quality management system.

Furthermore, Clinical Research Strategies helps sponsors with their clinical development plans and regulatory discussions by advocating preparedness and openness to eliminate hidden surprises and unnecessarily repeating work later. "We have written clinical protocols and investigator brochures, and federal grants, conducted literature reviews and market assessments, and assembled regulatory documentation to empower clients during those early discussions with regulators," says Alethea. This enabled the company to conduct early-phase clinical trials and to assist the development of several remarkable products, including a first-in-class medical device for Alzheimer's disease, regenerative medicine biologic products for diabetes, non-invasive ventilator weaning device, COVID diagnostics, digital therapeutics for patient monitoring and mental health, and opioid-sparing cannabinoids.

A Testimony to the Value Proposition

With such a powerful service portfolio and proven value proposition, Clinical Research Strategies serves as a highly sought-after partner for Life Sciences companies. Alethea recalls their recent collaboration with a US-based medical imaging company that had a suite of radiology devices in the market for more than ten years. Highly dependent on legacy devices, the client approached Clinical Research Strategies to help them comply with the current EU MDR regulatory requirements. The company conducted a full gap assessment to identify the issues that prevented them from complying with the regulatory changes and leveraged its expertise to help them bridge those gaps.



Alethea Wieland,
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Clinical Research Strategies created comprehensive clinical evaluation reports that helped the client meet current regulatory requirements. The overall project was complex and time-consuming, with 80 well-established radiological medical devices and accessories. However, Clinical Research Strategies was able to complete the project in eight months. This same client has provided repeat business by adding more service requests in clinical operations and global regulatory strategy.

Facilitating Future Innovations

Such instances of success exhibit the dedication of Clinical Research Strategies' team of experienced industry veterans toward assisting Life Sciences companies to jumpstart their business. Anticipating rapid evolutions in the Life Sciences regulatory landscape, Clinical Research Strategies is planning to enhance the capabilities of its offerings with an intention to serve its clients better. Having an in-depth understanding of the regulatory environment, the company can outrun its competition by aligning with the new paradigm in an agile fashion. "We aim at serving as a competent solution for organizations, helping them spearhead innovations in the Life Sciences space. This way, we bring the latest in decentralized trial methods and regulatory discussion to clients who need a practical, cost-effective approach," concludes Alethea. LS

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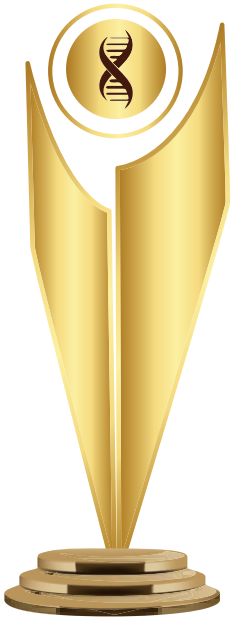

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The annual listing of 10 companies that are at the forefront of providing exemplary services and solutions to obtain Life Science Compliance and in turn transform the business bottomline