LESIRG

Consultants to the life sciences industry

QUALITY ASSURANCE & REGULATORY COMPLIANCE

Lesirg provides quality assurance and compliance services to pharmaceutical, biotechnology, radiopharmaceuticals and medical device companies assisting them in interfacing with regulators and addressing regulatory questions and problems.

Our consultants assist clients in developing appropriate GMP documentation, perform internal and supplier/contractor compliance audits, manage and facilitate technology transfers, and work with client's various departments to implement GMP-compliant processes and procedures.

GAP ANALYSIS & INSPECTION READINESS

The firm assists clients performing gap assessments against applicable regulatory requirements, develop mitigation strategies and a corrective action plan, address gaps, and enhance inspection readiness. Lesirg has successfully assisted clients prepare for and pass regulatory inspections.

REMEDIATION STRATEGIES

Lesirg enjoys multidisciplinary consultants that can integrate to your teams during complex remediation activities. Our compliance consultants will help you design the remediation plan that's most convenient to your operations and budget, and our validation and QA consultants can assist your team in deploying the strategy, revising the policies and procedures, implementing and improving quality system elements to help you remediate with minimal interruptions to your ongoing operations.

FACILITY COMMISSIONING & VALIDATION

Our team includes validation specialists with extensive expertise in commissioning and validation of pharmaceutical and biotechnology facilities. The firm offers clients complete validation packages, starting with building and implementing master validation plans and strategies, to validation project management and executions. The company performs validation on plant utilities (PW, WFI, HVAC) and equipment, including all required documentation and assists in the design and implementation of plant & process specific cleaning validation programs.

VALIDATION OF COMPUTERIZED SYSTEMS

Lesirg offers compliant and tailor-designed computer validation support. Our consultants will help you define and implement computer system validation policies, data integrity policies, and help you validate your GMP-related software applications to their intended use. We have extensive experience in various applications commonly used in the life science industries, from Documents Management Systems, to Learning Management Systems, and Enterprise Resource Planning (ERP) systems.

PRODUCTIVITY & EFFICIENCY IMPROVEMENT

Our Consultants are experienced professionals in building and implementing productivity improvement programs. With our systemic approach for efficient problem solving, we help clients develop lean thinking and strategies for process improvement by removing redundancies, minimizing variability and increasing OEE through Kaizen events.

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SUPPLY CHAIN QUALITY ASSURANCE

The firm provides site evaluations and auditing services for clients assisting them in optimizing and qualifying their supply chain. We provide aid in building lean and risk-based suppliers management programs and our associates are multilingual expert auditors in various regulated industries. We have performed hundreds of audits of manufacturers, suppliers of APIs, excipients, raw materials, as well as packaging components and support laboratory and testing services on 4 continents. We complete audit reports within 10 business days following each visit and offer follow-up services with select suppliers on an as-need basis.

CUSTOMIZED TRAINING

The firm provides customized training services and assists in creating and delivering specific workshops and training content. Our consultants are particularly proficient in designing and delivering GMP Training, investigations, validation, out of specifications handling, and other facilitation events.

Pierrino Torbey

Founder and President

After gaining his early quality assurance and compliance expertise with multinational firms from pre-clinical toxicology testing, to finished product contract manufacturing, biologics and sterile fill and finish operations, Mr. Torbey went on and started Lesirg Consultants in 2008 in Montreal Canada.

The boutique consulting firm provides quality and compliance services to the FDA-regulated industries, from small molecules manufacturers, API manufacturers, finished dosage form manufacturers, to medical devices and analytical testing laboratories.

Mr. Torbey has over 22 years of experience in building and remediating quality management systems, and assisting companies advance their products and platforms development in the most manufacturing-friendly and efficient manner while always ensuring full compliance with applicable regulatory requirements.

Mr. Torbey has worked with over 200 sites across 4 continents, either performing audits and site assessments, or remediating deficiencies and assisting the organizations comply with regulatory requirements applicable to their product and jurisdictions. He has worked with API manufacturers, biological manufacturing companies and contract manufacturing organizations for solid dose, sterile and non-sterile manufacturing, vaccine development and manufacturing, and most recently with new technologies such as viral vectors production and mRNA technologies.

His particular expertise lies in his abilities to connect with the clients, energize the teams and lead compliance projects with utmost efficiency. Mr. Torbey is fluent in English, French, Spanish and Arabic. He holds a Bachelor's degree in Biology, a Master's degree in Physiology along with graduate studies in Management. He is an active member of the Parenteral Drugs Association, an accomplished auditor and team builder.

Since 2008, Mr. Torbey has personally provided *ad hoc* and *ad interim* quality management services to high tech, biotech drug and device companies. He has consistently and successfully helped these organizations prepare for and pass inspections by the U.S. FDA, Health Canada, and EU EMA.

He is an expert in providing mock audit services, providing guidance in facility layout and design, quality systems development, and personnel training.

He has travelled extensively and have enjoyed interacting and working with companies and teams from various backgrounds and cultures.

He is currently working on building and integrating the US-based team for the new offices in the Research Triangle Park in North Carolina, USA.