

QUALITY ASSURANCE AND REGULATORY COMPLIANCE

Lesirg Consultants provide quality assurance and compliance services to pharmaceutical, biotechnology and medical device companies assisting them in interfacing with regulators and addressing regulatory questions and problems. Our consultants assist clients in developing appropriate ISO and GMP documentation (policies, manuals, SOPs), perform internal and supplier/contractor compliance audits, and work with client's various departments to implement GMP-compliant processes and procedures.

FACILITY DESIGN, ENGINEERING & VALIDATION

Our team includes seasoned engineers with extensive expertise in design, building and commissioning pharmaceutical and biotechnology facilities. The firm offers engineering and validation of 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.

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 contract manufacturers, suppliers of APIs, excipients, raw materials, as well as packaging components and support laboratory and testing services both domestically and abroad. We complete audit reports within 5 business days following each visit and offer follow-up services with select suppliers on an as-need basis.

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.

CUSTOMIZED TRAINING

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