HIBISCUS CONSULTING
YOUR COMPLIANCE EXPERTZ

QUALITY ASSURANCE & REGULATORY COMPLIANCE

Hibiscus Consulting provides quality assurance and compliance services to pharmaceutical, biotechnology, Food, Nutraceuticals 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. Hibiscus has successfully assisted clients prepare for and pass regulatory inspections.

REMEDIATION STRATEGIES

Hibiscus 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, biotechnology and Medical device 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

Hibiscus 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.

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