Industry knowledge, Process expertise Working for you.....

TRAINED, EXPERIENCED RESOURCES & CUSTOMISED, TIME TESTED PROCESSES AT EACH PHASE OF PROJECT IMPLEMENTATION

Auditing Services

Vyomus Consulting is a Regulatory Science and Product Development Consulting firm, serving Business to Business (B2B) Customers in highly regulated industries. Our services help Biopharmaceuticals, Medical Devices, Diagnostics, Cosmetics & Wellness, Food & Nutrition organisations Commercialise products, Reduce time to market, Achieve compliance and Grow their business efficiently and effectively.

At Vyomus, our auditing teams include former senior executives from top Pharma, Biotechnology, Clinical Development companies, top tier consultancies, Fortune 500 enterprises, and leading outsourcing service providers.

This industry knowledge - grounded in years of industry and regulatory experience, knowledge gained by going through training programs and local regulatory nuances, combined with process expertise and our customized time tested auditing process ensures the audit process to be thorough and at par with world class regulatory audits - and hence assist you in managing regulatory demands in an effective manner.

Various services provided by the audit group include Independent Functional Auditing, Independent Compliance auditing, Gap-auditing, Self-inspections/auditing, Technical advisory services for quality organisations within customer organisation. This brings you more in line with what is accepted as regulatory compliance in Europe, North America and India and gives you a valuable head start against your competitors when you vie for business from your customers.

The team at Vyomus is flexible to fit your needs. We can provide selected or comprehensive services as required to meet your specific program needs.

Independent Auditing Services

CLINICAL DEVELOPMENT

- Standard Operating Procedures
- Clinical Process Audits
- GCP Audits (ICH and Indian GCP)
- Clinical Study Audits (Phase I to IV; BA/BE Studies - EMEA; FDA; WHO etc.,)
- Clinical Facility Audits
- Essential Documents Audit
- Vendor Audits / Due Diligence
- Risk Management Plan Audits

CLINICAL DATA MANAGEMENT

- Standard Operating Procedures
- Process Audits
- GCDMP and Study Audits
- Facility Audits
- Facility Audits
- Vendor Audits / Due Diligence

COMPUTER SYSTEMS

- Computer Systems Validation
- 21 CFR Part 11 (EMEA, FDA)
- Standard Operating Procedures
- Process Audits
- Vendor Audits / Due Diligence

GLP and GPVP AUDITS

- Preclinical studies
- Animal Testing Facilities
- Pharmacovigilance Process and Projects

Who does VYOMUS Serve ?

Emerging, mid-size and large - Pharma, Biotechnology, Medical devices, CRO's and Life Sciences companies

Industry Focus

Biologicals, Vaccines, rDNA products NBE's, NCE's, NME's, Medical devices, Diagnostics Generics and Formulations.

Why Vyomus ?

- Provides, localized strategic and process expertise to attain business competitiveness - delivering faster, quicker, approvable projects
- Projects tracked in real time, delivered on schedule within agreed service levels - reducing development costs
- Faster design, planning and implementation processes - leading to increased ROI.

Vyomus® Consulting
Regulatory & Commercialisation Experts

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