Complya Asia

Shanghai, China

The Complya Asia team provides the full spectrum of Quality Assurance (GMP, GCP, GLP) services throughout China, Singapore, Japan, India, and the region. Our consultants are available to perform vendor and mock-FDA audits, and to provide comprehensive training and remediation services within Asia.

Call us to learn more. 617.475.3470

complya consulting

A ➤ PHARMALEX Company

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QA SERVICES

STRATEGIC SUPPORT

- > Develop phase appropriate Quality System
- > Gap Analysis and Remediation and Implementation
- > Pre-Approval Inspection Readiness (Mock PAI Audit)
- > Warning Letter and Consent Decree Remediation

OPERATIONAL SUPPORT

- > Supplier and Internal Audits
- > Document Control
- > Deviation and CAPA Remediation
- > SOP Generation
- > Interim support (Junior through Senior level roles)

RA SERVICES

REGULATORY STRATEGY (Domestic and Global)

- > Preclinical, Clinical, and Commercial Strategy Plans
- > Regulatory Agency Relations

REGULATORY SUPPORT

- > Regulatory Filings and Support
- > Labeling Review
- > Advertising and Promotional Material Review
- > Regulatory CMC (Chemistry, Manufacturing and Controls)

AREAS SERVED*

Lifecycle

Emerging	Established	Mature
Phases I II & III	One Product	Multiple Products
Proceeding through clinical trials and heading to first product	With one or more commercial products and a growing clinical process	Multiple commercial products and a deep clinical pipeline

Complya provides GLP, GCP & GMP services across a company's lifecycle.

IND Filed = Initial New Drug Application
IDE = Investigational Device Exemption

NDA = New Drug Application
BLA = Biologics License Application
PMA = Premarket Approval

** Complya also supports regulatory compliance in Europe and Asia.*

OUR CONSULTANT MATCHING PROCESS

P E A R L

Personality	Experience	Availability	Rate	Location
Whether you need a detail-oriented expert to review reams of analytical data, or a strong leader to facilitate strategic planning sessions, we listen carefully and identify the right person for the job.	Consultants are not "one size fits all." We think hard about each consultant's skills and background to best leverage their experience for the success of your project.	10 hours a day or 10 hours a year: we can identify a consultant with the availability to help out, whatever your need.	We give you the best value on each project by factoring in your budget and selecting a consultant at the right level.	Our team consults across the U.S., and we are rapidly expanding in Europe and Asia. If you need on-site project help, chances are we will have someone available.

OTHER GXP SERVICES

VALIDATION

- > Qualification of facilities, equipment, utilities, and processes
- > Independent QA review of validation protocols, data, and report

ELECTRONIC SYSTEMS

- > Electronic Data Management Systems (EDMS)
  - > CSV (21 CFR part 11 Compliance)
  - > Hands on transfer support
  - > Customized user training

QUALITY CONTROL SUPPORT

- > Hands on expertise in microbiology and analytical chemistry

Testimonials

"We have worked with Complya for several years on clinical and GMP auditing projects and found [the Complya team] to be highly experienced, flexible, dependable, very professional and just plain nice to do business with. We will continue to use their services for many years to come."

> Senior Director of Quality,
Boston Area Biopharmaceutical Company

"I have really enjoyed working with Complya for our project needs. They worked hard to find the right people for our projects, and provide on a continuing basis just the right amount of service we require."

> Director of Global Regulatory Affairs
CMC Biologics,
International Biopharmaceutical Company

"We couldn't have asked for a more professional, personable, knowledgeable group of Quality Experts!"

> Senior QA Associate,
International Biotechnology Company

"Complya has been a dependable resource for rapidly sourcing talented personnel. It has been a pleasure to work with the team at Complya and I will certainly utilize their resources for future projects."

> Director of Manufacturing & Logistics,
Boston Area Biotechnology Company

MATCHING TALENT > GETTING RESULTS

> Raising the Bar

QA AND RA EXPERTS RAISING THE BAR
TO HELP YOU ACHIEVE REGULATORY COMPLIANCE

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