GENBIOCA
Domain Led, Technology Services Company

website: www.genbioca.com
enquiry: sales@genbioca.com

WE ARE THE TRUSTED REGULATORY AFFAIRS AND COMPLIANCE PARTNER

We support RAC requirements across
Americas, Europe and Asia
and other geographies as well

HOW WE WORK?

GenBioCa SME's working alongside industry experts will:

- **Mitigate GxP compliance risks**
- **Manage remediation**

GenBioCa has pool of SMEs from the Industry who can assist you from Basic Documentation in RAC to remediation to Internal Audits

We work with the leading pharma companies, Med Device companies

Audits

General GxP audits
FDA type mock Pre-Approval Inspections
Verification audits
Effectiveness checks
Gap analysis and Consulting
Quality systems
Management control

Data Integrity

Directed audits
Analysis
Subject matter training
Procedure development
Interviews of staff
Internal investigations
Fraud evaluation

Inspection Support

Hosting
Front/back room support
Mock interviews
Readiness Assessments
Application conformance reviews

Technical Writing

Writing SOP's
Validation
Protocols and reports
Annual product reviews
FDA correspondence
Audit responses
Strategic plans
Other technical reports

Strategic Advisory

Communications
Regulatory submissions
Health Authority meetings
Consent decree remediation
Verification activities
Form 483
Warning Letter responses

Learning and Development

Scale up competencies through workshops
Trainings to retool
Reskill and upgrade regulatory understanding with coaching from experts from the industry