# Due Diligence Expert Services

PharmaBioServ


Our 29 years working in the Health Care Regulated Industry and innumerable hours of regulatory **knowledge** by our **experts** makes **Pharma-Bio Serv** your preferred partner for your due diligence process!

Our services are essential when evaluating risks coming from:

## INDs

- Communications, Meeting outcomes and minutes, Commitments
- Clinical sites status regarding GCP compliance
- Investigators public records

## DMF, ANDA, NDA, BLA, 510k, PMA

- Detailed review of dossiers and regulatory strategies
- Communications with Health Authorities, meeting outcomes and minutes, commitments, and approvals
- Evaluation of Safety Studies
- Evaluation of Modules 2, 3, 4, and 5
- Evaluation of Medical Device Technical Files and submitted special controls
- Changes submitted to dossiers and Supplements under evaluation
- Pharmacovigilance reports and post-registration reports and notifications

## Manufacturing Sites

- Available technology
- Installed and in use operational capability
- Evaluation of the supply chain end-to-end operations
- Main company and CMO registration status and product listings
- Regulatory Classification, compliance, and inspection history, including individual observations, import alerts, recalls, and regulatory actions
- Communications, EIR, FDA 483, Warning Letters

## Our SME will perform for you:

- On-site assessments of compliance and GMP readiness against the main Health regulatory Agencies (FDA, EMA, PDMA, ANVISA)
- Review of public records
- Management and Management Control Assessments
- Knowledge maps of site personnel
- Quality agreements evaluation for CRO, CDMO and CMO, Contract Labs, API manufacturers, Drug Product Manufacturer, Sterilizers, Raw Material Suppliers, Warehouses, any other third-party contractor
- Operational Effectiveness evaluations
- Evaluations of technology platforms and volume capabilities
- Cost of Goods determination
- New product introduction business cases
- Risk assessments

**Pharma-Bio Serv** provides the scientific and regulatory information you need to confidently make your business strategic decisions!

**Pharma-Bio Serv** will assess the risk following a proven a systematic methodology to ensure technical and regulatory information accuracy and compliance.

**www.pharmabioserv.com** **+1-787-278-2709**