NAYA®
LIFE SCIENCES

QUALITY AND REGULATORY SERVICES

We are committed to providing efficient regulatory and quality services to help our clients ensure quality throughout the product development process and post-approval lifecycle management.

We address all challenges that could impact your product quality - cGMP compliance, QMS implementation, documentation management, or training and we employ our experience and knowledge to provide you with professional advice in all areas of regulatory affairs.

www.naya-ls.com

QUALITY ASSURANCE

To support our clients in ensuring compliance with all contractual specifications, mandatory regulations, and quality standards, we provide quality assurance and control throughout the entire supply chain, in every part of the world.

Our quality assurance solutions are aimed at controlling product quality and avoiding manufacturing non-compliant products. They run through the entire project life cycle to help you reduce the inherent risks in the project.

OUR QUALITY ASSURANCE SERVICES INCLUDE:

- Quality strategy development
- Quality systems design and build & implementation of integrated quality system elements
- Consultancy on compliance with GMPs and ICH Q8-Q10 directives and EU legislation
- System mapping and transition assistance to new Best Practice Models
- Change control/management development, De-bugging, Analysis
- Deviations/Investigations/CAPA Systems
- Quality policy, Quality charter, Quality counsel
- Assistance with the selection of a database /system to support QS
- Product quality review & Annual product quality review consultancy
- Laboratory investigations (OOS, OOT) strategy
- Quality risk management strategy
- Recall and complaints strategy
- Qualification and Validation
- Quality engineering
- Self-inspection and quality audits
- Contract production & analysis technology transfer

DOCUMENTATION SYSTEMS

- Product quality review
- Complaints and product recalls
- Good Documentation Practice (System design and management)
- Document design & preparation
- Manufacturing batch records
- Standard Operating Procedures
- Policy documents
- Quality agreements
- Master plans
- Validation documents
- Specialist reports
- Specification preparation

NAYA®
LIFE SCIENCES

QUALITY CONTROL

To help our clients fully meet product specification requirements, we provide an integrated and effective quality management system to enhance their market competitiveness while improving product quality.

Our quality control services use a comprehensive management model to help our clients assure the quality of their products as per the set standards.

OUR LABORATORY OPERATIONS AND SERVICES INCLUDE:

- QC Strategy
- Assessments/QC flow
- Laboratory design, flow, and operation
- Value Stream Improvement
- Sample Management
- Data Management Systems
- Mentoring

OUR QC TEST CONSULTING SERVICES INCLUDE:

- Pharmaceutical microbiology
- Endotoxin by gel clot
- Bioburden and Bacteriostasis / sterility testing
- Total Organic Carbon (TOC)
- Environmental Monitoring of ISO classified rooms per ISO and USP Guidelines
- High Purified water testing per USP, EP
- Product release testing per FDA/ICH/EU guidelines
- Stability Studies and adherence to ICH guidelines for Stability testing
- Qualification and Validation of Assays
- ELISA testing
- in vitro whole cell bioassays
- In-process testing
- Reference standard providing
- 00% visual testing of all drug product containers

NAYA®
LIFE SCIENCES

REGULATORY SERVICES

We advise and assist pharmaceutical, biotech and healthcare companies in the development and implementation of innovative and global regulatory strategies to accelerate the development and registration of products at all development stages.

Working together, we invest our expertise in empowering our clients to stay ahead of any compliance risks.

Our regulatory services include:

DOSSIER PREPARATION AND REVISION (FOR PHARMACEUTICAL PRODUCTS) BASED ON EMA &EU GMP, ICH M4

- Common Technical Dossiers (CTD)
- Dossiers as per country-specific guidelines
- Dossier conversion (from one country to another)
- Conversion of Non-CTD to CTD
- Product life cycle management (Renewal and Variations)

CONSULTANCY

- Pre-clinical study requirement determination and consultancy
- Clinical study requirement determination and consultancy
- Dossier Registration consultancy
- Post-marketing surveillance report consultancy (PSUR)

MEDICAL WRITING

- Nonclinical Study Reports (Module 4 of CTD)
- Clinical Study Reports (Module 5 of CTD)