QUALITY SYSTEMS OVERVIEW

OVANTIC LIFE SCIENCES QUALITY SYSTEM IS COMPRISED OF THE FOLLOWING SYSTEMS AND SUB-SYSTEMS

Ovantic Life Sciences operates under a culture of continuous regulatory preparedness. Our facilities, quality systems, and documentation frameworks are structured to meet and exceed the requirements of U.S. FDA regulations and global pharmaceutical standards. We maintain a state of perpetual inspection readiness to ensure operational transparency, traceability, and compliance integrity across all divisions.

Ovantic aligns its operations with the following regulatory frameworks:

- 21 CFR Parts 210 & 211 – Current Good Manufacturing Practice (cGMP)
- 21 CFR Part 11 – Electronic Records & Electronic Signatures
- ICH Q7 – Good Manufacturing Practice for APIs
- ICH Q8 – Pharmaceutical Development
- ICH Q9 – Quality Risk Management
- ICH Q10 – Pharmaceutical Quality System
- FDA Establishment Registration & FEI Requirements
- U.S. Import/Export Compliance Standards

Ovantic maintains a fully documented and controlled Quality Management System (QMS) designed to support audit readiness and continuous improvement. Key components include:

- Controlled SOP governance with document revision tracking
- Deviation management and Corrective & Preventive Action (CAPA) systems
- Internal audit cycles and mock inspection protocols
- Vendor qualification and supplier audit programs
- Training documentation with competency verification
- Data integrity compliance aligned with ALCOA+ principles
- Batch record traceability and retained sample programs

Ovantic's global sourcing and U.S. finishing model incorporates structured regulatory safeguards to ensure full compliance and traceability:

- Qualified foreign supplier audits and documentation review
- U.S.-based final-stage processing under cGMP controls
- Third-party analytical verification and COA reconciliation
- Chain-of-custody documentation
- Cold-chain validation where applicable
- Controlled warehousing with environmental monitoring

Compliance infrastructure at Ovantic reduces regulatory exposure, minimizes operational risk, and enhances enterprise valuation. Our proactive approach mitigates:

- Regulatory enforcement risk
- Import delays and detention exposure
- Batch documentation deficiencies
- Product recall vulnerability
- Supplier qualification gaps

Ovantic maintains executive-level oversight of regulatory affairs to support:

- FDA inspections and regulatory correspondence
- Import detention resolution and product release coordination
- NDC compliance and labeling review
- Stability program oversight
- Orphan drug development regulatory strategy
- Due diligence readiness for institutional partners and investors

Compliance is not a department at Ovantic Life Sciences — it is our operating philosophy. Our regulatory posture is designed to support scalable growth, orphan drug commercialization, peptide platform expansion, and strategic pharmaceutical partnerships.