

Regulatory Affairs Specialist Competency Matrix

Competency Area	Competency	Entry Level	Mid Level	Advanced Level
Regulatory Knowledge	Understanding of FDA, EMA, USDA, ICH, and international regulatory frameworks.	Understands basic regulatory requirements and terminology.	Applies regulatory knowledge in preparing submissions and ensuring compliance.	Advises on global regulatory strategy and leads interactions with agencies.
Regulatory Submissions	Preparation and submission of INDs, NDAs, BLAs, MAAs, and related documents.	Assists in compiling data and documentation for submissions.	Prepares and reviews submissions independently with minimal supervision.	Leads submission strategy, negotiates with regulators, and manages approval timelines.
Quality & Compliance	Ensuring organizational adherence to regulatory and quality standards.	Follows SOPs and supports audits.	Conducts internal audits and ensures corrective actions are implemented.	Designs compliance programs and represents the organization during inspections.
Labeling & Documentation	Developing and reviewing product labels, package inserts, and regulatory documents.	Supports preparation of labeling documents under supervision.	Reviews and finalizes labeling content for compliance.	Directs labeling strategy, ensures alignment across global markets.
Clinical & Preclinical Support	Supporting clinical trial applications and compliance.	Understands basics of clinical trial regulations (GCP, GLP).	Prepares clinical trial applications, monitors compliance.	Advises on clinical strategy, supports multinational trial approvals.
Risk Assessment & Management	Identifying and mitigating regulatory risks.	Recognizes potential compliance risks under guidance.	Assesses risks and recommends mitigation measures.	Leads risk management strategy, advises executive leadership.
Communication & Liaison	Serving as point of contact with regulatory agencies and internal teams.	Communicates regulatory updates to internal teams.	Coordinates agency communications and prepares response packages.	Leads negotiations with regulators, represents company in official meetings.
Regulatory Intelligence	Monitoring and interpreting regulatory changes, trends, and policies.	Tracks updates in regulatory requirements.	Analyzes changes and provides guidance to teams.	Shapes organizational strategy based on global regulatory intelligence.