

Compliance Roadmap

BY COMPANY STAGE/MATURITY

Key compliance priorities from early development through commercialization.

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STAGE 1

Early / Clinical

2+ years to launch

Focus by OIG Element	PHASE A · Pre-Clinical	→ PHASE B · Clinical
People & Governance	Name Compliance owner	Plan governance and fractional CCO; Culture
Policies & Procedures	Core corporate policies (Code, ABAC)	HCP Interactions, 3 rd -party due diligence, Quality
Training & Education	Executive and Board training	Onboard new hires
Lines of Communication	Stand up hotline / inbox	Emphasize tone at the top
Monitoring & Auditing	Ad-hoc; Observe activities to learn risks	Scope risk-based testing
Enforcement & Discipline	Begin integration with HR	Align disciplinary roles and consistency
Response & CAPA	Case-by-case process	Establish CAPA methodology and tracking
IT Systems	Quality Management System (QMS)	LMS within Quality

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STAGE 2

Medical / Pre-Launch

~0–24 months to launch

Focus by OIG Element	PHASE A · Field Medical	→ PHASE B · Launch Planning
People & Governance	Formalize the CCO role and recruit FTE	Scale team (build vs. outsource)
Policies & Procedures	Medical and Patient Advocacy policies	Commercial policies and SOPs
Training & Education	Leadership and Functional Area training	Rep onboarding and credentialing
Lines of Communication	Socialize "speak-up" and the CCO post-hire	Tone at the middle; First culture survey
Monitoring & Auditing	Test key controls / high-risk areas	Build the post-launch monitoring plan; Data access
Enforcement & Discipline	Review incentive-compensation structures	Formalize investigation protocols
Response & CAPA	Pilot CAPA on monitoring findings	Pilot CAPA on investigations
IT Systems	CRM, Concur, LMS (non-quality), MedComms	HCP Engagements, Promo Materials, Transparency

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STAGE 3

Commercial

Post-launch & ongoing

Focus by OIG Element	PHASE A · Launch	→ PHASE B · Mature
People & Governance	Compliance as Business Partner; Board reporting	Compliance Champions; Program assessment and trends
Policies & Procedures	Close policy gaps and deepen SOPs	Full document lifecycle management; Simplification
Training & Education	Rep onboarding live; NSMs; eLearning modules	Recertification / annual training; Evaluate outcomes
Lines of Communication	Track hotline trends; Hotline awareness	Report trends to the Board and Business Partners
Monitoring & Auditing	Live monitoring and transactional audits	Annual risk assessments; Risk-based sampling
Enforcement & Discipline	Execute routine investigations; Resource complex cases	Apply consistent discipline and evaluate bias
Response & CAPA	Formalize CAPA process	Track remediation; Ensure preventative actions are working
IT Systems	Dashboards, Case Management, External Funding	More sophisticated systems; Enhance automation

BUILD HABITS THAT PREVENT COMPLIANCE PROBLEMS, NOT A PAPER PROGRAM FOR REGULATORS.