

Regulatory Outsourcing Readiness Checklist

Scope & Strategy

- Defined regulatory tasks to be outsourced (e.g., submissions, QMS, PMS)
- Clear internal goals and reasons for outsourcing (cost, speed, bandwidth)
- Internal team alignment and stakeholder approval secured

Documentation & Access

- Key technical files and regulatory history compiled
- Document sharing system in place (e.g., SharePoint, Google Drive)
- Access to QMS, risk files, and prior audit reports prepared

Internal Coordination

- Designated point of contact for the outsourced team
- Review timelines and meeting schedules defined
- Communication SOP (calls, tools, frequency) agreed upon

Compliance & Integration

- Regulatory authority expectations and submission deadlines mapped
- Partner access to necessary systems (eQMS, LIMS, Doc control) granted
- Role clarity between internal QA/RA and external consultants

Monitoring & Feedback

- Success metrics or KPIs defined (timeliness, accuracy, outcomes)
- Review and feedback schedule agreed (e.g., monthly check-ins)
- CAPA and continuous improvement loop established