

Quality Outsourcing Readiness Checklist

Organizational Readiness & Scope

- Have you defined the scope of quality tasks to be outsourced?
- Have stakeholders aligned on outsourcing objectives and expectations?
- Are key internal contacts identified for communication and collaboration?
- Do you have a timeline and budget in place for outsourced activities?

Confidentiality & Systems Access

- Is a Non-Disclosure Agreement (NDA) signed or prepared for execution?
- Have role-based access controls been set up for external consultants?
- Are relevant tools (QMS, document repositories, ticketing systems) accessible?

Documentation Availability

- Are your technical files and design history files up to date?
- Do you have a version-controlled SOP library?
- Are internal audit reports and CAPA logs available for review?

Regulatory & Compliance Background

- Have you conducted a recent gap assessment or internal audit?
- Do you have a documented risk management file aligned with ISO 14971?
- Are you aligned with applicable standards like FDA 21 CFR 820, ISO 13485, or EU MDR?

Performance Metrics & Governance

- Have you defined KPIs or SLAs for outsourced quality deliverables?
- Is there a reporting mechanism in place (e.g., weekly updates, dashboards)?
- Are escalation protocols documented and understood by internal teams?

Training & Change Management

- Have internal teams been briefed about the outsourcing process?
- Is there a training or onboarding plan for the external quality partner?
- Are roles and responsibilities clearly mapped to avoid overlap or confusion?