



Transition Management Checklist for Regulatory Affairs Outsourcing

Pre-Transition Planning

- Internal RA/QA roles and responsibilities documented pre-handoff
- Timeline and milestones for transition defined and communicated
- Data migration plan approved (document formats, ownership, systems)
- Pre-transition knowledge capture sessions scheduled
- Confidentiality agreements reaffirmed for legacy team and new partner

Knowledge Transfer & Onboarding

- Introductory meetings between internal and outsourced teams conducted
- Product portfolio and pipeline overview provided to external team
- Historic submission data and regulatory rationale shared
- Training conducted on internal tools, naming conventions, and templates
- Cross-functional stakeholder directory shared with responsibilities

Systems Access & Environment Setup

- Access credentials issued for shared drives, document repositories, QMS
- External team onboarded into communication and project tools
- Workflow automation or task assignments configured in PM systems
- Folder structure, version control, and metadata guidelines explained
- Test uploads conducted to ensure compatibility and access rights

Documentation Handover

- Regulatory submissions archive handed over in chronological order
- Current project documentation and ongoing submissions briefed
- List of open actions with timelines (e.g., RA queries, post-market reports)
- Compliance tracking tools updated with ownership reassignment
- References to internal SOPs and standards provided for alignment

Transition Monitoring & Quality Checks

- Parallel run for 2–4 weeks with both internal and external teams involved
- Daily or weekly sync meetings for issue resolution during transition phase
- Handoff completion sign-off after 100% of defined deliverables verified
- Transition feedback documented from both internal and external teams
- Audit readiness rechecked with new ownership and documentation trail