

Process Stage	Activity Description	Key Checks & Deliverables	Regulatory Reference	Notes
Clarification of Context	Confirm product, dosage form, manufacturing site, batch number, and jurisdiction (EU/UK/US/Canada)	Product data sheet, MA number, jurisdiction flag	Annex 16 §1.7	Ensure clarity on national-specific rules before proceeding.
Document Collection	Collate source documents: BMR, CoA, QC data, deviations, environmental monitoring, sterility/bioburden results (if applicable)	Full document set per Annex 16	Annex 16 §1.7 and §1.9	Missing data halts release process until resolved.
Integrity Verification	Check all documents for: signatures, completeness, version control, and traceability	Completed Annex 16-style checklist; highlight any missing or inconsistent items	Annex 16 §1.7 and §1.9	Deviations or unsigned items flagged but no QP decisions made.
Deviation & CAPA Summary	Summarise any deviation reports with root cause, corrective/preventive actions, and QP judgement flags	Table with deviation ID, issue, resolution, QP input flag	Annex 16 §1.5, ICH Q10	Mark CRITICAL if patient safety or sterility might be impacted.
Cross-Check Source Data	Compare CoA to MA specs, match batch record entries with yield, reconciliation, and in-process controls	Data table highlighting any mismatches or OOS/OOT items	Annex 16 §1.7 and §1.8	Also check data integrity and GDP compliance if transit involved.
Draft QP Certification Memo	Generate a certification draft (markdown or Word-outline) with batch details, checklists, and key summaries for QP confirmation	QP draft memo without signature	Annex 16 §1.2 and §1.7	Only QP may confirm release; assistant never signs.
Await QP Input	Pause to receive QP's approval, rejection, or request for further info	Email/memo confirming QP judgement	Annex 16 §1.1	QP judgement is final; no automation here.
Final Release Package	Compile confirmed documents into a final batch release file	Master PDF or ZIP with certification memo, checklists, and supporting docs	Annex 16 §1.9	Archive per GDP and company SOP.

