

PHARMACEUTICAL QUALITY AGREEMENT

Responsibility Mapping Worksheet | A non-confidential preparation aid for MAHs / sponsors and contract manufacturers

Use this worksheet to prepare a discussion—not as a signed agreement, legal advice, or a regulatory determination.

For each activity, identify the accountable party, performing party, reviewer/approver, notification trigger and controlled record. Tailor every allocation to the product, site, target market and applicable law. Contract wording can organize interfaces; it does not erase statutory responsibilities.

Five-question operating test

Who performs? Who reviews the evidence? Who makes/approves the decision? Who must be notified, and by when? Which record is authoritative, where is it retained, and who can retrieve it?

Responsibility map — discuss and complete with the other party

Activity / topic	MAH / sponsor — proposed role	Contract manufacturer — proposed role	Decision / interface to agree	Evidence, owner & timing to record
1. Scope & governance	Confirm legal entities, products, dosage forms, sites, markets, activities, exclusions, terminology and effective date.	Confirm site, licensed scope, facilities, quality-system interface and activities accepted.	Parties approve controlled scope; unresolved jurisdiction or product scope is escalated before work.	Signed quality / technical agreements; product-site-market matrix; named owners; review date.
2. Regulatory & dossier control	Own MAH / sponsor decisions where applicable; identify approved commitments and required filings for each market.	Provide accurate site, process and manufacturing records; assess regulatory impact of proposed site activities.	Agree who prepares, reviews, approves and submits each change or response; statutory duties remain with each party.	Regulatory responsibility matrix; filing calendar; controlled dossier references; escalation contacts.
3. Technical transfer & training	Provide authorized knowledge package, product/process history, known risks and qualified trainers.	Assess transfer feasibility; appoint lead; qualify/validate applicable systems and methods; document training and results.	Joint gap/risk assessment, transfer plan, acceptance criteria and stop/go decisions.	Approved transfer protocol; training records; raw data; transfer report; open-item log.
4. Change control	Assess product, dossier, market and supply impact; define required approvals before implementation.	Initiate changes affecting site, materials, process, equipment, methods or controls; provide impact evidence.	No product-affecting change is implemented until required written approvals and regulatory steps are complete.	Change request; impact assessment; risk assessment; approvals; effectiveness check; closure evidence.
5. Suppliers & materials	Set material/product requirements and any market-specific supplier constraints; approve changes as agreed.	Qualify/control suppliers within assigned scope; receive, sample, test, store and trace materials as agreed.	Define supplier approval rights, critical-material notification and disposition of nonconforming material.	Approved supplier list; specifications; CoA review rules; traceability; qualification and change records.
6. Manufacturing & sterility assurance	Provide approved process knowledge and product-specific critical quality/risk information.	Execute operations under its quality system and applicable requirements; maintain contemporaneous records and controls.	Assign review, escalation, notification and joint risk decisions for sterility assurance, shared-line risk and interruption.	Master/batch records; environmental and process records; line-clearance; risk assessments; escalation log.
7. Testing & analytical methods	Provide methods, specifications, reference standards and known method limitations where authorized.	Perform assigned sampling/testing; qualify or transfer methods; report atypical, OOS/OOT and invalid results promptly.	Agree test ownership, independent review, retest rules, invalidation authority and decision timelines.	Approved methods/specs; transfer/validation protocols; raw data; result review; sample chain of custody.

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8. Qualification & validation	Define product/market needs and participation or review expectations.	Plan, execute and document assigned facility, equipment, cleaning, process, sterilization/aseptic and method work.	Agree protocol approval, witness/oversight, acceptance criteria, deviations and revalidation triggers.	Approved protocols/reports; deviation closures; training; lifecycle / periodic review records.
9. Deviations, OOS/OOT & CAPA	Assess product, patient, market and filing impact; make decisions assigned to the MAH / sponsor.	Contain, record, investigate and propose actions for events arising at the site; preserve evidence and notify promptly.	Set severity tiers, notification clock, joint investigation interface, decision authority and CAPA effectiveness rules.	Event SOP; time-stamped notifications; investigation; impact assessment; CAPA; effectiveness verification.
10. Batch review & disposition	Define any MAH review / disposition responsibilities and market-release pathway.	Review manufacturing/testing records and certify or release only within the role and legal authority applicable to it.	Clearly distinguish site release, QP certification where applicable, MAH disposition and market release.	Batch record checklist; release package; unresolved deviation status; named decision maker; disposition record.
11. Records, data & access	Specify records needed for oversight, filing, investigation and lifecycle management.	Maintain complete, accurate, traceable records under assigned retention controls; provide agreed access and copies.	Define systems of record, data exchange, audit trails, retention, retrieval times, privacy and security boundaries.	Record inventory; retention schedule; access protocol; transfer logs; business-continuity and retrieval test.
12. Stability & retained samples	Define product strategy, market commitments and any sponsor/MAH sampling or stability obligations.	Perform assigned storage, testing and sample controls; notify excursions, missed pulls or adverse trends.	Agree protocol ownership, pull schedule, alert/action limits, trend review and escalation.	Stability protocol; chamber/excursion logs; sample inventory; results; trend and notification records.
13. Complaints, recalls & safety	Lead or coordinate market-facing complaint, recall and pharmacovigilance decisions where legally assigned.	Investigate manufacturing-related complaints; preserve samples/records; rapidly transmit safety/quality signals.	Set 24/7 escalation routes, decision rights, authority reporting roles, mock-recall and reconciliation duties.	Complaint/recall SOP; contact tree; decision log; reconciliation; effectiveness check; safety exchange log.
14. Audits & inspections	Set risk-based oversight; coordinate applicable authority interactions in its remit.	Enable agreed audits and relevant inspections; provide truthful records and timely remediation evidence.	Define notice, access, scope, confidentiality, observation response, CAPA ownership and urgent regulator notification.	Audit plan; inspection communication SOP; reports; response/CAPA tracker; closure verification.
15. Subcontracting & continuity	Review material subcontracting and supply-continuity impact where approval is assigned.	Disclose proposed subcontracted activities; control only as permitted by law and agreement; maintain continuity plans.	Define prior written approval, due diligence, flow-down obligations, emergency notification and exit/transfer support.	Approved subcontractor list; scope map; qualification; business-continuity/contingency plan; exit records.
16. Review & improvement	Participate in product-quality and governance reviews; assign decisions and track commitments.	Supply agreed quality metrics, risk signals, trends and overdue actions; maintain effective quality systems.	Set review cadence, quorum, thresholds, escalation path, minutes and agreement-update triggers.	Quarterly/annual review pack as applicable; minutes; KPI definitions; action owners; revision history.

For each row, record names/roles, agreed notification periods, escalation contacts, source SOPs and the approval record. Replace “proposed” allocations with project-specific, mutually reviewed language.

Implementation checks before signature

Use as a gap-finding list; confirm the final agreement against the governing regulatory framework and the contract documents.

Check	Questions to close	Owner / evidence / due date
Scope consistency	Do the quality agreement, manufacturing/technical agreement, product list, site scope and current authorization tell the same story? Are exclusions and interfaces explicit?	Owner: _____ Evidence: _____ Due: _____
Responsibility clarity	Can a trained person identify one accountable decision owner for each high-risk event? Are performance, review, approval and notification roles distinguished?	Owner: _____ Evidence: _____ Due: _____
Timeliness	Are the clocks measurable (for example, immediate containment, prompt initial notice, defined investigation update and closure target) and consistent with regulatory reporting duties?	Owner: _____ Evidence: _____ Due: _____
Sterile-product controls	Are aseptic/sterilization assurance, media simulation, environmental monitoring, contamination control, validation oversight and critical notifications allocated and evidenced?	Owner: _____ Evidence: _____ Due: _____
Data and access	Can each party access the records needed for oversight, investigation, inspection and lifecycle management, including audit trails and subcontracted records where applicable?	Owner: _____ Evidence: _____ Due: _____
Release language	Does the agreement distinguish manufacturing-site release, any required QP certification, MAH disposition and placing product on a market? Avoid ambiguous use of "release."	Owner: _____ Evidence: _____ Due: _____
Change and transfer	Are prior approvals, regulatory impact assessment, technical-transfer acceptance criteria, training, validation and no-go/stop conditions defined?	Owner: _____ Evidence: _____ Due: _____
Continuity and exit	Are supply interruption, disaster recovery, material shortage, record transfer, ongoing stability, complaint handling and orderly technology transfer addressed?	Owner: _____ Evidence: _____ Due: _____
Review and revision	Are periodic review, quality metrics, action tracking, version control and update triggers defined so that written agreements match operating procedures?	Owner: _____ Evidence: _____ Due: _____

How to use this safely

Keep the first exchange factual, non-confidential and specific to the product, site and target market.

- Start with non-confidential project facts only. Do not place patient information, complete formulas, unpublished regulatory files, detailed process parameters, trade secrets, credentials or personal data in an uncontrolled worksheet or email.
- If the contemplated work involves China-marketed drugs, review the NMPA announcement and relevant license / product-specific requirements with qualified regulatory and legal professionals. Its scope should not be generalized to every country, product or development-stage arrangement.
- This worksheet is an educational industry discussion aid, not a representation that any named company, site, product or individual has a particular authorization, capacity, customer, project or compliance status.

Source notes & limits

Official materials reviewed for this worksheet; source versions and applicability should be rechecked when an agreement is negotiated.

1. U.S. FDA, Contract Manufacturing Arrangements for Drugs: Quality Agreements, Guidance for Industry (Nov 2016).

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/contract-manufacturing-arrangements-drugs-quality-agreements-guidance-industry>

FDA describes its current thinking for defining and documenting parties' manufacturing activities for contract drug manufacturing subject to U.S. CGMP. FDA guidance is nonbinding; it is not a substitute for applicable law.

2. European Commission, EudraLex Volume 4, Chapter 7: Outsourced Activities.

https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en

EU GMP framework material for outsourced activities. Confirm the current chapter text, effective status and the applicable role of the MAH/manufacturer/QP for the product and market.

3. NMPA Announcement No. 134 of 2025, Strengthening Supervision and Administration of Contract Manufacturing of Drugs (issued 30 Dec 2025; English page updated 14 Apr 2026).

https://english.nmpa.gov.cn/2026-04/14/c_1175737.htm

China-specific requirements concerning contract manufacture of marketed drugs, including party responsibilities, evaluation, technology transfer, quality-system connections, risk communication and oversight. It should not be presented as a universal global rule.

4. NMPA, Provisions for Supervision and Administration of Drug Manufacturing (2022 English translation).

https://english.nmpa.gov.cn/2022-06/30/c_785630_2.htm

Relevant Chinese manufacturing-supervision provisions. Check the authoritative Chinese text and any later amendments before relying on a translation.

5. ICH Q10, Pharmaceutical Quality System (June 2008).

https://database.ich.org/sites/default/files/Q10_Guideline.pdf

International harmonized quality-system model. It informs lifecycle quality-system thinking; it does not allocate every responsibility in a specific contract.

LIMITATION

This document provides general information for business discussion only. It is not legal, regulatory, medical or quality-system advice; not a contract or signature-ready template; and not evidence of regulatory approval, certification, inspection outcome or project fit. The governing legal text, product authorization, site scope and professional advice control.

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