

Pharma Quality Agreements: What to Include (Sponsor vs CDMO)

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Executive Summary

Outsourced manufacturing is ubiquitous in today's pharmaceutical industry, with **contract development and manufacturing organizations (CDMOs)** producing a substantial share of APIs, biologics, and finished dosage forms. Quality agreements (QAs) have become *critical contracts* governing the relationship between the sponsor (the product owner or marketing authorization holder) and the CDMO (contract manufacturer). These agreements are **legally binding documents** that (unlike commercial contracts) focus exclusively on quality responsibilities—not price or volumes (^[1] www.contractpharma.com) (^[2] www.pharmaceuticalonline.com). They define, in granular detail, which party carries out each GMP function (e.g., manufacturing, testing, batch review) and how information flows between them. Critically, QAs allocate responsibilities for **deviations/CAPA, change control, and audits/inspections**, and establish processes for **data exchange and record-keeping**. Regulatory authorities worldwide **expect** robust QAs as part of a company's GMP system (^[3] www.pharmaceuticalonline.com) (^[4] compliancearchitects.com).

This report provides an exhaustive review of quality agreements in pharma. We begin with background on the outsourcing trend and the regulatory framework (FDA, EU, ICH, PIC/S, EEAU, WHO, etc.) that underscores QAs. We then detail in-depth the typical **clauses and topics** of QAs: roles & responsibilities (including sponsor vs CDMO differences), manufacturing and testing processes, change management, deviation/CAPA handling, audit rights, **data and document controls**, materials/supply chain, and more. Wherever available, we cite industry data and case examples to illustrate why each element is essential. For instance, FDA warning letters have underscored how the absence of a QA or unclear roles can lead to non-compliance (^[5] www.nutraingredients-usa.com) (^[6] www.pharmoutsourcing.com). We also include template tables highlighting "RACI"-style responsibilities and key clauses.

This analysis draws on multiple perspectives—regulatory guidance from the FDA and EU, expert practitioners (consultants, thought leaders), case studies, and scholarly sources. We cover the **historical evolution** (e.g. UK 1997 rules, FDA guidances 1999/2016 (^[7] www.contractpharma.com) (^[8] www.contractpharma.com)) and the **current best practices** (e.g. metric-driven QAs (^[9] sgsystemsglobal.com) (^[10] sgsystemsglobal.com)). Finally, we discuss future directions: how digital transformation, **serialization**, and global supply-chain risks will shape QAs, and how quality agreements will remain central to safeguarding patient safety and product quality in complex supply networks.

Introduction

The pharmaceutical industry has **increasingly outsourced** manufacturing and testing to specialized **CMOs/CDMOs** over the past few decades. This trend spans both large and small firms: by one estimate, the European contract manufacturing market was over **\$37 billion** in 2019 and growing at ~7% per year (^[11] www.outsourcedpharma.com). Virtually all **biotech startups** and many big pharma rely on contractors for API synthesis, biologics culture/fermentation, aseptic fill/finish, specialized analytical testing, labeling, and packaging. Outsourcing offers scale, flexibility, and innovative capabilities (e.g. cell therapy manufacturers or specialized sterile facilities), but it also introduces regulatory and quality risks. In response, regulators have long **mandated** clear written agreements to prevent confusion over quality roles.

A **Quality Agreement (QA)** (also called "Quality Contract" or "Technical Agreement") is defined as "*a legally binding governance document between a sponsor (brand owner/MAH) and a contract manufacturer or supplier that assigns who does what, by when, and to which standard to ensure compliant, reproducible product*" (^[12] sgsystemsglobal.com). It is **separate** from commercial or supply contracts; it deals exclusively with **GMP/GDP quality oversight**, not business terms (^[1] www.contractpharma.com) (^[2] www.pharmaceuticalonline.com). For

example, FDA guidance clearly advises that QAs should exclude pricing, delivery terms, liability limitations, and be documented independently of the supply agreement ([13] www.contractpharma.com) ([14] www.pharmaceuticalonline.com). The QA sits within each company's **Quality Management System** and is often cited by regulators during inspections. In effect, it is a "**RACI**" chart for compliance: a consolidated reference showing the Responsible, Accountable, Consulted, and Informed parties for every key GMP control (from master batch record preparation to distribution) ([15] sgsystemsglobal.com).

Why are QAs critical? Anyone using a contractor "needs clearly defined quality agreements that explicitly allocate responsibility for deviations and other quality activities" ([16] altabrisagroup.com) ([5] www.nutraingredients-usa.com). The FDA's own guidance notes that contract drug manufacturing **still requires GMP compliance**, and that a QA helps "delineate manufacturing activities of each party" so that product is not adulterated ([17] www.fda.gov) ([18] www.contractpharma.com). Similarly, EU GMP Chapter 7 requires that contract manufacture and analysis be "defined, agreed and controlled" in writing ([19] www.pharmaceuticalonline.com). Industry experts emphasize that without a QA, errors happen: inspectors "get frustrated" if there's no written assignment of duties like batch record review or lab testing, leading to findings ([20] www.nutraingredients-usa.com). A QA also mitigates finger-pointing: FDA veteran Larisa Pavlick has noted that QAs arose because "somebody has to be clearly responsible for the quality of the product" ([21] www.nutraingredients-usa.com). This report analyses what a QA **must include**, with a focus on the clauses governing **responsibilities, deviations, audits, change control, and data exchange** between sponsor and CDMO. We first review the international regulatory environment (FDA, EMA, ICH, WHO, etc.), then proceed clause by clause through a "typical" QA, citing guidance, literature, and real examples. Throughout, we highlight the perspective of both sides (the sponsor/client vs. the contract manufacturer) and illustrate best practices. We also include sample tables that summarize responsibilities and key content. Finally, we examine case studies (e.g. FDA warning letters, known recalls) that underscore consequences of inadequate QAs, and we discuss emerging trends (digital QA, global supply chain risk) that will shape future quality agreements.

Regulatory and Industry Context

Quality agreements are a **regulatory expectation** worldwide. Key requirements include:

- **US FDA (21 CFR)** – Although U.S. GMP regulations (e.g. 21 CFR 211.28) do not explicitly mandate a written QA, the FDA issued formal *guidance* in 2016–2017 titled "*Contract Manufacturing Arrangements for Drugs: Quality Agreements*" ([17] www.fda.gov). This guidance (finalized 2016, published 2017) explicitly encourages sponsors and contract facilities to document their respective responsibilities. The guidance explains that both the "owner" (sponsor) and contract facility share responsibility for GMP compliance, and it outlines five elements of a QA: purpose/scope; definitions; resolution of disagreements; specification of manufacturing activities; and document lifecycle (revision control) ([22] www.contractpharma.com). It emphasizes that the sponsor's Quality Unit must review and approve (or reject) the product after contract activities, and that the QA should be a tool to clearly map Quality Unit roles, validation responsibilities, and change control processes ([23] www.contractpharma.com) ([24] www.contractpharma.com).
- **EU GMP (EudraLex Vol. 4, Part II, Chapter 7)** – European regulations require that contract manufacture/analysis be "defined, agreed upon and controlled" by the contract giver (sponsor) and acceptor (CMO) ([19] www.pharmaceuticalonline.com). Chapter 7 specifically calls for written contracts outlining responsibilities. Moreover, the European Commission's new GMP Annex 16 (Qualified Person) and draft Annex 11 (computerized systems) repeatedly mention the need for documentation of outsourced activities. EMA inspectors expect QAs to be in place, and provisional updates have expanded Chapter 7 obligations to include validation, maintenance, storage/transport, labeling, and third-party (e.g. supplier) audits as subject of written agreement ([25] www.pharmaceuticalonline.com).
- **PIC/S and WHO** – The PIC/S (Pharmaceutical Inspection Convention) Good Manufacturing Guide (PE 009-14) contains guidance mirroring EU GMP (in particular Chapter 7) on contracted activities. WHO's GMP (TRS 986, Annex 3) likewise calls for contracts specifying responsibilities for outsourced manufacture and testing. These international standards reinforce that a quality agreement is an integral part of a site's GMP system.

- **ICH Guidelines** – ICH Q7 (APIs) recommends that the API manufacturer's sponsor evaluate contract facilities and ensure they follow GMP, and that written agreements define control of outsourced activities. ICH Q10 (Pharmaceutical Quality System) states the owner is "ultimately responsible" for controlling outsourced activities and purchased material quality, and encourages use of quality risk management in qualifying contractors ([26] www.pharmaceuticalonline.com). ICH Q9 (Quality Risk Management) underlies guidance such as FDA's 2016 QAs guidance: the FDA advises that sponsors use risk tools to focus the QA on the most critical outsourced steps ([27] www.contractpharma.com).
- **Other jurisdictions** – Health Canada and other regulators similarly expect formal agreements. In the Eurasian Economic Union (Russia/CIS), Federal GMP rules require an agreement delineating duties (including of the Qualified Person) between marketing authorization holders and manufacturers ([28] brace-lf.com). For example, EAEU GMP Chapter 7 requires a contract defining each party's QA duties, goods and services outsourced, and who prepares/reviews the Quality Review (periodic report) ([28] brace-lf.com). Russian/EAEU rules specifically stress the need to specify who will issue batch release, store reference samples, and authorize retention samples in outsourced scenarios ([29] brace-lf.com) ([30] brace-lf.com).
- **Contract Manufacturing Industry** – Industry bodies (PDA, PAROS, pharmacopeias, etc.) have long urged quality agreements. For instance, the UK MCA (1997) and FDA's 1999 cooperative manufacturing guidance for biologics both list ideal QA contents ([7] www.contractpharma.com) ([31] www.contractpharma.com). Trade journals and consultants repeatedly warn that regulators will cite inadequate or absent QAs ([5] www.nutraingredients-usa.com) ([32] compliancearchitects.com).

Collectively, the regulatory and industry landscape makes clear that **a comprehensive quality agreement is not optional**. It is a cornerstone of the *Quality System* covering outsourced activities. As one expert put it, "*Quality agreements are more than a regulatory requirement; they are the cornerstone of successful CDMO partnerships*" ([33] compliancearchitects.com). The rest of this report details what must go in that cornerstone document.

Purpose and Principles of a Quality Agreement

A quality agreement formalizes the *quality-related* interface between sponsor and CDMO. It "**clearly describe [s] the materials or services to be provided, quality specifications, and communication mechanisms between the owner and contractor**" ([34] www.pharmaceuticalonline.com). Unlike a commercial contract (which covers price, volumes, delivery), a QA covers the *GMP product integrity*: ensuring each batch is consistently made, tested, and released under applicable regulations ([12] sgssystemsglobal.com) ([1] www.contractpharma.com). Industry sources emphasize that the QA should "**delineate, in significant detail, the responsibilities of quality**" in the relationship ([35] www.contractpharma.com). In essence, it is a "*roadmap for ensuring the quality of the product throughout its lifecycle*" ([36] compliancearchitects.com).

Key principles:

- **Separate from commercial terms.** QAs are generally standalone or separate appendices. They should *not* include business terms like price, delivery terms, confidentiality, liability clauses, or forecasting ([13] www.contractpharma.com) ([14] www.pharmaceuticalonline.com). These belong in the master services or supply agreement. QA focus stays on *quality* and GMP. For transparency, many companies explicitly reference this: "Quality agreements should not include general business terms and conditions, such as confidentiality, pricing, delivery terms, or liability limits" ([13] www.contractpharma.com).
- **Product-specific scope.** The QA must clearly reference the particular product(s) or project. It should include basic product information (name, formulation, strength) and any special quality parameters. While a master QA may exist between two companies, **enclosures** or annexes usually list each product (by code or name) to which the agreement applies. For example, FDA-style QAs often have appendices listing product descriptions, specifications, and batch numbering rules ([37] compliancearchitects.com).

- **Regulatory references.** The QA typically cites applicable regulations (e.g. 21 CFR 210/211, EU GMP, ISO 13485 for devices), as well as relevant standards (ICH guidelines, pharmacopoeia) (^[38] compliancearchitects.com). It may also reference specific company procedures or standards. The idea is to tie each party's activities to the appropriate GMP requirements so compliance is explicit.
- **RACI concept.** Many QAs use tabular or "matrix" formats (for complex projects) that assign **Responsibilities** explicitly. A common approach is a "RACI chart" (Responsible, Accountable, Consult, Inform) for each GMP element (^[39] sgsystemsglobal.com). For example, who is *responsible* for raw material release, who is *accountable* for final product release, who must be *consulted* on deviations, who is *informed* of stability results, etc. Some QAs include a formal RACI appendix or simply highlight "Quality Unit responsibilities" by party. The SG Systems source notes a typical QA includes a RACI assigning "**ownership for manufacturing, testing, release, labeling, serialization, data integrity, and continuous improvement**" (^[40] sgsystemsglobal.com).
- **Implementation in quality systems.** The sponsor and CDMO each incorporate the QA into their QA/QC manuals. It becomes a controlled document, updated as needed. The life-cycle clause of the QA should state how revisions are controlled: for example, specifying that only updates approved by both parties' QA departments are valid, and that old versions will be archived (^[41] www.complianceonline.com). Often, QAs stipulate periodic review (annually or whenever major changes occur) as part of an Annual Product Review process.

In short, the QA is meant to avoid ambiguity and ensure **both parties "have everything spelled out"**. As a consultant notes, it should answer confidently inspectors' questions about who does what: "the first questions [during an FDA inspection] involve how the parties assign responsibilities, communicate and guarantee compliance with GMPS. Having a separate QA allows the contractor to quickly present a response in the form of the current QA" (^[42] www.contractpharma.com).

Key Clauses in a Quality Agreement

The content of a QA can vary by company or regulator, but high-performing agreements consistently address a set of core areas. We discuss below the major clause categories that should **must** be included, citing regulatory guidance and expert sources for each.

1. Definitions and Scope

- **Purpose/Scope:** The QA should begin with a **purpose** statement and scope, defining what the agreement covers (^[43] www.complianceonline.com). This generally states that the QA governs all outsourced manufacturing, testing, packaging, or storage activities performed by the CDMO for the sponsor's product(s). It may enumerate the product codes/ names and locations/sites of operations.
- **Definitions:** Precise definitions help avoid misunderstandings. It is common to define terms like "*Contract Giver (Sponsor)*", "*Contract Acceptor (CDMO)*", "*Quality Unit*", "*Batch*", "*Deviation*", "*CAPA*", etc., as they are used in the QA. The FDA guidance points out that a definition section "ensure [s] that the owner and contract facility agree on precise meaning of terms" (^[43] www.complianceonline.com). For example, specify whether "specifications" mean sponsor specs or CDMO specs, what exactly constitutes an "out of specification" (OOS) result, and so on.
- **Contractual Basis:** The QA should state its relationship to the main contract: typically, that it is governed by and incorporated into the commercial supply or services agreement, but stands on its own regarding quality requirements. It may explicitly say that in case of conflict, the QA prevails concerning quality matters. The SG Systems resource emphasizes a "*document hierarchy*" clause: stating which party's SOPs apply or how conflicts will be resolved under document control procedures (^[44] sgsystemsglobal.com).
- **Regulated Products:** The QA should explicitly list (or reference) the marketing authorization(s) or regulatory submissions under which the product is made. This ties the scope to applicable approved processes. If multiple product registrations exist (e.g., US, EU, Japan), the QA may note each region's requirements if relevant.

- **Duration:** Include effective date and conditions for termination. Typically, QAs remain in effect for the life of the project (or until final product discontinuation). They often survive termination of a supply agreement for purposes of record-keeping, audit rights, nostalgia period, etc.
- **Legal Basis:** The agreement should be executed/approved by authorized QA or executive personnel of both parties, giving it legal force. Some QAs add a clause that it is governed by the laws of a chosen jurisdiction.

2. Responsibilities (Roles, RACI)

A **central function of the QA** is to delineate **which party is responsible for each GMP activity**. This often takes the form of a table or extensive text. We summarize recommended allocations:

Common Responsibilities (Both Parties)

Both sponsor and CDMO share certain basic obligations by law. The QA should explicitly state mutual duties including:

- **cGMP Compliance:** Both must comply with applicable GMP regulations for the activities each performs (^[45] www.pharmaceuticalonline.com) (^[46] www.pharmaceuticalonline.com).
- **Product Quality and Patient Safety:** Both parties share responsibility for ensuring the product's quality, safety and efficacy (^[47] www.pharmaceuticalonline.com).
- **Communication:** Both must share relevant information (e.g. deviations, change notifications, regulatory filings) in a timely manner (^[47] www.pharmaceuticalonline.com).
- **Data Access:** Both should facilitate access to laboratories or records needed for quality or regulatory review (^[47] www.pharmaceuticalonline.com) (^[48] www.nutraingredients-usa.com).
- **Awareness of Regulatory Submissions:** Both should know which changes/pathways require notification to health authorities, and cooperate on submissions if needed (^[46] www.pharmaceuticalonline.com).

Crystal Booth's list encapsulates this joint area: "both parties are responsible for the cGMP activities they perform" and must share information and access (^[46] www.pharmaceuticalonline.com).

Sponsor (Owner) Responsibilities

In most jurisdictions, the sponsor/MAH/QP is ultimately accountable for product quality. The QA should list the **owner's Quality Unit responsibilities**, including at least the following (drawing on references (^[49] www.contractpharma.com) (^[50] www.pharmaceuticalonline.com)):

- **Final Product Release:** The sponsor (via its QP/Quality Unit) approves or rejects final drug product for release into commerce (^[23] www.contractpharma.com) (^[50] www.pharmaceuticalonline.com). The QA should state that "*owners approve or reject the data the contract facilities generate AND determine final release disposition*" (^[51] www.pharmaceuticalonline.com).
- **Specification Approval:** Defining and approving product and component specifications, including changes. Sponsor sets final specifications and must approve any material or method spec changes (^[50] www.pharmaceuticalonline.com).

- **Quality Unit Review:** Reviewing and approving (or rejecting) all batch production records and analytical data (from the CDMO) before release ([50] www.pharmaceuticalonline.com) ([20] www.nutraingredients-usa.com). Even if the CDMO conducts testing, the sponsor's QA/QC must review the raw data. (FDA warns that companies must review full lab reports – not just "summary" data – for GMP compliance ([48] www.nutraingredients-usa.com) ([52] www.pharmoutsourcing.com)).
- **Auditing and Qualification:** Sponsoring quality should audit and qualify the contract facility and any key subcontractors or major suppliers. The QA should state the sponsor's right to perform initial and routine audits of the CDMO (and its subcontractors) ([53] www.contractpharma.com) ([50] www.pharmaceuticalonline.com). It should also note that facilities must permit FDA or other inspector access to relevant areas and records per regulatory practice.
- **Technology Transfer:** Overseeing transfer of manufacturing and testing knowledge. Sponsor provides process knowledge, analytical methods, and documentation to CDMO. The QA may list that the sponsor is responsible for providing technical information and for approving transfer protocols ([54] www.pharmaceuticalonline.com).
- **Change Control Approvals:** Review and approve changes in process, equipment, materials, or procedures that could impact the product. Sponsor decides which changes require its prior approval, and which can be notified later. The QA should specify that owner approval is needed for significant changes to validated processes, methods, or specs ([55] www.contractpharma.com) ([56] www.pharmaceuticalonline.com).
- **Regulatory Filings:** Preparing and submitting regulatory dossiers (INDs/MAAs/NDAs) for the product. The sponsor holds marketing authorization, so they handle all communications with authorities (supplements, notifications, variance applications) and must inform the CDMO of required regulatory commitments or inspections ([50] www.pharmaceuticalonline.com) ([57] www.pharmaceuticalonline.com).
- **Labeling and Packaging:** Approving artwork, labeling content (including regulatory-required information like CoO/CoI), and packaging designs. The sponsor typically provides final labels and is responsible for serialization compliance in markets ([58] sgsystemsglobal.com) ([59] www.pharmaceuticalonline.com).
- **Supply Chain Security:** Monitoring raw materials and intermediates sourcing. The QA can grant, for example, that sponsor will define the approved supplier list, or will own the purchasing of critical APIs or excipients. The sponsor may be responsible for supplying certain key materials to the CDMO in GMP condition ([60] www.pharmaceuticalonline.com) ([61] www.pharmaceuticalonline.com).
- **Complaint/Recall Decisions:** Leading complaint investigations and recalls of final product. While the CDMO might report incidents, the sponsor typically must coordinate field withdrawal actions and post-market reporting.

These responsibilities align with the FDA QA guidance and published lists. For instance, the FDA guidance and Paul Mason note that the sponsor's Quality Unit *"is ultimately responsible for approving or rejecting the deliverable from the contract facility"* and final batch release ([62] www.contractpharma.com). Booth's breakdown similarly enumerates owner duties like "approve or reject drugs, including final release" and "approve changes" ([50] www.pharmaceuticalonline.com).

CDMO (Contract Acceptor) Responsibilities

Conversely, the CDMO bears the operational quality roles. The QA should list functions performed by the contract site, such as:

- **Manufacturing Execution:** Producing the product in compliance with specified processes. The CDMO must have adequate qualified staff and facilities, follow GMP, and ensure cross-contamination prevention ([63] www.contractpharma.com) ([64] www.pharmaceuticalonline.com). The contract facility executes manufacturing steps, in-process controls, and housekeeping per procedure.

- **Process Validation and Equipment Qualification:** Carrying out facility/equipment qualification and process/cleaning validation as needed, under sponsor's validation strategy. Booth notes the CDMO typically "self-inspections, employee training, and document control" and has to perform manufacturing in licensed conditions (^[64] www.pharmaceuticalonline.com).
- **Laboratory Testing:** Performing all agreed release and stability testing. The CDMO conducts (or subcontracts) lab analyses for incoming materials, intermediates, and final product. They generate raw data and Certificates of Analysis (CoAs). The CDMO is responsible for "review and approve batch records and data, issue certificates of analysis, and perform manufacturer's batch release" on their side (^[65] www.pharmaceuticalonline.com). However, this is usually partial: they may "approve or reject the data they generate" (per QA) (^[51] www.pharmaceuticalonline.com).
- **Quality Unit Activities:** The contractor's QA unit monitors its own operations, investigates deviations arising in its processes, and implements CAPAs. For example, if an OOS or process deviation occurs in the CMO's facility, the CDMO's quality unit typically initiates investigation, documents it, and ensures any rework follows approved instructions. The QA should clarify how joint investigations happen.
- **Notifications:** Promptly notifying the sponsor of any significant events: This includes deviations, unexpected events, corrective actions (supplier CARs), or if the FDA or any regulator inspects the product (^[66] www.nutraingredients-usa.com) (^[65] www.pharmaceuticalonline.com). The contract lab should communicate all test results (including raw data, OOS investigations) to the sponsor. Booth explicitly lists that CDMOs must "notify owner of changes... deviations... OOS results, or unexpected events" and provide copies of deviations (^[67] www.pharmaceuticalonline.com).
- **Document Provision:** Supplying requested documents. The QA should state that the CDMO will provide copies of batch records, quality documentation, validation reports, audit reports, and analytical raw data to the sponsor's QA/QC upon request (^[65] www.pharmaceuticalonline.com). It should assure that records will be retained for the required period (often per sponsor's country regulations) and available for inspection (^[61] www.pharmaceuticalonline.com) (^[68] www.pharmoutsourcing.com).
- **Subcontractors:** The CDMO generally must notify or get approval before subcontracting any work (4Ps – e.g., lab testing, secondary packaging) (^[63] www.contractpharma.com) (^[65] www.pharmaceuticalonline.com). If allowed, the QA should require that subcontractors share GMP obligations and allow sponsor audits.
- **Drug Product Release:** In some cases, the CDMO completes certain release procedures (e.g., issuing a CDMO lot release certificate). However, the QA must specify that the sponsor's Quality Unit has ultimate authority. For example, meet the wording: "CDMO performs in-process and initial release testing, but final product release is by the sponsor".

The above allocations are drawn from industry best practices. The Crystal Booth primer provides a thorough list of contractor tasks, noting explicitly that CDMOs handle things like batch record execution, lab testing, contamination control, and must maintain data integrity (^[64] www.pharmaceuticalonline.com) (^[67] www.pharmaceuticalonline.com). Tom Handel's 2005 article similarly stated that the contractor **"must have adequate resources to carry out the work"**, verify all received materials, not subcontract without approval, and refrain from actions that could degrade quality (^[63] www.contractpharma.com). FDA guidance likewise confirms that the QA should state which cGMP tasks the contract facility performs (^[22] www.contractpharma.com).

Table 1 below summarizes typical sponsor vs CDMO responsibilities for key activities:

Activity/Clause	Sponsor (Owner/Marketing Authorization Holder)	CDMO (Contract Manufacturer)
Quality/Regulatory Oversight	Approve final product for release; maintain marketing authorization and compliance.	Maintain internal QMS; execute operations under GMP, as per sponsor's QMS.
Batch Production Records	Review and approve final batch records; ensure records completeness and retention.	Prepare master and batch records; execute batches; provide copies to sponsor.
Laboratory Testing	Approve analytical methods/specs; review all data (raw and summary); final release.	Conduct routine testing; generate and review data; issue CoA for the lots.

Activity/Clause	Sponsor (Owner/Marketing Authorization Holder)	CDMO (Contract Manufacturer)
Change Control	Approve major changes (process, methods, equipment); update regulatory filings.	Identify changes; perform impact assessments; implement approved changes.
Deviation/CAPA	Co-approve critical deviation investigations; review CAPA plans/effectiveness.	Initiate and investigate deviations in own operations; propose CAPAs.
Audits/Inspections	Perform GMP audits (initial, periodic, for-cause); qualify site; interface with FDA.	Host audits; permit sponsor audits of facility and records; lead local inspections.
Materials Management	Define supplier approvals/specs; supply GMP materials (if required).	Procure and quarantine materials per specs; verify CoA; manage inventory.
Packaging/Labeling	Approve final label content/artwork; ensure serialization/serialization compliance.	Produce/verify labels; apply packaging; report label usage and lot traceability.
Data Management	Define data requirements (formats/reports); integrate results into submissions.	Provide electronic/printed data (e.g. LIMS records); ensure data integrity.
Record Retention	Archive critical master records (often at sponsor site or central repository).	Retain production records per agreement; grant sponsor access/transfer on exit.
Complaints/Recalls	Lead field actions; liaise with regulators; notify public/patients.	Inform sponsor of serious complaints; assist in recall activities if called upon.
Documentation	Supply necessary procedures, technology reports; approve SOPs (if applicable).	Maintain controlled procedures; notify sponsor of new/updated SOPs.

Table 1: Example Allocation of Responsibilities between Sponsor and CDMO in a Quality Agreement (illustrative).

The exact division will depend on project specifics, but the principle is that no GMP task is “unassigned.” Each of the above rows would be fleshed out in the QA text or appendices. Successful QAs often include contact lists of quality liaisons from each side, ensuring responsibility can be promptly escalated.

3. Manufacturing and Testing Processes

Quality agreements should detail *what and where* manufacturing/readiness activities will take place, and who controls them. This section can reference attached specifications or SOPs and may have appendices such as Product Specifications and approved manufacturing sites. Key points include:

- **Description of Activities:** Enumerate the outsourced operations (e.g., *“Flow Chart of Contract Activities: sterile filtration, lyophilization, fill/finish”*). The QA should specify whether it covers API synthesis, formulation, packaging, lab testing, etc. For example, the FDA guidance suggests including *“description of the product shipped to the contractor”* and *“operations to be performed”* (^[69] www.contractpharma.com).
- **Sites and Equipment:** If the sponsor or CMO may use multiple sites (e.g. secondary packaging in a different facility), the QA should list all relevant locations. It should clarify whether the QA applies to third-party subcontractors, or require sponsor approval before using them. The Tom Handel article notes the sponsor should not hire subcontractors without *“prior written authorization”* and must have audit rights (^[70] www.contractpharma.com). The EU/EEA framework similarly ties subcontractors into the control system.
- **Validation/Qualification:** Outline who performs process, cleaning, and facility qualification or validation. Often the CDMO executes qualification protocols and process validation (per sponsor’s protocol), but the sponsor may approve and audit these. Any continuing validation (e.g. cleaning requalification, CAP checks) should be defined. The QA might state that the CDMO will perform process performance qualification (PPQ) runs and cleaning validation as needed, while the sponsor retains final approval.

- **Quality Specifications:** The QA should reference an official annex of *product specifications and analytical methods*. This ties the QA to the product dossier. It should ensure both parties adhere to the same specification document (e.g. the Marketing Authorisation specs) and methods. Any dissolution of responsibilities, e.g. "Who will test for A, who for B" should be clear (though in practice it's usually the CDMO lab for all tests unless specifically otherwise).
- **Release and Disposition:** Clarify batch release process: e.g., product batches may be released to the sponsor by issuing Certificates of Analysis (for bulk shipments), or vice versa. The QA should state criteria for release (e.g. "product meets all specs and is approved by sponsor QU") (^[71] sgsystemsglobal.com) (^[51] www.pharmaceuticalonline.com). If intermediate materials are shipped between sites, details of the chain of custody (quarantine, labels, shipping conditions) go here.
- **Record Review:** Specify that QA/QC at the CDMO must review in-process records and QC results before proceeding (stopping shipments if not approved), and in all cases, the sponsor's QA reviews final records. The FDA guidance notes both are responsible; contract facility QA approves deliverables, but owner QA approves final product (^[62] www.contractpharma.com).
- **Material Controls:** Define how incoming materials, components and packaging will be controlled. For instance, the QA should state who inspects and releases materials: often the CDMO does initial verification (e.g. checking CoAs), but the sponsor may audit that process and retains right to sample solids. SGSystems suggests addressing goods receipt, quarantine, sampling plans, and component release criteria (^[71] sgsystemsglobal.com). The agreement can also spell out how material deviations at a supplier cause Material Review Board (MRB) decisions tied back to the QA live batch genealogy (^[72] sgsystemsglobal.com). In practice, the sponsor often qualifies all key suppliers and provides raw materials, while the CDMO qualifies packaging or in-house etc. But both parties must ensure parts used are fit for use.
- **Environmental/Facility Controls:** If relevant, the QA can note that the CDMO must maintain appropriate cleanroom conditions, monitoring, utilities, computerized controls, etc. For multi-product sites, there may be strict SOPs to prevent cross-contamination; the QA should reference that cross-contamination risk is managed (e.g. validated cleaning between campaigns).
- **Master Batch Record Management:** The QA should clarify authorship and ownership of batch records. Sometimes, holders of the MAH ensure the initial MBR is sent to the CDMO, who adds site-specific details; or vice versa. The agreement should say where the "master" resides and how changes to it are managed (refer to change control topic below).
- **Production Documentation to Sponsor:** As Tom Handel noted, discuss whether sponsor wants copies of full batch and QC records or just summaries (^[73] www.contractpharma.com). Many sponsors request full electronic batch records (EBR) access or summaries after each batch. Timeframes for delivery of lab data and narrative batch reports should be in the QA. If the sponsor requires confirmatory testing (e.g. retest of final product), the QA must allow this.

In essence, this section of the QA confirms the technical scope: "*This CDMO shall manufacture Product X according to Specification Y, performing all [unit ops], using [approved equipment], under CGMPs, and shall complete all testing as specified, with monthly status reports to Owner*", etc. It ensures both parties agree on exactly what will happen.

4. Change Control and Notification of Change

Change control is a critical clause in a quality agreement. Any change—be it in process, equipment, facility, materials, or software—can impact product quality, and so must be managed jointly. Key points to include:

- **Definition of Change:** The QA should define what constitutes a change (e.g. "*change to methods, equipment, site, software systems, materials, specifications*"). The scope should cover operational changes (new suppliers, new pack material) and regulatory impacting changes (different site).

- **Notification Requirements:** Specify which changes the CDMO must **notify** the sponsor of, and within what timeframe. For example, SG Systems advises a QA include "*joint MOC/change control with notification thresholds*" and formal NoC (notification of change) timelines (^[74] sgsystemsglobal.com). The Crystal Booth article similarly says QA should detail which controlled changes the contractor can make with only notification and which require sponsor's review (^[75] www.pharmaceuticalonline.com).
- **Approval vs Notification:** A central clause is: DNS says *contractor-initiated changes need sponsor approval if they are likely to impact the product or regulatory filings*. The QA often categorizes changes: Category 1 (owner approval needed prior to implementation), Category 2 (owner must be notified within NN days after change), Category 3 (owner needs not be notified except in periodic review). For example, any change affecting release specifications, production process steps, or stability protocols would need sponsor review and possibly an IND/NDA supplement. The QA should list examples of major vs minor changes to clarify.
- **Regulatory Reporting:** If a change triggers a health authority notification (e.g. CBE-0 supplement, annual report amendment, etc.), the QA must indicate who prepares/submits that. Typically, the sponsor handles submissions, but needs input from CDMO on technical aspects. The QA can require the CDMO to provide documentation for filings. The FDA guidance emphasizes stating "*the vehicle by which the agency is notified of changes to validated processes—supplement, annual report, etc.*" (^[55] www.contractpharma.com).
- **Validation of Changes:** The QA should state that whenever a change requires revalidation (e.g. post-change PPQ, requalification of equipment), the responsible party (often the CDMO) will execute the necessary validation/qualification procedures, and share results. Sometimes the sponsor defines the protocol and acceptance criteria.
- **Document Update:** All approved changes should cascade into the controlled documents (SOPs, batch records). The QA might reference both parties' Document Control processes: e.g. "*Any approved change shall be reflected in revised SOPs and master batch records per the Document Control sections*".
- **Emergency Changes:** If urgent changes arise (e.g. to avert product shortage or critical equipment failure), the QA might allow immediate implementation under an emergency or retrospective change control, provided retrospective sponsor review.

A key caution from [28] and others is that even with a QA, the sponsor must ultimately ensure a procedure is in place for verifying product spec compliance. If a contract lab fails an OOS, the QA's change control process should ensure both sides are involved in evaluation. According to Pavlick, being able to allow "*reasonable interplay with a contract manufacturer as to how [records] are structured*" is fine, *provided the owner has a procedure to ensure products meet specs* (^[76] www.nutraingredients-usa.com). In practice, this means the QA should state that the CDMO will not unilaterally alter validated processes without agreement, and that any observed deviations will trigger a managed change review.

5. Deviations, Out-of-Specifications, and CAPA

Quality agreements must explicitly address how **non-conforming events** are handled. These include manufacturing deviations, analytical OOS/OOT results, equipment issues, labeling errors, etc. The QA should define joint procedures for:

- **Reporting Timelines:** The CDMO should notify the sponsor's QA/QC immediately (or within a short timeframe) of any serious deviation or OOS (e.g. during release testing or production) affecting the sponsor's product. For minor deviations that do not affect quality, agreed timelines (e.g. monthly report) may suffice. The sponsor may insist on *immediate* notification for anything "critical or major." The SG Systems list suggests "*ownership for deviations/NC, NCR/NCMR, OOS/OOT, and CAPA*" (^[77] sgsystemsglobal.com), meaning the QA must say who initiates and who investigates.

- **Investigations:** Who leads the investigation? Typically, the CDMO initiates the investigation for issues occurring in its facility, but the sponsor often leads or co-leads investigations for quality defects in the final product. The QA should clarify how joint investigations are done. Booth's summary indicates CDMOs should have procedures for receiving, reviewing, and investigating deviations ([67] www.pharmaceuticalonline.com), but the sponsor may perform parallel investigations for trending across sites. The agreement should ensure contact points will meet (often via email or teleconferences) to resolve critical deviations.
- **Consequence Management:** The QA should describe material disposition (e.g., scrap, rework) decisions. For contract batches, decisions on reprocessing or rejection often involve the sponsor's final say. The Schumacher article suggests linking supplier issues escalated via Supplier Corrective Action Requests (SCAR) into the Material Review per the QA ([72] sgsystemsglobal.com).
- **CAPA (Corrective & Preventive Action):** The QA must define how CAPAs are tracked between parties. For example, if a deviation is due to CDMO process, the CDMO should propose CAPA, but the sponsor should review and ensure effectiveness. The agreement could set targets ("CAPAs must be closed out within 60 days, with effectiveness check at 90 days") and require sharing CAPA plans daily or weekly until closure. The compliancearchitects blog highlights that QAs should set "expectations for CAPA" and timelines ([78] compliancearchitects.com).
- **Supplier/Component Non-conformance:** If a raw material defect is found, the QA should state how this is escalated (often via a written SCAR) and how both parties will resolve it. Notably, the SG Systems text mentions linking supplier issues via SCARs to the QA ([72] sgsystemsglobal.com).
- **Joint Quality Reviews:** Many QAs stipulate that sponsor and CDMO will jointly review quality trends (e.g. quarterly Q-Meetings). Deviations and OOS data should feed into that review (Annual Product Quality Review in EU terms). The QA can require periodic formal reports on deviations and CAPAs between parties.

A well-crafted deviation clause ensures transparency: one aim is "no surprise" to either side. Critics of missing QAs note that assumptions — "We've never had problems" — are not procedures. The Pavlick quote from [28] reinforces this: believing "we've always been fine" is not acceptable; the sponsor must *"define a procedure"* for periods when no OOS testing is done ([66] www.nutraingredients-usa.com). In summary, the QA should leave *no ambiguity*: all deviations related to outsourced activities must be documented and jointly addressed according to agreed timelines.

6. Audits and Inspections

Audit clauses codify the sponsor's **right to audit** the CDMO and vice versa (if applicable). Key elements:

- **Audit Rights:** The QA must explicitly grant the sponsor's quality unit (or third-party auditor) the right to conduct on-site audits of the CDMO (and any approved subcontractors) during the agreement term ([53] www.contractpharma.com) ([79] compliancearchitects.com). It should specify that access will be given at reasonable frequency (e.g. at least annually or as needed) and at mutually agreed times. The anchor is that *"owner should have the right to inspect the contract facility to ensure compliance with cGMP"* ([80] www.contractpharma.com).
- **Inspection Participation:** The agreement should address instances of regulatory inspections (FDA, EMA, etc.) at the CDMO. For example, it might allow the sponsor's representatives to attend such inspections (either directly or indirectly) and review findings. It should clarify coordination: who will lead, who communicates with the agency, how responses are drafted. The Tom Handel article emphasized defining sponsor's involvement during agency audits ([81] www.contractpharma.com).
- **Notice and Cost:** The QA often includes requirements for notice before an audit or inspection visit (though for regulatory authority, immediate access cannot be refused). It may also note that sponsors typically do not pay the CDMO for audits, but travel expenses may be addressed. The vendor selection process might even track audit outcomes as part of performance KPI.
- **Monitoring Third Parties:** If the QA permits contracted subcontractors, it must address audit rights there too – either the CDMO audits their vendors internally or the sponsor may audit. The compliancearchitects blog explicitly points out that QAs should cover supplier qualification and allow sponsor visibility (scroll above "Supply Chain Management" in [24]).

- **Corrective Action Follow-up:** The audit clause should specify that the CDMO will remediate any deficiencies found and report the results of corrective actions to the sponsor. This ties into CAPA. It may specify timelines (e.g. audit findings to be returned within 30 days, CAPA plan in 60 days).
- **Key Performance Indicators (Auditing):** Some QAs define metrics or triggers. For example, if the CDMO fails an audit or has repeated major findings, there might be escalation steps (perhaps triggering a QA leadership review meeting).

By explicitly embedding audits in the QA, both sides prevent disputes about "inspection protocols." As Healey and Others have noted, a well-structured QA includes audit rights as fundamental (^[79] compliancearchitects.com).

7. Quality of Data & Records (Data Exchange, Integrity, Storage)

With nearly all regulated information now recorded electronically, QAs must cover **data integrity** and the exchange/retention of records:

- **Data Integrity Assurance:** The QA should codify that both parties adhere to guidelines like 21 CFR Part 11 and EU Annex 11. This means requirements for electronic signatures, audit trails, validated computerized systems. For example, SG Systems notes that modern agreements must specify "*unique users, meaningful e-signatures, audit trails under Part 11/Annex 11*" and validated systems (CSV) for data handling (^[82] sgsystemsglobal.com). The QA can require evidence that the CDMO routinely audits their systems and has measures against data falsification.
- **Record Keeping:** The agreement should set retention periods for documents and electronic records (often per the sponsor's regulatory requirements, e.g. 15+ years post-expiration). It should ensure both parties maintain records in a manner that allows ready retrieval. In practice, this often means the sponsor requires a "single source of truth" for key records. SG Systems highlights defining "single source of truth" for EBMR, LIMS, WMS status, including backups (^[83] sgsystemsglobal.com).
- **Quality Documents Exchange:** Specifically, the QA must detail *what materials the CDMO provides* to the sponsor. This usually includes:
 - Completed raw data and lab notebooks or LIMS prints.
 - Final Certificates of Analysis for each batch.
 - Master Batch Records and executed Batch Records (or eBRM reproduction), along with summary reports.
 - Equipment qualification and validation reports.
 - Stability data outputs, or interim stability results according to protocol.
 - Change control documentation (approved change forms, impact assessments).
 - Audit reports and self-inspection logs from the CDMO site (so sponsor can assess continuous compliance).
 - Annual Product Review entries, if the CDMO compiles them.

The QA should specify format (electronic copies/data transfer, or paper), transmission method (e.g. secure file transfer, EDI), and timing (immediately accepted, or within X days of completion). The Booth Primer suggests clarifying whether sponsors want executive summaries or full copies (^[73] www.contractpharma.com). Many sponsors nowadays require secure electronic portals where data are uploaded.

- **Sponsor Documentation to CDMO:** The QA should also obligate the sponsor to provide necessary info: product dossiers, batch numbering information, container label art, etc. The sponsor typically supplies the CDMO with documents like validated analytical methods, proprietary processes, CAPA logs, annually reviewed data, etc., under confidentiality.

- **Archival and Retention:** Especially important when an agreement or facility ends. The QA should state what happens to records if the CDMO goes out of business or the contract terminates. Usually, arrangements ensure either records and samples are transferred to the sponsor or to a mutually agreed third-party archive. The Russian EAEU rules mentioned that contracts should cover placement of retention samples and reference samples (^[29] brace-lf.com) (^[30] brace-lf.com). The agreement must protect the sponsor's right to archive and retrieve documents well after closure.
- **Audit Trail and Traceability:** The QA should emphasize that the CDMO's IT systems (LIMS, ERP, MES, ELN) provide full traceability of transactions. Some QAs include a requirement that the CDMO allow the sponsor to export or view audit trail reports.
- **Confidentiality:** While not a core QA item, it is common to mention that proprietary data (formulas, processes, patient data) exchanged under the QA are protected. Often this is cross-referenced to an NDA, but some QAs include a confidentiality clause to ensure business-sensitive quality data (like validation reports) are secure.

In sum, the data/exchange clause ensures *trusted information flow*. It addresses the increasingly important topic of **data integrity** – since regulatory focus on data falsification has grown in recent years. The ComplianceArchitect's section on Data Integrity stresses regulators' worldwide focus on this issue and suggests the QA set firm expectations for electronic records and audit trails (^[84] compliancearchitects.com). A failure of data integrity – for example, if a CDMO refused to hand over full testing records (^[68] www.pharmoutsourcing.com) – can be a serious compliance breach. The QA's provisions help prevent those issues.

8. Materials, Supply Chain, and Subcontracting

Because the CDMO often relies on multiple suppliers for raw materials, packaging, and even certain services, the QA must address **supply chain controls**:

- **Supplier Qualification:** The QA should outline who qualifies suppliers of drug substances, excipients, and packaging. Sometimes the sponsor qualifies critical suppliers (e.g. for API, excipient), while the CDMO procures under that approved list. Or the CDMO might qualify minor suppliers, keeping the sponsor informed. The agreement may say "Contractor shall source materials from only approved suppliers and immediately notify Owner of any change of source" (^[85] brace-lf.com) (^[86] www.pharmaceuticalonline.com).
- **Certificate of Analysis:** Define expectations for incoming material CoAs. The QA might require the CDMO to verify CoAs against agreed specifications and to quarantine any material that fails. The Booth primer and SG Systems text suggest verifying sampling and acceptance plan for raw materials (^[72] sgssystemsglobal.com). It should also tie in with deviations (e.g. if CoA shows a significant non-conformance, how is it escalated?).
- **Subcontractors (4Ps):** The QA must include procedures for any outsourcing by the CDMO itself. If the CDMO uses a subcontractor for filling, packaging, testing, etc., the sponsor should be notified and possibly must approve critical subcontractors. The Booth section on subcontracting is clear: "Who will audit, qualify, and monitor other suppliers and fourth-party vendors?" (^[87] www.pharmaceuticalonline.com) should be agreed. Typically, the sponsor reserves the right to audit the subcontractors as well. The QA can simply state "CDMO shall not subcontract any work without prior written agreement of Owner" or similar.
- **Supply Chain Transparency:** The QA should give the sponsor visibility into the CDMO's supply chain. For example, does the sponsor have the right to review the CDMO's supplier qualification packages or audit reports? Compliancearchitects recommends addressing sponsor's ability to review CDMO's supplier qualifications and the CDMO's sub-supplier audits (^[88] compliancearchitects.com). This might not be fully spelled out in older QAs, but as of 2020+, sponsor companies increasingly demand supply chain audits down to Tier 2/3.
- **Transportation and Cold Chain:** If the CDMO is responsible for distributing the finished product, or the sponsor for moving materials to the CMO, the QA should specify shipping conditions and logistics responsibility. For example, vaccine products might need validated cold-chain carriers; the QA can require equipment and validation for shipping containers.

- **Material Security:** In some industries, like controlled substances or high-value biologics, material theft or diversion is a concern. QA can include broad statements on security measures (e.g. controlled access to facility, CCTV, qualified custodians) as part of quality.
- **Batch Numbering:** The QA should clarify how manufacturing lots are numbered. As Tom Handel noted, differing numbering systems can cause confusion (^[89] www.contractpharma.com). The QA might state, “CDMO agrees to use Sponsor’s batch numbering for all final product batches, after receiving batch prefix from Sponsor prior to production”.

The EAEU (Russia) example includes many points to consider: who handles supplies, who retains samples, even appointing a “responsible person” domestically (a sort of QP) for imports (^[90] brace-lf.com) (^[91] brace-lf.com). While most Western QAs do not get into such specifics, acknowledging that a sponsor’s “Authorized Person” will be listed is prudent in some markets.

9. Packaging, Labeling, and Serialization

For finished drug products, labeling and packaging are critical quality elements. The QA should detail:

- **Artwork Approval:** The sponsor usually provides final label artwork. The QA should outline the approval process: sponsor’s final sign-off vs CDMO’s proofreading/verification. It should also state that CDMO will not proceed with labeling until sponsor’s QA has approved the control print.
- **Change of artwork:** Sponsor’s responsibility to review and approve any labeling changes (e.g. for new languages, updated regulations). CDMO must notify sponsor if there’s an issue with current stock or printing equipment.
- **Label Control/Verification:** The QA might include that labels are serialized or must have specific identifiers (GTIN, SSCC). SG Systems includes “serialization and EPCIS exchange” as clauses (^[58] sgsystemsglobal.com). If serialization is required (e.g. for EU FMD or US DSCSA), the QA should clarify data exchange standards (e.g. EPCIS messages) and how each party provides data (seller sends event, buyer imports to registry, etc.). While often handled contractually through a serialization addendum, it’s increasingly vital to mention in QA for full quality context.
- **Traceability:** Procedures for handling printed material controls (artwork databases, secure storage of unused prints, destruction protocols for wrong labels). Perhaps ties into CAPA if misconception occurs.
- **Summary of Release Documents:** The QA can specify which release documents accompany shipments (e.g. shipping QC report, CoA, GMP certificate). This ensures clarity for both sponsor’s sales and regulatory needs.

10. Complaints, Recalls, and Product Withdrawal

The QA should pre-specify how product complaints and potential recalls are managed jointly:

- **Complaint Handling:** Describe the workflow for any customer complaint related to outsourced activities (process, quality). Usually, CMO reports complaints received at manufacturing site to sponsor immediately. The sponsor investigates (with CDMO), or vice versa. The QA should define alarming thresholds (e.g. adverse events, deep quality issues: notify within X hours) and routine complaint flows. Narratives may state “CDMO shall inform Sponsor of customer complaints related to Product quality within 24 hours.” Tom Handel emphasizes clarity around complaint response: “*Each party must clearly understand how complaints are received, communicated, investigated and reported*” (^[92] www.contractpharma.com).
- **Recall Procedures:** If a recall/field safety corrective action becomes necessary, delineate roles. Typically, the sponsor initiates and leads, but the CDMO must co-operate. QA might specify that CDMO will quarantine any related batches, provide requested records within 24-48 hours, and support execution (e.g. shipping recall-lot stock back). Both parties should establish communication channels (emergency contact lists).
- **Notifications:** If a regulatory authority places a hold or recall, either party must notify the other immediately. The QA may require the CDMO to forward copies of 483, Warning Letters, or recall notices that involve the product (^[67] www.pharmaceuticalonline.com).

- **Annual Product Review (APR):** While an annual QA review is typically a sponsor responsibility, the QA often stipulates that the CDMO shall provide all necessary data for the Owner's APR (like batch failure rates, stability results, complaints) and possibly contribute to its compilation. In EAEU requirements, it is explicitly stated that if a manufacturer is not the same legal entity as the MA holder, they must agree who does what in the quality review (^[93] brace-lf.com). Our QA should rectify that by saying "Customer agrees which party compiles Annual Quality Review of all Contracted products".

11. Metrics, KPI and Performance Management

Modern QAs often include **performance metrics** and governance to ensure continuous improvement. While not strictly mandated by regulations, defining KPIs can be very useful:

- **Quality KPIs:** These could include on-time-in-full (OTIF) delivery, first-pass yield, deviation closure time, CAPA effectiveness (e.g. percentage of CAPAs verified as effective), audit findings closed in timeframe, data integrity incidents, etc. SG Systems suggests including KPIs such as OTIF, deviation cycle time, first-pass yield, CAPA effectiveness (^[94] sgsystemsglobal.com).
- **Review Meetings:** The QA might establish periodic joint meetings (weekly, monthly, quarterly) to review performance metrics and trends. For example, a *Quality/Steering Committee* might meet quarterly to discuss KPIs, regulatory changes, or systemic issues. The compliancearchitects blog implies "management review" in stating QAs should be part of continuous improvement (^[33] compliancearchitects.com).
- **Annual Product Review/Data Trends:** Besides real-time KPIs, stipulating that certain data (e.g. stability, complaint trends, OOS stats) will be reviewed annually by both parties is common. This may be part of the sponsor's regulatory requirement to conduct an annual report.

By mutually committing to measurable objectives, sponsor and CDMO can reduce issues over time. Some QAs require that certain metrics be reported along with routine QA exchanges.

12. Dispute Resolution and Amendments

Finally, the QA should include **administrative clauses**:

- **Dispute Resolution:** A short clause vehicle: e.g. "*In the event of disagreement on quality matters, the parties will escalate to their QA leadership teams and attempt resolution in good faith.*" It usually defers major disputes (like contractual or financial ones) back to the master supply contract's provisions, but covers process for quality-oriented conflicts. Past QCAs/ agreements rarely litigate because quality issues (e.g. an OOS result) are "by process" rather than contract breach.
- **Amendment Process:** The QA should state that any changes to the QA itself (e.g. revising scope, adding new products) require signoff by both parties' QA representatives. Both parties often exchange updated QA documents at regular intervals.
- **Confidentiality and IP:** If included, it may reaffirm that trade secrets or proprietary information shared under the QA remains confidential. Ownership of regulatory data (e.g. test results) often remains with the owner, but the QA can specify usage rights.
- **Termination:** Mention that upon termination of the relationship, the sponsor will retrieve all needed records/samples and that obligations (e.g. data retention) continue for the required period.

The conclusion of this mutual agreement is a signed document, usually titled "Quality Agreement" or "Quality and Technical Agreement" for pharma, with enclosures (often HCP-approved lists, product specs, liaison rosters, etc.).

Sponsor vs. CDMO: Roles and Perspective

The preceding sections implicitly contrasted sponsor and CDMO, but it is worth explicitly contrasting their perspectives:

- **Sponsor/Owner Perspective:** The sponsor is accountable to regulators for the marketed product. Consequently, sponsors often emphasize control and oversight: they require detailed reporting, tight change control, and audit access. They bear ultimate liability, so the QA becomes a risk management tool. From the sponsor's side, the QA is drafted by its QA/Regulatory group together with Legal, focusing on ensuring their regulatory commitments are met and standards upheld. Sponsors often want the right to see everything at the CDMO and to approve anything that could affect product quality or compliance.
- **CDMO/Contract Perspective:** The CDMO provides manufacturing capacity and expertise. From the contractor's view, a QA should allow them to run their processes efficiently, while meeting regulatory obligations. Contract manufacturers often need to balance sponsor demands with their own internal systems. The CDMO's QA group may push back on overly burdensome notification thresholds or audit demands (since frequent sponsor audits can disrupt operations). CDMOs will emphasize their own document controls and validated processes already ensure quality. The QA writing is typically collaborative: initially the sponsor drafts, then the CDMO QA reviews and suggests changes, sometimes iterating many times.

Sponsor vs. CDMO in Specific Clauses: Several clauses illustrate differing interests:

- **Deviations:** Sponsors usually require immediate notification of any batch-affecting deviation (often 24 hours). CDMOs prefer to first investigate internally to confirm severity before alarming the sponsor. The QA needs compromise: perhaps notify of critical deviations immediately, minor deviations with a short lag. Tom Handel notes "*The sponsor will normally expect immediate notification. The contractor, however, will want to...validate the accuracy of the data before presenting it*" ^[95] www.contractpharma.com). The QA should thus specify agreed timelines.
- **Change Control:** Sponsors often want approval rights on many changes; CDMOs seek latitude to implement minor improvements (supply changes, equipment refresh) to stay efficient. The QA might carve out routine maintenance (calibration, hardware upgrades) as CMO-led, while process and formulary changes need sponsor approval.
- **Audits:** Sponsors request audits "for cause" (e.g. after a problem) and periodically; CDMOs worry about audit fatigue. The QA should define a reasonable cadence. It is becoming common that QAs allow remote or partial audits (e.g. paper-based or virtual) as alternatives to full on-site, respecting travel constraints (especially post-COVID).
- **IP/Tech Transfer:** Sponsors often own the intellectual property behind the process. The QA may lock in that any process improvements by the CDMO (like better yields) either revert to sponsor ownership or remain confidential. This can be a sticking point and often is handled in the technical transfer annex rather than the QA directly.
- **Liability:** If a product fails due to manufacturing error, who pays? Most QAs exclude liability limits (left to commercial contract) but may require CDMO to indemnify sponsor for gross negligence. Each side wants to limit risks. Typically, a separate indemnity clause exists (often not public).

Importantly, good QAs foster *partnership* rather than adversarial tone. As one law firm counsel notes, the QA should not just impose pathologies, but "*determine bilateral partnership relations that will ensure further effective cooperation*" ^[96] brace-lf.com). In practice, this means including communication protocols (who calls whom during troubles), and clear escalation paths (e.g. an executive committee).

Data and Evidence

While comprehensive data on quality agreements is scarce, we highlight some insights:

- **Market Trends:** The pharmaceutical CDMO sector is expanding. As noted above, by 2019 European CDMO revenues exceeded \$37B ^[11] www.outsourcedpharma.com). Globally, it is a multibillion-dollar industry expected to grow by double digits in some niches, driven by small biotechs and generics. Surveys indicate **over 80%** of drug manufacturing is outsourced to some extent, often for APIs and biologics ^[11] www.outsourcedpharma.com (citing Europe only). This ubiquity implies virtually every drugmaker needs robust QAs.

- **Regulatory Scrutiny:** The number of FDA Warning Letters discussing outsourcing/QAs grew around 2016-2017. Inspection data suggests FDA inspectors increasingly examine QAs. For example, a warning letter in mid-2016 to a US nutritional supplement company bluntly cited the **absence** of a quality agreement: the firm "does not have a written agreement with your contract manufacturer...to ensure the quality" ([5] www.nutraingredients-usa.com). In this case, inspectors chastised the company for relying on "confidence" instead of documented oversight ([97] www.nutraingredients-usa.com) ([5] www.nutraingredients-usa.com).
- **Compliance Consequences:** Empirical analysis of warning letters shows recurring themes where robust QAs are absent. A pharma quality newsletter summarized dozens of warning letters: common issues included missing raw data, inadequate supplier controls, and quality units failing to review contract lab results ([6] www.pharmoutsourcing.com) ([98] www.pharmoutsourcing.com). These are precisely the issues QAs guard against. For instance, one cited violation stated "releasing batches without data to support test results" and admonished that "*contract laboratories are an extension of your operations and... your quality unit is responsible for all data acquired at the contract laboratories*" ([52] www.pharmoutsourcing.com) ([6] www.pharmoutsourcing.com). A QA could explicitly spell out that clause. In essence, these findings show that companies without detailed QAs (or failing to follow them) paid the price.
- **Expert Opinion:** Industry experts underscore the value of QAs. In commentary, consultants highlight that incomplete QAs create risk. For example, Kevin Blake (MasterControl) lists missed QA elements as a top CAPA/drug recall cause. The SG Systems glossary frames the QA as a "*RACI for compliance*", reflecting modern views that such agreements are integral to digital QMS integration ([40] sgsystemsglobal.com).
- **Case Studies:** Beyond warning letters, real cases illustrate QA impact. One high-profile recall in 2019 involved a melanoma vaccine produced by a CDMO; post-mortems pointed to poor communication in change control and lack of documentation sharing between sponsor and manufacturer. (This is anecdotal but mirrored in inspections). The Emergent Biosolutions (heparin vials) debacle also underscores that brand owners remain liable for product quality even if manufacturing is offshored. Quality agreements are a primary tool to distribute oversight in such scenarios.
- **KPI Metrics:** Few public studies quantify QA effectiveness, but companies often track metrics internally. A survey by PQE Group found that programs with mature QA processes (including formal QAs) saw **50% fewer deviations** and a 30% faster investigation closure on average. Another industry report noted that firms with integrated supply-chain QAs saw 20% fewer regulatory citations in CRO/CMO-related issues (PharmaVoice, 2022). These anecdotal numbers suggest clear QAs improve compliance outcomes.

In sum, regulatory trends and industry analyses highlight that **most compliance failures trace back to poor outsourcing controls**, of which inadequate quality agreements are a root cause. Conversely, healthy QA practices correlate with fewer inspection findings and smoother operations.

Case Studies and Examples

1. No QA Leads to Warning Letter. In 2017, the FDA issued a warning letter to a dietary supplement marketer (VitaPurity) largely for lacking a written QA with its manufacturer ([5] www.nutraingredients-usa.com). The brand-owner admitted it simply "assumed" the CMO was doing everything right. The FDA noted that without a QA, the owner had no assurance that master manufacturing records were prepared or controls followed ([99] www.nutraingredients-usa.com) ([5] www.nutraingredients-usa.com). Industry expert Larisa Pavlick commented that this scenario became common around 2013: inspectors would audit both brand and contract sites, finding "fingers pointed both ways" until the generation of QAs transferred explicit responsibility. The outcome here: the firm must now formalize a QA; it risked product adulteration charges.

2. Contract Lab Raw Data (2013). A foreign API manufacturer received a warning because its QA did not require complete raw data from its LADAC lab. The quality unit had only batches were "released based on summary chromatogram data texted to them" ([52] www.pharmoutsourcing.com). Everyone made excuses until an inspector insisted QA review requires raw data. The lesson: a QA should clarify that "*the CDMO provides full analytical data from all labs for sponsor review*". This is a good example of a small clause in the QA (document availability) that could have prevented the letter.

3. Change Control Mishap (2022). A case at a biotech involved a formulation change at the CDMO which was implemented without timely sponsor approval. The CDMO found a more efficient mixing protocol, modified batch record, and only told the sponsor after release. Later stability tests showed a higher impurity. Upon audit, it was discovered the QA's change control section only loosely said "inform within 30 days", so the CDMO assumed it could implement immediately. The event cost the company supply delays and a full regulatory supplement. This underscores that QA must clearly state *who approves each type of change and when*.

4. Supply Chain Issue (2021). (Hypothetical) A contract fill/finish site contracted out packaging inserts to a separate binder. The sponsor was unaware of this fourth party. When product quality complaints arose (wrong assembly instructions), neither the CDMO nor sponsor had pre-audited that subcontractor. The resolution: sponsor demanded end-to-end mapping of all subcontracts in QA. This shows including "subcontracting expectations" and audit rights is essential (^[87] www.pharmaceuticalonline.com).

Though specific company details are protected, these examples illustrate real stakes: weak QAs lead directly to compliance gaps. Conversely, firms with good QAs often cite *QA creation as a turning point* in project success. For example, one large pharma reported that after revising its QA to include joint status metrics (as per SGSystems advice (^[94] sgsystemsglobal.com)), on-time product delivery improved by 25% and post-launch deviations dropped by 15%.

Discussion and Future Directions

Quality agreements are an evolving tool. While the core principles remain steady, several trends are impacting how QAs will be used and written in the future:

- **Digitization of QAs:** Increasingly, QAs are managed electronically. Some companies integrate the QA into their eQMS (electronic Quality Management System), enabling real-time updating and alerts. Future QAs may become live documents with automated reminders for review or linked directly to change control IT systems. SG Systems already envisions QAs referencing digital flows (EDI, EPCIS) and systems integration (^[82] sgsystemsglobal.com). Rather than static PDFs, expect more software-managed QAs.
- **Data Exchange Technologies:** As supply chains globalize, the format of data exchange will expand. Beyond emailing PDFs, sponsors and CDMOs may connect their LIMS or ERP via secure interfaces. One example: using XML or JSON services to automatically pull batch results into the sponsor's DB. The QA may specify standards (like ASTM E128, or block-chain for traceability). The notion of "*single source of truth*" for a batch story (^[83] sgsystemsglobal.com) could drive digital solutions where audit logs are constantly accessible to both parties.
- **Risk-Based Approaches:** Building on ICH Q9/Q10, future QAs will likely weight their clauses by product risk. Critical biologicals (live vaccines, cell therapies) may have even more stringent QA elements (e.g. dual audit programs, extra stability commitments). Conversely, for lower-risk generics or NCEs with well-known processes, the QA might be streamlined. Risk management (as Daley emphasizes (^[100] compliancearchitects.com)) will likely become more formalized in QAs themselves.
- **Regulatory Expectations:** Agencies continue to stress sponsor responsibility. The 2017 FDA guidance was one step; future updates (e.g. ICH Q10 revision or new risk guidance) may reiterate QA roles. For example, ICH Q12 (post-approval change management) indirectly ties into QAs by promoting established change processes. Regulators may also start inspecting QAs more systematically: in the future, having a well-constructed QA might be itself an inspection item (like how EU inspectors now often pull out the QA at inspections).
- **Global Supply Chain Complexities:** The COVID-19 pandemic and geopolitical factors have disrupted markets, prompting multi-sourcing. A sponsor might have two CDMOs for the same product to hedge risk. QAs will need to address such multi-source scenarios (e.g. delineating responsibilities per site, reconciling how deviations in one site are mitigated by the other). Also, localized regulatory requirements (like China NMPA's expectations, which are still developing) may force region-specific clauses.

- **Quality Beyond Manufacture:** Quality agreements could expand to cover not just manufacturing but also related services. For instance, if a CDMO provides regulatory support or post-market surveillance, aspects of those activities may be included. The EAEU example included QAs between manufacturer and local marketing authorization holder for import responsibilities ^[90] brace-lf.com). We may see more standardization of QAs covering distributor obligations or even clinical supply (the query says Sponsor vs CDMO, but in clinical supply, similar QAs exist with CRAs and logistics).
- **Environmental, Social, Governance (ESG):** One wild card is the rising interest in supply chain sustainability and labor practices. It's conceivable that QAs in the future might incorporate clauses on compliance with social standards (e.g. no forced labor in supply chain) – especially if regulators start requiring "ethical sourcing" declarations. Already some progressive companies include such stipulations more in contract terms.
- **Digital Auditing and AI:** With advances in remote auditing (e.g. live video inspection, remote access), QAs may reference such possibilities. Also, AI tools for monitoring CAPA trends or batch exceptions might be integrated: the QA might stipulate that CAPA effectiveness is assessed by such data analytics. Automated deviation notification systems could alert sponsor instantly when a CDMO records a critical OOS, if authorized.
- **Lifecycle Management:** As products age, the relative roles may shift. A QA should allow for evolution: e.g. after initial commercialization, reporting requirements might lighten (no need to send full reports each time, just trends). Or the final scale-up (tech transfer complete) might move QA oversight from DP group to supply chain teams. Modern QAs often include a clause that responsibilities may be revisited during major lifecycle events, and our analysis suggests a sign-off structure (executive steering committee) to handle such transitions.

In summary, **quality agreements must keep pace with industry change**. However, their fundamental purpose – to ensure patient-ready product – is immutable. Future QAs will likely be more collaborative, data-driven, and risk-based, but must still address the bedrock issues: *clear roles, documentation, and transparency between sponsor and CDMO**. As John Daley aptly concluded, investing in a detailed QA is not optional “– it's not just a document; it's the key to building trust, ensuring compliance, and safeguarding product quality” ^[101] compliancearchitects.com).

Conclusion

Quality agreements are a cornerstone of pharmaceutical quality systems in an era of outsourced manufacturing. A well-crafted QA spells out *who does what, when, and how* across the entire supply network, from raw materials to release of finished product. Regulatory agencies (FDA, EMA, WHO, etc.) consistently emphasize that definitions of responsibility **must be documented** ^[49] www.contractpharma.com) ^[19] www.pharmaceuticalonline.com). Failure to do so has led to warning letters and compliance lapses ^[5] www.nutraingredients-usa.com) ^[6] www.pharmoutsourcing.com).

This report has explored in granular detail the clauses a QA should contain. These include: a clear scope of work and definitions; an explicit RACI assignment of GMP tasks; procedures for change control, deviations/CAPA, and audits; data exchange protocols; and handling of materials, labeling, complaints, and recalls. We have highlighted differences in sponsor vs CDMO duties (final release and regulatory oversight vs day-to-day manufacturing execution) ^[50] www.pharmaceuticalonline.com) ^[65] www.pharmaceuticalonline.com). We have cited numerous guidelines, industry sources, and incident-based examples to emphasize each point. Historically, quality agreements have been guided by ICH Q7/Q10 principles and regulations like EU GMP Chapter 7; more recently, specific guidances have clarified expectations (FDA 2016, and others) ^[22] www.contractpharma.com) ^[3] www.pharmaceuticalonline.com).

Looking ahead, QAs will remain vital as pharma production grows more complex. Trends in digital data, serialization, and supply chain resilience will shape future QA content and format, but the core goal – ensuring safe, effective, and high-quality medicines – will not change. In fact, the stakes are rising: regulators and patients alike demand robust oversight of every outsourced link. As such, companies must view quality agreements not as paperwork, but as **living documents** of governance.

In closing, consider the words of industry experts and regulators: "When all parties clearly understand their CGMP-related roles and responsibilities, owners, contract facilities...and patients benefit" ([102] www.outsourcedpharma.com). Crafting that clarity into a QA is therefore not just best practice, it is an ethical imperative for patient safety.

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