Quality Agreement Template for Regulatory Starting Materials ("RSMs") and Critical Materials

between company “x” and company “y”

Contents

17. Sub-contracting
18. Packaging
19. Labelling
20. Storage and Distribution (incl. Supply Chain Traceability)
21. Deviations / OOS
22. Complaints
23. Blending of production batches into commercial batch

IV. Signatories

V. Contacts

VI. List of Appendices

VII. History / Change Log

Use instructions for sections I to III:

Text highlighted in yellow indicates items to be filled in by the user of this template.

Text highlighted in blue is optional

Notes in orange boxes are **for information/explanation purposes only**, and they would not appear in the actual Quality Agreement.

Text in green boxes represents recommended specific conditions for "**exclusive PRODUCT**" only, i.e., RSMs exclusively made for one customer under a toll manufacturing contract, also known as "Custom Synthesis, where a Supplier manufactures a product in accordance with a process transferred by a Customer or (co-)developed between Customer and Supplier). These articles should be removed if not applicable.

I. Introduction / Purpose / Scope

Note: Introduction: This document is recommended to be used for RSMs and Critical Materials, with the actual materials hereafter referred as PRODUCTs. .

The purpose of this document is to define the individual responsibilities in relation to the quality aspects of manufacturing, control and acceptability of the products manufactured and supplied to CUSTOMER by SUPPLIER to ensure compliance with the standards described in chapter III "Quality Responsibilities".

To achieve this purpose, this Quality Agreement includes a detailed list of the activities associated with the manufacture, inspection, compliance and acceptability of the products as defined in article I.2 below. Unless otherwise indicated, responsibility for each activity is assigned to either CUSTOMER or SUPPLIER, or to both Parties.

I.1 Parties to the agreement

Note: Although the APIC template is intended for Quality Agreements between RSM "manufacturers" and their customers (i. e. the API manufacturers), the more general term "SUPPLIER" is used in the template instead of "MANUFACTURER".

The SUPPLIER can be the manufacturer or a party that is selling the material but not producing it. In the latter case, unless the manufacturer is co-signing the agreement, the commercial partner should ensure that all parts of the agreement relating to manufacturing are agreed between the SUPPLIER and the manufacturer(s) in a separate agreement.

This Quality Agreement is by and between < full supplier name > located at < full supplier address >, hereafter referred to as SUPPLIER and < full customer name > located at < full customer address >, hereafter referred to as CUSTOMER.

SUPPLIER manufactures and/or supplies PRODUCT(s) that is/are suitable for API production to CUSTOMER. If the SUPPLIER does not manufacture the PRODUCT(s), SUPPLIER will ensure that all parts of the Quality Agreements related to the manufacture are agreed with the manufacturer. CUSTOMER and SUPPLIER may each be referred to herein individually as a "Party" and collectively as the "Parties."

Note: In case the Party that supplies the PRODUCT(s) is a different legal entity within the same company, or the manufacturing sites involved in the manufacture of the PRODUCT(s) are different legal entities of the same company, the following additional paragraph would be appropriate:

SUPPLIER sells and markets products produced by itself or its affiliates, inter alia <full affiliate(s) name> located at <full affiliate(s) address>, which affiliates (as sub-contractors) have the ability to manufacture and SUPPLIER intends to supply the products. SUPPLIER is responsible for the trade and sample packaging of the released products. Each reference to

SUPPLIER shall in the following hence be interpreted as a reference to SUPPLIER and/or the manufacturing entity, as applicable.

Note: If necessary, the following definition of "Affiliate" may be added to the preceding paragraph or listed in the Definitions section (I.4).

For the purposes of this Quality Agreement, the term "Affiliate" shall mean any company controlling, is controlled by or is under common control with the respective Party. The term "control" shall mean the possession, directly or indirectly, of more than 50 % of the respective shares or the power to direct the management or policies of such company or Party.

I.2 Products and production process covered by the agreement

This Quality Agreement pertains to the following product(s), hereafter referred to as PRODUCT: <list here or refer to Appendix XX>.

If relevant define starting point in (each) production process.

I.3 Site(s) involved

Note: The SUPPLIER sites involved in the manufacture of PRODUCT, can be specified here, if needed, or may be referred to in an appendix. If the sites involved are not listed in this agreement, it should be indicated where the agreed sites are specified. The sites can also be sites of affiliates of the SUPPLIER (see also I.1). CUSTOMER sites receiving the PRODUCT may be listed as well.

I.4 Definitions, abbreviations and references **(optional section)**

<List definitions/abbreviations>

Note: Definitions of timelines from the glossary may be included here in order to get clarity on terms like 'immediately' or 'promptly'.

Affiliate	An organization that is officially connected with or controlled by another, usually larger, organization.
ALCOA	See under "Data Integrity"
API	An Active Pharmaceutical Ingredient is any substance that provides pharmacological activity or other direct effect in the diagnosis, mitigation, treatment, cure or prevention of disease, or affects the structure or function of the body in humans or animals.

CAPAs	Corrective and Preventative Actions are improvements to an organization's process to correct or eliminate causes of deviations, incidents, non-conformities or other undesirable situations that have or could be predicted to occur.
CMO	Contract Manufacturing Organization: a company that specializes in providing manufacturing services to other businesses on a contractual basis.
Conformances	Conformity or agreement with a standard, specification or rule.
Critical Material / CSM	Critical Starting Materials are essential for the quality and safety of the final product and must meet specification before use.
Custom Synthesis	A custom synthesised chemical is generally understood to be one that is made specifically to a drug substance manufacturer's requirement, either in-house or externally, or available for purchase but where the only use is for pharmaceutical manufacture.
Customer Supplied Starting Material	Starting material purchased and provided by the customer to the supplier/producer for the purposes of producing the registered starting material.
Data Integrity	The degree to which data management is in-line with ALCOA principles. A fundamental requirement of GxP. ALCOA: A commonly used acronym for "attributable, legible, contemporaneous, original and accurate", which puts additional emphasis on the attributes of being complete, consistent, enduring and available – implicit basic ALCOA principles. Further developments of this principle are summarized as ALCOA(+) or ALCOA(++).
Deviations	Departure from an approved instruction or established standard, this could also include a non-conformity where the expected result deviates from expectation.
Exclusive Product	A product produced in whole or in part by a third-party under exclusivity so that they are the only customer to receive the produced product and any related data.

ICH Q3 (R9)	International Council for Harmonization Q3C (R9) Residual solvents - Scientific guideline
Incidents	An event where a deviation or non-conformance has occurred.
OOS	Out of Specification, a situation where a test result of a product, material or sample falls outside the predetermined specification or acceptance criteria.
Reprocessing	Subjecting a product that does not conform to standards or specifications to one or more processing steps that are different from the established manufacturing process to obtain acceptable quality intermediate or finished product (e.g., recrystallizing with a different solvent).
Rework	Introducing a product, including one that does not conform to standards or specifications, back into the standard process and repeating a process or step that is part of the established manufacturing process.
RSM	Registered Starting Material: a material that is used in the production of an API and that is incorporated as a significant structural fragment into the structure of the API. The RSM is used to identify the starting compound(s) in the drug substance´s route of synthesis and is the point from where on regulatory change control and current good manufacturing practices (cGMPs) begin.
Shelf-Life/Retest Period	The period of time during which the product is expected to remain within specification provided that the product has been stored under the defined conditions and in the final packaging.
Toller	Toll manufacturing or tolling is outsourcing all or part of the manufacturing to a third-party company where the customer provides some or all the raw materials or semi-finished products to be used by the toller. The work of the third-party company is to provide services to process the raw materials or products to the customers required specifications.

II. General Provisions

Note: The general provisions mentioned hereunder are required for a stand-alone Quality Agreement, however, in case the Quality Agreement is part of or appendix to a Supply Agreement they would usually be included in the Supply Agreement and do not need to be repeated in the Quality Agreement.

II.1 Effective date

This Quality Agreement shall become effective and binding upon the date of the final signature.

Note: In case the effective date is not determined by the final signature, the effective date should be given elsewhere in the Quality Agreement.

II.2 Term of agreement

This Quality Agreement shall remain in effect for five (5) calendar years from the effective date. Either party may terminate this agreement by giving six months advance written notice to the other party. This agreement shall be automatically renewed for additional five (5) year periods, on the same terms and conditions as set forth herein. After the second 5 years it is recommended to review the content of the agreement and resign by all involved parties.

*Note 1: The definition of the period of validity "*until 2 years after the last delivery of PRODUCT by SUPPLIER to CUSTOMER*" is very common, hence recommended by APIC. This could be different by each company's preference.*

Note 2: Be careful in case of several products governed by the same Quality Agreement. The agreement related to each product will end accordingly to the date of the last delivery of the concerned PRODUCT.

Note 3: Termination of the Quality Agreement calls for discontinuation of the business. In this hypothesis, some obligations (e.g., articles 21.02, 21.03, 22.04, or 22.06) will nevertheless remain applicable as far as they are appropriately worded (e.g., "notwithstanding article II.2, the Parties acknowledge that this obligation shall remain applicable after termination of the Quality Agreement") or listed in a survival clause (see II.9). Otherwise, intentional termination by one party shall give birth to subsequent obligation to immediately negotiate a new agreement between SUPPLIER and CUSTOMER.

II.3 Related agreements

If a supply agreement is in place between SUPPLIER and CUSTOMER, and there are any inconsistencies between the supply agreement and the Quality Agreement, the supply

agreement will take precedence over the Quality Agreement in all non-quality related matters unless otherwise stated in the supply agreement. The Quality Agreement will take precedence in all quality related matters.

II.4 Amendments

Amendments to this Quality Agreement shall be in writing and signed by appropriate representatives of both Parties.

The appropriate contacts are listed in section V.

Note: Appendices may be amended in the same manner as the agreement without the need for revision, review or approval of the agreement in its entirety.

II.5 Confidentiality (optional section)

Note: It is recommended to refer to a separate document pertaining to confidentiality, e.g., confidentiality agreement (also referred to as a confidential disclosure agreement) but may be defined here according to SUPPLIER and/or CUSTOMER policy. A very brief example is given below.

Both Parties will take all reasonable measures to ensure the confidentiality of all correspondence and information that pertains to the execution of this agreement.

II.6 Resolution of quality disputes (optional section)

Quality-related disagreements between SUPPLIER and CUSTOMER that are not resolved in the normal course of business shall be brought to the attention of the appropriate contact person at SUPPLIER and CUSTOMER, in writing, as listed in section V. Both parties shall use all reasonable efforts to agree to a reasonable resolution to the disagreement and agree to work jointly to develop a strategy for such resolution. SUPPLIER and CUSTOMER further agree to record such resolution in writing.

If resolution of a quality related disagreement cannot be reached, the dispute resolution procedures in the commercial agreement shall be followed. In the absence of a commercial agreement or a dispute resolution procedure and in the case of a PRODUCT non-compliance with this Quality Agreement, CUSTOMER reserves the right to terminate the agreement on providing one month's written notice.

The following dispute resolution procedure, as an example, may be applied:

In case of dispute between the Parties in connection with this Quality Agreement, upon request by a Party, the Parties shall consult with each other in good faith to resolve their disagreement. If the Parties fail to resolve their dispute, either Party may request that the dispute be resolved promptly by submitting the same to an independent expert of recognized repute within the pharmaceutical industry of the country governing the production of the products, mutually agreed upon by the Parties. The Party requesting the referral of the dispute to an expert shall

notify the other Party of such request and in such notice shall set out the names of three proposed experts. The other Party shall, within 10 business days after receiving such notice, select one of the proposed experts and shall within such period so notify the requesting Party. If such notice is not given by the end of such 10 business days period, then the requesting Party shall select the expert of its choice from the list submitted to the other Party and the other Party shall be deemed to have agreed to this selection. The expert shall act as expert and not as an arbitrator and his or her decision shall be final and binding on the Parties. The fees and costs of the expert shall be borne by the Party whose position is not sustained by the expert.

II.7 Choice of Law (optional section)

Note: A choice of law should always be specified in a supply agreement. If a reference shall also be included in the Quality Agreement the following wording is recommended:

"The Parties agree that this Quality Agreement shall be governed by and construed in accordance with the law applicable to the supply agreement between the Parties or their Affiliates pertaining to the PRODUCT."

In the absence of a supply agreement, alternative language may be as follows:

"This Agreement is subject to ***<country> law*** *excluding its renvoi principles. Place of jurisdiction for all disputes possibly arising out of or in connection with this Agreement shall be <****city****>".*

Typically, the law of the country where the CUSTOMER is located is chosen. For instance, in Europe (except e. g. Denmark and the UK), the new EU Regulation No. 593/2008 - "Rome I" - will apply as of December 17, 2009, and as most of the jurisdictions it declares that the law of the country where the party required to effect the characteristic performance of the contract has its habitual place of residence shall govern the contract.

II.8 Survival Clause (optional section)

All obligations required of CUSTOMER and SUPPLIER by an applicable regulatory authority or effective regulations shall survive termination of this Quality Agreement.

In detail, < list particular provisions > shall survive < give number > years from expiration or termination of this Quality Agreement.

Note: This clause relates to provisions that by their sense or context are intended to be continued beyond termination of the Quality Agreement, for instance the right to audit, maintenance of lot traceability, responses to complaints or authority requests, ongoing studies, or document/record/sample retention. This clause is more common in the custom synthesis business. If new regulations or laws become applicable later, the Quality Agreement needs to be amended.

III. Quality Responsibilities

[C = CUSTOMER; S = SUPPLIER]

	Responsibilities	C	S
1	**Applicable Quality Standard / Regulatory Compliance**		
1.01	Will manufacture PRODUCT in compliance with the requirements defined in this table and the following international recognized standards: <supplier standards>. In the absence of reference to international recognized standards: Have at least a Quality Management system in place to ensure that the requirements of this Quality Agreement are met.	-	**X**
1.02	Will have sufficient and qualified personnel to complete the required tasks.	**X**	**X**
1.03	Will maintain valid manufacturing, import, or distribution license(s), regulatory approvals as applicable. Upon request, providing update of such licenses.	**X**	**X**
1.04	Will inform CUSTOMER in case of any change in licence status, including regulatory approvals, that affects supply of PRODUCT within 5 business days	-	**X**
1.05	Will provide test procedures, shelf live supporting data, statements, and other quality or regulatory documents as mutually agreed between the parties (see also 8.02, 10.04 and 12).	-	**X**
2	**Change Control**		
2.01	Will have a documented and effective change control system in place. Will inform CUSTOMER of any intended changes, included but not limited to the following: • Change of ownership of the company • Change in synthetic route, raw materials, including solvents and catalysts used during the manufacturing process (incl. introduction of new solvents or ICH Q3C Class 1 solvents) (*) • Introduction of the use of recovered solvents • Relaxation or deletion of a specification (*) • Significant change of the test methods for release testing (i.e. with impact on the test results), including Certificate of Analysis • Changes in equipment type (e.g. filter to centrifuge) • Implementation of / Changes in major IT systems (ERP, LIMS, MES) that manage or control quality-relevant operations • Batch scale changes potentially impacting final product properties or quality • Changes impacting product certificates (e.g. residual solvents, GMO, TSE, allergen, animal origin status) • Changes to the manufacturing or testing location (incl. subcontracting) (*) • Packaging and labelling • Retest dates and storage conditions • Any other changes that potentially impacts the final product quality SUPPLIER shall notify CUSTOMER within a reasonable time (items with * at least 6 months), prior to implementation, and provide CUSTOMER with the necessary change documentation to allow CUSTOMER to assess the potential impact of the change upon the PRODUCT supplied or its use by CUSTOMER.	-	**X**

	Responsibilities	C	S
3	**Audits**		
3.01	Will allow CUSTOMER or its representatives to carry out on-site audits by appointment and free of charge. Will permit all reasonable access to the manufacturing, packaging, warehousing, and laboratory areas related to the manufacture of PRODUCT, including pertinent documentation. Audits may be routine audits or to address specific quality issues related to the manufacturing of PRODUCT or in response to AGENCY / CUSTOMER requirements.	-	**X**
3.02	Will send the results of the audit and the observation(s) to SUPPLIER by means of a written report.	**X**	-
3.03	Will send to CUSTOMER a formal response to the audit observations including any relevant CAPAs and timelines for implementation.	-	**X**
3.04	May disclose, upon request by regulatory authorities or as required by applicable law, all or part of its audit report to regulatory authorities without prior approval by SUPPLIER.	**X**	-
3.05	In case of critical quality incidents or critical GMP deficiencies, will allow CUSTOMER to conduct "for-cause" audits at SUPPLIER's facilities until the issue is resolved to both parties' mutual reasonable satisfaction.	-	**X**
4	**Specifications**		
4.01	Will set standard specifications, include reference to methods used, for PRODUCT and intermediates	**X**	**X**
4.02	Will mutually agree upon specification, incl. reference to methods used, for PRODUCT, which may include customer-specific items	**X**	**X**
4.03	Optional (if not managed in a separate document): Specifications for PRODUCT are detailed in Appendix XX.	-	-
5	**Building and facilities**		
5.01	Will have appropriate control procedures in place to ensure that only authorised personnel can access SUPPLIER's facilities.	-	**X**
5.02	Will have appropriate pest control procedures in place	-	**X**
5.03	Will ensures that the PRODUCTs in scope of this agreement are not manufactured in facilities used for <to specify by the user >	-	**X**
6	**Laboratory Controls**		
6.01	Will perform sampling and testing of PRODUCT	-	X
6.02	Will provide to CUSTOMER any in-house methods used for testing according to the agreed specifications (where there are no compendial methods).	**X**	**X**
6.03	Optional: Will apply, upon request, (validated) CUSTOMERs methods for release of the product.	-	**X**
6.04	Will use adequately qualified or certified reference standards.	-	**X**
6.05	Will store all reference standards in accordance with the suppliers recommended storage conditions and use within their given retest or retest date.	-	**X**
6.06	Optional: Will provide to CUSTOMER reasonable quantities of any non-compendial, commercially not available reference standards necessary to perform the tests included in the PRODUCT specification.	**X**	**X**
	Note 6.1: a definition of "reasonable" might be given here.		

	Responsibilities	C	S
6.07	Will use testing equipment that is proven suitable for intended use /calibrated, either regularly or prior to use, and properly maintained.	-	**X**
6.08	Will store PRODUCT retention samples, in containers that are equivalent to or more protective than the commercial packaging. Samples are to be retained for at least one (1) year after the latest retest date assigned by the SUPPLIER.	-	**X**
7	**Product Release**		
7.01	Will release PRODUCT Batches for Delivery to CUSTOMER. The release indicates that the product meets the agreed-upon specifications, and all relevant deviations (including OOS) and changes have been properly addressed and resolved, ensuring the safety and quality of the product.	-	**X**
7.02	Optional: May, alternatively, provide a pre-shipment sample to CUSTOMER. CUSTOMER will test that sample, and if OK, will give its approval for shipment to SUPPLIER. To be added here, as applicable.	**X**	**X**
7.03	Optional: Will only ship any PRODUCT to CUSTOMER until the PRODUCT is released, unless prior written approval has been received from CUSTOMER to perform such a shipment under quarantine.	**X**	**X**
8	**Product Shelf Life**		
8.01	Will assign retest dates, storage and shipping conditions, supported by data.	-	**X**
8.02	Will re-assess retest dates following significant process or packaging changes.	-	**X**
8.03	Will provide supporting shelf live data to CUSTOMER upon reasonable request.	-	**X**
9	**Certificate of Analysis / Conformance**		
9.01	Will provide a Certificate of Analysis for each batch of PRODUCT shipped to CUSTOMER.	-	**X**
9.02	Will date and sign the Certificate of Analysis by an authorized representative of the SUPPLIER's Quality Unit, or it may be generated by a computer system, that provides a level of control equivalent to that provided by a signature.	-	**X**
9.03	The Certificate of Analysis states that the batch is suitable for release, and includes – as a minimum – ❑ SUPPLIER name and address, ❑ Name and address of original manufacturer, if SUPPLIER is not the original manufacturer ❑ PRODUCT name and grade (if applicable), ❑ SUPPLIER batch/lot number, ❑ Reference to the agreed specification (if applicable), ❑ Test parameters, and corresponding specification requirements, ❑ Test results (numerical, where applicable) for each chemical, physical or microbiological test performed. Any tests that are not executed on every batch (e.g. skip lot testing) should be clearly marked as such. ❑ Date of manufacture, date of release and expiration or retest date of the PRODUCT	-	**X**
	Note 9.1: the Certificate of Analysis may be attached to the Quality Agreement as an appendix; in any case it should match the PRODUCT specification		
10	**Certificates, Statements and Declarations**		

	Responsibilities	C	S
10.01	Will provide any applicable certificates and statements at the approval of this Quality Agreement and any time these certificates are renewed/updated.	-	**X**
11	**Process Robustness Monitoring**		
11.01	Will provide, upon request, periodic summaries including an overview of deviations/incidents, changes, yields, and test results to CUSTOMER.	-	**X**
12	**Documentation**		
12.01	Will maintain a record keeping system that will ensures full traceability from initial data record for the manufacture, testing, storage and release of each Product unit sold or delivered to CUSTOMER. These records should be available for review by CUSTOMERS during on-site audits or on specific requests (e.g. for incident investigation purposes).	-	**X**
12.02	Will store the original master batch records, the executed batch records, analytical records, and all other original documentation that is related to the manufacture, testing, storage and release of a particular batch of PRODUCT, protected from destruction and unauthorised access, for at least one (1) year after the latest retest date of the batch assigned by SUPPLIER or for three (3) years after distribution of the batch, whichever is the longer. As an exception, the following documents should be stored for at least three (3) years after supply of the last batch of PRODUCT to CUSTOMER: • Shelf live supporting documents • Documents supporting suitability/qualification of equipment, facilities and utilities used in the production of the product(s) in scope • Change control documents related to the product(s) in scope	-	**X**
12.03	Will make the original records related to the manufacture of PRODUCT available for CUSTOMER during an on-site audit.	-	**X**
12.04	Will take care that documentation practices and data handling (paper and electronic) are understood and followed by all employees ensuring data integrity.	-	**X**
12.05	***For exclusive PRODUCT:*** Upon CUSTOMER request, SUPPLIER will promptly make copies of the original batch production and control records available for CUSTOMER.	-	**X**
12.06	***For exclusive PRODUCT:*** SUPPLIER will offer CUSTOMER the option to take over the manufacturing and related documents before destruction after **XX** years	-	**X**
13	**Materials for manufacture of PRODUCT**		
13.01	Will set specifications for materials (incl. starting materials, raw materials, process aids, and packaging materials, as applicable)	-	**X**
13.02	Will purchase materials according to specifications	-	**X**
13.03	Will store materials according to appropriate conditions	-	**X**
13.04	Will sample and inspect or test incoming materials, as appropriate. Materials supplied by qualified vendors can be subject to reduced testing but a minimum ID testing (or visual examination of containers, labels and documentation in case of hazardous or highly toxic raw materials) needs to be performed for each delivery and each lot.	-	**X**
13.05	Will qualify and monitor material suppliers (with the exception of materials supplied by CUSTOMER)	-	**X**
	For exclusive PRODUCT in case CUSTOMER manages or supplies input materials (13.06 to 13.13.):		
13.06	Will be in charge of the qualification and management of the critical raw material	X	-

	Responsibilities	C	S
13.07	Will provide all relevant information (i.e. in the form of a report of qualification memo) with regard to the critical raw material	X	-
13.08	Will maintain SPECIFICATIONS and analytical methods for the critical raw material	X	X
13.09	Will inform CUSTOMER of any OOS investigations and any other deviating results related to the critical raw material	-	X
13.10	Will be responsible for issuing and managing complaints towards the supplier of the critical raw material	X	-
13.11	Will make release decision of affected batch(es).	X	X
13.12	Will request information from manufacturer via CUSTOMER. If SUPPLIER is to contact manufacturer directly with consent of CUSTOMER, CUSTOMER will always be included in correspondences between SUPPLIER and supplier of the critical raw material	-	X
13.13	Will notify SUPPLIER of any relevant changes related to the critical raw material	X	-
	Note 13.1: for exclusive PRODUCT, if necessary and agreed by the parties, responsibilities with respect to purchasing, manufacturing, and testing of materials and intermediates before the RSMs may be added here.		
14	**Suitability of processes / systems**		
	Note 14.1: The use of 'validation' has been avoided in this paragraph because validation is not an expectation for raw materials / non-registered process steps.		
14.01	Will maintain and calibrate equipment, utilities and facilities	-	**X**
14.02	Will maintain documentation proving the suitability/qualification of equipment, utilities, and facilities	-	**X**
14.03	Will maintain documentation proving consistency of manufacturing and cleaning process	-	**X**
14.04	Will maintain documentation proving the suitability of Analytical methods for the intended use	-	**X**
	For exclusive PRODUCT (14.05 to 14.08):		
14.05	Will provide to CUSTOMER, on request, copies or summaries of documentation mentioned in 14.02, 14.03 and 14.04.	-	**X**
14.06	Will prepare the Master Batch Record for the PRODUCT	-	**X**
14.07	Will review and approve the Master Batch Record prior to manufacture of commercial PRODUCT batches.	**X**	**X**
14.08	Optional: Will share with SUPPLIER information on toxicity of PRODUCT and raw materials, process aids and intermediates, if available.	**X**	-
14.09	Optional: Will share with SUPPLIER information on risk for formation/presence and contamination of PRODUCT with mutagenic impurities, if available. Risk assessment should consider all raw materials, process aids and intermediates used in route of synthesis of PRODUCT.	**X**	-
14.10	Optional: Will share with SUPPLIER information on risk for formation/presence and contamination of PRODUCT with nitrosamines/vulnerable amines/nitrosating agents. Risk assessment should consider all raw materials, process aids and intermediates used in route of synthesis of PRODUCT.	**X**	-
	Note 14.2: for exclusive PRODUCT, more stringent acceptance criteria for cleaning may be agreed between both parties if requested by CUSTOMER. Such special agreements should be included here.		

	Responsibilities	C	S
15	**Reprocessing / Reworking**		
15.01	Reprocessing (i.e. repeating one or more steps of the standard process) of a PRODUCT batch is permissible; the reason for the reprocessing must be investigated and documented, respectively.	-	**X**
15.02	Will demonstrate that the reprocessed batch is of at least equivalent quality (including shelf live) as a normal batch.	-	**X**
15.03	Delivery of batches obtained by reworking (i.e. purification by using process steps **different** from the original process) is only acceptable provided written approval by the Customer.	-	**X**
15.04	***For exclusive PRODUCT:*** Will report any reprocessed batches and the reasons for the reprocessing to CUSTOMER.	-	**X**
15.05	***For exclusive PRODUCT:*** Optional: Will obtain prior approval from CUSTOMER, in case reprocessing is deemed necessary.	-	**X**
16	**Contamination prevention**		
16.01	Will have appropriate processes for cleaning; to prevent cross-contamination with previous products and the cleaning effectiveness is demonstrated via analytical verification	-	**X**
16.02	Will take appropriate measures to protect product from any contamination from the environment/surroundings (e.g. foreign matter).	-	**X**
17	**Sub-contracting**		
17.01	Will use its established systems for evaluation, qualification, approval and /monitoring of all sub-contracted services with impact on PRODUCT manufactured. Evidence of such qualification should be available during audit by the CUSTOMER.	-	**X**
17.02	Will notify CUSTOMER of any change to existing sub-contractors or introduction of new sub-contractors used for manufacturing or testing of PRODUCT.	-	**X**
17.03	Will remain fully responsible for the quality of the materials or services provided by sub-contractors and for all commitments as agreed upon with this Quality Agreement.	-	**X**
17.04	***For exclusive PRODUCT:*** Will not subcontract any of its obligations under this Quality Agreement unless CUSTOMER provides prior written approval to SUPPLIER for such subcontracting.	-	**X**
18	**Packaging**		
18.01	Will apply suitable traceability measures to primary packaging materials, to enable that the packaging material manufacturer's batch can be traced from the batch of PRODUCT supplied.	-	**X**
18.02	Optional: Will foresee final packaging intended for shipment of goods with tamper-proof seals.	-	**X**
18.03	Optional: Will pack the PRODUCT using the components, closures and tamper evident seals as specified in Appendix **XX**.	-	**X**
	Note 18.1: the list in Appendix XX may include both primary packaging materials and secondary ones, e.g., pallets, wrapping etc. There may be the need to define and explain any coding on the seals.		
19	**Labelling**		
19.01	Will perform labelling operations in a manner that prevents mislabelling and mix-ups.	-	**X**
19.02	Will consider applicable regulatory requirements to permit shipments without delays or other issues (e.g., at customs).	-	**X**

	Responsibilities	C	S
	Notes 19.1-19.3: *1: the shipping label may include additional information (e.g., CUSTOMER material code); details may be defined in the Supply Agreement.* *2: labelling should be described in sufficient detail if done on behalf of the CUSTOMER.* *3: an example of the label may be provided in an appendix to the Quality Agreement.*		
19.03	Optional: Will indicate the retest date on the PRODUCT label.	-	**X**
19.04	***For exclusive PRODUCT:*** Optional: Will use the following batch/lot number format <xxyyzz> where <xx> means <…> and <yy> …..	-	**X**
20	**Storage and distribution**		
	The following text is written for a case where the SUPPLIER is responsible for the transportation from the manufacturing site to the CUSTOMER's receiving site (and needs to be changed/removed, if responsibilities are different).		
20.01	Will ensure prevention of deterioration, contamination, or adulteration, during packaging, storage, and shipping of PRODUCT	-	**X**
20.02	Will use wooden pallets marked as Heat Treated (HT) for all outbound shipments Optional: Will comply with any applicable country specific requirements or laws, concerning their treatment.	-	**X**
20.03	Will provide, upon request or after revision, an up-to-date SDS (Safe Data Sheet)	-	**X**
20.04	***Alternative text for exclusive PRODUCT:*** Will provide an up-to-date SDS to SUPPLIER before the first production and after each change to the SDS.	**X**	-
21	**Deviations / OOS**		
21.01	Will document and investigate all deviations, out-of-specification (OOS) results. All investigations must be closed prior to release of PRODUCT batches (see also 7.01).	-	**X**
21.02	Optional: Will inform CUSTOMER in case of major deviations having a potential impact on the quality of the delivered product (e.g. data compromising retest date, microbial contamination).	-	**X**
21.03	Will promptly and appropriately notify CUSTOMER, in case of critical quality incidents observed only **after** shipment of batches of PRODUCT to CUSTOMER.	-	**X**
	For exclusive PRODUCT (21.04 to 21.07):		
21.04	Will promptly inform CUSTOMER of any deviation that might affect the quality of a batch of material and provide supporting documentation of the investigation. Optional: Will not perform batch disposition until approval of the deviation has been received from CUSTOMER.	-	**X**
21.05	Will promptly provide any advice on the handling of the deviation or the affected material (e.g., on root cause analysis or corrective actions), so that further production is not unreasonably hindered.	**X**	-
21.06	Will provide copies of investigation reports regarding quality incidents (critical deviations, OOS results, or similar), as applicable.	-	**X**
21.07	Will participate in any full-scale investigation concerning OOS results.	**X**	-
22	**Complaints**		

	Responsibilities	C	S
22.01	Will promptly notify SUPPLIER, upon detection, any defect or shortage	**X**	-
22.02	Will communicate all complaints related to the PRODUCT to SUPPLIER in writing.	**X**	-
22.03	Will acknowledge the receipt of the complaints responding the CUSTOMER within two business days.	-	**X**
22.04	Will provide an intermediate status report within 10 business days and a full complaint investigation report, including corrective and preventive action within 30 calendar days of acknowledgement of the complaint.	-	**X**
22.05	Will make relevant information and samples of the affected PRODUCT batch(es)/lot(s) available in a timely manner to assist in the investigation of SUPPLIER (as appropriate).	**X**	-
22.06	Will inform if any received complaint from other customers also has a serious impact on batches previously supplied to CUSTOMER.	-	**X**
23	**Blending of production batches into commercial batch**		
23.01	Will maintain blending process protocols (if applicable). Records of the blending process should allow traceability back to the individual batches that make up the blend.	-	X
23.02	Will release batches to be blended. Only batches that comply with the agreed specifications (see related appendices) are acceptable to be blended. Unique lot-numbers should be assigned to every blended batch.	-	X
23.03	Will base the retest date of the blended batch on the manufacturing date of the oldest batch in the blend.	-	X

IV. Signatories

Agreement of the Parties to perform the activities and fulfil the responsibilities detailed in this Quality Agreement is indicated by the representatives' approval below:

< CUSTOMER name >	**< SUPPLIER name >**
Name	Name
Title / Quality Function	Title / Quality Function
Date and Signature	Date and Signature
< CUSTOMER name >	**< SUPPLIER name >**

Name	Name
Title / Function	Title / Function
Date and Signature	Date and Signature

V. Contacts

Note: List the relevant contact persons (name, position, phone number, e-mail) from each party that will be responsible for communications related to this Quality Agreement. This information can alternatively be provided in an appendix.

< CUSTOMER name >	**< SUPPLIER name >**
Name	Name
Title / Quality Function	Title / Quality Function
Phone	Phone
E-mail	E-mail

Name	Name
Title / Function	Title / Function
Phone	Phone
E-mail	E-mail

Name	Name
Title / Function	Title / Function
Phone	Phone
E-mail	E-mail

VI. List of Appendices

Examples of documents typically attached to a Quality Agreement (list not exhaustive):

- List of PRODUCT(s) in scope

For each product in scope

- Route of synthesis / description of the processes
- PRODUCT specification(s)
- Example CoA
- List of subcontractors and/or affiliates associated with the manufacture, testing or storage,
- Example label
- Information on storage/transport conditions,
- Description of the packaging.

VII. History / Change Log

Version Number	Prepared By	Approval / Signature date	Reason for Change
01	Taskforce team "Supplier Management"		Initial version, based on APIC Quality Agreeement Guideline & Template (2024)