IPEC FEDERATION

The International Pharmaceutical Excipients Council

Quality Agreement

Template(s)

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Note: It is recommended to apply version control according to company standards.
(The use of company letterhead may be considered.)

NOTE: This template commonly applies to Manufacturer and Distributor. However, a choice must be made in section L to use either the Manufacturer or the Distributor Template as appropriate.

Scope

This Quality Agreement (QA) including its Responsibility Table defines the scope and responsibilities of the parties for the GMP / GDP requirements as they relate to the excipients listed.

Parties to the Agreement

This Quality Agreement is by and between <Supplier Name> with office at <address>, hereafter referred to as <Supplier> and <Customer Name> with office at <address>, hereafter referred to as <Customer>. Whereas <Supplier> supplies excipients, referenced in section C, suitable for pharmaceutical use to <Customer>.

NOTE: Supplier / Customer name can be expanded to include further descriptive information about the company such as "Company X, a manufacturer of pharmaceutical excipients duly organized and existing under the laws of <list appropriate jurisdiction>". Consideration should be made to include the Supplier's and Customer's affiliates covered by this Agreement.

Specify Excipients covered by this Agreement.

This Agreement pertains to the following excipient(s), hereafter referred to as <Excipients>: <list or see attachment>.

Excipient list:

Supplier Product Number	Supplier Product Name	Customer Product Number	Customer Product Name
123456	Name1	111111	Name5
567890	Name2	222222	Name6
987654	Name3	333333	Name7
321098	Name4	444444	Name8

NOTE: The table may be extended with other types of information. e.g., product types, production location, brand names.

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Definitions and References - Quality Criteria / Systems

Supplier will conduct all its activities concerning the Excipients in accordance with the following quality criteria and / or system(s):

NOTE: The Parties may remove what is not applicable. If there is anything else that applies, it may be added to the list of quality criteria after mutual agreement.

Current versions:

- The Joint IPEC – PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients (for excipient manufacturers) [2]
- The IPEC Good Distribution Practices Guide for Pharmaceutical Excipients (for excipient distributors) [3]
- NSF/IPEC/ANSI 363 Good Manufacturing Practices (GMP) for Pharmaceutical Excipients [4]
- EXCiPACT® Certification Standards for Pharmaceutical Excipient Suppliers: GMPs and GDPs [5]
- USP General Chapter 1078 Good Manufacturing Practices for Bulk Pharmaceutical Excipients [6]
- Pharmacopoeias, as applicable for compendial Excipients (e.g. Ph. Eur., USP) [7,8]
- ISO 9001 Quality Management Systems [9]
- ISO 14001 Environmental Management Systems [10]
- Other regional certifications, as applicable

For specific processes as detailed in the Responsibility Table the following guides are included:

NOTE: The references mentioned below are essential elements within the Responsibility Table. Therefore, they should not be removed without adjustment of the Responsibility Table.

- The IPEC Significant Change Guide for Pharmaceutical Excipients [11]
- Certificate of Analysis Guide for Pharmaceutical Excipients [12]

NOTE: The parties may mutually decide if the glossary definitions will be used as reference.

- The IPEC General Glossary of Terms and Acronyms [1]

Site(s) involved.

NOTE: Sites supplying Excipients should be mutually agreed upon. The Supplier sites involved can be specified here if needed (may refer to an attachment). If the sites

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involved are not listed in this Agreement, it should be indicated where the agreed sites are specified.

Use of Third Parties

NOTE: If Third Party information is considered confidential, specify how this information can be disclosed to the customer, for example under confidentiality agreement.

Action: Select one of the two paragraphs underneath and remove the one that's not applicable.

If the Supplier is the Excipient manufacturer:

If <Supplier> uses third parties to manufacture, package, **label**, test, release, store or handle Excipients, such use is set forth <list here or specify attachment>. **Significant Changes** in the use of third parties as set forth in this Agreement will not be made without prior written notification to <Customer>. (*NOTE: Would be as detailed in Responsibility Table section 5.0, **Change Control**.)* <Supplier> shall, however, retain all obligations under this Agreement whether or not a third-party manufacturer, packages, labels, inspects, tests, releases, stores or handles Excipients.

If the Supplier is a distributor:

If <Supplier> uses third parties to store or handle Excipients, such use is set forth <list here or specify attachment>. Significant Changes in the use of third parties as set forth in this Agreement will not be made without prior written notification to <Customer>. (*NOTE: Would be as detailed in Responsibility Table section 5.0, Change Control*) <Supplier> shall, however, retain all obligations under this Agreement whether or not a third party stores or handles Excipients.

Responsibilities regarding manufacture, packaging, **labelling**, testing and release of the Excipients are confirmed by the Excipient manufacturer in the Manufacturer's Quality Statement (see attachment).

NOTE: If Third Party information is considered confidential, specify how this information can be disclosed to the customer, for example under confidentiality agreement.

Assignment

Neither party shall have the right to assign any or all of its rights or obligations under this Agreement without the other party's prior written consent, which shall not unreasonably be withheld. The foregoing notwithstanding, prior written consent shall not be required in connection with a merger, consolidation, or a sale of all or substantially all of party's

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assets to a third party, except if such merger, consolidation or sale is with a competitor of the other party.

NOTE: The legal language in this example may be excluded based on review. Companies may choose to remove this section.

Term of Agreement

This Agreement shall become effective and binding upon the date of the final signature for an initial period of <YEARS> and will continue automatically, for as long as the supply of Excipients to Customer lasts, for <X> years afterwards.

Unless any party gives notice of termination at least six months prior to the end of the current term.

NOTE: Automatic renewal may be a case-by-case decision of the parties.

Confidentiality

Subject to and consistent with any other confidentiality agreements between the Parties relating to the exchange of specific information, all information, in any form, disclosed by one party to the other party under this Agreement will be maintained strictly confidential for a period of <X> years after termination of this Agreement, and will be used solely for the purpose of performing obligations under this Agreement.

NOTE: Confidentiality provisions may be contained within a separate agreement (example: supply agreement or non-disclosure agreement).

Companies may choose to modify, remove, or note this section as "not applicable".

Other Agreements

In the event of any conflicts or inconsistences between the <Applicable Agreements> (e.g., supply agreement) and this Quality Agreement, this Quality Agreement shall prevail solely with respect to any of the quality and compliance provisions set forth herein.

NOTE: When a supply agreement or other similar agreement exists or is being generated at the same time as the quality agreement, reviewers should assure that any quality provisions captured in the supply agreement should not conflict with the quality agreement; if so, a provision should identify and clarify which agreement supersedes in the event of a conflict.

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Companies may choose to modify, remove, or note this section as "not applicable".

Choice of Law and Place of Jurisdiction

This Quality Agreement shall be governed by and interpreted in accordance with the laws of <Country>. The court of <City/State>, <Country> shall have sole and exclusive jurisdiction.

NOTE: This example language merely gives some guidance on potential wording and should be reviewed with the parties' legal departments. A choice of law and a place of jurisdiction should be agreed to between the parties and designated here and should be in line with other agreements as applicable.

QA Responsibility Table

The responsibilities of each party are given in the Attachment as noted in Section P.


Manufacturer's Template


Distributor's Template

Action: Select the Manufacturer's Template or Distributor's Template as appropriate.

Manufacturer's Quality Statement

The responsibility of the manufacturer's quality commitments and responsibilities as it relates to the Manufacturer's Quality Statement is given in the Attachment as noted in Section P. The excipient manufacturer allows <Distributor name> to share the Manufacturer's Quality Statement with the excipient customer or regulator.


Manufacturer's Quality Statement

Action: Companies may choose to modify, remove, or note this section as "not applicable".

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Contacts

Supplier		Customer	
Contact #1	<Name><function>	**Contact #1**	<Name><function>
	<Email>		<Email>
	<Location>		<Location>
	<Phone number>		<Phone number>
Contact #2	<Name><function>	**Contact #2**	<Name><function>
	<Email>		<Email>
	<Location>		<Location>
	<Phone number>		<Phone number>

NOTE: List the contact persons from each party that will be responsible for communications related to this Agreement. Some contacts may be within the Quality organization, and others may not be (for example, Procurement). Therefore, listing all contacts that are relevant to the agreement is prudent. This information can be provided in an Attachment.

Approval Signatures

NOTE: Companies may choose to modify this section according to company standards.

Supplier	**Customer**
_____	_____
Signature, Date	Signature, Date
_____	_____
Name (print):	Name (print):
_____	_____
Function:	Function:

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List of Attachments

NOTE: A list of attachments that are commonly attached to the QA, and which are referenced in this template are shown here. Templates are provided for the first three in the list.

It is good practice to number the Attachments.

It is dependent upon both parties to assure the QA and its Attachments are maintained as current, accurate documents during the entire effective period.

- Responsibility Table: Manufacturer's Template or Distributor's Template (MANDATORY). *NOTE: remove Template that's not used*
- Manufacturer's Quality Statement
- List of Excipients covered by this Quality Agreement (if not already listed in Section C)
- List of Site(s) involved (if not already listed in Section E)
- List of Third Parties (if not already listed in Section F)
- List of contact persons from each party (if not already listed in Section N)
- Attached copies (e.g., Specifications, Example **Certificate of Analysis**, etc.)

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