The IPEC Quality Agreement Guide and Template

2009

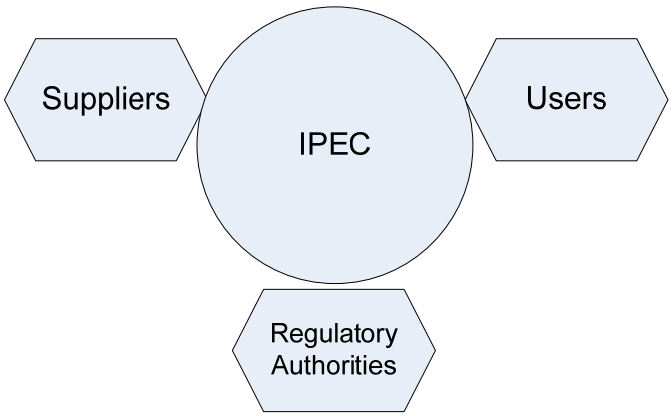
This document represents voluntary guidance for the pharmaceutical excipient industry and the contents should not be interpreted as regulatory requirements. Alternative approaches to those described in this guide may be implemented.

FOREWORD

IPEC is an international industry association formed in 1991 by manufacturers and end-users of excipients. It is an association comprising four regional and country pharmaceutical excipient industry associations covering the United States, Europe, China and Japan (which are known respectively as IPEC-Americas, IPEC Europe, IPEC-China and Japan PEC). IPEC's objective is to contribute to the development and harmonization of international excipient standards, the introduction of useful new excipients to the marketplace and the development of best practice and guidance concerning excipients.

IPEC has three major stakeholder groups;

1. Excipient manufacturers and distributors, who are considered suppliers in this document,
2. Pharmaceutical manufacturers, who are called users, and
3. Regulatory authorities who regulate medicines.



This document offers best practice and guidance in the establishment of a quality agreement between a buyer and a supplier of an excipient. The excipient supplier may be a manufacturer or a distributor (or both). The Guide highlights the factors to consider when planning and executing a such agreement between the parties.

ACKNOWLEDGEMENTS

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IPEC-AMERICAS

- Alexa Smith, Colorcon
- Priscilla Zawislak, Hercules Incorporated
- Craig Scott, JRS Pharma LP
- Laura Horne, Mutchler, Inc.
- David B. Klug, sanofi-aventis
- Maria Guazzaroni Jacobs, Pfizer
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- Chris Armstrong, Evonik
- Judy Emmert, Abbott
- Ann Van Meter, Dow
- Cindy Libonati, Purdue Pharma L.P.

IPEC EUROPE

- Johanna Eisele, Evonik Röhm GmbH
- Karen M. Hudson,, Lilly UK
- Iain Moore, Ph.D., Croda Europe Ltd,

INTRODUCTION

In the current regulatory environment surrounding excipients, pharmaceutical manufacturers are under increasing pressure to develop better knowledge of their excipient supply chain. As part of solidifying supplier relationships, quality agreements have been introduced because they are considered to be beneficial in a supply relationship and are required in some jurisdictions for manufacturing under contract. They enable excipient users and suppliers to create a quality partnership between the two companies. Quality agreements are legally binding agreements that are mutually negotiated between users and suppliers of excipients. They are intended to be an agreement between quality departments. The purpose of the quality agreement is to define who is responsible for quality activities and how quality issues will be resolved that will allow excipient suppliers to provide safe products that are suitable for the user's intended application. By clearly delineating GMP (good manufacturing practice) responsibilities, costly product quality issues resulting from miscommunication can be reduced or eliminated.

Due to the increasing desire to have quality agreements in place with key suppliers, there has been a trend to use templates to get a large number of agreements in place quickly. Many companies, both users and suppliers, have developed their own templates to address quality agreements. Unfortunately, these individual templates have often been designed to cover multiple types of products (excipients, active pharmaceutical ingredients and/or packaging) and been presented in an inflexible manner. The result of this has been extensive negotiations between companies, significant time and resources spent, and fewer agreements completed.

IPEC is committed to improving communications between excipient users and suppliers. As part of that on-going effort, IPEC has developed the IPEC Quality Agreement Template. The IPEC Quality Agreement Template is designed to provide excipient users and suppliers a common starting point to create quality agreements that address fundamental quality issues specific to the manufacture and use of excipients. By utilizing the IPEC Quality Agreement Template, users and suppliers will be able to reduce the time and effort needed to complete successful quality agreements. Having appropriate quality agreements in place can significantly improve communications, limit product quality issues that result from misunderstandings, and improve supply chain relationships.

SCOPE AND PURPOSE

The IPEC Quality Agreement Template is designed to be a flexible model for crafting quality agreements where an agreement is desired. It is intended to define the appropriate topics that should be addressed in a quality agreement related to excipients. The template is designed to be global in scope thus being suitable for use in many regions. There is both a manufacturer template and a distributor template. The information below is provided to assist in determining which template is appropriate for the individual situation.

Manufacturer Template: Designed for use between the original manufacturer and either the end user or a distributor. The original manufacturer is the company manufacturing a material to the stage at which it is designated as a pharmaceutical starting material.

Distributor Template: Designed for use between the distributor and the end user. Distributors are those parties handling the excipient after the point at which the excipient is

transferred outside the control of the original manufacturer's material management system. Distributors include those parties involved in trade and distribution, reprocessors, repackagers, transport and warehousing companies, forwarding agents, brokers, traders and suppliers other than the original manufacturer.

A quality agreement is intended to be a formalized, joint agreement on quality responsibilities and activities defining both the user's and supplier's respective obligations as they relate to quality. They are intended to address quality commitments between the parties and are based on the quality procedures in place. However, quality agreements cannot take the place of an audit.

Quality agreements are not designed to replace commercial supply agreements but rather complement them. Other agreements may contain references to quality responsibilities and activities. During periodic reviews of these other agreements, excipient users and suppliers may wish to consider replacing specific quality information in the agreement with reference to a quality agreement.

FORMAT OF THE EXCIPIENT QUALITY AGREEMENT DOCUMENTS

The IPEC Quality Agreement Template format is a combination of a legal-style format and a tabular format. The Introduction/Purpose section of the template is presented in a legal-style format and the Quality Responsibilities section is presented in a tabular format. The legal style format addresses the terms and conditions and scope of the agreement. The tabular format allows for quick and easy identification of quality responsibilities which are the central point of the agreement. The template addresses the main quality points and responsibilities that should be included in a quality agreement appropriate for excipients; however, it does not list every element of the quality system used. It is not necessary to reiterate agreement on every point of the quality system when general agreement on the applicable quality criteria has been stated. However, included in the template are quality responsibilities that may require action by one or both parties.

The format is intended to be flexible with the template offering the elements needed for most excipient quality agreements. Modifying the template should be done with care and only as necessary to avoid lengthy negotiations. It is suggested that excipient suppliers prepare in advance a quality agreement based on the template to be used to begin the negotiation process with their customers when a quality agreement is requested.

As with any binding agreement, it is advisable to seek the review of legal counsel of all companies that are party to the agreement.

QUALITY AGREEMENT RESPONSIBILITIES AND REVIEW

Effective implementation of any quality agreement is dependent on both excipient supplier and user ensuring that the obligations of the agreement are consistent with the quality systems at the respective sites. Use of a template allows a supplier to conduct this review once, prior to initiating any quality agreements with users. Any obligations or commitments added during the negotiation phase of an agreement should require additional review of the affected quality systems to assure compliance prior to signature. When a supply 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 are also reflected and/or not contradicted in the quality agreement.

It is dependent upon both parties to assure the quality agreement is maintained as a current, accurate document during the entire effective period. Amendment(s) and/or addendum(s) may be needed to assure the current requirements and/or responsibilities are reflected in the quality agreement. Both parties are responsible for reviewing requests for amendments/addendums to assure the quality systems support such changes.

All quality agreements and amendments/addendums require legally binding signatures. It is the responsibility of each party to assure the signatures in the quality agreement reflect the legally binding signatures representing each party.

Manufacturer's Quality Agreement Template

1. Introduction/Purpose

Scope

Parties to the agreement

Example wording:
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 suitable for pharmaceutical use to <Customer>.

Note: Company 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>.

Specify excipients covered by agreement

Example wording:
This agreement pertains to the following excipient(s) (or excipient processes/types/locations, etc), hereafter referred to as <Excipients>: <list or see attachment>.

Definition of the quality criteria

Example wording:
Supplier will manufacture, test and release the <Excipients> in accordance with the following quality criteria:

Examples of potential quality criteria:

IPEC PQG GMP, current version **(Primary Reference)**
Others as applicable:
GMP as published in USP General Chapter <1078>, current version
ISO-9001, current version
WHO Guideline on GMP, current version
United States FD&C Act Misbranding and Adulteration Provisions
Documented HACCP Concept
Other regional certification, as applicable

Responsibilities for quality activities

Example wording:
This Quality Agreement will outline the responsibilities of <Supplier> and <Customer> with regard to the quality activities described in the quality criteria listed above.

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 appendix). If the sites involved are not listed in this agreement, it should be indicated where the agreed sites are specified.

Use of third parties

Example wording:
If <Supplier> uses third parties to manufacture, package, label, test or release <Excipients>, such use is set forth <list here or specify attachment>. Changes in the use of third parties as set forth in this agreement will not be made without prior written notification to the <Customer>. <Supplier> shall, however, retain all obligations under this Agreement whether or not a third party manufactures, packages, labels, inspects, tests, releases or handles <Excipients>.

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

Term of agreement

Example wording:
This Agreement shall become effective and binding upon the date of the final signature and shall remain in effect until 2 years after the last delivery of <Excipients> by <Supplier> to <Customer> unless <Customer> specifically requests an extension of the Agreement. Either party may terminate this Agreement by giving 6 months written notice to the other party. After such termination, and if so requested by <Customer>, <Supplier> will negotiate with <Customer> in good faith a subsequent Quality Agreement.

Assignment

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

Confidentiality (optional)

Note: May define here according to <Supplier>'s policy or refer to other documents pertaining to confidentiality, e.g. confidentiality agreement (also referred to as a confidential disclosure agreement).

Other agreements

Example wording:
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.

Choice of Law

Note: If a choice of law is not specified in a supply agreement, a choice of law should be agreed to between the parties and designated here.

2. Compliance

   See attached QA Responsibility Table.

3. Manufacturing, Packaging and Labeling

   See attached QA Responsibility Table.

4. Documentation and Records

   See attached QA Responsibility Table.

5. Storage and Distribution

   See attached QA Responsibility Table.

6. Change Control

   See attached QA Responsibility Table.

7. Non-Conformance

   See attached QA Responsibility Table.

8. Auditing

   See attached QA Responsibility Table.

9. Quality Contacts

   List the contact persons from each party that will be responsible for communications related to this agreement. This information can be provided in an attachment.

10. Signatories

11. References

12. List of Attachments

Quality Agreement Responsibility Table

Responsibilities	Supplier	Customer	NA
Compliance			
Conform to the Joint IPEC-PQG GMP Guide and/or other quality criteria defined in the scope of this agreement. The current versions of the defined quality criteria in effect at the time of this agreement are attached. (Attachment of quality criteria is optional.)	X	X	
Mutually agree upon specifications for the Excipients which are the subject of this agreement. Specifications in place at the time of this agreement are attached. (Attachment of specifications is optional.)	X	X	
Changes to the agreed upon specifications must be mutually agreed upon and communicated in writing between the parties to this agreement, except for compendial changes which can be implemented without mutual agreement. Compendial changes must be implemented by the compendial implementation date.	X	X	
Ensure that the specifications for compendial excipients are in compliance with the current compendia.	X	X	
Manufacture Excipients that conform to the mutually agreed upon specifications.	X		
Upon request, disclose to the Customer recent regulatory agency inspections and findings pertaining to the Excipients.	X		
Notify promptly if, in the course of a regulatory inspection, negative findings are made related to the quality of the Excipients supplied.	X	X	
Shall have a quality agreement with third parties used for production, packaging, testing or processing the Excipients in any manner, which could be viewed during an audit.	X		
Manufacturing, Packaging and Labelling			
Document that manufacturing and packaging process are fit for purpose. Demonstrate the commissioning of critical systems and equipment used in the manufacture and control of the Excipient. Demonstrate that cleaning procedures are appropriate and their effectiveness has been demonstrated.	X		
Samples will be retained for a period of ____ years from _____ (specify).	X		
Agree upon special labelling requirements.	X	X	

Documentation and Records			
Certificate of Analysis will be supplied with each batch.	X		
Certificate of Analysis will be prepared either according to the current IPEC-Americas *Certificate of Analysis Guide for Bulk Pharmaceutical Excipients* or an agreed upon alternative that is defined in this agreement (an example COA may be attached).	X		
Agree upon special Certificate of Analysis requirements.	X	X	
Where applicable, electronic signatures used on the Certificates of Analysis must conform to the requirements of the IPEC-Americas *Certificate of Analysis Guide for Bulk Pharmaceutical Excipients* or an agreed upon alternative that is defined in this agreement.	X		
Records required by the agreed upon quality system will be maintained for a period of ____ years from _____ (specify).	X		
Storage and Distribution			
Maintain and supply upon request documentation that supports the recommended storage and transportation conditions plus re-evaluation or expiry dates.	X		
Ensure that Excipients are stored and shipped in accordance with manufacturer's recommended storage conditions.	X	X	
Where applicable, agree upon requirements for reusable shipping containers.	X	X	
Change Control			
Changes will be evaluated and communicated based upon agreed criteria and timelines. Refer to the IPEC-Americas *Significant Change Guide* or specified alternative that is defined in this agreement.	X		

Non-Conformance			
All non-conformance should be investigated. Where applicable this includes the identification of the root cause, a risk analysis (including the risk to other lots and the impact to other test results) of the actions taken for correction of the problem, prevention of future occurrence and the formal conclusion by Supplier's Quality Assurance. If an investigation reveals that there is an impact to Excipients received by the Customer, Supplier shall inform Customer without unreasonable delay.	X		
Out of Specification (OOS)			
Out-of-specification (OOS) test results should be investigated and documented according to a documented procedure.	X		
Deviations			
If significant deviations from an established process are recorded, there should be evidence of suitable investigations and a review of the quality of the Excipients.	X		
Complaints			
Have a written procedure to investigate and document quality related complaints. A root cause analysis, actions taken for correction of the problem, prevention of future occurrence and the formal conclusion will be provided to the Customer within a reasonable time after receipt of the complaint.	X		
Complaints made shall at least indicate the Supplier's batch number of the excipient and complaint subject. The complaint shall be communicated to the Supplier within a reasonable time after receipt of the excipient. Samples will be provided where appropriate and available.		X	
The parties shall cooperate in the exchange of information required to effectively conduct an investigation.	X	X	
Recalls			
In the case of a recall of the Excipients, Supplier shall inform Customer without unreasonable delay of the planned recall.	X		
Have a written recall procedure.	X		
Customer shall notify Supplier of any finished product recall which has been investigated or is under investigation and has potential to be related to the quality of the Excipients, as soon as possible.		X	

The parties shall cooperate in the exchange of information required to effectively conduct a recall or recall investigation.	X	X	
Auditing			
Have the right to audit Supplier's facilities, systems and documentation, as they relate to the manufacture of Excipients, at mutually agreed upon times.		X	
Allow Customer to audit facilities, systems and documentation, as they relate to the manufacture of Excipients, at mutually agreed upon times.	X		
If required, a confidentiality agreement will be executed within a reasonable period of time prior to the audit.	X	X	
Customer shall issue a confidential written audit report to the Supplier, which will include audit observations, within X days (mutually agreed upon timeline).		X	
Supplier shall issue responses within X days (mutually agreed upon timeline) to all observations in writing to Customer Quality Assurance. Where the Supplier commits to a corrective action, a description and timeframe for completion will be included in the written response.	X		
Where applicable, agree upon requirements for auditing third parties used in association with excipients production, processing, warehousing, or testing.	X	X	

Distributor's Quality Agreement Template

1. Introduction/Purpose

Scope

Parties to the agreement

Example wording:
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 suitable for pharmaceutical use to <Customer>.

Note: Company name can be expanded to include further descriptive information about the company such as Company X, a distributor of pharmaceutical excipients duly organized and existing under the laws of <list appropriate jurisdiction>.

Specify excipients covered by agreement

Example wording:
This agreement pertains to the following excipient(s) (or excipient processes/types/locations, etc), hereafter referred to as <Excipients>: <list or see attachment>.

Definition of the quality criteria

Example wording:
Supplier will conduct all activities concerning the Excipients in accordance with the following quality criteria:
Examples of potential quality criteria:

- IPEC Good Distribution Practices Guide for Pharmaceutical Excipients, current version **(Primary Reference)**
- Others as applicable:
- ISO-9001, current version
- WHO Guideline Good Trade and Distribution Practices for Pharmaceutical Starting Materials, current version
- NACD Code of Management Practice
- Cefic/ FECC Safety and Quality Assessment Systems (SQAS) Distributor/European Single Assessment Document (ESAD II) Assessment (Section F and G)
- United States FD&C Act Misbranding and Adulteration Provisions
- Other regional certification, as applicable

Responsibilities for quality activities

Example wording:
This Quality Agreement will outline the responsibilities of <Supplier> and <Customer> with regard to the quality activities described in the quality criteria listed above.

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 appendix). If the sites involved are not listed in this agreement, it should be indicated where the agreed sites are specified.

Manufacturer and Use of Other Third Parties

Example wording:
Agreed upon manufacturer, manufacturing site(s) and other third parties are disclosed in <attachment><EIP><other document>. Changes in the use of third parties as set forth in this agreement will not be made without prior written notification to the <Customer>. Supplier shall, however, retain all obligations under this Agreement whether or not a third party manufactures, packages, labels, inspects, tests, releases or handles Excipients.

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

Term of agreement

Example wording:
This Agreement shall become effective and binding upon the date of the final signature and shall remain in effect until 2 years after the last delivery of <Excipients> by <Supplier> to <Customer> unless <Customer> specifically requests an extension of the Agreement. Either party may terminate this Agreement by giving 6 months written notice to the other party. After such termination, and if so requested by <Customer>, <Supplier> will negotiate with <Customer> in good faith a subsequent Quality Agreement.

Assignment

Example wording:
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 assets to a third party, except if

such merger, consolidation or sale is with a competitor of the other party.

Confidentiality (optional)

Note: May define here according to <Supplier>'s policy or refer to other documents pertaining to confidentiality, e.g. confidentiality agreement (also referred to as a confidential disclosure agreement).

Other agreements

Example wording:
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.

Choice of Law

Note: If a choice of law is not specified in a supply agreement, a choice of law should be agreed to between the parties and designated here.

2. Compliance
   See attached QA Responsibility Table

3. Manufacturing, Packaging and Labeling
   See attached QA Responsibility Table

4. Documentation and Records
   See attached QA Responsibility Table

5. Storage and Distribution
   See attached QA Responsibility Table

6. Change Control
   See attached QA Responsibility Table

7. Non-Conformance
   See attached QA Responsibility Table

8. Auditing
   See attached QA Responsibility Table

9. Quality Contacts
   List the contact persons from each party that will be responsible for communications related to this agreement. This information can be provided in an attachment.

10. Signatories
11. References
12. List of Attachments

Quality Agreement Responsibility Table

Responsibilities	Supplier	Customer	NA
Compliance			
Conform to the *IPEC Good Distribution Practices Guide for Pharmaceutical Excipients* and/or other quality criteria defined in the scope of this agreement. The current versions of the defined quality criteria in effect at the time of this agreement are attached. (Attachment of quality criteria is optional.)	X	X	
Supplier will have a Quality Agreement(s) with the original manufacturer and/or any third parties used for production, packaging, testing or processing the Excipients in any manner that could be viewed during an audit of the Supplier.	X		
Mutually agreed upon specifications for the Excipients which are the subject of this agreement. Specifications in place at the time of this agreement are attached. (Attachment of specifications is optional.)	X	X	
Changes to the agreed upon specifications must be mutually agreed upon and communicated in writing between the parties to this agreement, except for compendial changes which can be implemented without mutual agreement. Compendial changes must be implemented by the compendial implementation date.	X	X	
Ensure that the specifications for compendial excipients are in compliance with the current compendia.	X	X	
Supply Excipients that conform to the mutually agreed upon specifications.	X		
Upon request, disclose to the Customer recent regulatory agency inspections and findings pertaining to the Excipients.	X		
Notify promptly if, in the course of a regulatory inspection, negative findings are made related to the quality of the Excipients supplied.	X	X	
Processing, Packaging and Labelling			
Where applicable, appropriately document all processes related to the Excipients such as processing and packaging are fit for purpose. Demonstrate the commissioning of critical systems and equipment used. Demonstrate that cleaning procedures are appropriate, and their effectiveness has been demonstrated..	X		

If Excipients are repackaged, processed or packaged from bulk, samples will be retained for a period of ____ years from _____ (specify).	X		
Agree upon special labelling requirements.	X	X	
Documentation and Records			
Certificate of analysis will be supplied with each batch in accordance with the *IPEC Good Distribution Practices Guide for Pharmaceutical Excipients* or an agreed upon alternative that is defined in this agreement.	X		
Where applicable, the certificate of analysis will be prepared either according to the current IPEC-Americas *Certificate of Analysis Guide for Bulk Pharmaceutical Excipients* or an agreed upon alternative that is defined in this agreement (an example COA may be attached).	X		
Agree upon special certificate of analysis requirements.	X	X	
Where applicable, electronic signatures used on the Certificates of Analysis must conform to the requirements of the IPEC-Americas *Certificate of Analysis Guide for Bulk Pharmaceutical Excipients* or an agreed upon alternative that is defined in this agreement.	X		
Records required by the agreed upon quality system will be maintained for a period of ____ years from _____ (specify).	X		
Storage and Distribution			
Maintain and supply upon request documentation that supports the recommended storage and transportation conditions plus re-evaluation or expiry dates.	X		
Ensure that Excipients are stored and shipped in accordance with manufacturer's recommended storage conditions.	X	X	
Where applicable, agree upon requirements for reusable shipping containers.	X	X	
Change Control			
Changes will be evaluated and communicated based upon agreed criteria and timelines. Refer to the IPEC Americas *Significant Change Guide* or specified alternative that is defined in this agreement.	X		

Non-Conformance			
All non-conformance should be investigated. Where applicable this includes the identification of the root cause, a risk analysis (including the risk to other lots and the impact to other test results) of the actions taken for correction of the problem, prevention of future occurrence and the formal conclusion by Supplier's Quality Assurance. If an investigation reveals that there is an impact to Excipients received by the Customer, Supplier shall inform Customer without unreasonable delay.	X		
Out of Specification (OOS)			
Out-of-specification (OOS) test results should be investigated and documented according to a documented procedure.	X		
Deviations			
If significant deviations from an established process are recorded, there should be evidence of suitable investigations and a review of the quality of the Excipients.	X		
Complaints			
Have a written procedure to investigate and document quality related complaints. A root cause analysis, actions taken for correction of the problem, prevention of future occurrence and the formal conclusion will be provided to the Customer within a reasonable time after receipt of the complaint.	X		
Complaints made shall at least indicate the Supplier's batch number of the Excipients and complaint subject. The complaint shall be communicated to the Supplier within a reasonable time after receipt of the Excipients. Samples will be provided where appropriate and available.		X	
The parties shall cooperate in the exchange of information required to effectively conduct an investigation.	X	X	
Recalls			
In the case of a recall of the Excipients, Supplier shall inform Customer without unreasonable delay of the planned recall.	X		
Have a written recall procedure.	X		
Customer shall notify Supplier of any finished product recall which has been investigated or is under investigation and has potential to be related to the quality of the Excipients, as soon as possible.		X	

The parties shall cooperate in the exchange of information required to effectively conduct a recall or recall investigation.	X	X	
Auditing			
Have the right to audit Supplier's facilities, systems and documentation, as they relate to the handling of Excipients, at mutually agreed upon times.		X	
Allow Customer to audit facilities, systems and documentation, as they relate to the manufacture of Excipients, at mutually agreed upon times.	X		
Agree on requirements for auditing by the Customer the original manufacturer or other third parties.	X	X	
If required, a confidentiality agreement will be executed within a reasonable period of time prior to the audit.	X	X	
Customer shall issue a confidential written audit report to the Supplier, which will include audit observations, within X days (mutually agreed upon timeline).		X	
Supplier shall issue responses within X days (mutually agreed upon timeline) to all observations in writing to Customer Quality Assurance. Where the Supplier commits to a corrective action, a description and timeframe for completion will be included in the written response.	X		

GLOSSARY

Active Pharmaceutical Ingredient (API) - Any substance or mixture of substances, intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient of the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure or any function of the body of man or animals.

Agreement – Arrangement undertaken by and legally binding on parties.

Batch (Lot) – A specific quantity of material produced in a process or series of processes so that it can be expected to be homogeneous. In the case of continuous processes, a batch may correspond to a defined fraction of the production. The batch size can be defined either by a fixed quantity or by the amount produced in a fixed time interval.

Batch Number (Lot Number) – A unique combination of numbers, letters and/or symbols that identifies a batch and from which the production and distribution history can be determined.

Certificate of analysis – A document listing the test methods, specification and results of testing a representative sample from the batch to be delivered.

Cefic – The European Chemical Industry Council

Commissioning – The introduction of equipment for use in a controlled manner.

Contract – Business agreement for supply of goods or performance of work at a specified price.

Corrective Action - A change implemented to address a weakness identified in a management system.

Critical – A process step, process condition, test requirement or other relevant parameter or item that must be controlled within predetermined criteria to ensure that the excipient meets its specification.

Customer – The organization receiving the excipient once it has left the control of the excipient manufacturer; includes brokers, agents and users.

Deviation – Departure from an approved instruction or established standard.

Distributor – All parties in the distribution/supply chain starting from the point at which an excipient is transferred outside the control of the original manufacturer's material management system including parties involved in trade and distribution, (re)processors, (re)packagers, transport and warehousing companies, forwarding agents, brokers, traders, and suppliers other than the original manufacturer.

Excipient – Substances other than the API which have been appropriately evaluated for safety and are intentionally included in a drug delivery system.

FECC – European Federation of Chemical Distributors

GDP – Good Distribution Practice. GDP deals with the distribution of products, including requirements for purchase, receiving, storage and export. GDP regulates the movement of products from the premises of the manufacturer to the end user, or to an intermediate point by means of various transport methods.

GMP – Good Manufacturing Practice. Requirements for the quality system under which drug products and their ingredients are manufactured. Current Good Manufacturing Practice (cGMP) is the applicable term in the United States. For the purposes of this guide, the terms GMP and cGMP are equivalent.

IPEC – International Pharmaceutical Excipients Council

IPEC PQG – International Pharmaceutical Excipients Council and the Pharmaceutical Quality Group.

ISO – International Organization for Standardization.
Label – The display of written, printed or graphic matter on the Immediate container of the excipient (inactive ingredient) product.
Labeling – All written, printed or graphic matter accompanying an excipient at any time while it is in-transit to the customer or being held for sale after shipment or delivery to the customer.
Lot – see Batch
Lot Number – See Batch Number
NACD – National Association of Chemical Distributors
Manufacturer – A party who performs the final processing step.
Original Manufacturer – Person or company manufacturing a material to the stage at which it is designated as a pharmaceutical starting material.
Packaging – The container and its components that hold the excipient for storage and transport to the customer.
Procedure – Written, authorized instruction for performing specified operations.
Quality Agreements - Legally binding agreements that are mutually negotiated between users and suppliers. They are intended to be an agreement between quality departments. A quality agreement is intended to be a formalized, joint agreement on quality responsibilities and activities defining both the users and suppliers respective obligations as they relate to quality. They are intended to address quality commitments between the parties and are based on the quality procedures in place.
Quality Assurance – The sum total of the organized arrangements made with the object of ensuring all excipients are of the quality required for their intended use and that quality systems are maintained.
Recalls – A process for withdrawing or removing a pharmaceutical material from the distribution chain because of defects in the materials or complaints of a serious nature. The recall might be initiated by the manufacturer/importer/distributor or a responsible agency.
Record – Document stating results achieved and/or providing evidence of activities performed. The medium may be paper, magnetic, electronic or optical, photography etc. or a combination thereof.
Retained Sample – Representative sample of a batch/delivery that is sufficient quantity to perform at least 2 full quality control analyses and will be kept for a defined period of time.
Site – A location where the excipient in manufactured. This may be within the facility but in a different operational area or at a remote facility including a contract manufacturer.
Specification – The quality parameters to which the excipient, component or intermediate must conform and that serve as a basis for quality evaluation.
Supply chain – For the purpose of this guideline, supply chain is defined as all steps in the entire chain of distribution starting from the point at which an excipient is transferred outside the control of the original manufacturer's material a management system downstream to the final user of the excipient.
Supplier – Person or company providing pharmaceutical starting materials on request. Suppliers may be distributors, manufacturers, traders, etc.
User – A party who utilizes an excipient in the manufacture of a drug product or another excipient.
USP/NF – United States Pharmacopeia/National Formulary
Validation – A documented program that provides a high degree of assurance that a specific process, method or system will consistently produce a result meeting predetermined acceptance criteria.
WHO – World Health Organization