IPEC
EXCIPIENT INFORMATION PACKAGE (EIP): TEMPLATE AND USER GUIDE

2009

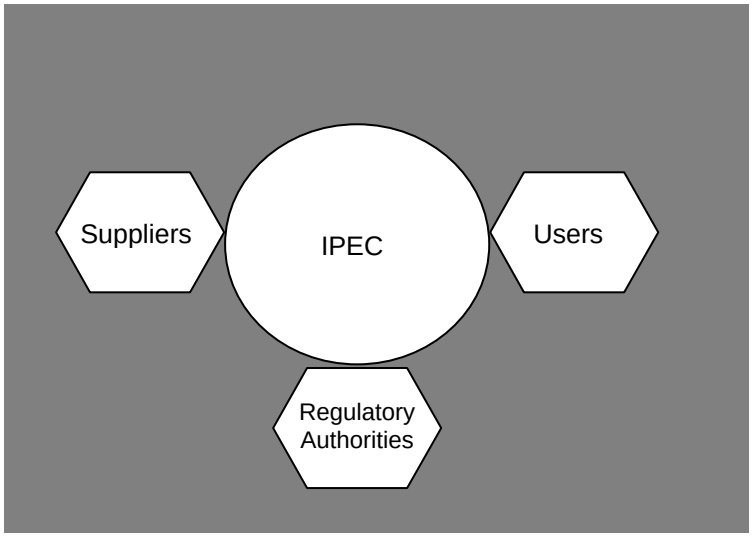
This document represents voluntary guidance for the pharmaceutical excipient industry and the contents should not be interpreted as regulatory requirements. Alternative approaches to those described in this guide may be implemented.

FOREWORD

IPEC is an international industry association formed in 1991 by manufacturers and end-users of excipients. It is an association comprising four regional pharmaceutical excipient industry associations covering North America, Europe, China and Japan (which are known respectively as IPEC-Americas, IPEC Europe, IPEC-China and JPEC). 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 called suppliers
2. Pharmaceutical manufacturers, who are called users
3. Regulatory authorities who regulate medicines



This document offers best practice and guidance in the establishment of an excipient information package. The excipient supplier may be a manufacturer or a distributor (or both). The Guide highlights the factors to consider when preparing such a package.

ACKNOWLEDGEMENTS

This guideline is the result of the hard work and substantial resources, of IPEC member companies. IPEC greatly appreciates the many hours the following individuals devoted to develop this guide and the generous support of their employers for providing the necessary time and resources.

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
- Londa Ritchey, Wyeth
- Chris Armstrong, Evonik
- Judy Emmert, Abbott
- Ann Van Meter, Dow
- Cindy Libonati, Purdue Pharma L.P.

IPEC EUROPE

- Iain Moore, Croda
- Kevin McGlue, Colorcon Limited
- Carl Mroz, Colorcon Limited
- Rebecca Roberts, Colorcon Limited

INTRODUCTION

SCOPE AND PURPOSE

In order to use an excipient, users need to obtain a significant amount of data about the excipient manufacturer, distributor, where applicable, and the excipient itself. Many users have resorted to sending questionnaires and surveys to obtain this information using their own individual formats. Often these surveys and questionnaires address essentially the same quality and regulatory concerns. It is also difficult in some cases, due to the phrasing of specific questions, to interpret the intent of the question.

While excipient suppliers want to provide information to the user as quickly as possible, many excipient suppliers receive such a large volume of questionnaires and surveys from their customers that they are unable, due to resource constraints, to individually complete each customer's specific form. Further, because these surveys and questionnaires vary to some degree in the specific questions asked, if a change in the information occurs, it is virtually impossible for the excipient supplier to determine which completed surveys and questionnaires are affected by the change. Significant time and resources are spent, both by the user and supplier, to send, complete, return, review and track these non-standardized questionnaires and surveys.

This guide was developed in order to address these issues. It defines the Standardized Excipient Information Package that comprises:

- Product Regulatory Datasheet
- Site Quality Overview
- Site And Supply Chain Security Overview

The primary goal of the template is to provide standards for the exchange of data between excipient suppliers and users that will simplify this process. By responding to surveys, questionnaires and other requests for information in this format, excipient suppliers can respond in a timely and efficient manner to all requests as well as ensure that consistent information is provided. Excipient users will be able to anticipate the type and format of the standard data that they receive from excipient suppliers. This will assist both users and suppliers in the task of information management. In the future, electronic transmission of this data for direct download may be possible. Additionally, this standardization will facilitate any necessary change notifications pertaining to previously supplied information further strengthening the excipient suppliers' change notification program.

FORMAT OF THE EXCIPIENT INFORMATION PACKAGE DOCUMENTS

The Excipient Information Package (EIP) is set up much like a Material Safety Data Sheet (MSDS) with designated sections to include specified data. Each section covers specific topics. The minimum topics that should be covered in each section are defined, however, additional related information can also be provided at the discretion of the excipient supplier. If particular topics are not applicable to a particular excipient or site, it should be so indicated in the document. Where information is considered confidential, the document should reflect how the excipient user can obtain this information. For example, the document may state that the information may only be obtained under a confidentiality agreement.

The presentation and format of the information is at the discretion of the supplier Short, bulleted formats are encouraged. Specific phrasing is not prescribed but suggested phrasing is provided in some sections and can be used if desired. Job titles should be used rather than names.

These documents should be version controlled by the excipient supplier. Suppliers should have a process in association with their management of change policy for updating EIP documents in a timely manner including updates to company and product information and EIP template revisions. The current version of the EIP template can be found on the IPEC website.

The documents do not require signatures, however they must be an official company document.

APPLICATION AND USAGE

The EIP documents are intended for individuals experienced and competent in the area of evaluating excipient suppliers and should not be viewed as a replacement for audits. While the documents are intended to form a complete package of information, each document within the EIP was designed to also be functional as a stand-alone document and therefore, some basic information may be common among the documents.

In order to provide additional guidance on specific topics, IPEC maintains a Regulatory Reference Guidance. The Regulatory Reference lists links to the specific regulatory references applicable in different regions to various sections in the EIP documents. These references can provide preparers of EIP documents detailed guidance on the information that needs to be addressed in various sections. IPEC's Regulatory Reference Guidance is accessible through the IPEC-Americas website at the following address: www.ipecamericas.org.

SECTION BY SECTION EVALUATION OF THE EXCIPIENT INFORMATION DOCUMENTS

I. Product Regulatory Datasheet

The Product Regulatory Datasheet is designed as a means to assist in communicating to the user important physical, manufacturing and regulatory information specific to the excipient. This information is intended to facilitate the use of the excipient in drug products. Not every point is necessarily applicable to each excipient.

The following sections are expected to be included in the document unless otherwise specified.

Section 1 – General Product Information

This section provides identification information for the product .

Topics for this section:

- Product name/code
- Scope of document
- Other general product information (optional)

Section 2 – Manufacturing, Packaging, Release Site and Supplier Information

This section provides general information about where the product is manufactured and other supply chain information. Include cross references to the Site Quality Overview and Site and Supply Chain Security Overview, where applicable.

Topics for this section:

- Sites of manufacturing, processing, packaging, product release and other related sites such as warehousing, terminals, contract labs, etc.
- Exclusive distribution channels (if applicable)
- GMP or GDP compliance statement, as applicable
- Multi purpose / dedicated equipment

Section 3 – Physico-chemical Information

This section provides general information about the chemistry and physical characteristics of the product and its manufacture.

Topics for this section:

- CAS number
- Origin information (synthetic, animal, vegetable, mineral, product of biotechnology, product of fermentation, etc.)
- Synonyms (including INCI name if applicable) (Optional)
- Morphological form (Optional)
- Brief description of manufacture (blend, reaction, continuous / batch process etc.)
- Mixed excipient ingredient statement
- Country of origin for ingredients used in mixed excipients (optional)

Section 4 - Regulatory Information

This section includes information related to the regulatory status of the excipient as well as addressing pertinent product specific topics of general regulatory concern.

Topics for this section:

- Compendial compliance (for example, *USP-NF*, FCC, PhEur or BP, JP, JPE, JSFA) and other regulatory status (For example, 21 CFR, GRAS, other status as a food additive, European cosmetic directive compliance)
- Drug Master File (DMF) or EDQM Certificate of Suitability or other Master File availability
- BSE / TSE Information (both related to the product and the potential for cross-contamination). EDQM Certificate of Suitability information, if applicable
- Viral safety, if applicable
- Allergens / Hypersensitivities Information (both related to the product and the potential for cross-contamination) – Reference the Regulation or specific allergens evaluated.
- GMO Information
- Residual Solvents Information
- Metal catalyst and metal reagent residues
- Kosher / Halal status
- Irradiation treatment, if applicable
- Bioburden/pyrogens (Optional)
- Other concerns, as applicable, such as Proposition 65, aflatoxins or other toxins, preservatives, latex, silicones, status with respect to use in foods labelled as organic or as containing organic ingredients, etc. (Optional)

Section 5 - Miscellaneous Product Information

This section should be used by the supplier to provide any additional information that may be pertinent to the product but is not covered elsewhere in this document or in the other EIP documents.

Topics for this section:

- Explanation of the lot/batch numbering system
- Description of batch definition
- Expiration date and/or recommended re-evaluation interval
- Specific storage and shipping conditions which are required to assure excipient quality
- Common uses (Optional)
- Nutritional information (Optional)
- Packaging e.g. specification, size, types, new/recycled, bulk tankers, type of tamper evidence devices and labelling information (Optional)

Section 6 – Revisions

This section provides information related to version control for the document. The document should have a date and a version number. This section should also describe the changes made since the last revision.

Section 7 - Contact Information

This section explains how the user should contact the supplier to get additional information, if needed, regarding the topics provided in this document.

II. Site Quality Overview

The Site Quality Overview is a tool to assist in evaluating the manufacturing practices and quality systems of suppliers, as well as a reference to inform users of the systems in place to assure appropriate GMP requirements. The "Joint IPEC-PQG Good Manufacturing Practice Guide for Pharmaceutical Excipients 2006" was used as the basis to construct this document and should serve as the primary source for evaluating responses provided by the supplier. Users of this document should be familiar with the introduction, definitions, and general guidance that are contained within the IPEC-PQG GMP Guide, and should refer to the guide if further details are needed.

The Site Quality Overview is intended to communicate a summary of the Quality Systems and GMP used to manufacture the excipient(s). It may not necessarily include all of the details covered in an audit, nor are all of the points necessarily appropriate to every site.

The following sections are expected to be included in the document unless otherwise specified.

Section 1 - Site Overview

The purpose of this section is to describe the supplier's organization and production capabilities.

Topics for this section:

- Scope
  - Site Name(s)
  - Address(es)
  - Excipients covered by this document (optional)
- Corporate ownership (if different from site identified in Scope)
- Customer audit policy (optional)
- Site Details
  - General Site Information (e.g. size, history, number of employees, shift operations, site plan, union workforce (optional), etc)
  - Site activities conducted (e.g. blending, packaging, testing, R&D)
  - Primary applications of products produced at this site (pharmaceutical, food, cosmetic, etc)
  - Facility production of antibiotics, steroids, or hormone products
  - Organizational chart (including responsibility for product release)
  - Use scope and control of sub-contractors, if applicable

Section 2 - Compliance Evidence

This section should be used to describe any specific compliance information pertinent to the facility being described.

Suggested examples of compliance information:

- ISO registration information e.g. 9001, 14001, OHSAS 18001, etc. (number, registrar, copies of certificates)
- GMP Inspections by Competent Authorities (Regulatory Agencies) including outcome
- General GMP statements
- Other certifications or external audit programs: IPEA, AIB, GMA-SAFE, BRC, etc.

Section 3 – IPEC-PQG GMP Compliance Details:

This section should be used to address how the supplier complies with each applicable element of the IPEC-PQG GMP Guide. Non-applicable elements should be noted as such. For more detail on the specific items that may be covered under each topic, please refer to the IPEC-PQG GMP Guide. Parenthetical references in the document template refer to sections in the IPEC-PQG GMP Guide. Additional reference information can be found in the IPEC-PQG GMP Audit Guideline for Pharmaceutical Excipients.

Section 4 - Miscellaneous Site Information

This section should be used by the supplier to provide any additional information that may be pertinent to the site but is not covered elsewhere in this document or in the other EIP documents. This section is optional and should be used as needed.

Suggested topics for this section:

- Risk management plans such as HACCP
- Statistical Process Control / Process Analytical Technology (PAT)

Section 5 – Revisions

This section provides information related to version control for the document. The document should have a date and a version number. This section should also describe the changes made since the last revision.

Section 6 - Contact Information

This section explains how the user should contact the supplier to get additional information, if needed, regarding the topics provided in this document.

III. Site And Supply Chain Security Overview

The Site And Supply Chain Security Overview is designed to provide users with information concerning the supplier's plans to ensure the protection of the product and the continuity of supply. It is intended to provide a high level overview of these plans while preserving confidential information.

The following sections are expected to be included in the document unless otherwise specified.

Section 1 - Scope

The purpose of this section is to identify the manufacturing site and distribution site(s) (where applicable) covered by this document.

Topics for this section:

- Scope
- Site Name(s)
- Address(es)
- Excipients covered by this document (optional)
- Corporate ownership (if different from site identified in Scope)

Section 2 - Supply Chain Security

The purpose of this section is to describe how the supplier assures the integrity of the excipient during storage and distribution and also complies with appropriate regulations to the user. Also covered should be any arrangements to comply with appropriate regulations concerning the transportation of the excipient. More details on these issues can be found in the IPEC Good Distribution Practices Guide 2006.

Topics for this section:

- Controls to assure the integrity and security of the product in transit from manufacturer to end user. The following are suggested areas that may be discussed where applicable:
  - Evaluation of carriers
  - Tamper evident packaging
  - Environmental control (if appropriate)
  - Qualification of distributors
  - Qualification of forwarders/brokers
  - Qualification of intermediate storage locations
  - Repacking/relabelling activities
- Registrations with the FDA under the BioTerrorism Act, if applicable
- C-TPAT or AEO Participation, if applicable
- Approved distributors and how material pedigree/traceability is assured (where applicable) (Optional)

Section 3 - Security Information

The purpose of this section is to describe the elements of the supplier's overall security program.

Topics for this section:

- Scope of security plan including:
  - Roles and Responsibilities, including title of person responsible for implementing security
  - Policies & Procedures
  - Training
  - Data and computer system protection
  - Site access control (e.g. security fencing, visitor registration, employee badges, employee training, vehicular access, camera monitoring)
- Personnel security

- Pre-employment background checks
- Background checks on temporary and contract personnel
- Training
- Termination of employees or contractors and preventing subsequent access to the site and computer systems

Section 4 - Safety & Environmental Information

The purpose of this section is to describe the supplier's personnel safety and environmental programs.

Topics for this section:

- Description of documented health and safety program
- Registrations to ISO 14001, OHSAS 18001 and/or Responsible Care etc.
- Description of documented emergency response plan

Section 5 - Miscellaneous Site Information

This section should be used by the supplier to provide any additional information that may be pertinent to the site but is not covered elsewhere in this document or in the other EIP documents. This section is optional and should be used as needed.

Suggested topics for this section:

- Corporate social responsibility programs
- Business continuity plans

Section 6 – Revisions

This section provides information related to version control for the document. The document should have a date and a version number. This section should also describe the changes made since the last revision.

Section 7 - Contact Information

This section explains how the user should contact the supplier to get additional information, if needed, regarding the topics provided in this document

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EIP DOCUMENT TEMPLATES

COMPANY LOGO/LETTERHEAD/OFFICIAL STATIONERY/COMPANY DOCUMENT

PRODUCT REGULATORY DATASHEET

Section 1 – General Product Information

Product name/code

Scope of document

Other general product information (optional)

Section 2 – Manufacturing, Packaging, Release Site and Supplier Information

Sites of manufacturing, processing, packaging, product release and other related sites such as warehousing, terminals, contract labs, etc.

Exclusive distribution channels (if applicable)

GMP or GDP compliance statement, as applicable

Multi purpose/dedicated equipment

Section 3 – Physico-chemical Information

CAS number

Origin information (synthetic, animal, vegetable, mineral, product of biotechnology, product of fermentation, etc.)

Synonyms (including INCI name if applicable) (Optional)

Morphological form (Optional)

Brief description of manufacture (blend, reaction, continuous / batch process etc.)

Mixed excipient ingredient statement

Country of origin for ingredients used in mixed excipients (optional)

Section 4 - Regulatory Information

Compendial compliance and other regulatory status

Drug Master File (DMF) or EDQM Certificate of Suitability or other Master File availability

BSE/TSE Information (both related to the product and the potential for cross-contamination)

EDQM Certificate of Suitability information, if applicable

Viral safety, if applicable

Allergens/Hypersensitivities Information (both related to the product and the potential for cross-contamination) – Reference the Regulation or specific allergens evaluated

GMO Information

Residual Solvents Information

Metal catalyst and metal reagent residues

Kosher/Halal status

Irradiation treatment, if applicable

Bioburden/pyrogens (Optional)

Other concerns, as applicable (Optional)

Section 5 - Miscellaneous Product Information

Explanation of the lot/batch numbering system

Description of batch definition batch sizes

Expiration date and/or recommended re-evaluation interval

Storage and shipping conditions (where necessary to assure excipient quality)

Common uses (Optional)

Nutritional information (Optional)

Packaging e.g. specification, size, types, new/recycled, bulk tankers, type of tamper evidence devices and labelling information (Optional)

See User's Guide for other optional information to include in this section

Section 6 Revision history

See User's Guide for suggested information to include in this section

Section 7 Contact Information

See User's Guide for suggested information to include in this section

COMPANY LOGO/LETTERHEAD/OFFICIAL STATIONERY/COMPANY DOCUMENT

SITE QUALITY OVERVIEW

Section 1 Facility Overview

Scope

- Site Name(s)
- Address(es)
- Excipients covered by this document (optional)

Corporate ownership (if different from site identified in Scope)

Customer audit policy (optional)

Site Details

- General Site Information (e.g. size, history, number of employees, shift operations, site plan, union workforce (optional), etc)
- Site activities conducted (e.g. blending, packaging, testing, R&D)
- Primary applications of products produced at this site (pharmaceutical, food, cosmetic, etc)
- Facility production of antibiotics, steroids, or hormone products
- Organizational chart (including responsibility for product release)
- Use scope and control of sub-contractors, if applicable

Section 2 - Compliance Evidence

Include as applicable:

ISO registration number and registrar certificates

GMP Inspections by Competent Authorities (Regulatory Agencies) including outcome

General GMP statements

Other certifications or external audit programs

Section 3 – IPEC-PQG GMP Compliance Details:

Site compliance with the IPEC-PQG GMP Guide 2006 (if another level of GMP are used please specify). Parenthetical references are from the IPEC-PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients 2006.

Quality Management Systems-Excipient Quality Systems (4)

- General Requirements (4.1)
- Documentation Requirements (4.2)
- Change Control (4.3)

Management Responsibility (5)

- Management Commitment (5.1)
- Customer Focus (5.2)

- Quality Policy (5.3)
- Planning (5.4)
- Responsibility, Authority and Communication (5.5)
- Management Review (5.6)

Resource Management (6)

- Provision of Resources (6.1)
- Human Resources (6.2)
- Infrastructure (Facilities and Equipment) (6.3)
- Work Environment (6.4)

Product Realization (7)

- Planning of Product Realization (7.1)
- Customer-Related Processes (7.2)
- Design and Development (7.3)
- Purchasing (7.4)
- Production and Service Provision (7.5)
- Control of Measuring and Monitoring Devices (7.6)

Measurement, Analysis and Improvement (8)

- General (8.1)
- Monitoring and Measurements(8.2)
- Control of Nonconforming Product (8.3)
- Analysis of Data (8.4)
- Improvement (8.5)

Section 4 Miscellaneous Site Information (Optional)

See User's Guide for suggested information to include in this section

Section 5 Revision history

See User's Guide for suggested information to include in this section

Section 6 Contact Information

See User's Guide for suggested information to include in this section

COMPANY LOGO/LETTERHEAD/OFFICIAL STATIONERY/COMPANY DOCUMENT

SITE AND SUPPLY CHAIN SECURITY OVERVIEW

Section 1 - Scope

Site Name(s)

Address(es)

Excipients covered by this document (optional)

Corporate ownership (if different from site identified in Scope)

Section 2 - Supply Chain Security

Controls to assure the integrity and security of the product in transit from manufacturer to end user. The following are suggested areas that may be discussed where applicable:

- Evaluation of carriers
- Tamper evident packaging
- Environmental control (if appropriate)
- Qualification of distributors
- Qualification of forwarders/brokers
- Qualification of intermediate storage locations
- Repacking/relabelling activities

Tamper evidence

Registrations with the FDA under the BioTerrorism Act, if applicable

C-TPAT or AEO Participation, if applicable

Approved distributors and how material pedigree is assured (where applicable) (Optional)

Section 3 - Security Information

Scope of security plan including:

- Roles and Responsibilities, including title of person responsible for implementing security
- Policies & Procedures
- Training
- Data and computer system protection
- Site access control (e.g. security fencing, visitor registration, employee badges, employee training, vehicular access, camera monitoring)

Personnel security

- Pre-employment background checks
- Background checks on temporary and contract personnel
- Training
- Termination of employees or contractors and preventing subsequent access to the site and computer systems

Section 4 - Safety & Environmental Information

Description of documented health and safety program

Registrations to ISO 14001, OHSAS 18001 and/or Responsible Care etc.

Description of documented emergency response plan

Section 5 - Miscellaneous Product Information

See User's Guide for suggested information to include in this section

Section 6 Revision history

See User's Guide for suggested information to include in this section

Section 7 Contact Information

See User's Guide for suggested information to include in this section

DEFINITIONS AND GLOSSARY

21 CFR	Title 21 of the United States Code of Federal Regulations Product Regulatory Datasheet – Section 4
AEO	Authorised Economic Operator – status applied to organisations in Europe which permits them to regulatory relief from customs inspections and documentary requirements. Akin to C-TPAT in that it also requires supply chain security measures to be implemented. Site and Supply Chain Security Overview – Section 2
Aflatoxins	The aflatoxins are a group of structurally related toxic compounds produced by certain strains of the fungi *Aspergillus flavus* and *A. parasiticus*. Under favorable conditions of temperature and humidity, these fungi grow on certain foods and feeds, resulting in the production of aflatoxins. The most pronounced contamination has been encountered in tree nuts, peanuts, and other oilseeds, including corn and cottonseed. Aflatoxicosis is poisoning that results from ingestion of aflatoxins in contaminated food or feed. Product Regulatory Datasheet – Section 4
AIB	The American Institute of Baking Site Quality Overview – Section 2
Allergens	A substance that causes an abnormal response by the immune system to certain proteins found in the substance. Product Regulatory Datasheet – Section 4
Animal Sourced	Contains starting materials of animal origin. Product Regulatory Datasheet – Section 3
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.
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. Product Regulatory Datasheet – Section 5
Bioterrorism Act	The United States Public Health Security and Bioterrorism Preparedness and Response Act of 2002 Site and Supply Chain Security Overview – Section 2
BP	British Pharmacopoeia Product Regulatory Datasheet – Section 4
BRC	British Retail Consortium Site and Supply Chain Security Overview – Section 2
BSE	Bovine Spongiform Encephalopathy, a slowly progressive, degenerative, fatal disease affecting the central nervous system of

	adult cattle. The exact cause of BSE is not known but it is generally accepted by the scientific community that the likely cause is infectious forms of a type of protein, prions, normally found in animals cause BSE. In cattle with BSE, these abnormal prions initially occur in the small intestines and tonsils, and are found in central nervous tissues, such as the brain and spinal cord, and other tissues of infected animals experiencing later stages of the disease. There is a disease similar to BSE called Creutzfeldt-Jacob Disease (CJD) that is found in people. A variant form of CJD (vCJD) is believed to be caused by eating contaminated beef products from BSE-affected cattle. Product Regulatory Datasheet – Section 4
CAS Number	Chemical Abstracts Service Registry Number. The CAS Registry is the largest substance identification system in existence. When a chemical substance, newly encountered in the literature, is processed by CAS, its molecular structure diagram, systematic chemical name, molecular formula, and other identifying information are added to the Registry and it is assigned a unique CAS Registry Number. Product Regulatory Datasheet – Section 3
Certificate of Suitability to the European Pharmacopoeia (CEP)	Certification granted to individual manufacturers by the European Pharmacopoeia when an excipient or active ingredient is judged to be in conformity to a monograph or General Chapter 5.2.8 on "Minimising the risk of transmitting animal spongiform encephalopathy agents via medicinal products" Product Regulatory Datasheet – Section 4
Country of Origin	Country of manufacture, meaning the last country in which a substantial transformation of the product occurred. A substantial transformation occurs if a new article with a different name, character, and use is created. Product Regulatory Datasheet – Section 3
C-TPAT	Customs-Trade Partnership Against Terrorism is a joint government (US Customs)-business initiative to build cooperative relationships that strengthen overall supply chain and border security. Site and Supply Chain Security Overview – Section 2
Drug Master File (DMF)	A Drug Master File (DMF) is a submission to the Food and Drug Administration (FDA) that may be used to provide confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more human drugs. Product Regulatory Datasheet – Section 4
EDQM	European Directorate for the Quality of Medicines Product Regulatory Datasheet – Section 4
Excipient	Substances other than the API which have been appropriately evaluated for safety and are intentionally included in a drug delivery system.
Expected	Elements of the EIP documents that should be included and addressed in the EIP documents.

Expiration Date	The date beyond which a product may no longer conform to relevant specifications. Product Regulatory Datasheet – Section 5
FCC	Food Chemicals Codex Product Regulatory Datasheet – Section 4
GDP	Good Distribution Practice 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. Product Regulatory Datasheet – Section 2
GMA - SAFE	The GMA (Grocery Manufacturers Association) - SAFE assessment is a thorough description of a food production, handling or storage facility's policies and practices, documented by a skilled auditing practitioner and communicated through a web based data management & reporting system that allows individual users of the assessment to determine if the audited facility will meet their own standards. Site Quality Overview – Section 2
GMO	Genetically Modified Organism, meaning an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination. Product Regulatory Datasheet – Section 4
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. Product Regulatory Datasheet – Section 2 Site Quality Overview – Section 2 Site Quality Overview – Section 3
GRAS	"GRAS" is an acronym for the phrase Generally Recognized As Safe. Under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act (the Act), any substance that is intentionally added to food is a food additive, that is subject to premarket review and approval by FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excluded from the definition of a food additive. Product Regulatory Datasheet – Section 4
HACCP	Hazard Analysis Critical Control Point Site Quality Overview – Section 4
Halal	The term indicates that an item is permitted and fit for consumption by Muslims. Product Regulatory Datasheet – Section 4

Hypersensitivity	A violent reaction by the immune system to a substance that is normally considered harmless. Product Regulatory Datasheet – Section 4
INCI Name	International Nomenclature of Cosmetic Ingredients as defined in the Cosmetic, Toiletry and Fragrance Association's (CTFA) publication, the Cosmetic Ingredient Dictionary and Handbook. Product Regulatory Datasheet – Section 3
IPEA	International Pharmaceutical Excipients Auditing, Inc. Site Quality Overview – Section 2
ISO	International Organization for Standardization Site Quality Overview – Section 2
ISO 14001	The International Organization for Standardization's family of standards on environmental management Site and Supply Chain Security Overview – Section 4
OHSAS 18001	International occupational health and safety management system specification. Site and Supply Chain Security Overview – Section 4
JP	Japanese Pharmacopoeia Product Regulatory Datasheet – Section 4
JPE	Japanese Pharmaceutical Excipients Product Regulatory Datasheet – Section 4
JSFA	Japanese Standards for Food Additives Product Regulatory Datasheet – Section 4
Kosher	The term indicates that an item is fit for consumption according to Jewish law. Product Regulatory Datasheet – Section 4
Mineral Based	Contains starting materials of mineral origin. Product Regulatory Datasheet – Section 3
MSDS	Material Safety Data Sheet
Mixed Excipient	A mixed excipient is defined as a simple physical mixture of two or more compendial or non-compendial excipients produced by means of a low- to medium-shear process where the individual components are mixed but remain as discrete chemical entities, i.e. the nature of the components is not chemically changed. Product Regulatory Datasheet – Section 3
Nutritional Information	The declaration of specific nutritional components such as total calories, calories from fat , total fat, saturated fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium, iron. Product Regulatory Datasheet – Section 5
Optional	Suggested topics that should be considered for inclusion in an EIP document.
Organic (organically grown)	Specific practices addressing livestock breeding, cultivation of crops, the level of processing and the production of food. Product Regulatory Datasheet – Section 4
Pedigree	Documentation that provides traceability of the material throughout the supply chain. Site and Supply Chain Security Overview – Section 2

PhEur	European Pharmacopoeia Product Regulatory Datasheet – Section 4
Process Analytical Technology (PAT)	A system for designing, analyzing, and controlling manufacturing through timely measurements (i.e., during processing) of critical quality and performance attributes of raw and in-process materials and processes with the goal of ensuring final product quality. Site Quality Overview – Section 4
Product of Biotechnology	A product derived from any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use. Product Regulatory Datasheet – Section 3
Product of Fermentation	A product derived from a process in which living cells harvest fuel molecules from a substance in order to generate ATP for their own energy needs. During that process, metabolic and bio-chemical alteration of the physico-chemical makeup of the fermented product occurs. Product Regulatory Datasheet – Section 3
Proposition 65	The California Safe Drinking Water and Toxic Enforcement Act of 1986, better known by its original name of Proposition 65, is "right to know" legislation regarding substances known to the State of California to cause cancer or birth defects or other reproductive harm. Product Regulatory Datasheet – Section 4
Recommended Re-evaluation Interval	The period beyond which the bulk pharmaceutical excipient should not be used without further appropriate re-examination. Product Regulatory Datasheet – Section 5
Residual Solvents	Residual Solvents, USP/NF General Chapter <467> Residual solvents are defined as organic chemicals that are used or produced in the manufacture of active substances or Excipients, or in the preparation of medicinal products. ICH Q3C Impurities: Residual Solvents Product Regulatory Datasheet – Section 4
Responsible Care	A voluntary program to achieve improvements in environmental, health and safety performance. Adopted by most Chemical Industry associations worldwide. Site and Supply Chain Security Overview – Section 4
Site	A location where the excipient is manufactured. This may be within the facility but in a different operational area or at a remote facility including a contract manufacturer. Product Regulatory Datasheet – Section 2 Site Quality Overview – Section 1 Site and Supply Chain Security Overview – Section 1
Statistical Process Control	Statistical process control involves using statistical techniques to measure and analyze the variation in processes. Site Quality Overview – Section 4
Supplier	A manufacturer or distributor who directly provides an excipient to the user.

Synthetic	Products which are not derived from starting materials sourced from plants, animals or minerals and that are not products of fermentation. Note: Also see specific regional or national organic food legislation for additional information on the use of the term synthetic. Product Regulatory Datasheet – Section 3
TSE	Transmissible Spongiform Encephalopathies. TSE's are rare forms of progressive neurodegenerative disorders that affect both humans and animals and are caused by similar uncharacterized agents that generally produce spongiform changes in the brain. Specific examples of TSE's include: scrapie, which affects sheep and goats; BSE, which affects cattle; transmissible mink encephalopathy; feline spongiform encephalopathy; chronic wasting disease (CWD) of mule deer, white-tailed deer, black-tailed deer, and elk; and in humans, kuru, Creutzfeldt-Jakob disease, Gerstmann-Straussler syndrome, fatal familial insomnia, and variant Creutzfeldt-Jakob disease (vCJD). Product Regulatory Datasheet – Section 4
USP-NF	United States Pharmacopeia/National Formulary Product Regulatory Datasheet – Section 4
Vegetable Sourced	Contains starting materials of plant origin. Product Regulatory Datasheet – Section 3