IPEC
STANDARDIZED EXCIPIENT INFORMATION PROTOCOL USER GUIDE

2005

Version 0 September 2005

ACKNOWLEDGEMENTS

This guide was prepared by The International Pharmaceutical Excipients Council (IPEC). IPEC is an international industry association, with a distinguished worldwide membership of chemical, pharmaceutical and food firms that develop, manufacture, sell and use pharmaceutical excipients. IPEC was formed in 1991 to address prevalent industry concerns related to the harmonization of international excipient standards, the introduction of useful new excipients to the marketplace, and the development of good manufacturing practices for excipients. IPEC is an umbrella organization comprised of three regional pharmaceutical excipient industry associations in the United States, Europe, and Japan. The objective of the three organizations, which are known respectively as IPEC Americas, IPEC-Europe and JPEC, is to promote the safety and efficacy of finished dosage forms worldwide.

This guideline is the result of the hard work and substantial resources, of IPEC-Americas 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.

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INTRODUCTION

SCOPE AND PURPOSE

In order to use an excipient, excipient users need to obtain a significant amount of data about the excipient maker, distributor, where applicable, as well as about the excipient itself. In order to obtain this large volume of information in some organized fashion, many excipient users have resorted to sending questionnaires and surveys to obtain the needed information. While excipient suppliers want to provide the needed information to the user as quickly as possible, unfortunately 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. Often these surveys and questionnaires address essentially the same quality and regulatory concerns. 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. It is also difficult in some cases, due to the phrasing of specific questions, to interpret the intent of the question. Significant time and resources are spent, both by the user and supplier, to send, complete, return, review and track these unstandardized questionnaires and surveys.

In order to address these issues, the IPEC Standardized Excipient Information Protocol was developed. It defines the Standardized Excipient Information Package which includes the Site Quality Overview, the Product Regulatory Datasheet and the Site And Supply Chain Security Overview. The primary goal of the protocol is to provide standards for the exchange of data between excipient suppliers and excipient users that will simplify this exchange and enable the reallocation of resources on both the side of the excipient supplier and excipient users to more meaningful tasks. By responding to surveys, questionnaires and other requests for information in this manner, excipient suppliers can respond in a timely and efficient manner to all requests as well as insure that consistent information is provided in all cases. Excipient users will be able to anticipate the type and format of the standard data that they need from excipient suppliers. This will assist both users and makers in the task of information management. In the future, electronic transmission of this data for direct download to the excipient user's databases may be possible. Additionally, this standardization will facilitate any necessary change notifications pertaining to previously supplied information further strengthening the excipient supplier's change notification program.

FORMAT OF THE STANDARDIZED EXCIPIENT INFORMATION PACKAGE DOCUMENTS

The Standardized Excipient Information Package (EIP) documents are set up much like a Material Safety Data Sheet (MSDS) with designated sections that include specified data. Each section of the documents covers specific related topics. The Protocol defines the minimum topics that should be covered in each section however, additional related information can also be provided at the discretion of the excipient supplier. If particular

topics specified in the Protocol are not applicable to a particular excipient or site, it should be so indicated in the document. Additionally, some information may be considered confidential. If this is the case, the document should reflect how the excipient user can obtain this information if it is required. For example, the document may state that the information may only be obtained under a confidentiality agreement. How the information is displayed is not defined. The look of the documents is also left to the excipient supplier preparing them; however, a question and answer format is not necessary and is not preferred. Short, bulleted formats are encouraged. Like MSDSs, the documents do not require signatures however, they must be in an official company format. Specific phrasing is also not specified but suggested phrasing is provided in some sections and can be used if desired. These documents should be version controlled by the excipient manufacturer. Roles should be used rather than names.

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 is putting together a Regulatory Reference Guidance. The Regulatory Reference will list links or information related 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. Initially IPEC's Regulatory Reference Guidance will be accessible through the IPEC-Americas website at the following address: www.ipecamericas.org and later through IPEC at www.ipec.org.

SECTION BY SECTION EVALUATION OF THE STANDARDIZED EXCIPIENT INFORMATION DOCUMENTS

I. Product Regulatory Datasheet

The Product Regulatory Datasheet was 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 - Product Information

This section provides identification information for both the product and the supplier.

Topics for this section:

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

Section 2 – Manufacturing, Packaging and Release Site Information

This section provides general information about where the product is manufactured and other supply chain information

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 compliance statement

Section 3 – Physical/Chemical Information

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

Topics for this section:

- CAS number
- Origin information (synthetic, animal, vegetable, mineral, product of fermentation, etc.)
- Brief description of manufacture (blend, reaction, etc.)
- Synonyms (including INCI name if applicable) (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 EDQM Certificate of Suitability, BP, JP, JPE) and other regulatory status (For example, 21 CFR, GRAS, other status as a food additive, European cosmetic directive compliance)
- Drug Master File (DMF) 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
- 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/Organic Volatile Impurities (OVI) Information
- Kosher/Halal status
- Other concerns, as applicable, such as heavy metals, residual catalysts, Proposition 65, aflatoxins or other toxins,

preservatives, latex, silicones, status with respect to use in foods labeled 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 and/or recommended reevaluation interval
- Common uses (Optional)
- Nutritional information (Optional)
- Package size offerings and/or types (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 reader 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 was designed as a tool to assist in evaluating the manufacturing practices and quality systems of excipient suppliers, as well as a reference to assist excipient suppliers in informing excipient users of the systems in place to assure appropriate GMP requirements to deliver consistent product quality. 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 GMP Guide, and should refer to the guide if further details are needed.

The Site Quality Overview is intended to address the foundation of the requirements, and not all of the details, necessary to manufacture excipients in compliance with applicable GMP. 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
  - Address
  - Excipients covered by this document (optional)
- Corporate ownership (if different from site identified in Scope)
- Site Details
  - General Site Information: size, history, insurance, union background
  - 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 type bulk pharmaceuticals
  - Organizational chart

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 (number and registrar)
- Regulatory (GMP) inspection information including outcome
- General GMP statements
- Other certifications or external audit programs: IPEA, AIB, FPA, etc.

Section 3 - IPEC GMP Compliance Details:

This section should be used to address how the supplier complies with each applicable element of the IPEC 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 GMP Guide. Parenthetical references in the document template refer to sections in the IPEC GMP Guide. Additional reference information can be found in IPEC's Audit Guide for Bulk 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:

- 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 reader 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 excipient users with information concerning the excipient supplier's plans to insure the protection of the product and the continuity of supply. It is intended to provide an overall picture of the supplier's plans while preserving the integrity of the plans by covering only the basic elements and is not intended to reveal specific details of the supplier's security controls.

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 site covered by this document.

Topics for this section:

- Scope
  - Site Name
  - Address
  - 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 generally how the supplier plans to preserve the supply chain in the event of unexpected events as well as regulatory compliance and physical protection related to shipping.

Topics for this section:

- Registrations with the FDA under the BioTerrorism Act
- C-TPAT Participation
- Contingency plan established to identify and mitigate business interruption (e.g. raw material supply, energy supply, equipment outages, catastrophes, potential logistical issues)
- Product Security during transportation, storage and distribution

Section 3 - Security Information

The purpose of this section is to describe generally 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, vehicles, camera monitoring)
- HM232 Site Security Plan (DOT HAZMAT, 49 CFR 172) (if applicable)
- 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 generally the supplier's personnel safety program.

Topics for this section:

- Description of documented health and safety program
- Registrations to ISO 14000 and/or ACC 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:

- Policy on the use of child labor (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 reader should contact the supplier to get additional information, if needed, regarding the topics provided in this document.

EIP DOCUMENT TEMPLATES

COMPANY LOGO/LETTERHEAD/OFFICIAL STATIONERY

PRODUCT REGULATORY DATASHEET

Section 1 - Product Information

Product Name/Code
Scope of Document
Other General Product Information (Optional)

Section 2 – Manufacturing, Packaging and Release Site 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 Compliance Statement

Section 3 – Physical/Chemical Information

CAS Number
Origin Information
Brief Description of Manufacture
Synonyms (Including INCI Name, if applicable) (Optional)

Section 4 - Regulatory Information

Compendial Compliance and Other Regulatory Status
Drug Master File (DMF) or other Master File Availability
BSE/TSE Information (both related to the product and the potential for cross-contamination)
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/Organic Volatile Impurities (OVI) Information
Kosher/Halal status
Other concerns as applicable (Optional)

Section 5 - Miscellaneous Product Information

Lot/Batch **Numbering System**
Description of Batch Definition
Expiration **and/or** Recommended Reevaluation **Interval**
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

SITE QUALITY OVERVIEW

Section 1 Facility Overview

Scope

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

Corporate Ownership (if different from site identified in Scope)

Site Details

- General Site Information: size, history, insurance, union background
- 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 type bulk pharmaceuticals
- Organizational chart

Section 2 Evidence of Compliance

ISO-9000 Registration Number and Registrar

Other Certifications or External Audit Programs

Last FDA (or Other GMP Governmental Agency) Inspection and Outcome

Section 3 GMP Compliance Details

Description of how this site complies with IPEC GMP principles (if another level of GMP are used please specify). Parenthetical references are from the IPEC/PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients which was published for international release in January 2006.

Quality Management Systems-Excipient Quality Systems (4)

- General Requirements (4.1)
- Documentation Requirements (4.2)

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

SITE AND SUPPLY CHAIN SECURITY OVERVIEW

Section 1 - Scope

Site Name
Address
Excipients Covered By This Document (Optional)
Corporate Ownership (if different from site identified above)

Section 2 - Supply Chain Security

Bioterrorism Act Registrations
C-TPAT Participation
Contingency Plan To Identify and Mitigate Business Interruption
Transportation, Storage and Distribution Product Security

Section 3 - Security Information

Security Plan Scope
- Roles And Responsibilities Including Title Of Person Responsible For Implementing Security
- Policies & Procedures
- Training
- Data And Computer System Protection

Site Access Control
HM232 Site Security Plan (DOT HAZMAT, 49 CFR 172) (if applicable)
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 14000 and/or ACC Responsible Care etc.

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 **C**ode of **F**ederal **R**egulations Product Regulatory Datasheet – Section 4
ACC Responsible Care	The **A**merican **C**hemistry **C**ouncil has implemented Responsible Care, a voluntary program to achieve improvements in environmental, health and safety performance beyond levels required by the U.S. government. Site and Supply Chain Security Overview – Section 4
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 **A**merican **I**nstitute of **B**aking 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	**B**ritish **P**harmacopoeia Product Regulatory Datasheet – Section 4

BSE	**B**ovine **S**pongiform **E**ncephalopathy, 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	**C**hemical **A**bstracts **S**ervice 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
C-TPAT	**C**ustoms-**T**rade **P**artnership **A**gainst **T**errorism 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	**E**uropean **D**irectorate for the **Q**uality of **M**edicines 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	**F**ood **C**hemicals **C**odex Product Regulatory Datasheet – Section 4
FPA	The **F**ood **P**roducts **A**ssociation is a trade association serving the food and beverage industry in the United States and worldwide. Site Quality Overview – Section 2
GMO	**G**enetically **M**odified **O**rganism, 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	**G**ood **M**anufacturing **P**ractice. 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 **G**enerally **R**ecognized **A**s **S**afe. 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	**H**azard **A**nalysis **C**ritical **C**ontrol **P**oint 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
HM 232	US Department of Transportation (DOT) Regulation, 49 CFR Part 172, **H**azardous **M**aterials: Security Requirements for Offerors and Transporters of Hazardous Materials Site and Supply Chain Security Overview – Section 3
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 14000	The International Organization for Standardization's family of standards on environmental management 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
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
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
OVI	Organic Volatile Impurities, USP/NF General Chapter <467> Product Regulatory Datasheet – Section 4
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 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 Date	That date beyond which the bulk pharmaceutical excipient should not be used without further appropriate re-examination. Product Regulatory Datasheet – Section 5
Residual Solvents	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
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	**T**ransmissible **S**pongiform **E**ncephalopathies. 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	**U**nited **S**tates **P**harmacopeia/**N**ational **F**ormulary Product Regulatory Datasheet – Section 4
Vegetable Sourced	Contains starting materials of plant origin. Product Regulatory Datasheet – Section 3

DOCUMENT REVISION HISTORY

DATE	DOCUMENT VERSION	REVISION DESCRIPTION
September 19, 2005	0	Initial Issue