The International Pharmaceutical Excipients Council

Excipient Information Package

User Guide and Template

Part IV: Sustainability Overview

Version 1
2023

This document represents voluntary guidance for the excipient industry and the contents should not be interpreted as regulatory requirements. Alternatives to the approaches in this guide may be used to achieve an equivalent level of assurance for excipient quality.

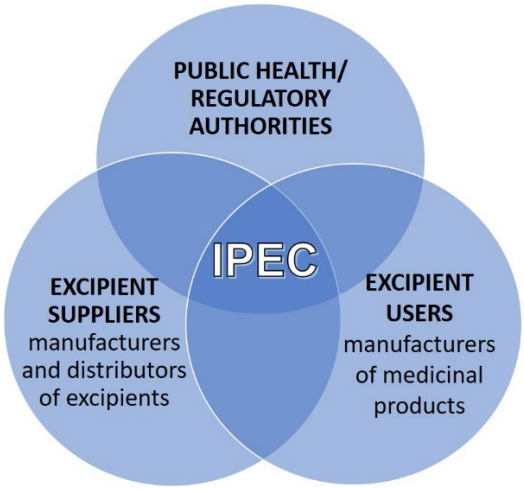
This guide was created to help companies understand current expectations on this topic and is not intended for use by third party certification bodies to conduct audits or to certify compliance with the guide.

FOREWORD

The International Pharmaceutical Excipients Council (IPEC) is an international industry association formed by excipient manufacturers, distributors, and end-users. At the current writing there are regional pharmaceutical excipient industry associations located in the Americas, Europe, Japan, China, and India. IPEC's objective is to contribute to the international excipient standards development and harmonization, provide information useful for new excipient development and introduction, and offer best practice and guidance concerning excipient development.

IPEC has three major stakeholder groups;

1. Excipient manufacturers and distributors, defined as suppliers in this document,
2. Medicinal (drug) product manufacturers, defined as excipient users in this document, and
3. Public health and regulatory authorities.



This section of the guide is intended to be voluntary, to indicate best practice, and to be globally applicable. However, it should be recognized that the laws and regulations applying to excipients

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will vary from region to region and country to country. In addition, the rules and regulations are continually evolving. It is the responsibility of the reader to review the most current version of any applicable regulatory requirement. Versions referenced in the guide were based on versions available at the time the guide was published.

In this guide, pharmaceutical excipient(s) will be referred as excipient(s). This guide may be applied to veterinary medicines, as appropriate and include reference to specific veterinary guidances and regulations.

Throughout the guide, justification implies that a decision is made based on a scientific, quality and/or regulatory considerations.

This guide offers best practice and guidance in the establishment of an excipient sustainability information package. It is not mandatory or binding and each company can make decisions on their focus areas and specific topics to be included in this section.

> *Note: Refer to the "International Pharmaceutical Excipients Council Glossary: General Glossary of Terms and Acronyms [1]" for definitions. The first use of a term found in the glossary will be in **BOLD**.*

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ACKNOWLEDGEMENTS

This guide was developed by representatives of the associations which constitute the IPEC Federation (IPEC). The IPEC Federation greatly appreciates the many hours devoted by the core team of individuals and other contributors listed below, to make this guide available to IPEC members and the broader excipient community. Equally, IPEC extends its thanks to the employers of those same contributors who provided the necessary time and resources, without which, this guide would not be possible.

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1 INTRODUCTION

1.1 Background

The IPEC **Excipient Information Package** (**EIP**) (containing Part I, II and III) [2] was developed as a means of efficiently communicating information about the **excipient** including Product Regulatory Datasheet (Part I), Site Quality Overview (Part II) and Supply Chain and Security Overview (Part III). The information provided facilitates and aids the excipient **user** in their qualification of the excipient supplier and the excipient.

Part IV of the EIP focuses on sustainability matters relating the excipient supplier and the excipient(s). The information provided by the excipient supplier using Part IV of the EIP is generally expected to provide suitable and sufficient information related to sustainability policies and commitments made by the excipient supplier, thus aiding the excipient users' own commitments to sustainability.

1.2 Purpose and Scope

Part IV of the EIP facilitates the communication of the excipient supplier's information on sustainability policies and related matters with their customers in a standardized way. This avoids suppliers having to complete individual customer questionnaires and allows for a faster response to enquiries about sustainability information.

This guide is intended to provide insight on topics related to sustainability and communication of sustainability initiatives pertaining to excipient **manufacturer**s and suppliers and the products they supply.

When considering the use of this guide, manufacturers and **distributor**s should consider how it may apply to that specific organization's sustainability initiatives and/or products. The diversity of excipients and operations means that some principles of the guide may not be applicable to certain products and processes.

This guide is applicable to excipients used in the manufacture of medicinal products. Information in the guide may also apply to excipients used in veterinary medicines.

1.3 Principles Adopted

This is an international guide. As such, it cannot specify all national legal requirements nor cover in detail the particular characteristics of every excipient.

When considering the use of this guide, manufacturers and distributors should consider how it may apply to that specific organization's product. The diversity of excipients means that some principles of the guide may not be applicable to certain products and processes. The term "should" indicates recommendations that are expected to apply unless shown to be inapplicable or

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replaced by an alternative that provides at least an equivalent level of quality assurance. Note that “should” does not mean “must” or “shall”.

1.4 Format of the EIP Sustainability Section

The content and format of the information is at the discretion of the supplier to decide what and how much information to include. It is recommended that the excipient supplier consider the typical needs of excipient users when determining how much detail to provide for a specific topic. If some topics are not applicable to an organization or their specific product, a particular excipient or site, these should be indicated as such in the document. If the excipient supplier is aware of new expectations that have developed since the last publication of this guide, they should consider adding such information to the appropriate EIP document.

Where information is considered confidential, the document should explain how the excipient user might obtain this information. For example, the document may state that the information may only be obtained under a confidentiality agreement or viewed during a physical audit.

Sustainability information can be communicated in the same style as other sections of the EIP. Short, bulleted formats are encouraged. When referring to personnel, job titles, functions or roles should be used rather than names to minimize the need for updates. The document that is shared with the excipient user should be in a file format that cannot be edited (for instance, pdf).

EIP documents do not require signatures; however, they should be official company documents. Suppliers should review the EIP periodically and consider adding a review date even if no changes have been made.

The following sections describe the type of information that may be relevant to excipient users in the sustainability document.

2 ENVIRONMENT, SOCIAL AND GOVERNANCE INITIATIVES

The United Nations Sustainable development goals [3] sets the background and framework for sustainability expectations around environmental, social and governance issues. The overall goal is to share information on environmental, social, and governance (ESG) topics with excipient users. The scope of the information can cover the excipient manufacturer as a whole or relevant business segments of the company.

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The information can be shared through:

1. **Platforms** such as: Sustainable Agricultural Initiative (SAI) [4], Sedex [5], EcoVadis [6], Together for Sustainability [7].
2. **Certification schemes** such as: International Sustainability & Carbon Certification (ISCC) [8] and REDcert.[9]
3. **Annual company sustainability report(s)**
4. **Customer questionnaires** requiring time-consuming individual communication with each customer.
5. **Excipient Sustainability Information Package** designed to include company-specific responses to a selection of typical core customer questions

Some examples of topics and subtopics usually referred to in ESG documentation are listed below (non-exhaustive list) and information can be based on company policies, actions and/or reports/results.

2.1 Environmental Initiatives

This section provides general information to demonstrate how an excipient manufacturer performs as a steward of nature:

- Greenhouse gas (GHG) emissions reduction
- Water use reduction
- Energy use reduction – "clean" energy use
- Use of harmful chemicals or pollutants reduction
- Transportation impact reduction
- Land impact – if relevant (**contamination**, deforestation, etc.)
- Natural resource conservation
- Animal welfare

Contents to consider, as applicable:

- Company environmental policy, procedures, and practices (including employee training). (if applicable, reference membership with external organization such as EcoVadis, [6]).
- Company commitment to reduce the total greenhouse gas (GHG) emissions.
- Company policy to reduce water consumption or manage conservation.
- Company plans to reduce fossil fuel and gas consumption.

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- Company program for the measurement and improvement of its energy and water consumption as well as emissions into the air etc. If applicable, location for where the company publishes these details.
- Company program(s) to reduce and track performance of topics such as biohazardous waste, radioactive waste, wastewater emissions, chemical and hazardous substances consumption and emissions
- Top management role(s) informed about legal proceedings or regulatory notices involving environmental performance.
- Company evaluation for the potential impacts of activities on biodiversity.
- For product(s) that is (are) derived from animals, company measures taken to ensure that animal welfare is considered and maintained.

2.2 Social Considerations

This section provides general information to demonstrate how an excipient manufacturer manages relationships with employees, suppliers, customers, and the communities where it operates:

- Commitment to human rights
- Modern slavery
- Diversity, equity and inclusion (gender, disability etc.)
- Equal employment opportunity
- Workplace safety
- Fair wages

Content to consider, as applicable:

- Child Labor:
  - Company policy to ensure that no children (as defined by local/relevant legislation) are employed, apart from apprentices, summer jobs, school or education related internships employed which are limited in time.
- Non-Discrimination and Fair Treatment:
  - Company non-discrimination policy for: hiring, compensation, access to training, promotion, termination or retirement based on race, caste, national origin, religion, age, disability, gender, marital status, sexual orientation, union membership or political affiliation.
  - Company policy forbidding any form of verbal, physical or psychological threats, abuse or harassment.

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- Language Barrier:
    - Company contract of employment for direct employed worker(s) and provisions for translation, as applicable, to ensure the contract is in a language that each employee can understand.
- Freedom of Association:
    - Mechanism(s) to allow employees and management to collectively express concerns and issues.
- Wages, Benefits, and Working Hours:
    - Overtime policy showing that overtime is voluntary at the facility or company (except for legally defined situations of urgency or emergencies that require the full workforce)
    - Facility or company guarantee that all wages are at the legal minimum or industry benchmark standards, whichever is higher (excluding overtime wages)
    - Assurance that the minimum salary paid by the company allows the employee to make a living according to local standards
    - Assurance that there are no unjustified reductions made from wages (e.g., for required safety protection equipment, medical expenses, transport, accommodation, meals, training and disciplinary measures).
- Medical Care:
    - Company prevention program provisions (e.g., back therapy training, healthy eating, anti-smoking programs)
    - Company guarantees access to medical care for the employees in case of emergency. Company policy to ensure provisions for sufficiently stocked and maintained first aid boxes in different areas (e.g., manufacturing site, offices, warehouses).
    - Site substance register(s) and provisions for employee hazardous training if materials containing restricted substances (e.g., asbestos, polychlorinated biphenyls (PCBs)) are present on site.
- Ethics Policies & Practices:
    - Company litigation history, including regulatory notices of violation or consent orders with respect to ethics compliance within a defined time period.

2.3 Governance

This section provides general information to demonstrate how an excipient manufacturer deals with a company's leadership, executive pay, audits, internal controls, and shareholder rights.

Content to consider, as applicable:

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- Describe the nature of the legal entity responsible for this information (e.g., private company limited by shares, public limited company, partnership, state owned corporation, subsidiary company, charity, “not for profit” association).
- Company diversity, ethics policies.
- Company public endorsement of:
  - Global Reporting Initiative (GRI) [10]
  - UN Global Compact [3]
  - Together for Sustainability [7]
  - EcoVadis [6]
  - Sedex [5]
  - **Responsible Care** [11]
  - Others (please state which)

  As applicable, provide a copy or link to the public statement for each.
- Company roles and responsibility for sustainability.
- As applicable, link or contact to company sustainability report.
- Company process for communicating their sustainability commitment to employees.
- Communication of and awareness by all employees and contractors of company’s sustainability commitment. As applicable, describe how this is achieved.
- Company sustainability objectives (examples) and targets for the organization.
- Company process showing that the sustainability policy and objectives apply to contractors and 3rd party workers. As applicable, describe how this is achieved.
- Company policy for monitoring for adherence to the sustainability policy, objectives and managing for non-conformances.
- Mechanism for personnel (employees, contractors etc.) to notify top management of incidents and deviations.
- Process for how personnel can make incident reports without fear of retribution.

3 PRODUCT SUSTAINABILITY ATTRIBUTES

Product specific sustainability data may be provided if available and relevant. This may include assessment of product specific footprint information (e.g., GHG emissions) or other attributes as applicable.

Content to consider, for example:

- Product specific Scope 1, 2 and 3 emissions assessment
- Product Life Cycle Assessments

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- Natural and/or nature-based feedstocks
- Environmental impact/biodegradability etc.
- Recyclable/compostable
- Sustainable packaging

4 SOURCING AND SUPPLY INITIATIVES

It is important for all excipient manufacturers to be aware of where their resources come from, how they are made. A supplier's commitment to a Corporate Social Responsibilty (CSR) program should be established where feasible. The intent of this section is to describe what an excipient manufacturer is doing to enable Sustainable Procurement within their supply chain which includes purchased materials, hired services, **component**s/parts suppliers and the governing principles.

The following topics may be covered in line with specific company policies and practices.

4.1 Corporate Responsible Sourcing/Sustainable Procurement Policy

This section provides general information for company's sustainable procurement policy. Metrics and milestones as applicable may be discussed in this section.

Content to consider, as applicable:

- Supplier CSR code of conduct
- Company integration of social and environmental principles into buyers' performance evaluation
- Company policy for on-site audits of suppliers regarding environmental or social issues
- Company policy, as applicable, for accepting third party certification
- Policy for purchasing sustainable resources.
- Company process for assessing suppliers for ethical behavior and reputation risk (include: health, safety, environment (HSC)) prior to selection and engagement.
- Describe company measures taken to control the origin of raw materials (e.g., audit)
- Describe company process for ensuring supply chain transparency
- Company specific training of buyers on social and environmental issues within the supply chain.

4.2 Suppliers/Subcontractors Engagement

This section provides general information for the company procurement and supply chain suppliers/subcontractors environmental issues and labor practices.

Content to consider, as applicable:

- Supplier/subcontractor assessment and approval on environmental or social issues

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- Mechanisms to identify “red flag triggers” (e.g., incomplete responses from suppliers)
- Procedure to disengage with a non-responding supplier (after several attempts)
- Corrective actions to facilitate supplier ability to build on environmental or social issues
- Supplier commitment to sustainability principles

- Company specific training of suppliers on social and environmental issues

4.3 Sourcing of Material

This section provides general information for the company procurement and supply chain sourcing for raw materials.

Content to consider, as applicable:

- Conflict minerals (e.g., gold, tantalum, tungsten, tin):
  - Company policy and statement for excipients related to use of conflict minerals
- Other items to consider:
  - Sourcing of natural feedstocks (e.g., sustainable palm, coconut etc.)
  - Use of pesticides,
  - Impact on biodiversity
  - Deforestation

5 HEALTH AND SAFETY

It is important for excipient manufacturers to consider worker, employee and excipient user health and safety related to excipient manufacture and/or use (exposure). Sustainability includes manufacturer’s establishment and implementation of a good health and safety management system and is closely related to the manufacturing process, chemical and biological properties of excipients and their raw materials.

Contents to consider, as applicable:

- Company (facility) Health & Safety policy, procedures, and practices.
- Number of significant Health & Safety incidents that occurred at the facility over a defined time period.
- Company (facility) policy for providing HSE (Health, Safety & Environment) training to employees (full-time, temporary, or contractor).

5.1 Legal Awareness and Industry Standards

This section includes a description of legal awareness and industry standards as they relate to personnel health and safety.

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Contents to consider, as applicable:

- Company policy and guidelines to comply with applicable laws, regulations and international standards.
- Designated person or structure assuring responsibility or promotion.

5.2 Product Safety (Hazard Information)

This section includes a description of "product safety" and its reference to the physical health and safety of workers, employees and excipient users with regard to final or intermediate products. Safety Data Sheets containing all necessary safety-relevant information should be made available and provided for all hazardous substances to customers and other parties in case of a legitimate need.

Contents to consider, as applicable:

- Company policy/procedure for registering products according to legislation in the countries in which it operates
- Company policy/procedure for maintaining current Safety Data Sheets (SDS) for all hazardous materials used or stored on-site (raw materials, intermediates, products) and making them readily available to employees.
- Company policy/procedure for ensuring proper **labelling** (Globally Harmonized System (GHS) [12] label or Dangerous Goods (DG) [13] labels as legally required) of all hazardous materials/dangerous goods, substances, raw materials, and final products handled.

5.3 Transportation Safety

This section includes a description of how the company complies with applicable dangerous goods regulations and describes related procedures or checklists (e.g., loading / unloading filling and discharging operations). Describe the system to ensure that complete shipping documents are provided containing all necessary dangerous goods information.

5.4 Process Safety

This section includes a description of the company procedures and processes for managing and maintaining all production processes in accordance with the applicable safety standards.

Contents to consider, as applicable:

- Standard operating procedures / safety instructions and (preventive) maintenance programs.
- Company processes for hazardous materials management.

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- Documentation showing how primary and/or secondary containment and safety measures are addressed, as necessary.
- Company policy/procedure for qualified personnel to perform regular systematic safety reviews on processes.

5.5 Occupation Health and Safety (Worker Protection)

This section includes a description and communication of how the company protects personnel from chemical, biological and physical hazards and risks.

Contents to consider, as applicable:

- Company procedures for determining the need for personal protective equipment (PPE) according to the risks identified
- Availability of PPE/safety equipment for personnel as identified (safety showers, eye wash etc.).
- Company policy/procedure to identify and evaluate hazards to human health and key mitigation measures (e.g., hazardous chemicals/labeling, noise etc.)
- Company policy/procedure to ensure availability of personnel occupational health checkups
- Company policy/procedure to ensure proper hygiene practices
- Description of company incident management and reporting system covering, for example, certain types of incidents, reporting lines, consequences and corrective actions required.
    - Evidence that corrective actions are identified and implemented for each incident.

5.6 Emergency Preparedness

This section includes a description of company emergency preparedness and response scenarios and procedures expected for mitigation, responding to and recovering from an emergency. It includes planning, training, conducting drills, testing equipment and coordinating activities.

Contents to consider, as applicable:

- Company procedure and process for handling emergencies (e.g., tornados, floods, spills, releases of hazardous materials).
    - trained emergency response team (on/off-site),
    - facility safety (equipment, personnel etc.) and evacuation procedures as applicable,
    - employee training programs and emergency drills etc.
    - community action plans as applicable

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6 BUSINESS CONTINUITY PLAN (BCP)

The focus of this section is to provide a high-level overview of business continuity and is not intended to document a company's detailed BCP plan/process. Typically, BCP includes strategic and operational structure for a company to supply product and services, without interruption, in the event of an incident or catastrophe. Some elements of business continuity may be described in Supply Chain and Security overview (EIP Part III) [2].

Contents to consider, as applicable:

- Assessment of risks as applicable.
  - Incidents/catastrophes
  - Operational structure (single/multiple locations etc.)
  - Warehousing
  - Site equivalency (when multiple manufacturing locations)
  - Raw material planning
  - Resource plan (human)
  - Communication plan to all stakeholders
  - Business infrastructure (IT system backup etc.)
- Disaster recovery plan if applicable.

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7 REFERENCES

IPEC documents referenced below can be accessed at the following website links:

IPEC-Americas page : https://ipecamericas.org/

IPEC Europe page : https://www.ipec-europe.org/guidelines.html

1. The International Pharmaceutical Excipient Council General Glossary of Terms and Acronyms.
2. The International Pharmaceutical Excipient Council Excipient Information Package User Guide and Template, Version 4, 2020.
3. UN Global Compact - https://www.unglobalcompact.org/
4. Sustainable Agricultural Initiative (SAI) - https://www.nifa.usda.gov/topics/sustainable-agriculture
5. Sedex - https://www.sedex.com/
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11. Responsible Care - https://icca-chem.org/focus/responsible-care/
12. Globally Harmonized System (GHS) label - https://www.osha.gov/hazcom/global
13. Dangerous Goods (DG) label; https://www.icao.int/safety/DangerousGoods.

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