

Pharmaceutical Industry Principles for Responsible Supply Chain Management

This document outlines the Pharmaceutical Industry Principles for Responsible Supply Chain Management (the “Principles”) for ethics, labor, health and safety, environment and related management systems. The Principles may be voluntarily supported by any business in the pharmaceutical industry.

Companies supporting the Principles:

- will integrate and apply these Principles in a manner consistent with their own supplier programs.
- believe that society and business are best served by responsible business behaviors and practices. Fundamental to this belief is the understanding that a business must, at a minimum, operate in full compliance with all applicable laws, rules and regulations.
- are aware of differences in culture and the challenges associated with interpreting and applying these Principles globally. While companies supporting the Principles believe that what is expected is universal, it is understood that the methods for meeting these expectations may be different and must be consistent with the laws, values and cultural expectations of the different societies of the world.
- believe the Principles are best implemented through a continual improvement approach that advances supplier performance over time.

Ethics

Suppliers shall conduct their business in an ethical manner and act with integrity. The ethics elements include:

1. Business Integrity and Fair Competition

All corruption, extortion and embezzlement are prohibited. Suppliers shall not pay or accept bribes or participate in other illegal inducements in business or government relationships. Suppliers shall conduct their business consistent with fair and vigorous competition and in compliance with all applicable anti-trust laws. Suppliers shall employ fair business practices including accurate and truthful advertising.

2. Identification of Concerns

All workers should be encouraged to report concerns or illegal activities in the workplace without threat of reprisal, intimidation or harassment. Suppliers shall investigate and take corrective action if needed.

3. Animal Welfare

Animals shall be treated humanely with pain and stress minimized. Animal testing should be performed after consideration to replace animals, to reduce the numbers of animals used, or to refine procedures to minimize distress. Alternatives should be used wherever these are scientifically valid and acceptable to regulators.

4. Privacy

Suppliers shall safeguard and make only proper use of confidential information to ensure that company, worker, and patient privacy rights are protected.

Labor

Suppliers shall be committed to uphold the human rights of workers and to treat them with dignity and respect. The Labor elements include:

1. Freely Chosen Employment

Suppliers shall not use forced, bonded or indentured labor or involuntary prison labor.

2. Child Labor and Young Workers

Suppliers shall not use child labor. The employment of young workers below the age of 18 shall only occur in non hazardous work and when young workers are above a country's legal age for employment or the age established for completing compulsory education.

3. Non-Discrimination

Suppliers shall provide a workplace free of harassment and discrimination. Discrimination for reasons such as race, color, age, gender, sexual orientation, ethnicity, disability, religion, political affiliation, union membership or marital status is not condoned.

4. Fair Treatment

Suppliers shall provide a workplace free of harsh and inhumane treatment, including any sexual harassment, sexual abuse, corporal punishment, mental or physical coercion or verbal abuse of workers and no threat of any such treatment.

5. Wages, Benefits and Working Hours

Suppliers shall pay workers according to applicable wage laws, including minimum wages, overtime hours and mandated benefits.

Suppliers shall communicate with the worker the basis on which they are being compensated in a timely manner. Suppliers are also expected to communicate with the worker whether overtime is required and the wages to be paid for such overtime.

6. Freedom of Association

Open communication and direct engagement with workers to resolve workplace and compensation issues is encouraged.

Suppliers shall respect the rights of workers, as set forth in local laws, to associate freely, join or not join labor unions, seek representation and join workers' councils. Workers shall be able to communicate openly with management regarding working conditions without threat of reprisal, intimidation or harassment.

Health and Safety

Suppliers shall provide a safe and healthy working environment, including for any company provided living quarters. The Health and Safety elements include:

1. Worker Protection

Suppliers shall protect workers from over exposure to chemical, biological, physical hazards and physically demanding tasks in the work place and in any company provided living quarters.

2. Process Safety

Suppliers shall have programs in place to prevent or mitigate catastrophic releases of chemicals.

3. Emergency Preparedness and Response

Suppliers shall identify and assess emergency situations in the workplace and any company provided living quarters, and to minimize their impact by implementing emergency plans and response procedures.

4. Hazard Information

Safety information relating to hazardous materials - including pharmaceutical compounds and pharmaceutical intermediate materials - shall be available to educate, train, and protect workers from hazards.

Environment

Suppliers shall operate in an environmentally responsible and efficient manner to minimize adverse impacts on the environment. Suppliers are encouraged to conserve natural resources, to avoid the use of hazardous materials where possible and to engage in activities that reuse and recycle. The environmental elements include:

1. Environmental Authorizations

Suppliers shall comply with all applicable environmental regulations. All required environmental permits, licenses, information registrations and restrictions shall be obtained and their operational and reporting requirements followed.

2. Waste and Emissions

Suppliers shall have systems in place to ensure the safe handling, movement, storage, recycling, reuse, or management of waste, air emissions and wastewater discharges. Any waste, wastewater or emissions with the potential to adversely impact human or environmental health shall be appropriately managed, controlled and treated prior to release into the environment.

3. Spills and Releases

Suppliers shall have systems in place to prevent and mitigate accidental spills and releases to the environment.

Management Systems

Suppliers shall use management systems to facilitate continual improvement and compliance with the expectations of these principles. The management system elements include:

1. Commitment and Accountability

Suppliers shall demonstrate commitment to the concepts described in this document by allocating appropriate resources.

2. Legal and Customer Requirements

Suppliers shall identify and comply with applicable laws, regulations, standards and relevant customer requirements.

3. Risk Management

Suppliers shall have mechanisms to determine and manage risks in all areas addressed by this document.

4. Documentation

Suppliers shall maintain documentation necessary to demonstrate conformance with these expectations and compliance with applicable regulations.

5. Training and Competency

Suppliers shall have a training program that achieves an appropriate level of knowledge, skills and abilities in management and workers to address these expectations.

6. Continual Improvement

Suppliers are expected to continually improve by setting performance objectives, executing implementation plans and taking necessary corrective actions for deficiencies identified by internal or external assessments, inspections, and management reviews.