



Pharmaceutical Industry Principles for
Responsible Supply Chain Management

IMPLEMENTATION GUIDANCE



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Introduction

This Implementation Guidance Document (the Guidance Document) conveys the spirit and intent of the Pharmaceutical Industry Principles for Responsible Supply Chain Management (the Principles) by providing a framework for improvement and examples of business practices and performance related the Principles.

The Principles articulate broad descriptions of *what* is expected.

The Guidance Document illustrates some examples of *how* to meet those expectations.

Responsible business behavior throughout the supply chain is important for:

- sound, uninterrupted, competitive and cost-effective global business,
- good working conditions, and
- environmental protection.

This set of guidance supports and further clarifies the Principles in each of the following areas: Management Systems, Ethics, Labor, Health and Safety, and Environmental Protection.

Sample program elements are included in this document for each area. If these program elements, or their *functional equivalents*, are present in supplier practices, they should help to achieve performance expectations, to assist verification strategies and to address potential supply chain concerns of purchasers or of a third party acting on their behalf.

While every effort has been made to ensure that the Guidance Document is helpful, the program elements included here do not represent the *only* way to achieve the intent of the Principles. It is therefore up to each supplier to determine whether the practices or approaches to implementation are adequate.

This Guidance Document is consistent with the commitment to continual performance improvement along the supply chain. Neither the Principles, nor the Guidance Document, establish any new directives, business directions or corporate policies. Rather, taken together, they seek to articulate and promote good business practices and behavior. Moreover, it is not the intent of either the Principles or Guidance Document to replace, or conflict with, any applicable legal or regulatory requirement. Those obligations shall always take precedence.

It is recognized that the present status of supplier programs associated with the Principles may require additional effort. In situations where existing programs do not meet the spirit and intent of the Principles, an adequately resourced action plan can drive and sustain a process of measurable and continual improvement. Each organization will determine its own unique priorities and acting on those priorities will likely result in a phased approach to implementation over time. Elements from this Guidance Document may assist in determining those aspects that are relevant to their organization.

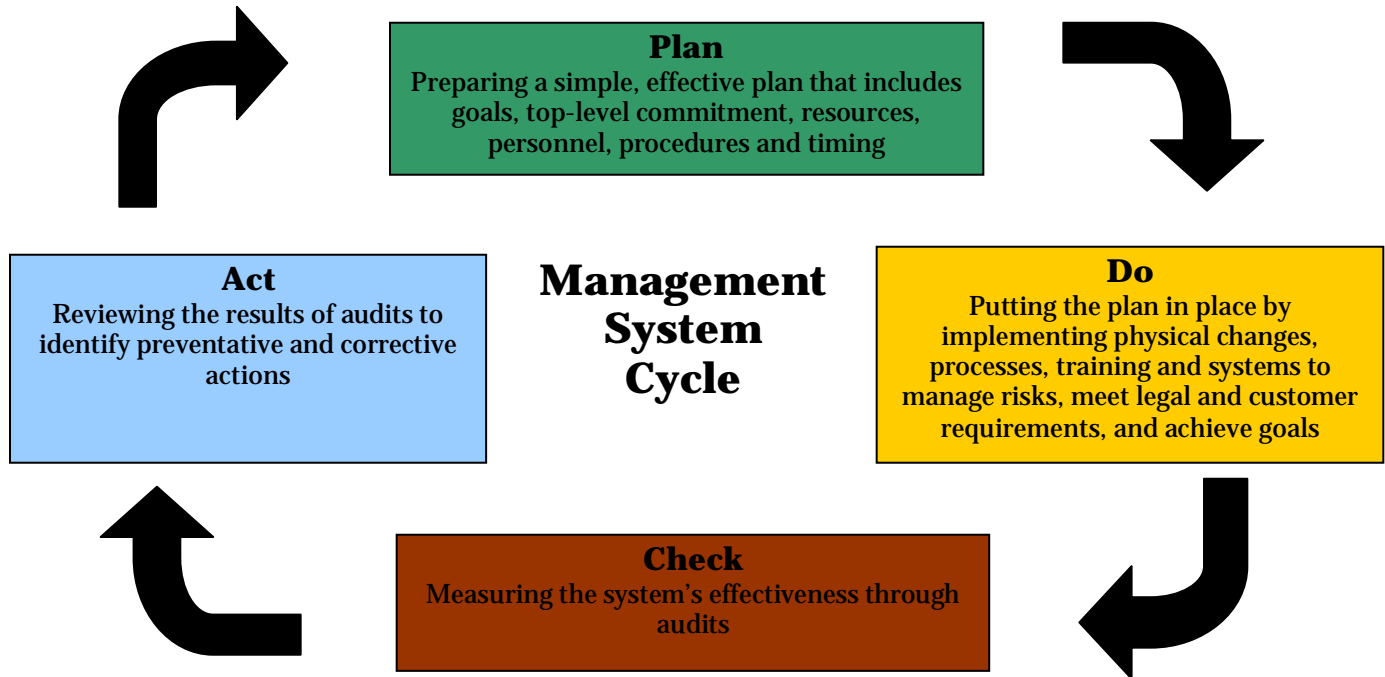
In addition, suppliers can encourage their suppliers to promote the good practices throughout the supply chain.

Questions regarding the Principles or the Guidance Document should be directed to <http://www.pharmaceuticalsupplychain.org>.

Management Systems

Suppliers shall use management systems to facilitate continual improvement and compliance with the expectations of the Principles.

Many businesses have shown that management systems facilitate consistency, reliability and continual improvement at sites that use them. A management system that covers each of the areas of the Principles is essential to making continual improvement. Below is an outline of a basic management system. In addition, this section of the Guidance Document includes examples of management system components that could be part of a management systems approach.



1. Commitment and Accountability

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

Sample Program Elements

- Relevant aspects of the Principles are incorporated into annual business plans
- Accountabilities are known and clearly defined and communicated
- The concepts of the Principles appear in documents and in communications to employees and suppliers
- The Principles, or relevant topics, are the subject of external communications and presentations demonstrating commitment and progress
- Resource allocations and budgets support the work to be accomplished so that the Principles are not compromised to meet business demands
- The organization uses its influence to share the Principles within additional supply chain relationships
- Accountabilities for overseeing conformance to the Principles are clearly incorporated into job descriptions and measures of performance
- Coordinators or networks of key accountable individuals are clearly supported by management to achieve business objectives in a workplace that values the Principles
- Budgets are based on realistic gap analyses, action plans and timelines

2. Legal and Customer Requirements

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

Sample Program Elements

- Relevant legal, customer-driven, local and voluntary performance obligations are identified, interpreted and communicated in such a manner as to be thoroughly understood and acknowledged by those individuals having responsibility for results
- A reliable and up-to-date method exists to identify and track emerging legislation, regulations and laws, and other commitments applicable to the Principles' impact on business operations
- A reliable and up-to-date method exists to keep informed of operating requirements such as permit conditions, specific or individual customer requirements, or community commitments relative to provisions of the Principles
- Compliance deficiencies against internal and external obligations are accurately tracked and resolved through some form of written action plan
- Programs are in place to verify compliance status and progress
- Methods exist to reliably receive, investigate and resolve employee and community complaints or allegations of non-compliance against internal and external obligations and commitments
- Various types of internal and external compliance reporting methods are in place and are relevant to the importance and nature of the obligation to report
- Periodic reports of fines and penalties are reported to employees and key stakeholders for purposes of measuring improvement and progress in the context of regulatory obligations

3. Risk Management

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

Sample Program Elements

- A method exists to identify, assess and prioritize the (a) business, (b) reputation and (c) legal risks associated with each Principle as they relate to both normal and unexpected operating situations (e.g. activist protests, natural disasters, etc.)
- Risk assessments are performed and updated whenever there is a significant change in operations or product design
- Risk assessment processes reflect important customer requirements or practices
- Risk results are grouped in terms of categories of probability and consequences to the organization and to the overall supply chain
- Responsibility for managing the risk assessment processes is clearly documented and communicated
- Appropriate risk assessment results are communicated within the organization and incorporated into business plans and objectives for mitigation
- Adverse consequences are clearly described so that mitigating and preventative actions can be implemented
- Risk assessment results are accurately documented, retained and made available pursuant to record retention and other policies, including auditors and authorized third-party experts
- For the purpose of consistency and subsequent updates, the result of risk assessments are peer-reviewed within the organization among competently trained experts or third party consultants

4. Documentation

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

Sample Program Elements

- The organization maintains documentation on key issues, for example: audit findings; injury & illness logs; worker benefits and pay information; inspections by regulatory agencies; worker complaints; performance assessments.
- Documentation requirements address pertinent aspects of the Principles, Sample Program Elements, and other important obligations or requirements
- Documentation methods are in the form of the most suitable medium, (i.e., paper, electronic), and are accessible on demand for review or updating
- Documentation meets pre-determined and clearly established quality standards in terms of accuracy, verification, and retention
- Record retention policies are sufficient to define organizational ownership, management control and other unforeseeable occurrences
- Systems are in place to ensure that those items requiring authorized signatures and/or special processing are handled appropriately
- Individuals responsible for managing various aspects of documentation and records retention are trained and held accountable through appropriate measures of performance
- Workers have the right to access records relevant to their own responsibilities, while respecting any requirements of confidentiality and data privacy

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.

Sample Program Elements

- Training modules address each area of the Principles and address the intent of expectations for responsible business behavior
- The organization establishes and effectively communicates training requirements to all personnel
- Training programs include appropriate and relevant results of the risk assessment and the potential consequences of departing from specified operating procedures and expectations
- Training is periodically reviewed for improvements in design and delivery, and to incorporate feedback suggestions
- Training program effectiveness is measured through an employee competency assessment
- New and transferring employees receive training as determined by the program requirements
- Employee advancement and succession planning considers the importance of individual and group performance and awareness pursuant to the Principles

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.

Sample Program Elements

- Management demonstrates to employees and others a commitment to continual improvement
- The organization performs periodic assessments of the status and effectiveness of policies, programs and performance relative to each Principle in order to measure progress, and set objectives

- The organization periodically compares its performance and management systems against other similar organizations, either locally or globally, in order to help assess progress
- The organization has developed a formal process for setting goals and performance improvement objectives related to the Principles
- Progress toward goals are reviewed and revised annually as part of ongoing business planning functions
- Performance objectives are relevant to the organization's size, capabilities, and the expectations of customers
- Achievement of performance objectives is linked to incentives and other measures of group and individual performance

Ethics

Suppliers shall conduct their business in an ethical manner and act with integrity.

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.

Sample Program Elements

- A culture and management ethic of zero tolerance to corruption, extortion and embezzlement is understood and accepted within the organization
- The organization has communicated a code of conduct or policy on business ethics that is comprehensive
- Key terms and expressions, such as "gift" are clearly defined and communicated
- Employee commitments to adhere to applicable policies and requirements are documented
- A reliable mechanism or approach is in place to anticipate, identify and resolve policy conflicts that may arise between various laws and regulations and supplier/contractor policies in the course of normal commercial transactions
- Organizations have a formal process to investigate violations of applicable policy
- Violations of applicable policy result in pre-established and clearly communicated disciplinary actions
- Instances of non-compliance are used to fairly and appropriately evaluate the adequacy of policy requirements and of employee understanding

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.

Sample Program Elements

- Management demonstrates commitment to encouraging employees to raise concerns regarding any aspect of business practice
- Consistent with other elements of the Principles, a policy statement or similar communication clearly states the organization's policy and procedures for internal reporting
- Employee training includes use of business-relevant examples of potential ethics violations.
- The organization strives to make it easy for all concerns or suggestions to be raised to the appropriate authorities
- There is a facility-appropriate mechanism that workers trust as a credible and safe way to raise concerns

- Companies have a process to initiate and conduct investigations in accordance with the Principles and other best practices
- The appropriate contacts are clearly identified and accessible to all employees without fear of reprisal or adverse consequence
- There are no adverse consequences for raising sensitive issues or for reporting factual situations concerning suspected violations of policy or law
- Action plans or investigations are initiated in a prompt and ethical manner where appropriate
- Reference is made to relevant results of the organization's risk assessment and potential consequences of non-compliance with company or legal requirements
- Criteria for launching an investigation are clearly defined and communicated as part of the overall program to provide effective communications
- Where feasible, an impartial, third party organization serves as facilitator to receive, consolidate, and follow-up on reported information

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.

Sample Program Elements

- Ethical and humane animal welfare practices are part of the culture of the organization
- Treatment and testing of animals is consistent to applicable international, domestic and voluntary guidelines, which are identified, documented and available to employees
- The use of animals is consistent to predetermined screening criteria that contemplates options to replace, refine and reduce animal testing or research
- Periodic oversight or review by qualified third parties is done to ensure sustained good practices and ethical treatment of animals
- Program deficiencies are corrected in a timely fashion with relevant resources to address the situation
- Accreditation or recognition by third-party organizations such as the Association for Assessment and Accreditation Laboratory Animal Care International is sought and maintained
- Animal testing and research strategies are pursued on a species-specific basis, as appropriate, to meet the spirit and intent of animal welfare management good practices
- Animal welfare practices are adjusted or modified to reflect special treatment or procedures as mandated by customer policies
- A process is in place whereby any conflicts with customer policies or practices are identified and resolved
- Individuals with oversight or day-to-day responsibilities are trained and knowledgeable about applicable requirements and present industry good practices
- Training and eligibility criteria are established, documented and followed pertaining to personnel permitted to be involved with animal welfare and management
- Individuals with animal welfare responsibility are accessible to employees having concerns or complaints
- General questions or concerns of suspected or actual non-compliance with animal welfare policies are encouraged without reprisal among employees
- Concerns and complaints are investigated pursuant to established protocols and procedures
- Violations, fines, audit results, allegations of non-compliance, and similar or related information is accurate, complete and made available upon request by appropriate authorities

4. Privacy

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

Sample Program Elements

- Applicable laws, regulations and policies pertaining to privacy and the safeguarding or exchange of confidential information are identified and understood
- Internal policies and procedures adhere to contemporary good practices and to customer requirements
- Methods are in place to oversee and verify compliance to privacy and confidentiality requirements
- Deviations from policy or requirements are addressed and corrective actions are taken as appropriate
- In all cases, the confidentiality and privacy of information concerning individuals is afforded the highest dignity and priority as part of sound, legal and ethical business practices
- Where policy or regulatory conflicts arise, the organization strives to adhere to the more stringent standard designed to provide the most protection
- Information categories and records to be treated as confidential are clearly defined and understood among the workforce and within the organization
- Individuals responsible for maintaining or managing programs governing the use and disclosure of confidential information are trained in relevant subject areas
- Persons legally entitled to access confidential information concerning themselves are advised of their rights and access is provided

Labor

Suppliers shall be committed to uphold the human rights of workers and to treat them with dignity and respect.

1. Freely Chosen Employment

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

Sample Program Elements

- The organization knows and complies with all applicable laws, regulations and conventions prohibiting the use of forced, bonded and indentured labor, as well as other forms of illegal labor practices that restrict the rights of individuals
- The organization reviews its employment policies and practices periodically with qualified legal professionals specializing in applicable laws, regulations and conventions
- The organization periodically audits or verifies compliance to internal policy and promptly corrects any deficiencies
- The organization has a fair and ethical system of hiring practices that is applied uniformly, whether directly or through a recruiter or other agent
- Hiring and employment policies and practices are managed and administered professionally by individuals who are held accountable for compliance with applicable policies and practices
- Individuals accountable for hiring and recruitment are knowledgeable with respect to applicable policies and practices
- The organization has a consistently applied process for making hiring and termination decisions
- The organization maintains complete and accurate employment records including such information as name, age, wages, job description, benefits, overtime, performance evaluations, etc.
- The organization maintains and discloses, in full, all terms and conditions of employment prior to recruitment and hiring
- Terms and conditions are communicated in a language familiar to prospective employees
- The organization ensures that hiring contractors adhere to the organization's policy on freely chosen employment

- The organization does not restrict or hamper in any manner an individual's right to terminate employment at will pursuant to applicable employment agreements
- The organization's contracts include no terms or penalties of any type that retain employees against their will
- The organization does not require fees or other obligations as a pre-condition of employment
- The organization provides access to basic sanitary and hygienic needs, such as drinking water and properly maintained bathroom facilities
- In situations where employee or family housing is provided, employees are free to move about including access to hygienic and sanitary facilities while not working

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.

Sample Program Elements

- Administrative systems are in place to verify, without exception, the age of employees through nationally or internationally recognized identity documentation (birth certificates, passports, etc.).
- The organization is knowledgeable and remains up-to-date on applicable laws, regulations and conventions designed to protect children and young workers from economic exploitation
- The organization defines and clearly communicates to management the age categories considered to be child and juvenile labor pursuant to applicable requirements and policy
- The organization's written hiring and employment policy specifies and posts minimum age requirements
- Periodic audits are conducted to ensure full compliance with child labor requirements and corrective action is documented and immediately implemented to rectify non-conformance
- The organization is familiar with customer policies and criteria to the extent that they impact or influence child labor practices
- The organization influences other business partners to meet similar child and young worker criteria
- In assigning work to young workers the organization avoids all forms of hazardous work and takes into account the developmental capabilities and limitations of the individual so as to put the best interests of the individual before such things as production quotas and other financially-driven criteria
- Special attention is directed through accountable individuals toward providing a safe work environment for young workers as defined by the International Labor Organization
- The organization ensures that no young worker is employed, or works, in violation of applicable compulsory schooling requirements
- Young workers work only the total number of hours permissible per week and are not assigned to overtime tasks or responsibilities

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.

Sample Program Elements

- The organization has written policies and programs to establish and maintain a diverse workplace environment and culture that is free of discrimination
- The application, implementation and enforcement of all policies, guidelines, procedures and other management tools are uniform and without discrimination
- Non-discrimination policies and programs exist and apply to all employees, regardless of job, management status or responsibility

- Decisions and actions affecting an individual's status are made solely on the basis of factors such as ability, merit and performance, and this written policy is periodically communicated to all employees within the organization
- The organization established and maintains an internal reporting mechanism through which matters of potential discrimination can be brought to the attention of accountable individuals in a confidential manner without fear of retribution
- Workers believe the system to investigate and follow-up on worker complaints and allegations involving potential discriminatory actions is fair and unbiased
- The organization provides diversity awareness training and coaching to all employees, with emphasis on those with management responsibilities
- Individuals with responsibility for maintaining a discrimination-free workplace are clearly identified and accessible to all employees
- The organization takes pre-determined and well-communicated disciplinary actions, as necessary, in response to breaches of policy compliance in an effort to demonstrate a culture of commitment and zero tolerance
- Individuals acting on behalf of, or at the request of, the organization, such as recruiters or consultants, recognize and support efforts to ensure a diverse and discrimination-free workplace
- Workers are not subject to testing or evaluation based on their reproductive status, such as pregnancy, or health status, as a condition of employment
- Differences in salary and other compensation benefits among employees, such as vacation or paid leave, are not used as a means of discrimination

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.

Sample Program Elements

- The organization ensures through various policies, programs and oversight that the rights and dignity of each individual within the workforce are preserved and respected at all times
- Individuals designated as responsible for ensuring fair treatment are knowledgeable of applicable laws, regulations and conventions
- The organization effectively communicates pertinent fair treatment policies to all employees
- A reporting mechanism is in place and accessible to all employees for the purpose of reporting complaints or potential infractions of policy
- Complaints are taken seriously and followed with an unbiased and accurate investigation, as warranted by specific circumstances
- In order to help build a culture of fair treatment, the organization strives to use behavioral incentives rather than discipline whenever possible
- The organization has communicated to employees a predetermined hierarchy of disciplinary actions associated with non-compliance or non-performance with known policy and performance expectations
- A system exists so that employees are counseled, warned, demoted or dismissed only for a cause of action of which they are aware
- Employees have the right to know and respond in advance of any actual or pending allegations that could result in adverse action taken by the organization
- The organization has a method to ensure that disciplinary actions, when necessary, are consistent with the seriousness of the incident and that all disciplinary measures imposed are consistently and fairly applied
- Wages, compensation and other earned benefits are not withheld or garnished as a means of disciplinary action

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.

Sample Program Elements

- The organization periodically reviews wage and payroll policies and procedures against legal requirements and industry practices
- Management has a method to determine and ensure that the average workforce is adequate in size, skill and resources to perform routine obligations without the steady use of overtime
- The organization has designated individuals with accountability for wage and compensation management
- Accountable individuals are knowledgeable in applicable wage and labor laws, regulations and conventions
- Systems are in place to accurately track hours worked for non-salaried employees and to identify potentially irregular and unusual work patterns, including excessive overtime
- Compensation systems ensure that employees are paid promptly and on a regular basis in a manner that is direct, convenient and which does not rely on such instruments as coupons, promissory notes or other forms of transfer
- The organization ensures that each employee receives an accurate payroll receipt with each payment and that each payment is accurately recorded in payroll logs that are subject to audit and verification
- The organization ensures that benefits are not used in place of earned wages
- Compensation incentive programs are documented and applied uniformly based on merit and performance
- Minimum wage requirements and working hour limitations are either posted, communicated or freely made available to employees upon request
- Overtime wage records are to be kept for each non-salaried employee for a period consistent with the organization's record retention program
- Work hour logs are periodically reviewed against accident and injury statistics to identify potential fatigue-related trends and other sources of injury
- The organization clearly distinguishes and communicates to each employee a breakdown of compensation components consisting of straight wages, overtime wages and other benefits
- Multiple systems exist to help detect the abuse or over-reliance on overtime
- Employees can determine which, if any, deductions are to be withheld for optional benefits such as meals and transportation

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.

Sample Program Elements

- Written policies and procedures addressing freedom of association recognize local, national and international law and conventions
- Where local laws and regulations conflict with generally accepted international practices the organization strives to seek a constructive and mutually agreeable resolution among the affected parties

- Specific measures are taken to create a culture of open, two-way communication among workers and management
- Mechanisms exist through which employees and management may collectively express concerns and issues in an effort to maintain cooperative and productive working relations
- Accountable individuals responsible for labor relations are identified and accessible to all employees or their representatives
- In an effort to ensure open communications, training programs are established and implemented to raise the general awareness of management and employee labor rights and responsibilities within the organization
- Standing committees and regularly scheduled interaction between management and workers occur in an open, fair and constructive manner
- Internal grievance procedures and follow-up actions are available to all employees without threat of retribution
- There is no prohibition or interference with employee rights to collective bargaining and employees are not penalized or threatened with retribution over differences of opinion or needs
- The organization does not misrepresent to employees their legal rights to associate freely or to seek improved working conditions and wages
- The organization does not threaten, discipline, penalize or coerce workers who exercise their individual rights or seek to organize other workers, nor refuse to hire workers based on past freedom of association activities with another employer

Health and Safety

Suppliers shall provide a safe and healthy working environment, including for any company provided living quarters.

A safe and healthy working environment for all workers and visitors is supported by a management systems approach. The following program areas are part of health and safety management:

Health & Safety

Management Systems Elements

1. Worker Protection

2. Process Safety

3. Emergency Preparedness and Response

4. Hazard Information

Key Topical Areas

Asbestos	Blood-borne Pathogens	Canteen	Child-care Management	Confined Spaces	Contractor Safety	Dormitory	Drinking Water	Electrical Safety	Emergency Action	Ergonomics	Fall Protection	Fire Safety Mgmt	General Work Environment	Injury/Illness System Mgmt	Heat Stress	Hazardous Energy	Maintenance Safety	Machine Guarding	Medical Services & First Aid	Non-ionizing/Radio Frequency	Occupational Exposure Limits	Occupational Health Management	Occupational Noise	Personal Protective Equipment (PPE) –	PPE – Respirators	Powered Motor Vehicles	Sanitation
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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.

Sample Program Elements

- The organization is knowledgeable and understands applicable laws, regulations, conventions and industry norms and practices
- The organization has policies and systems to effectively recognize, evaluate and control hazards in the workplace, as well as in company-provided transportation and living facilities such as buses and dormitories
- The organization fosters a culture that recognizes and values worker protection over all competing pressures and business obligations and demonstrates such commitment through health and safety performance goals and other means of tracking preventative measures
- Programs exist to ensure that equipment and installations comply with applicable codes and industry practices, including those for electrical safety, heating, ventilation and temperature control, equipment guarding and other areas, as warranted
- The organization establishes and maintains clean and orderly housekeeping practices, including safe lighting, aisles, passages and exits that are free from obstruction, easily accessible fire safety stations, sanitary hygienic facilities and eating and food preparation areas
- Exposure to physical, biological and chemical hazards adheres to applicable laws, regulations and conventions, as well as industry good practices
- The same standards of protection apply to all employees at all times while in company-provided, owned or managed facilities
- Worker protection programs include such disciplines as health, safety, industrial hygiene, ergonomics, occupational medicine and other related specialty areas
- Programs designed to protect workers are designed to address routine, as well as non-routine situations, potential hazards and exposures
- Systematic approaches to managing worker protection strive to implement a hierarchy of preferred engineering controls, administrative controls and, lastly, personal protective equipment where alternate measures are not practical or feasible
- Operations deemed to be potentially hazardous to employees are automated wherever feasible
- New equipment and process changes undergo complete safety and health reviews and assessments
- prior to start-up, the outcome of which is reviewed and approved by the appropriate accountable individuals
- Worker protection is under the direction of clearly identified and accountable individuals possessing the appropriate technical and managerial skills, training and knowledge
- Manufacturing or production goals are not set so high as to sacrifice the safety and health of the workforce
- Accident and injury statistics adhere to industry standards and are reviewed periodically by those accountable individuals qualified to understand and interpret results, and who have the authority to recommend and implement corrective actions, as necessary
- All forms and types of worker protection records are accurate and complete, and maintained in a manner that is retrievable for purposes of review or verification
- All forms of worker protection records are retained pursuant to applicable record retention policies
- Workers are encouraged by management to report incidents and concerns without fear of retribution and have access to appropriate accountable individuals and confidential internal reporting systems
- The organization recognizes, respects, and frequently solicits worker input and recommendations pertaining to real or potential hazards and innovative or practical solutions
- The organization supports joint worker and management committees for the purpose of fostering a culture and commitment to worker protection
- The organization has established and provided to employees pre-determined criteria for initiating an accident or injury investigation by qualified experts
- In situations where employees are subject to exposure monitoring of any type, the appropriate initial baseline data is collected and retained for purposes of comparative evaluation
- In the absence of sufficient information applicable to a particular situation the organization adopts the most protective approach practical
- The organization specifies through effective communications, including signs and training programs, the proper use and application of personal protective equipment

- The proper personal protective equipment is provided by the organization to those requiring such equipment
- Programs are in place to periodically ensure that all personal protective equipment is used properly and maintained in good working condition
- Women of child-bearing age are counseled in reproductive protection related to known occupational risks and exposures, and are not required to engage in work that is hazardous to themselves or to potential offspring

2. Process Safety

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

Sample Program Elements

- The organization has systems in place to ensure compliance with all applicable laws, regulations and industry good practices
- Process safety is treated as a priority, particularly where the potential for adverse consequences is known to exist
- Process safety reviews are conducted on a periodic basis and findings addressed prior to the start-up of new or modified processes
- The organization establishes and implements a comprehensive test and inspection program to be carried out and managed by competent professionals
- Process reviews are not limited to evaluating disruptions originating from within a particular process, and considers such external factors as natural disasters, terrorism and acts of sabotage
- Factors contributing to, and resulting from, change management are incorporated into process safety programs and awareness
- Process safety programs comply with customer specifications, as appropriate
- The organization conducts a periodic review of critical process safety functions, resources and staffing needs
- The organization has competent, technical professionals for the purpose of understanding and mitigating the potential risks inherent in the design and operation of all processes
- The accountability for ensuring process safety rests with technically qualified individuals having the authority and resources to effect process and design changes, as warranted
- Under the leadership of technically competent professionals, the organization develops scenarios that consider, and then adequately address, foreseeable occurrences that are independent of probability or likelihood
- The organization works with local authorities and community representatives on pertinent aspects of process safety and emergency preparedness
- The organization implements a series of checks and balances in administrative procedures and authorizations such that all process safety related matters receive proper review and approval prior to initiating changes or modifications
- Systems exist to ensure that all production and storage areas and containment vessels have the necessary design safeguards, such as fire detection and prevention systems, spill containment barriers, ignition source prevention, inert blanketing, etc.
- Systems exist to ensure that all materials are stored or housed in suitable containers according to inherent hazard characteristics, and that all materials are properly and clearly identified
- Programs exist to ensure the proper segregation and separate storage and handling of incompatible materials at all times
- Containment vessels, reactors and other process equipment are equipped with proper safety devices, such as pressure relief valves, flame arrestors, static discharge systems, etc.
- Instrumentation, detectors and other process safety sensing equipment are properly placed, maintained, calibrated and distributed so as to perform as intended in monitoring operations

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.

Sample Program Elements

- The organization is knowledgeable of applicable laws and regulations addressing emergency preparedness and response, as well as all pertinent reporting requirements
- The organization prepares and maintains emergency preparedness and response plans under the authority and oversight of competent and trained professionals
- Emergency preparedness and response plans address a range of scenarios that include disruptions caused by natural disasters, process safety incidents, spills, explosions, fires and releases, as well as civil unrest, sabotage, terrorism and other causes
- Emergency scenarios consider the potential impact or disruption to nearby schools, hospitals, communities and water supplies, etc., and incorporate prevailing meteorological conditions and other site-specific factors in different areas surrounding the site
- The organization has systems in place to ensure that all employees are familiar with emergency procedures and what to do in the event they are activated
- Emergency preparedness and response plan equipment and resources are in an ever-ready state of preparedness consistent with the scale of the response
- The organization designates program and capability oversight to a team of accountable individuals such that emergency preparedness and response leadership expertise and representation is always on duty and accessible
- Partial and full-scale drills are conducted and evaluated on a periodic basis with the cooperation and assistance of local authorities and community representatives, as appropriate, to ensure clear lines of responsibility and a coordinated effort
- The organization has pre-arranged such emergency support functions as medical personnel, employee counseling services, immediate fund transfers to expedite relief, temporary living and sanitary accommodations, food and water, hazardous waste disposal procedures and other necessary services and support
- Evacuation route plans and sequences are mapped in advance, tested and communicated to all personnel responsible for coordinating logistics
- All emergency exits and means of egress remain unobstructed at all times
- Fire suppression systems are tested and maintained regularly
- Systems exist to ensure that contact information distributed among first responders, emergency personnel and other key professionals is frequently verified and kept up to date
- Emergency preparedness and response plans contain complete hazard information for materials used or stored on site and are provided to local medical and emergency response authorities periodically
- The organization develops reliable secondary notification and communications strategies and capabilities in the event that normal communication channels are not available
- The emergency preparedness and response plan anticipates and addresses incidents and consequences of events originating at nearby facilities
- The emergency preparedness and response plan includes guidelines for immediate communications with the media, governmental authorities and the families of those who might be affected
- All emergency preparedness and response events are followed by a complete and accurate investigation to determine the root cause of the incident

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.

Sample Program Elements

- The organization maintains, at minimum, health and safety information in the form of a Material Safety Data Sheet, or equivalent, for each material used or stored on site
- Hazard information is readily accessible to employees and those with a legitimate need, such as customers, the local community and emergency response personnel
- When complete hazard information is not available for a particular material the supplier submits a written request to the manufacturer for such information and follow-up as necessary
- In the absence of local or national exposure standards for a particular material, the organization uses the most protective standards recognized as good industry practices elsewhere
- Hazard communication information is written or delivered in a language that is understood by employees
- Hazard rankings and ratings are consistent with those recognized by international laws and conventions and are updated as needed
- The organization ensures that employees are aware of and understand the hazardous nature of any materials with which they may work, as well as the need for any protective measures or equipment to prevent or minimize exposure
- Individuals with accountability for managing hazard information are professionally qualified and accessible to employees and others with a legitimate need for information
- Employees receive training on the appropriate use, storage, handling and disposal of hazardous materials with which they work
- New or transferring employees receive an orientation overview of general hazardous material handling and emergency procedures regardless of their particular function or responsibility
- The organization maintains written records, including employee confirmation of training participation, and it reviews such records periodically to ensure that training objectives have been met

Environment

Suppliers shall operate in an environmentally responsible and efficient manner and they shall 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.

Environmental management systems protect the health of workers, communities and the integrity of ecosystems. The following program areas are part of environmental management:

Environment							
Management Systems Elements							
1. Environmental Authorizations		2. Waste and Emissions			3. Spills and Releases		
Key Topical Areas							
Above-ground Storage Tanks	Air Emissions	Hazardous Materials	Hazardous Waste	Poly-chlorinated Biphenyls (PCB's)	Wastewater	Solid Waste	Under-ground Storage Tanks

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.

Sample Program Elements

- The organization has internal policies and procedures for managing environmental issues that at a minimum comply with all relevant laws, regulations and authorizations
- Appropriate management is knowledgeable and maintains up-to-date copies of all applicable environmental laws, regulations and local requirements
- Systems are in place to manage environmental performance and obligations that are consistent with recognized international norms, standards and industry practices
- The organization designates and holds accountable for program management a team of competent environmental professionals
- The organization ensures that environmental management obligations are adequately staffed and resourced
- In situations where activities are not subject to environmental requirements such as permit conditions, the organization will proactively understand and control environmental impacts and protect natural resources
- The organization ensures that all environmental requirements are kept up-to-date, filed in a timely manner, and that adequate lead time is allocated for pending renewals or necessary modifications and amendments
- Environmental requirements are accurate, complete, and bear the signatures, where appropriate, of the proper individuals
- Environmental requirements are effectively communicated to affected employees for the purpose of establishing and maintaining the proper operating conditions and for ensuring full compliance
- Environmental requirements are periodically audited for compliance and deficiencies are properly addressed
- Environmental requirements are subject to established record retention policies, procedures or requirements
- Systems exist to detect and report to the proper internal and external authorities any required routine reports, violations or exceptions to environmental requirements
- The organization maintains a system through which employees may report potential violations or concerns without fear of retribution
- The organization maintains a local inventory of material consumption and discharges that have the potential to impact the environment

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.

Sample Program Elements

- Appropriate management in the organization is knowledgeable about all applicable laws, regulations and industry practices relating to the management of waste and emissions
- Waste and emissions are managed according to a prioritized waste management and pollution prevention plan that seeks to reduce, recycle and treat waste material and effluent
- Systems exist to ensure that all pollution prevention and control equipment is operating properly and maintained as appropriate
- Appropriate management in the organization is knowledgeable about the impact of emissions on the surrounding environment and community, and takes steps to minimize such impacts

- The organization designates competent, trained and accountable individuals for the purpose of managing and overseeing the management of all waste and emissions pursuant to all applicable requirements and good practices
- The organization allocates the necessary human and financial resources to ensure the continuous and effective management of all waste and emissions
- The organization ensures that waste materials are segregated, stored and labeled in an orderly fashion and that secondary containment provisions are in place as required
- The organization establishes criteria for the approved use of waste management contractors and is familiar with the ultimate disposition of shipped waste materials
- Waste and effluent movement on- and off-site is accurately documented and manifested as required
- The organization tracks and reviews all fines and penalties in an effort to continuously improve performance
- Personal protective equipment is provided to employees where exposure to waste or emissions is determined to be potentially hazardous and no other means of protection are feasible
- Administrative systems exist to ensure that adequate training is provided and that such training meets all applicable requirements or good practice standards

3. Spills and Releases

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

Sample Program Elements

- The organization supports a culture that seeks to prevent unplanned spills, releases and other discharges to the environment
- Accidental release scenarios are used as the basis for contingency planning and countermeasure preparedness
- Spill and release contingency plans are integral to the organization's emergency preparedness and response plans
- Spill and release mitigation measures are integral to the organization's waste management plan and procedures
- Accountable individuals ensure on an on-going basis that all materials are identified, labeled and stored in appropriate containers, vessels, and locations and that such storage remains below lawful or predetermined on-site holding times, as applicable
- The organization determines and communicates threshold criteria to employees that describe when an unplanned release constitutes an emergency, as pre-defined by the organization
- Systems exist to provide emergency personal protective equipment and exposure monitoring equipment to first responders and to rapidly determine the quantity of material discharged
- Emergency containment equipment is maintained at strategically accessible locations and is appropriate for likely scenarios
- Storage and production areas are designed, where practical, to provide secondary containment in the event of an unplanned release
- Events leading to an unplanned release and which meet predetermined threshold criteria are followed by a root-cause analysis and recommendations to prevent subsequent releases

References

The Principles and the Guidance Document draw from the following reference materials and standards:

- Ethical Trading Initiative
- EU EMAS
- ILO Code of Practice in Safety and Health
- ILO International Labor Standards
- ISO 14001
- OECD Guidelines for Multinational Enterprises
- OHSAS 18001
- Responsible Care®
- SA 8000
- United Nations Convention Against Corruption
- United Nations Global Compact
- Universal Declaration of Human Rights