Supplier Quality Standard

1.0 Purpose

The purpose of this Supplier Quality Standard is to communicate the expectations and requirements of Akorn Pharmaceuticals to its suppliers.

These expectations are based on Akorn's philosophy of defect prevention and continuous improvement by developing quality into products and services rather than defect detection after they are produced.

The requirements within this standard are provided as a supplement to, and do not replace or alter the terms or conditions within Akorn's Purchase Orders, Quality Agreements, specifications and/or any agreement between Akorn and the supplier.

In this standard, sentences containing "shall" are regulatory requirements; sentences in *italics or containing "should"* are provided for guidance only.

2.0 Applicability

This standard applies to Akorn suppliers who provide:

- Contract Manufactured Finished Goods, i.e., any finished good, both those that carry the Akorn trademark, as well as distributed product
- Active Pharmaceutical Ingredients
- Excipients
- Materials/Parts (Packaging, Processing, Testing, Controlled Cleanroom Sterile)
- Printed Materials
- Services, which can impact product quality
- Contract Design and Development

3.0 Associated Documents

3.1 Reference

ISO 9001	:	Quality Management Systems – Requirements
ISO/TR10017	:	Guidance On Statistical Techniques For ISO 9001
ISO 13485	:	Medical Devices – Quality Management Systems – Requirements For Regulatory Purposes
ISO 14971	:	Medical Devices – Application Of Risk Management To Medical Devices
ISO 14001	:	Environmental Management Standard
ISO 17025	:	General Requirements for the Competence of Testing and Calibration Laboratories
ICH Q7	:	Good Manufacturing Practice Guide For Active Pharmaceutical Ingredients
ICH 8	:	Pharmaceutical Development
ICH 9	:	Quality Risk Management
ICH 10	:	Pharmaceutical Quality Systems Handbook
EudraLex Volume 1	:	Pharmaceutical Legislation Medicinal Products for Human Use
EudraLex Volume 2	:	Pharmaceutical Legislation Notice To Applicants And Regulatory Guidelines Medicinal Products For Human Use
EudraLex Volume 4	:	Good Manufacturing Practice (GMP) Guidelines
EUCD (MDD 93/42)	:	European Union Commission Directive –Medical Device Directive (MDD)
FDA 21 CFR Part 58	:	Title 21 Food and Drugs, Subchapter A General, Part 58 Good Laboratory Practice for Nonclinical Laboratory Studies

FDA 21 CFR Part 820	:	Title 21 Food and Drugs, Subchapter H Medical Devices, Part 820 Quality System Regulation
FDA 21 CFR Parts 210 & 211	:	Title 21 Food and Drugs, Subchapter C Drugs: General, Parts 210 & 211 cGMP in Manufacturing, Processing, Packaging, or Holding of Drugs and Finished Pharmaceuticals
FDA 21 CFR 110	:	Title 21 Food and Drugs, Subchapter B Food for Human Consumption, Part 110 Current Good Manufacturing Practice in Manufacturing, Packaging, or Holding Human Food
FDA 21 CFR 111	:	Title 21 Food and Drugs, Subchapter B Food for Human Consumption, Part 111 Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements
FDA 21 CFR Part 610	:	Title 21 Food and Drugs, General Biological Product Standards Health
FDA-2015-D-0198	:	Current Good Manufacturing Practice Requirements for Combination Products
FDA-2018-D-3894	:	FDA Data Integrity and Compliance With Drug cGMP Questions and Answers Guidance for Industry
Health Canada	:	Canadian Medical Device Regulations (CMDR)
Health Canada	:	Canada Good Manufacturing Practices (GMP) Guidelines
IPEC–PQC GMP	:	The Joint IPEC-PQC Good Manufacturing Practices Guide for Pharmaceutical Excipients
PIC/s	:	Guide to Good Manufacturing Practices for Medicinal Products

4.0 Definitions

Definitions are available in Appendix I of this standard.

5.0 Responsibility and Authority

It is the responsibility of the supplier to understand and ensure compliance with this standard and Akorn's, specifications and applicable service, supply and/or Quality agreements.

Global Quality Compliance personnel within Akorn are responsible for maintaining this standard and establishing, maintaining and evaluating approved suppliers.

6.0 Introduction

This standard emphasizes:

- The importance of establishing defined and mutually agreed upon requirements.
- The expectation that suppliers develop and maintain a comprehensive quality system that ensures Akorn receives product and services that conform to requirements.
- A continual focus on improvement in quality, cost, and innovation, including sustainability, to mutually benefit the supplier and Akorn.
- Manufacturing in accordance with appropriate current Good Manufacturing Practices (cGMP).

6.1 Supplier Expectations

Akorn's suppliers shall develop and maintain a management system to assure consistent conformance of their products and services to specified requirements.

Note: A quality system that demonstrates conformity to ISO 9001 establishes a base from which a supplier can focus on quality and continually strive to improve. Although not required by Akorn, suppliers are encouraged to have their conformance confirmed by an independent audit (such as 3rd party certification).

6.2 Suppliers are fully responsible for the quality of their products.

Suppliers shall ensure that each of their products or services comply with all the requirements mutually agreed to with Akorn as well as all applicable requirements defined by regulatory agencies (such as FDA, Health Canada and the European Union). Suppliers are accountable for and assume full responsibility for the quality of the products or services they provide. Approval and verification, by Akorn, of supplier's facilities, systems, and records does not absolve the supplier of the responsibility to provide acceptable product.

6.3 Suppliers are fully responsible for their supply chain.

Akorn's suppliers are responsible for the quality and material compliance related activities of their suppliers, subcontractors, service providers, and/or material sources. Suppliers shall document and verify that their suppliers' facilities, procedures, materials, and controls meet or exceed the agreed to requirements. Akorn should request supporting data of these evaluations. Akorn shall rely on its suppliers to maintain control of their supply bases, but reserves the right to audit or evaluate these sources to ensure supply chain safety and/or understand other potential impacts to Akorn.

7.0 Quality System Requirements

Akorn's suppliers shall have a defined quality system. *This section specifies the requirements of a comprehensive quality system that is important to ensure Akorn receives products and services that conform to requirements.*

7.1 Quality Manual, Policy and Objectives

The supplier shall document its quality system. *This should include a stated quality policy and quality manual.*

Note: A quality manual defines the structure of their quality system, by defining the scope of the quality system, by describing how processes of the quality system interact and by referencing documented procedures used to implement the quality system.

The quality policy defines a supplier's intent and direction with respect to Quality and serves as a general framework for action.

Measurable quality objectives shall be established. The supplier's quality objectives shall be measurable and consistent with the quality policy. Once quality objectives are established for relevant functions and levels of the supplier's organization they shall be monitored by the supplier to ensure an effective quality system and customer focus.

The supplier shall identify its necessary procedures and records that ensure effective operation and control of its processes.

7.2 Control of Documents

The supplier shall identify essential documents relating or pertinent to the quality system and control such documents. The supplier's document control methods shall ensure that only approved, issued, and effective documents are utilized.

Documents shall be legible and identifiable. With respect to documents which become obsolete but are retained, the supplier shall have a method of identification of such documents as obsolete and segregation of such documents to prevent accidental use.

The supplier shall comply with established data integrity guidance. Each supplier should have a stated data integrity policy, and address data governance via written procedures.

7.3 Control of Records

The supplier shall maintain legible, readily identifiable and retrievable records as evidence its products meet Akorn's requirements. *Examples of records a supplier should retain, to demonstrate its conformance to requirements, include test results, equipment verification records and calibration records.*

The supplier shall define how it identifies, stores, protects, retains and disposes of its records.

Note: *A supplier should determine its record retention period to be equivalent to the lifetime of the product, as defined by the supplier unless Akorn defines the record retention duration per the Quality Agreement.*

Note: The supplier should use Good Documentation Practices (GDP) when creating and maintaining records to ensure clear, complete and accurate information is recorded. Akorn recommends that the supplier have rules that describe GDP when approving, making handwritten entries on, copying, and/or modifying documents. Some GDP examples are avoiding the use of white out to make corrections, avoiding the use of pencil, ensuring records are dated correctly at the time created, recording the appropriate approvals, and ensuring personnel don't review and approve their own work.

7.4 Management Responsibility

The supplier shall ensure that responsibilities and authorities are defined, documented, and communicated within its organization. The supplier shall maintain the appropriate resources for an effective quality system.

7.5 Management Review

The supplier shall regularly review its quality system to ensure the ongoing suitability, adequacy and effectiveness of the quality system.

Note: A review of the quality system should include written documentation of audit results, customer feedback, process monitoring results, and product performance. After the review opportunities for improvement should be considered.

The supplier shall maintain records of its decisions or actions from the review in accordance with Section 7.3.

7.6 Design and Development Control

The supplier shall use specified requirements, specifications and drawings as the basis for its design and development plan.

Note: The plan, sometimes called a Quality Plan, defines the design stages with necessary steps and resources to assure the product satisfies Akorn's requirements. The plan should be maintained throughout the design process and should incorporate design reviews, verification and validation plans, monitoring activities, inspection criteria or test requirements.

The supplier's design verification shall be planned and recorded to confirm the supplier's design meets requirements.

The supplier's design validation activities shall be planned and recorded to confirm the product meets the user requirements and is fit for use.

The supplier shall use its design outputs to establish a controlled operation at its manufacturing, test or inspection location.

Note: *Design outputs are engineering drawings and specifications of the design, critical process parameters (CPP), critical to quality (CTQ) and product acceptance criteria.*

Akorn's suppliers shall implement a change process that ensures any effects on the product are understood. The supplier's change process shall include necessary reviews, verification of change and validation of the product before the change is implemented in accordance with Section 8.0.

7.7 Purchasing Controls

Akorn's suppliers shall define requirements and establish a supplier selection process that ensures that their suppliers have the potential and ability to meet specified requirements.

The supplier is responsible for the quality of all components and raw materials, and any GMP-impacting services, it purchases for its product. Where components and raw materials do not meet specified requirements, then the supplier shall document its mitigation activity. *If necessary, the supplier is responsible for additional controls to ensure its product satisfies requirements.*

When the supplier implements inspection or other activities to ensure that purchased product meets requirements then these methods and results shall be documented. Records shall be maintained in accordance with Section 7.3 and made available to Akorn upon request.

7.8 Production Provisions

The supplier shall document and control its production conditions to ensure its product meets specified requirements.

Note: This may require the supplier to make use of documented procedures, work instructions, reference materials, suitable equipment and specific monitoring and measurement devices where the absence of such could affect quality.

The supplier's controls shall be established using the appropriate design outputs and available at the manufacturing, test, or inspection location.

Note: This should include current engineering drawings and specifications, critical process parameters (CPP), critical to quality (CTQ) and product acceptance criteria.

The supplier shall protect product, equipment, and personnel against potential contamination.

Note: The supplier should document cleanliness requirements, monitor conditions or make special arrangements to protect product quality and health of personnel.

When a sterilization process is necessary, the supplier shall record its process parameters and maintain traceability for each production batch.

Akorn's suppliers shall employ process controls, which are consistent and appropriate for the operations being conducted. Where the operation may result in product not meeting specifications Akorn's suppliers shall implement documented mitigation activities, such as enhanced control plan, verification and inspection, or process control parameters.

Note: Process control is a system for ensuring that product consistently falls within predefined process parameters (limits).

Equipment, monitoring and measuring, labeling, packaging, cleanliness, and release activities shall

ensure the product meets Akorn's requirements. Records shall be maintained in accordance with Section 7.3 and made available to Akorn upon request.

7.9 Monitoring and Measuring of Process and Product

The supplier shall use appropriate measurement methods to monitor planned results of processes to confirm its product meets specified requirements. *Defining test methods in an established control plan or similar document should ensure testing is conducted in accordance with the established limits and frequency.*

Akorn's suppliers shall monitor critical to quality (CTQ) and product characteristics at appropriate stages of the production process to confirm that product produced meets requirements. Records of these results shall be used to authorize release of product to Akorn.

Note: Acceptance criteria for performance testing when planned and monitored are evidence the product meets requirements.

Products not meeting specified requirements are cause for the supplier to investigate the process for the cause, and take appropriate corrective action as necessary. Controls shall be in place to prevent product delivery to Akorn until the conformity of the product is confirmed.

7.10 Validation of Processes for Production

Akorn's suppliers shall qualify critical equipment and computerized systems before validation.

Note: This qualification should be carried out by conducting the appropriate design qualification (DQ), installation qualification (IQ), operational qualification (OQ), performance qualification (PQ) and/or process validation (PV).

When the output of a process is unable to be verified by testing, validation activities shall be conducted by the supplier using a documented procedure. The qualified individual that conducts the validation activity shall document its result and make the results available to Akorn upon request.

The supplier's validation shall confirm with objective evidence that the process consistently meets the planned outcome. Therefore, the supplier shall validate products made from its production tools, processes, and cycle times to confirm they meet the product requirements, specifications and parameters.

The supplier shall periodically review and maintain process parameters established during validation. These parameters are to be monitored and controlled to ensure product specifications continue to be met.

Note: If trends outside predefined process parameter limits are found the trend should be investigated, corrective action may be taken and revalidation considered.

Prior to implementing any modification to a process, the supplier shall complete necessary verifications and tests (including preliminary capability studies) to ensure the process produces product that meet specified requirements. The supplier shall implement changes in accordance with Section 8.0 Supplier Notice of Change.

7.11 Product Identification and Traceability

The supplier shall establish a system for the control of all materials.

Note: Control procedures are to ensure that products are properly identified and do not become mixed

with other orders.

The supplier shall identify product status throughout the production process to ensure that only product that has passed the required inspections and tests are shipped to Akorn.

The supplier shall establish a traceability system that tracks components from raw material through inspection, test, and final release operations, including rework and sub-supplier procedures.

7.12 Control of Inspection, Measuring, and Test Equipment

The supplier shall establish monitoring and measurement processes to ensure product meets specified requirements. Measurement uncertainty shall be known. The supplier is responsible for its gauges, tool masters, fixtures and measurement/test equipment and verifying the accuracy of measurements to ensure the integrity of the measurement system.

Note: Measurement uncertainty or measurement error may be defined within the measurement instrument's specification by its manufacturer.

The supplier shall ensure measuring and test equipment is routinely calibrated, inspected, checked and maintained with a documented procedure. Any standards the supplier uses for calibration shall meet applicable regulations, have specified directions and limits to ensure accuracy and precision. The supplier's records shall be available to Akorn upon request.

When nonconforming equipment is found the supplier shall confirm the validity of previous measurement results made with the nonconforming equipment. An impact analysis shall be performed by the supplier when a product is shipped after being approved by a measurement system operating outside of agreed upon limits of variation. Akorn shall be notified immediately when the impact analysis concludes Akorn's product is impacted.

Note: Akorn may require use of accredited laboratories for testing or calibration.

7.13 Internal Quality Audits

The supplier shall have an independent audit program; the program must ensure auditors cannot audit work that is their responsibility.

A supplier shall conduct internal audits in accordance with an established audit plan to ensure continued compliance with the quality system, internal procedures and customer requirements. Results and actions taken shall be documented. Such records shall be made available to Akorn upon request.

7.14 Control of Nonconforming Product

The supplier shall have a documented process to control product that does not meet requirements. Nonconforming product shall be identified, segregated and evaluated. The evaluation results of the nonconformance and its analysis of the impact to the product shall determine what action is to be taken with the product.

Disposition of the nonconforming product shall be reviewed and documented by an individual with the designated authority and appropriate expertise as well as Akorn representative, as defined in the Quality Agreement. The supplier shall record any actions, including any justification of use and approvals for disposition of the nonconforming product.

If the nonconforming product is corrected by the supplier, acceptance criteria shall be used to confirm the product meets requirements.

If the supplier detects nonconforming product after delivery, an impact analysis shall be performed by the supplier. Akorn shall be notified immediately, or as per the Akorn-supplier quality aqreement, when the impact analysis concludes Akorn's product is impacted.

Note: When a product nonconformance is identified by Akorn, a Supplier Corrective Action Report (SCAR) may be issued to the supplier. If a SCAR is issued, the supplier is expected to provide an appropriate response using appropriate systems.

7.15 Handling, Storage, Packaging, Preservation, and Delivery

The supplier shall comply with specified packaging requirements and instructions. Packing operations shall be controlled to prevent mislabeling, cross contamination, and/or adulteration.

Suppliers shall establish and follow packaging standards and methods to ensure that material is adequately protected from alteration, damage and contamination during transit. *Every effort should be taken to ensure package integrity.*

Supplier labeling shall meet applicable regulations and standards, remaining legible and attached to product during normal handling, storage and distribution conditions.

If applicable or when required, the supplier shall ensure labels have the correct expiration date, control number, handling, storage instructions and location of manufacture, and remain legible and affixed to the product.

7.16 Training

The supplier shall develop and maintain a competent workforce with the necessary education, skills, and experience to implement its quality system and ensure its product meets specified requirements.

When the supplier conducts training or takes other action to improve the competence of its workforce, the effectiveness of training or other actions taken shall be periodically evaluated.

The supplier shall maintain records that document workforce competence. Records for personnel should include education, training, or experience. Competency or training effectiveness should be periodically addressed.

Supplier personnel shall be aware of their responsibilities that prevent defects and ensure the quality of the supplier's product.

Note: The supplier can use defect awareness training to ensure personnel understand how improper job performance can cause product defects.

7.17 Analysis of Data

Akorn's suppliers shall use appropriate analysis of data to identify defects or opportunities to prevent defects. Such records shall be made available to Akorn upon request.

Note: The supplier should use data analysis to understand if its product conforms to requirements, if its processes achieve planned results, or if process or supplier trends may result in defects.

Akorn suppliers shall utilize the appropriate statistical techniques, when making decisions about products and monitoring process performance (i.e. first pass yield, SPC, etc.).

7.18 Continual Improvement

The supplier shall implement continuous improvement efforts.

Note: The supplier should use its quality objectives, audit results and management review process to facilitate overall improvement of its quality system.

7.19 Corrective Action and Preventive Action

Akorn suppliers shall establish and maintain documented procedures for implementing corrective and preventive action with disciplined problem solving methods.

Supplier corrective or preventive actions shall eliminate the causes of actual or potential non-conformities and be appropriate to the magnitude of problem or risk encountered.

The supplier's corrective actions shall prevent recurrence when a nonconformance to specification or requirements occurs.

The supplier's preventive actions shall prevent occurrence and eliminate potential nonconformance to specifications or requirements.

The supplier shall record any corrective and preventive action taken, its result and review the effectiveness of the action.

Note: Akorn may require the Supplier Corrective Action Request (SCAR) process be followed to make its root cause evaluation and conclusions available to Akorn.

8.0 Supplier Notice of Change (SNC)

Suppliers shall notify Akorn prior to making any change that may affect conformance to defined requirements, product quality, or a regulatory filing.

Note: The supplier should submit the notice along with any change documentation demonstrating the acceptability of the change, to GQC.SQMailbox@akorn.com.

The supplier's change control activities shall be planned and documented to assure compliance of products to requirements. *Akorn may require the supplier to make its evaluation data and conclusions available to Akorn.*

At a minimum, the supplier shall:

- Ensure that personnel executing the change are qualified
- Evaluate all changes for product or process risk (including efficacy and safety)
- Document and communicate changes to Akorn in writing prior to execution, and
- Obtain Akorn's approval, in writing prior to implementation.

9.0 Approved Supplier Requirements and Locations

Akorn purchases materials or services as outlined in Section 2.0 from suppliers that appear on Akorn's Approved Supplier List. Akorn shall evaluate and approve **each** supplier manufacturing location independently.

9.1 Selection and Evaluation

Akorn may consider financial standing, cost, product expertise, past performance (if known), technology, logistics, ability to manufacture in accordance with appropriate current Good Manufacturing Practices (cGMP), supply chain integrity, business continuity risk, and known significant environmental, safety or human rights compliance or other serious sustainability concerns when selecting a potential supplier.

Akorn evaluates and identifies selected potential sourcing partners as part of initial qualification and supplier approval. The supplier evaluation is completed on a risk basis to determine if each supplier is capable of meeting Akorn's quality, delivery, performance, and continuous improvement objectives.

A typical supplier evaluation may include:

- gathering and analysis of data about the supplier (such as quality system questionnaires, licenses, or certificates)
- an on-site audit of the quality system or
- regulatory compliance review by Akorn personnel
- completing the quality agreement.

NOTE: Concurrent material qualification may be required; and involve similar requirements as noted above. At minimum, these include gathering and analysis of data (e.g., BSE/TSE, Residual Solvents, other undesirable contaminants), establishment of confirmation of specifications, analyzing supplier samples, and utilizing materials in pilot/experimental, exhibit, or commercial product batches.

9.2 On-site Audit (Initial)

Akorn representatives may conduct an on-site audit to:

- Assess the supplier's facilities, quality system, and process controls and determine if there is potential impact on Akorn's manufacturing process
- Assign risk levels on purchased items, as appropriate, and determine if there is potential product or regulatory risk.
- Confirm the capability of the supplier to manufacture to Akorn's requirements.

9.3 Quality Agreements

Akorn requires a quality agreement for suppliers of contract manufactured goods, active pharmaceutical ingredients, excipients, parts/materials, assemblies and services or with any other supplier as deemed appropriate. A quality agreement is a supplier's commitment to meeting Akorn's quality expectations.

9.4 Regulatory Conformance

Akorn requires each supplier site have the appropriate regulatory approval for the product the supplier provides Akorn. The approval confirms the conformance of a supplier's facility relative to the production of a specific product to applicable regulatory requirements.

10.0 Supplier Monitoring

Akorn may commonly use the following criteria to rate or monitor a supplier's performance:

- Quality of products or materials provided
- Delivery performance
- Supplier responsiveness/communication
- Total Cost/Cost Containment
- Reduced sampling or testing/skip-lot testing programs
- Supplier certification

Each Akorn entity may periodically communicate results to their suppliers.

10.1 On-site Audits, Assessments, and Periodic Re-evaluation

At the discretion of Akorn, an on-site process audit at the supplier may be deemed necessary. Conditions which should warrant audits include quality issues, process changes, plant location changes or the criticality of the part. When an audit is necessary, Akorn should contact the supplier to schedule the on-site visit and confirm the agenda.

Akorn is committed to supplier development and may conduct supplier assessments and reviews to identify opportunities to improve quality, delivery, or productivity.

Akorn periodically re-evaluates suppliers, to maintain a satisfactory state of compliance. Re-evaluation may be completed by questionnaire, remote, or on-site audit.

10.2 On-Time Delivery of Quantity Ordered

Akorn calculates safety stock and plans production based on an expectation of 100% on-time delivery. Supplier's not meeting this expectation should thoroughly investigate the cause of each late delivery and implement corrective and preventive action plans to achieve continuous improvement.

11.0 Business Practices

11.1 Ethics and Compliance

Akorn's suppliers shall be law abiding and comply with legal requirements relevant to the conduct of all their businesses.

11.2 Confidential Information

Disclosure and use of confidential information obtained from Akorn when conducting business is defined and agreed to within the contract. When it is necessary to discuss confidential matters, a nondisclosure agreement shall be executed between Akorn and the Supplier before exchanging any information.

11.3 Regulatory

The supplier shall operate and conduct itself in accordance with current Good Manufacturing Practices (cGMP). The methods used in the design, manufacture, packaging, labeling, storage, installation and servicing of all products and services shall ensure Akorn product is safe and effective and in compliance with all applicable regulations.

The supplier shall notify Akorn upon receiving notification of any regulatory inspection or action of or relating to supplier's business activities with Akorn.

11.4 Environmental

Akorn is committed to developing manufacturing processes that are inherently less wasteful and hazardous, minimizing or eliminating adverse environmental impacts from the beginning.

Suppliers shall operate in an environmentally responsible manner and should be striving for, at a minimum:

- Elimination and reduction of restricted, toxic and hazardous constituents/substances in products.
- Tracking and reducing environmental impacts of their operations, including natural resource and energy consumption, greenhouse gas emissions, waste generation, waste water discharges, and air emissions.
- Preventing accidental releases of hazardous materials into the environment and adverse impacts on the local community.

11.5 Material Compliance

Suppliers shall agree to comply with all Akorn requests for information relating to material compliance, including but not limited to EU and other country Restriction of Hazardous Substances Directives and related substance declarations or evidence as requested, human rights supply chain related laws such as the U.S. Dodd-Frank Act (Conflict Minerals provisions) and related declarations, and EU and other

country Registration, Evaluation and Authorization of Chemicals (REACH directive) data by providing the material content data on the products / materials Akorn purchases from supplier. Supplier shall provide information in forms provided by Akorn or as agreed upon by the parties.

Akorn suppliers shall comply with all global environmental and human rights rules and regulations; including implementing programs to ensure products do not contain restricted or banned substances or take steps to ensure the raw materials do not originate from areas of conflict and significant human rights abuses (Conflict-Affected and High Risk Areas as defined by the OECD) and make the proper documentation available on a periodic basis as requested by Akorn or its authorized representatives. With regards to requests for the origin of substances in products, suppliers agree to cooperate with Akorn and conduct reasonable due diligence of its upstream suppliers to facilitate Akorn's compliance efforts.

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As used in this standard, the terms below have the following meaning. The definitions from the Akorn glossary have been used as the basis for this glossary.

Change is any modification to design, structure, or intended use of a product, process, or system within the scope of the Quality System. A change includes initiation, relocation, or retirement of a product, equipment, process, or system.

Computerized Systems are a broad range of systems including, but not limited to, automated manufacturing equipment, automated laboratory equipment, process control and process analytical, manufacturing execution, laboratory information management, manufacturing resource planning, clinical trials data, vigilance and document management systems. The computerized system consists of the hardware, software, and network components, together with the controlled functions and associated documentation.

Controlled Environment is a specific working area that has the primary objective of controlling one or more physical, chemical, or biological variables.

Correction is an immediate action taken to eliminate an existing exception or nonconformance.

Corrective Action is an action taken to eliminate the cause(s) of a detected, existing exception, non-conformance, or other undesirable situation, in order to prevent recurrence.

Critical Process Parameter (CPP) - A process parameter whose variability has an impact on a critical quality attribute and therefore should be monitored or controlled to ensure the process produces the desired quality.

Critical to Quality (CTQ) - Key characteristics of a product or process whose performance standards shall be met in order to satisfy the specified requirements. CTQs may overlap with Essential Characteristics and Essential Design Outputs. Performance CTQs representing top performance characteristics, when fully defined, should be measurable with a target, specification limit(s), and have a quality goal.

Critical System is a system that has the potential to directly impact the quality of the product produced such as, but not limited to, Distilled Water, Environmental Air, and Process Air systems.

Design Input is the physical and/or performance requirements of a device that are used as a basis for device design.

Design Output is the iterative result of a design effort during design and at the end of the total design effort.

Installation Qualification (IQ) is the documented verification that a system is installed according to written and pre-approved specifications.

Operational Qualification (OQ) is the documented verification that a system operates according to written and pre-approved specifications throughout all specified operating ranges.

Performance Qualification (PQ) is the documented verification that a system is capable of performing or controlling the activities of the processes it is required to perform or control, according to written and pre-approved specifications, while operating in its specified operating environment.

Preventive Action is action taken to eliminate the cause(s) of a potential exception, nonconformance, or other undesirable situation, in order to prevent occurrence.

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Product Change is a permanent or temporary modification made to the design or manufacture of a component or finished good.

Production Part Approval Process (PPAP) demonstrates the manufacturing process has the potential to produce product that consistently meets all requirements.

Quality Approved Suppliers are those sources selected and evaluated that have demonstrated evidence of being able to meet Akorn requirements and are listed on Akorn's Approved Supplier List.

Quality Manual defines the structure of a quality system with scope, a description of how processes of the quality system interact and by referencing documented procedures used to implement the quality system.

Quality Records are original or true copies of documentation proving that activities required by the quality system have occurred. Examples of quality records include: training records, change history files, test results, calibration records, exception reports, and master production records.

Requirement is a need or expectation that is documented in writing. Requirement may be related to the product, system or process.

Specifications are the physical, chemical, biological, and performance requirements of a product, written to an engineering level of detail, that are used as a basis for product design.

Supplier is any entity that provides goods and/or services to Akorn.