COLLEGIUM QUALITY & SAFETY POLICY

PURPOSE

- Collegium Pharmaceutical, Inc. ("Collegium") is committed to business practices and operations that promote the quality of our pharmaceutical products and ensure patient safety.
- We hold ourselves to the highest standards of quality and safety. We achieve this through full compliance with current Good Manufacturing Practices (cGMPs) and all applicable laws and regulations including but not limited to those set forth by the Food and Drug Administration (FDA) and Drug Enforcement Authority (DEA). Our medicines undergo exhaustive safety and quality assurance measures at every stage of the development process, from sourcing raw materials to product development, clinical trials and manufacturing and through patient use.
- To meet and adhere to the highest standards, Collegium has implemented an effective Quality Management System (QMS) with a central goal of consistently producing safe and effective products and ensuring that these activities are sustainable.
- Our robust quality management system helps us continuously monitor our manufacturing processes, detect and manage potential safety issues while preventing future issues, and ensure appropriate reporting to applicable regulatory agencies. Collegium personnel are similarly dedicated to being the best in the industry and delivering a best-in-class QMS. Strong support for quality and safety is demonstrated across the Company at all levels.

OUR APPROACH

- Collegium's QMS defines and formalizes our commitment to quality and safety, and documents processes, procedures and responsibilities for achieving quality policies and objectives.
- Implementation of QMS is described in our Quality Manual and executed through principles and procedures provided in Quality Policies, Standard Operating Procedures (SOPs) and attachments/forms to collect data. Effective implementation of the QMS system and its documented procedures are monitored through quality audits and reported periodically as governed by Collegium's Internal Audit Program.
- The elements of Collegium's QMS are broadly divided into management responsibility and commitment, resources, manufacturing operations and evaluation activities. High-level summaries of these elements are provided below.

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SCOPE AND APPLICABILITY

- This policy is applicable to all associates, contractors and third parties who do work on behalf of Collegium at all owned, leased or rented workplaces where Collegium has operational responsibilities.

MANAGEMENT RESPONSIBILITY & COMMITMENT

At Collegium, the President/CEO and Executive Team are fully committed to quality and endorse the QMS. The Executive Team's responsibilities in the QMS include identifying and providing adequate resources, including assignment of trained personnel, defining organizational structure, assigning authority and responsibility to the functional groups, and reviewing the quality systems as necessary.

Resources

Collegium established an organizational structure where a qualified designee from Executive Management is responsible for overseeing the quality system and operational activities. This designee is responsible for providing adequate resources to consistently manufacture a quality product, procure materials that are suitable for their intended purpose, processing the materials to produce finished drug products, and analytical testing of in-process and finished products, stability and reserve samples.

Personal Development/Training

Collegium maintains a documented procedure for identifying employee training needs and continuously providing effective training for all personnel. Quality & Safety personnel performing specific assigned tasks are qualified on the basis of appropriate education, training and/or experience, as required.

Control of Outsourced Operations

Collegium outsources manufacturing, packaging, analytical testing and stability activities. Our quality system calls for contracts (quality agreements) that clearly assign responsibility for the materials or services, quality specification responsibilities and communication mechanisms used in the manufacturing, testing and distribution of our products. A vendor qualification process (which may include an onsite audit of the facility/facilities) is conducted before selecting any facility/service provider with whom Collegium considers contracting. Collegium is ultimately responsible for approving or rejecting products or services provided under these agreements.

MANUFACTURING OPERATIONS

Purchasing Controls

Collegium has established purchase controls that are applicable to all current and potential GxP[1] service providers, suppliers and vendors based on defined acceptance criteria and their ability to comply with appropriate GMP, FDA and DEA regulations and any other relevant guidelines. Collegium has a written procedure for the qualification of GxP vendors and service providers.

Product Identification and Traceability

Collegium's contract manufacturers and suppliers have established systems and procedures to assist in product identification and traceability that are applied to incoming materials, in-process materials and finished products.

Process Controls

Collegium identifies and plans with the contract manufacturing organizations (CMOs) the production process, installation and service processes directly affecting product quality and ensure that they are carried out under controlled conditions. Controlled conditions include documented procedures, work instructions, monitoring process parameters, product specifications, in-process sampling and testing, environmental controls, contamination control, waste control, equipment maintenance and any other necessary controls. Validation is performed as needed to ensure a high degree of confidence in performance.

Handling Exceptions

Collegium has established systems to be initiated in response to exceptions identified during processing from raw materials, product testing or stability testing. The QMS describes systems that include escalation, notification, initial risk assessment, investigation, root cause analysis, product impact assessment and corrective and preventive actions. Collegium has written procedures to conduct investigations on out-of-specification (OOS) or out-of-trend (OOT) results.

[1] GxP: All regulations that govern Good Clinical Practices (GCP), GMP, Good Pharmacovigilance Practices (GVP) and Good Laboratory Practices (GLP) activities as stated by FDA, ICH and other regulatory authorities.

Corrective and Preventive Action (CAPA)

When a non-conformance issue is detected, a product/process impact assessment is performed, and the cause of the non-conformity is investigated. As necessary, procedures and practices are changed and implemented to prevent a recurrence and to ensure quality and safety.

EVALUATION ACTIVITIES

Annual Product Review (APR)

APRs are conducted for all commercial products manufactured for Collegium. Evaluation of the need for changes in specifications, production, manufacturing, control procedures and revalidation are assessed.

Internal Quality Audits

Collegium's Internal Audit Program governs planning and implementing internal quality audits to verify compliance with all aspects of the QMS and to determine its effectiveness. Internal audit results and corrective actions may be reported periodically and during Quality Management Review.

Material Review Board (MRB)

Non-conforming product (or potentially non-conforming product) is evaluated by a multi-disciplinary team which is responsible for the review of a non-conforming lot of material and recommending disposition. The MRB is headed by Quality Assurance Management and consists of management from Regulatory Affairs and Manufacturing.

Field Alert Reporting/Product Recall

Collegium has established and maintains documented procedure for the handling and investigation of Field Alert Reports and product recalls.

Complaint Files

Collegium has documented procedures for the handling and investigation of product complaints. These procedures assure that complaints are initiated, handled, and resolved in a timely manner. Routine analysis of complaint data is performed to identify trends that require escalation to Executive Management and possibly further action.

IMPLEMENTATION

Compliance Department

Compliance Department will implement a general employee training including:

- Periodic distribution of this Policy and its accompanying or applicable principles.

Quality Assurance Department

Quality Assurance Department has implemented and actively manages a role-specific training program to ensure that individuals performing tasks in the name of the company are appropriately trained as required per all local, state and federal regulations. Quality Assurance Department ensures that these training requirements are created by and regularly reviewed and approved by applicable department management.

Department Management

Management of each Department or other organizational unit must:

- Ensure that this Policy is embedded in their business activities and adhered to.
- Train, oversee and supervise employees in accordance with the principles articulated in this Policy, as applicable.

HISTORY

- Version 1.0 – February 2023

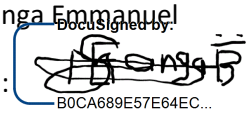
DEPARTMENT RESPONSIBILITIES:

OWNING, APPROVING AND STAKEHOLDER DEPARTMENT(S):

Department: Technical Operations

- Name: Scott Sudduth
- Signature: DocuSigned by: Scott Sudduth D28C597E03E7402...
- Title: EVP, Head of Technical Operations
- Date: 2/17/2023

Department: Compliance

- Name: Sanga Emmanuel
- Signature: 

- Title: Chief Compliance Officer
- Date: 2/17/2023