Quality Management in the Pharmaceutical Industry

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Introduction

In the Pharmaceutical Industry, Quality Management is defined as the crucial part of management function that determines and implements the management's policy, i.e., the overall intention and direction of an organization regarding quality, as formally voiced and sanctioned by senior management.

The key elements of quality management are:

- Quality Policy and Objectives
- Quality Manual
- Organizational Structure and Responsibilities
- Internal Processes
- Customer Satisfaction with Product Quality
- Continuous Improvement
- Document Control
- Quality Management System

The entirety of these actions is termed as 'Quality Assurance'.

Within an organization, quality assurance serves as a management tool. The concepts of quality assurance, GMP and quality control are unified aspects of quality management. The management of manufacturing organization must ensure that the quality of the pharmaceutical products fit for their intended use, comply with the requirements of the marketing authorization and do not place patients at risk due to inadequate safety, quality or efficacy. The attainment of these quality objectives is the responsibility of senior management and requires the participation and commitment of all levels within the organization.

Quality Assurance

Quality Assurance (QA) is a wide-ranging concept containing all matters that independently or jointly impact the quality of a product. It is the entirety of the provisions made with the object of safeguarding that pharmaceutical product are of the quality required for their intended use. QA is any systematic process of determining whether a product or service meets specified requirements. As a part of QA appropriate to the manufacture of pharmaceutical products, organization should ensure that:

- Pharmaceutical products are designed in compliance with good manufacturing practices (GMP) and good laboratory practices (GLP)
- Production and control operations are clearly written
- Managerial responsibilities are clearly written
- Controls on starting materials, intermediate products, and bulk products and other in-process controls
- Calibrations, and validations are carried out

- Finished product testing as defined procedures
- Pharmaceutical products are certified by authorized persons
- Quality is maintained throughout shelf-life
- Procedure for self-inspection and/or quality audit
- Deviations are reported, investigated, and recorded
- System for approving changes
- Evaluations of the quality of pharmaceutical products

Key points of Quality Assurance

A nicely drafted quality management policy of an organization shall comprise of following key Quality Assurance tools (not limited to):

- Good manufacturing practices for pharmaceutical products
- Good laboratory practices (GLP) for pharmaceutical products testing
- Sanitation and hygiene
- Qualification and validation
- Complaints handling
- Product recalls
- Contract manufacturing and analysis
- Self-inspection and quality audits
- Personnel
- Training
- Personal health
- Premises
- Equipment
- Materials
- Documentation
- Process Control
- Quality Risk Management

Good manufacturing practices (GMP) for pharmaceutical products

GMP which is an integral part of QA that ensures products are consistently produced and controlled to the quality standards appropriate to their intended use, should be practiced. The system should ensure that products are consistently produced and controlled according to quality standards. It should be designed to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing of final product.

Good laboratory practices (GLP) for pharmaceutical products testing

GLP is another part of QA that should ensure products and inputs are tested to meet the quality standards appropriate to their intended use. This should be implemented and promote the development of quality test data and provide a tool to ensure the management of laboratory procedures for national pharmaceutical

control laboratories involved in the analysis of active pharmaceutical ingredients (APIs), excipients and pharmaceutical products.

Sanitation and Hygiene

A high level of sanitation and hygiene should be accomplished in each phase of the manufacture of drug products. The scope of sanitation and hygiene covers personnel, premises, equipment and apparatus, production materials and containers, products for cleaning and disinfection, and anything that could turn out to be a source of adulteration to the product.

Qualification and Validation

In agreement with GMP, each pharmaceutical company should recognize what qualification and validation work is required to demonstrate that the critical aspects of their operations are controlled. The key elements of a qualification and validation program of a company should be clearly defined and documented in a validation master plan.

Complaints Handling

All complaints and other information concerning potentially defective products should be carefully reviewed according to written procedures and the corrective action should be taken.

Product Recalls

There should be a system to recall from the market, promptly and effectively, products known or suspected to be defective.

Contract Manufacturing and Analysis

Contract manufacturing and analysis must be correctly defined, agreed and controlled in order to avoid misunderstandings that could result in a product or work or analysis of unsatisfactory quality. Key items like the contract giver, the contract acceptor, the contract etc. shall be adequately established in written.

Self-Inspection and Quality Audits

The purpose of self-inspection is to evaluate the manufacturer's compliance with GMP in all aspects of production and quality control. The self-inspection program should be designed to detect any shortcomings in the implementation of GMP and to recommend the necessary corrective actions.

Self-inspections should be performed routinely, and may be, in addition, performed on special occasions, e.g., in the case of product recalls or repeated rejections, or when an inspection by the health authorities is announced. The team responsible for self-inspection should consist of personnel who can evaluate the implementation of GMP objectively. All recommendations for corrective action should be implemented. The procedure for self-inspection should be documented, and there should be an effective follow-up program.

Personnel

The establishment and maintenance of a satisfactory system of quality assurance and the correct manufacture and control of pharmaceutical products and active ingredients rely upon people. For this reason, there must be sufficient qualified personnel to carry out all the tasks for which the manufacturer is responsible. Individual responsibilities should be clearly defined and understood by the persons concerned and recorded as written descriptions. Key personnel and authorized personnel shall be identified

Training

The manufacturer should provide training in accordance with a written programme for all personnel whose duties take them into manufacturing areas or into control laboratories (including the technical, maintenance and cleaning personnel) and for other personnel as required.

Personal Health

All personnel, prior to and during employment, as appropriate, should undergo health examinations. Personnel conducting visual inspections should also undergo periodic eye examinations.

Premises

Premises must be located, designed, constructed, adapted, and maintained to suit the operations to be carried out. Areas like ancillary areas, storage areas, weighing areas, production areas, quality control areas etc. should be clearly and adequately identified and marked.

Equipment

Equipment must be located, designed, constructed, adapted, and maintained to suit the operations to be carried out. The layout and design of equipment must aim to minimize the risk of errors and permit effective cleaning and maintenance in order to avoid cross-contamination, build-up of dust or dirt, and, in general, any adverse effect on the quality of products.

Materials

The main objective of a pharmaceutical plant is to produce finished products for patients' use from a combination of materials. The purchase of starting materials is an important operation that should involve staff who have a particular and thorough knowledge of the products and suppliers. Intermediate and bulk products should be kept under appropriate conditions. Finished products should be held in quarantine until their final release, after which they should be stored as usable stock under conditions established by the manufacturer. Appropriate controls should be in place for the handling of rejected, recovered, reprocessed, and reworked materials. Procedures should be in place for handling of Recalled products and Returned goods.

Controls should be established in quality control laboratory and manufacturing areas for the handling of items like Reagents, Culture medias, Reference standards, Waste materials and Miscellaneous items.

Documentation

Good documentation is an essential part of the QA system and, as such, should exist for all aspects of GMP. Documents should have unambiguous contents: the title, nature and purpose should be clearly stated. They should be laid out in an orderly fashion and be easy to check. Reproduced documents should be clear and legible. The reproduction of working documents from master documents must not allow any error to be introduced through the reproduction process.

Key applicable documentation is:

- Labelling
- Specifications and testing procedures
- Specifications for starting and packaging materials
- Specifications for intermediate and bulk products
- Specifications for finished products
- Master formulae
- Packaging instructions
- Batch processing records
- Batch packaging records
- Standard operating procedures (SOPs) and records

Process Control

By setting up the control on the critical quality attributes and critical process parameters by monitoring and evaluating them continually. Key points which should be considered for process control are:

- Control of starting materials, packaging materials, intermediate, bulk, and finished products
- In-process controls
- Batch record review
- Stability studies
- Annual product quality review

Quality Risk Management

A Quality Risk Management program should be created to reduce risk to a manageable level and deliver high-quality products to protect patient's health. Organizations must ensure that risk management plans do not introduce new or residual risk, and future outcomes must be evaluated and followed up on, with the innovation risk being analyzed to see how the process may be improved. Any severe or considerable risk must be managed, along with a contingency plan, if essential, to monitor and control risk. Metrics that provide insight into performance, trends and potential risk should be analyzed. Risk management activities should be conveyed to stakeholders.

Conclusion

Regardless of the type of manufacturing facility, GMP is a critical part of running a high-quality facility. By being GMP compliant, facilities make a strong attempt to create a safe, high-quality, and sanitary environment to create safe and high-quality products for consumers. They are standards to strive for, particularly for facilities producing products that people consume, like pharmaceuticals.

References

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