



Number / Revision:

P-R-01_04

Title:

Quality management system**1. SCOPE**

- 1.1. This policy refers to the quality management activities at „Balkanpharma-Razgrad” AD.

The quality management system (QMS) of includes:

- The rules for Good Manufacturing Practice (GMP);
- The development of products;
- Quality risk management.

The quality system is applicable to new and existing products at all stages of their life cycles, i.e.:

▪ **Development of products:**

- Development of products;
- Formulation (including container/closure system);
- Production of investigational products;
- Development of industrial manufacturing process and scale-up;
- Development of analytical methods.

▪ **Process transfer:**

- Transfer of new products from development to production;
- Transfer of marketed products within or between manufacturing and laboratory facilities.

▪ **Industrial manufacture:**

- Supply and control of materials;
- Provision of facilities, utilities and equipment;
- Manufacture (including packaging and labelling);
- Quality Assurance and Quality Control;
- Release;
- Storage;
- Distribution.

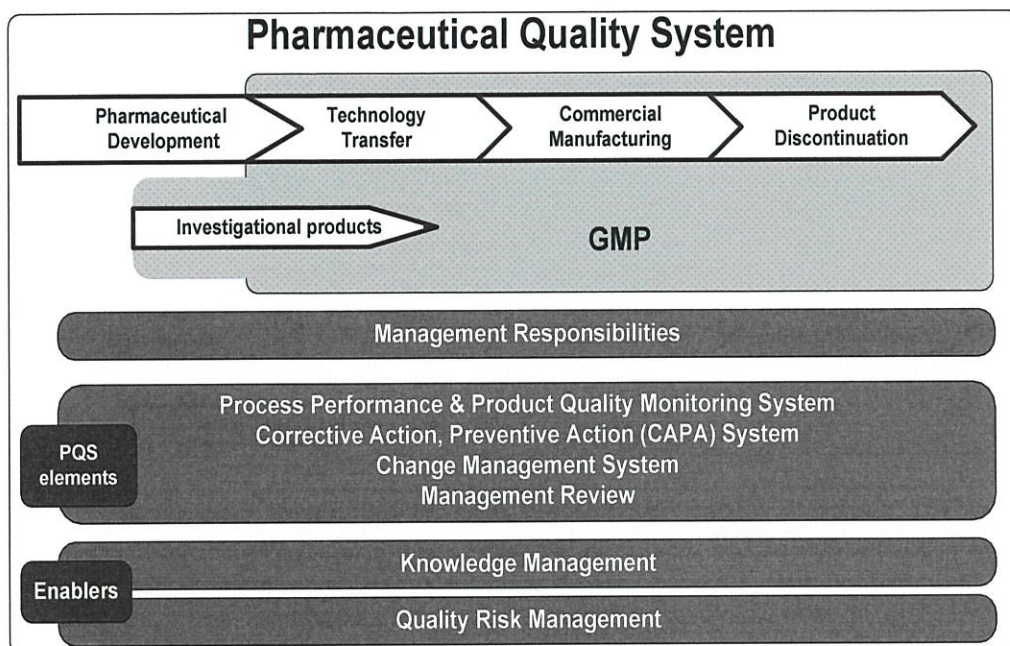
▪ **Discontinuation of production of product:**

- Retention of documentation;
- Retention of samples;
- Continuation of activities related to product assessment and reporting of results.

- 1.2. The quality system includes the following four elements:

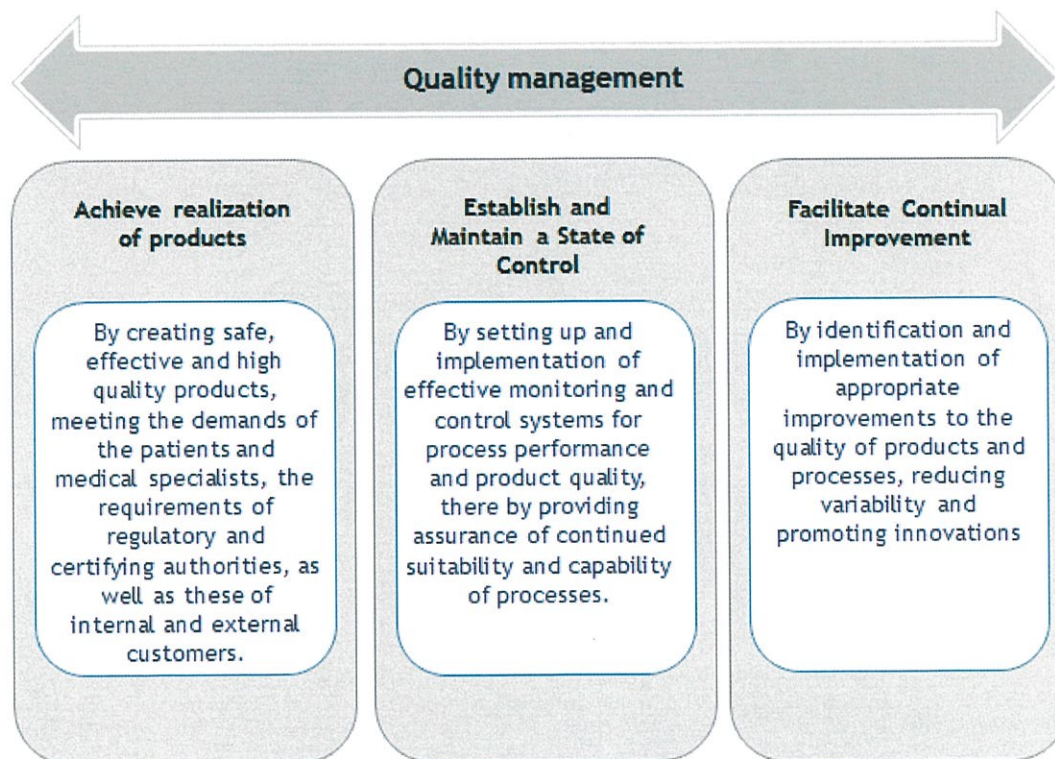
- Monitoring of process performance and product quality;
- A corrective and preventive actions system;
- A change management system;
- Management review of process performance and product quality.

- 1.3. The following flowchart shows the model of the quality management system employed in the company:



2. POLICY

- 2.1. „Balkanpharma-Razgrad” AD operates an effective quality management system which ensures the quality of the products and guarantees that the business operates in a safe and responsible manner and the products manufactured by the company are fit for their intended use, comply with the Marketing authorizations/ Process documentation and are safe, effective and of good quality.
- 2.2. The management of „Balkanpharma-Razgrad” AD is responsible for the setting up, implementation and maintenance of a quality system, which is to allow the company to achieve three major goals as follows



- 2.3. The individual and team roles, responsibilities, authority and relationships of all functional units related to the quality system are clearly defined, communicated and implemented observed at all company levels. The management guarantees that these relationships are observed at all levels.
- 2.4. The management of „Balkanpharma-Razgrad“ AD allots and provides sufficient and adequate resources (human, financial, materials, facilities and equipment) for the implementation and maintenance of the quality system, as well as for the continuous improvement of its effectiveness.
- 2.5. The management of „Balkanpharma-Razgrad“ AD is responsible for the development, introduction and maintenance of a documented system for quality management, complying with GMP and other Good practices (GXP), ISO 9001 and other regulatory and in-house requirements and customer requirements, as applicable.
- 2.6. The quality system and the management responsibilities include also control and review of the activities of the contractors and the quality of the purchased materials.
- 2.7. In the case of change of product ownership (e.g. through acquisition), the management define:
 - The future responsibilities of each party;
 - The scope of the information required for the transfer.
- 2.8. The quality objectives are specified for the respective functions and levels in the company and reflect the requirements of this Manual, the regulatory requirements, the relevant environmental aspects, risks related to health and safety, process capabilities, financial, operation and business requirements, as well as the views of the interested parties.
- 2.9. The management of „Balkanpharma-Razgrad“ AD conducts periodic reviews of the quality system to ensure its suitability, continuing validity, adequacy and effectiveness.

Approved by:	Signature:	Date:
Dimitar Papazov, Executive Director „Balkanpharma-Razgrad“ AD	-s-	15 Dec 2023
Stanko Stefanov, Executive Director „Balkanpharma-Razgrad“ AD	-s-	15 Dec 2023

DOCUMENT HISTORY			
Revision No	Issued (date), signature*	Reason for modification	Invalid (date), signature *
01	07 April 2010	New document	26 April 2011
02	26 April 2011	Updated in view of implementation of the quality management system for medical devices in an integrated system for management and recording of documentation in new templates (change requests № CC-R-3305 and CC-R-3452)	02 Sep 2011

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03	02 Sep 2011	Updated to include a flowchart of the company quality management system and rewording of texts (change request № CC-R-3671)	15 Dec 2023 -s-
04	15 Dec 2023 -s-	Updated in view of detailing of the goals and regulatory requirements for conformity of the quality management system (change request № CC-R-14626).	

** To be hand-filled by Specialist Document Control of „Quality Assurance”*

(In the event of any discrepancy between the English and Bulgarian versions, the Bulgarian version shall prevail.)