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Short communication

Quality management system and corporate quality assurance

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Introduction

Quality Management is a wide-ranging concept, which covers all matters, which individually or collectively influence the quality of a product. It is the sum total of the organized arrangements made with the objective of ensuring that medicinal products are of the quality required for their intended use.

Quality management system (QMS) in Alkaloid as part of Integrated management system (IMS) is comprehensively designed and correctly implemented on corporate level incorporating Good Manufacturing Practice and Quality Risk Management. It is fully documented and its effectiveness continuously monitored.

Organizational structure

ALKALOID AD Skopje is a shareholding company, consisting of two profit centers – Pharmaceuticals and Chemistry Cosmetics Botanicals and the Corporate Services. The company has 2 subsidiaries in Republic of North Macedonia and 17 subsidiaries and 3 representative offices abroad.

The complex organizational structure presents challenge for maintaining and continuous improvement of a shared corporate Quality Management System.

Standards

Pharmaceutical Quality System of ALKALOID AD Skopje – PC Pharmaceuticals is based on cGMP for medicinal products for human use and quality risk management, as well as international standards ISO 9001, ISO 14001 and ISO 45001 for all products of PC Pharmaceuticals, ISO 13485 (for in-license medical devices) and HACCP (for food supplements).

Quality Management System for of all subsidiaries is based on:

Identification and interpretation of relevant national and international laws, regulations, directives and guidelines;

Stipulate and implement internal requirements to ensure compliance;

Risk management;

Information management;

Quality improvement strategies for regulated activities and processes, products, systems and services;

Authorization of regulated documents where required;
Change and deviation system together with corrective actions and improvement actions;

Trending;

Stipulating the understanding of the processes;

Surveillance of quality improvement activities for compliance;

Ensure that quality aspects are addressed when cooperating with external parties;

Defined responsibilities and quality goals throughout the whole lifecycle of the activity;

Effectiveness of Quality Management System implemented in Alkaloid.

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Corporate quality assurance

Team for corporate QA function with Quality Assurance members from the head office Alkaloid AD Skopje and the major subsidiaries: Alkaloid d.o.o. Belgrade, Alkaloid-INT d.o.o. Ljubljana, Alkaloid KONS DOOEL Skopje has the responsibility for implementation of Quality Management System of Alkaloid on corporate level in the subsidiaries through creating corporate QA Policies and support in their implementation. The team operates according to annual plan and set objectives, presented in annual Plan of activities for Quality Assurance. Achieved results (objectives and measured KPIs) are presented in annual report.

The corporate QA is responsible for the performance and effectiveness of the QMS in accordance with the corporate policies.

Documentation system

Appropriate hierarchy of QMS documentation is established on four levels. Corporate (global) documents are first and second level documents.

Manual for integrated management system

Manual for IMS of Alkaloid is a first level corporate document which defines and documents the structure of the Integrated Management System and all operations which refer to the quality of Alkaloid's products.

Corporate policies for quality assurance

Corporate policies for quality assurance (Corporate QA Policy) are first level document, which in standard manner define the global framework and structural elements of a certain QA processes to be subsequently implemented on local level.

Corporate procedures

Corporate procedures are second level documents in IMS which define certain process and the process flow as well as responsibilities for all activities from the process.

Local standard operating procedures

In line with the corporate QA policies and procedures, local standard operating procedures (SOPs) are created or modified to integrate the corporate requirements but also include local specifics from the national legislation in the country the subsidiary is located.

Technical Agreements

Technical agreements are signed between the head office and each subsidiary of Alkaloid covering the responsibilities for adherence to the corporate policies and procedures, the outsourced activities, the products or operations to which they are related, and any technical arrangements

Self inspections

Self inspections are conducted by the corporate QA team in order to monitor the implementation and compliance with the corporate QA Policies and to propose necessary corrective and improvement measures.

Conclusion

Introduction of quality assurance processes on corporate level in the company is of great benefit in aligning and maintenance of a common Quality Management System in Alkaloid and compliance with all relevant regulatory requirements, applicable international standards and internal requirements.

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ICH guideline Q10 on pharmaceutical quality system https://www.ema.europa.eu/en/documents/scientific-guideline/international-conference-harmonisation-technical-requirements-registration-pharmaceuticals-human_en.pdf

ISO 9001:2015 Quality Management systems