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Comparative analysis of standard ISO 9001: 2015 and good manufacturing practice–Continues improvement perspective

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The European Medicines Agency (EMA) published a guideline ICHQ10: Pharmaceutical Quality System in January 2011. ICH Q10 guidance provided an example of the pharmaceutical quality system designed to cover the entire product life cycle, to ensure more efficient and effective product realization and to manage the quality risks. The implementation of ICH Q10 has led to the revision of Chapters 1, 2 and 7 of Good Manufacturing Practice (GMP) guidelines. Additionally, pharmaceutical industries were facing the implementation of various standardized management systems by International Standardization Organization (ISO) to achieve the sustainable development dimension. At this moment, the main question that arises is how to integrate these standards. Fortunately, revision of ISO standards is in progress and similar standard elements are recognized. Draft International Standard ISO 9001:2015 was issued in May 2014 and Final Draft International Standard (FDIS) is expected to be issued in May 2015. The aim of this paper was to provide a comparative analysis of the final draft of international standard ISO 9001:2015 and current GMP requirements. The above standards have been observed in terms of their similarities and disparities. Based on this analysis and considerations, the comprehensive model of Integrated Management System for pharmaceutical industry has been developed.

Biography

Valentina Marinkovic has completed her BSc, MSc, PhD at the Faculty of Pharmacy, University of Belgrade, Serbia. Her professional career built in two directions - academic and work in pharmaceutical industry. She published more than 150 publications in scientific and professional literature. She is Vice – president of the Untied Association for Quality in Serbia. Her current position is Regional Director of Quality for the West Balkans, with multinational company ALVOGEN. She is also Assistant Professor at University of Belgrade, Department of Social Pharmacy and Pharmaceutical Legislation.

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