CONSIDERATIONS ABOUT THE GMP – MODEL APPLIED IN DRUG MANUFACTURE INDUSTRY

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Abstract

This paper presents the principles of the quality assurance in the medicinal product manufacture industry, a short survey of a structure and the main elements of a Good Manufacturing Practice (GMP) principles based Quality Assurance System, which is compulsory for the drug manufacturers, stipulated by the current Romanian and international legislation . In this context the holder of a manufacturing authorization must ensure that the products comply with the requirements of the marketing authorization and do not place patients to any risk due to inadequate safety, quality or efficacy. There are defined basic concepts (Quality Control, GMP, Quality assurance, Quality management) and their inter-relation. Are described certain elements of „Gedeon Richter Romania" Ltd. 's experience obtained in the GMP based Quality Management System operation (validations, qualifications, maintenance system). The paper also propose to evidence the limitations of GMP based Quality Assurance System and the need for enlarging, extending this system with the specific, complementary elements of an established Quality Management System.