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Quality Risk Management (QRM) in Advanced Therapy Medicinal Products (ATMPs) and other areas of the biopharmaceutical industry

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Quality risk management (QRM) is an enabling process that supports the product life cycle and is an integral part of an organisation's pharmaceutical quality system (PQS). The ultimate goal of the QRM process is to bring focus and effort to the issues that impart the highest risk to product quality and/or patient safety. Therefore, as QRM is ultimately linked to the protection of the patient, a modern PQS cannot truly function properly in the absence of an effective, integrated QRM system. QRM is a systematic process for the assessment, control, communication and review of risks to the quality of the medicinal product. It can be applied both proactively and retrospectively. Therefore, the objective is not just to identify risk, but to provide information to help make better and informed decisions to mitigate and reduce risk, thus improving the process. Hence, it is critical to understand and effectively and optimally use the most appropriate risk management tools and approaches. The consistent and effective analysis of risks associated with manufacturing processes and quality systems typically leads to more robust decisions reduces uncertainty and leads to greater confidence in outcomes. These QRM elements must be embedded throughout the organisation through policies and procedures and reinforced via effective training. This presentation discusses best practice and my experience of successfully implementing this in high risk areas such as regenerative medicine but also other areas of the biopharmaceutical industry.

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GMP: New requirements for prevention of cross contamination

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GMP regulations and guidance often change, but the recent requirement to provide toxicological evaluations of products used in non-dedicated facilities so as to determine that the level of cross contamination minimises the potential for impact on patients, have put the pharmaceutical industry under severe pressure when companies attempt to fully comply with the guidence. As an example, companies who have made products for over 20 years in the same facility are now required to undertake extensive evaluations of these products within 12 months for medicinal products. This presentation explains the regulations and describes a criticality based and pragmatic approach to provide compliance with the regulation. How to deal with new EU requirments for setting health based exposure limits and thereby minimising cross contamination in shared facilities was described in *EudraLex – "Volume 4 Good manufacturing practice (GMP) Guidelines Chapter 3 and 5". EMA "Guideline on setting health based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities"* (EMA/CHMP/ CVMP/ SWP/169430/2012 Committee for Medicinal Products for Human Use (CHMP) Effective date 01 June 2015). When different medicinal products are produced in shared facilities, the potential for cross-contamination is a concern. Medicinal products provide a benefit to the intended patient or target animal; however as a cross contaminant, they provide no benefit to the patient or target animal and may even pose a risk. Hence, the presence of such contaminants should be managed according to the risk posed which in turn are related to levels that can be considered safe for all populations. To this end, health based limits through the derivation of a safe threshold value should be employed to identify the risks posed. The derivation of such a threshold value (e.g. permitted daily exposure (PDE) or threshold of toxicological concern (TTC)) should be the result of a structured scientific evaluation of all available pharmacological and toxicological data including both non-clinical and clinical data. Deviation from the main approach highlighted in this guideline to derive such safe threshold levels could be accepted if adequately justified.

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