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ICH Q9 risk management applied to the compliance challenges between cGMP & safety design issues in manufacturing pharmaceutical & biotechnology facilities

3 Case Studies: High potent (HP1@5) plants, Bio-safety containment (BSL1@4) facilities and explosive environment (ATEX 1@3)

In the pharmaceutical sector and related fine chemistry, biotechnology, cosmetics, so on, the manufacturing operations must be carried out in facilities with qualified equipment and validated processes to ensure the reproducibility of the productions batches and the conformity of the products to the specifications established during the validation.

The GMP focuses mainly on the critical aspects in terms of compliance, quality / sterility of the finished products, quality controls, and sanitization and cleaning procedures, however, these GMP criteria cover less the aspects related to the safety issues of facilities and the protection of employees as well. Also, additional standards and norms, such as: ICH, ISO, ASME-BPE, WHO, ISPE, inspection guides, should be used to fill the mentioned gaps.

In light of these constraints, the risks management represents a major tool and an essential step in the validation implementation during all the life cycle of a given pharmaceutical plant from its conceptual design (URS) until its operation.

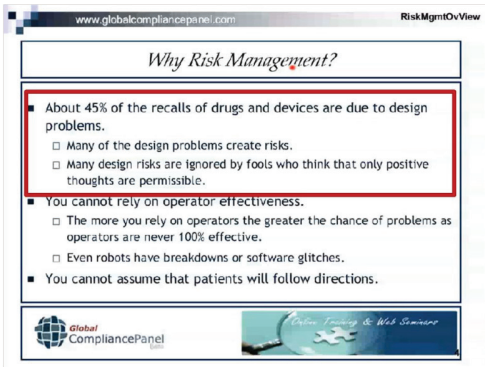
This new approach, thanks to the prior identification of critical parameters of pharmaceutical facilities, helps to orient and to optimize the steps of qualification (DQ, IQ, OQ, PQ) that arise. It allows to struggle the effort in a rational manner during the commissioning, and no need to repeat these tests during the subsequent qualification stages IQ, OQ.

In this perspective, only the tests are the most critical are then to be done during validation.

It will also assist in the choice of reasoned approaches for the management of the change controls (maintenance, metrology,...).

A few examples are treated during the presentation illustrating this approach C&Q.

Furthermore, through the examples presented, this risk management approach is quite justified in particular when it comes to deal with complex processes, multi-products plants, highly potent products (Cephalosporin, Betalactamin, Penicillin, Hormons, Cytotoxic, Oncological products) of grade HP1 to HP5 according to the standard Safe Bridge or equivalent) or by implementing flammable solvents (alcohol etc.) or explosive raw materials to character (sugar, starch, spyramicine, etc.) of grade ATEX1 to ATEX3, NFPA 30) as well as BSL1 to BSL4 of biological compounds containment (vaccines, veterinary...).



Therefore, as reported by Steven S. Kuwahara, about 45% of the recalls of drugs and devices are due to design problems. (http://www.pharmabioeng.com/index.php?page=links)

Like several multinationals, it is vital for the project managers, engineers, and validation specialists, quality assurance and production managers, good understanding of the basic elements of this approach of risk management applied to the validation according to ICH Q9, and this, in order to reduce the operating costs and investment (particularly by reducing the volume of validation), ensure quality of products and facilities cGMP compliance, of critical systems, equipment and clean utilities to meet the USP or PhEu, and the regulatory requirements of cGMP as well, but also the related standards ASME BPE (2012), ISO-14644, ICH Q9, ASTM 2500 and ISPE vol 1 @ 7.

Biography

Aziz Chraibi, eng., after having completed his studies in chemical & processes engineering with ENSIACET college of Toulouse (1986), and then a masters at the INP of Toulouse, followed by a thesis doctorate at the University of Perpignan (1990) which was postulated for the best thesis of CNRS award in 1990, began a career of more than 23 years in the pharmaceutical consulting, cGMP compliance and design review, audit and inspection to meet the good manufacturing practices (cGMP) from Health Canada, EMA/ANSM and FDA as well as standards such as ISO14644, ISO8573, ASME BPE 2012, USP797, USP, EuPh, JP, HSE, NFPA, ATEX, OSHA, ISO, ICH Q9, ASTM 2500, ISPE, etc. In 2007, he was admitted Health Canada Scientific Expert to carry out compliance audit of the facilities. It has in its assets more than 100 multidisciplinary projects made in Canada, but also in the international, involving, audit, compliance and design review, project management, conceptual design, basic (BOD) and detailed engineering, monitoring of "Commissioning and Benchmarking", FAT, installation & strat-up, SAT, and qualification as well.

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