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Assessing pharmaceutical equipment containment using surrogate monitoring (SMEPAC)

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Why? Regulatory situation states: "It is the first duty of the employer to protect (the health of) his employees." (taken from the UK COSHH rules) should be seen as general guidance when handling potent substances. In fact, approximately 30 percent of all people in western societies will develop some form of cancer during their lifetime. If one of these had been exposed to a carcinogenic substance, whilst working for a pharmaceutical company, there is the potential for a legal claim against the company. This could result in high cost compensation and in very bad publicity, unless the company can prove that the employee had been protected using best available technology. Equipment containment is the WORD, and to prove this efficient healthy containment "Protection of employee", we need to TEST. This testing is called Surrogate or SMEPAC testing. In my article, I will focus on how to assess pharmaceutical equipment containment via surrogate testing, methodology, and some explanatory illustrations from three famous contained equipment manufactures in Europe, that I used to deal projects design with them. In addition to other important highlights concerning dealing with highly toxic APIs.

Biography

Mootaz Halawany is a professional pharmacist, Quality Expert, having 25+ years experiences with famous pharmaceutical companies, in the fields of production, QC, and QA. His success is based on strong leadership, good organizational and analytical skills, and striving for the utmost quality. He helped his companies growth & prosperity, through acquiring many noted certificates, and participating in the project management of some modern sterile sites. During his career, he has attended many international training courses, and consequently developed a firm quality system. He also have a master in Business Management from Cambridge. My latest achievement is Project Quality Management for a state of the art containment facility for the production of highly toxic API products.

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