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Risk Assessment for Pharmaceuticals in Manufacturing Facilities

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Manufacturing of active pharmaceutical ingredients (APIs) and products in pharmaceutical industry requires qualitative and/or quantitative health based risk assessments for occupational (workers) safety purposes. Quantitative occupational health-based risk assessments involve the development of Occupational Exposure Limits (OELs) which allow the manufacturer to quantitatively assess worker exposure potential through industrial hygiene air monitoring. Alternatively, qualitative health-based risk assessment involves categorization ("banding") of API based on toxicity and potency, which provides a measure of relative hazard. The occupational health categorization is then linked to task-specific safe handling practices for worker protection purposes which involves use of personnel protective equipment (PPEs) or especially designed/separate facilities in particular cases. OEL determination requires evaluation and interpretation of toxicological, pharmacological and clinical data, selection of appropriate critical studies/endpoints for assessing health risk to workers and extrapolation to acceptable levels from these studies using appropriate factors. The responsibility of toxicologists tasked with setting OELs is to estimate a value that is protective of workers yet without being so overly protective that resources are unnecessarily spent. The talk would cover various topics including: i) risk assessment methodology, ii) various approached to calculate OELs, iii) approach for calculation of OEL for mixtures, iv) considerations for OEL calculation of large molecules, v) calculation of OEL in cases where data is insufficient e.g. raw materials, intermediates etc., vi) various guidelines involved, vii) important aspects in calculation of OEL for carcinogens, viii) occupational exposure banding.

Biography:

Varun is an American Board certified toxicologist (DABT). He received doctoral degree from Freie University, Berlin, Germany. Varun pursued post-doctoral work from Charité Medical University, Berlin. During his doctoral and post-doctoral tenure, he worked in the field of immunotoxicology. Later, he worked as a Study Director, Toxicology, at BSL Bioservice Scientific Laboratories, Munich, Germany. Presently, he is working as Senior Research Scientist at Lupin Ltd., India. In a scientific career spanning more than 17 years, he has got experience working in various fields. He has over 80 publications and has been serving as an editorial board member of various reputed journals.