

Letter to the Editor

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Health-Based Occupational Exposure Limits in Pharmaceutical or Chemical Manufacturing

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To the Editor,

Unexpected exposure to pharmaceuticals or chemicals at the site of manufacture can cause significant health hazards to the concerned personnel. Therefore, it is essential to protect the workplace from serious adverse effects by limiting the exposure to such chemicals to acceptable levels. Qualitative methods such as 'a fraction of therapeutic dose' or occupational exposure banding (OEB) are in practice and may be useful during the early periods of development, when insufficient toxicological and pharmacological data is available. However, this information is arbitrary and scientifically not defensible. With the implementation of risk-based manufacturing practices (Risk-MaP), the pharmaceutical or chemical industries are adopting a quantitative health-based approach to set an occupational exposure limit (OEL). This scientific approach utilizes all aspects of pharmacology, *in vitro* and *in vivo* toxicology, clinical therapeutics, and adverse effects profile, which will be put to perspective by qualified toxicologists to arrive at a maximum safety exposure limit. Among all, the no observed effect level (NOEL) for the most critical effect is the best starting point to derive the OEL limit. The limit at which the OEL is established related to the NOEL should be based on the presence or absence of the threshold value, the slope of the dose-response curve, the nature of the lead effect and the quality, relevance and extent of data available. The health-based OEL utilizes all the available data related to toxicology and applies scientifically acceptable daily exposure (ADE). Processes involved in OEL derivation including hazard identification, dose-response assessment, uncertainty factors analysis (e.g., interspecies, intraspecies, LOAEL to NOAEL, severity and bioavailability), measures to minimize subjectivity and the need for documentation to improve regulatory acceptance are described. Therefore, it is crucial to set or derive the OEL value for each pharmaceutical or chemical which does not pose a risk for the development of any health hazard to healthy workers in the pharmaceutical industry.