3D PHARM X CHANGE

SHARED FACILITY GUIDELINE

exposure limits / permitted daily exposure

NEW EU REGULATION REGARDING MANUFACTURING MEDICINAL PRODUCT

During the manufacturing of medicinal products in shared facilities, cross-contamination in the non-intended patient population can be a concern. Health based exposure limits, i.e. the permitted daily exposure (PDE), through the derivation of a safe threshold value to limit elemental impurities in the drug product is to be employed as of June 2016 for authorised human and veterinary medicinal products (EMA guideline, 2014). The PDE report provides a clear dose limit based on thorough clinical and non-clinical pharmacological and toxicological data and focusses on creating an acceptable margin of safety for patients (ICH Q3C, Q3D). The implications of the EMA guideline necessitates re-evaluation of current cleaning limits in relation to the newly derived health-based PDE's which are subjectable to inspection/audit by regulators or industry. This may enforce companies to renew cleaning validation activities, test method detection and sampling, and potentially lower detection limits.

CONTACT US

Do you have questions or would you like to discuss further possibilities? Please do not hesitate to contact Philip Kwant, Business Development, at philip@3d-pxc.com or +31 1 353 482 72.

WE OFFER A COMPLETE SOLUTION

3D-PharmXchange carries out the evaluation of all available pharmacological and toxicological data, and in concordance with ICH guidelines, constitutes a PDE report including a clear scientific rationale. We integrate all multiple variables, e.g. lowest observed efficacious doses (LOELs)/no observed adverse effect levels (NOAELs), pharmacokinetics (of various patient subpopulations), bioavailability and extrapolation to different routes of administration, genotoxic and mutagenic properties, anti-microbial data, sensitization potential, reproductive toxicity profiles and adverse/critical effects. Our service includes a peer-proofed template and can include quality control. If new data is available, an after-care principle can be implemented where new data is periodically checked and included, followed by an adaptation of the PDE when necessary. This dossier is developed by experts in the field of toxicology, CMC (formulation development), pharmacology and quality/regulatory.

THE RESULT

A comprehensive and concise PDE derivation is realized, in which all relevant data is included to form a clear scientific based evaluation that can be readily implemented. This document ensures complete compliance with regulatory requirements and standards.

OUR TRACK RECORD

We have experience in the strategic and operational implementation of over 60 PDE derivations for various top 10 Pharma companies. Therapeutic areas include, but are not limited to, oncology, immunology, endocrinology, gastroenterology, cardiology, genitourinary, respiratory, dermatology, psychotherapeutics, infections and infective diseases, and pain management.

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