RegSafe
Regulatory Safety Sciences

Consultant in Regulatory Toxicology
and Risk/Safety Assessment

RegSafe offers consultancy services and toxicological expertise in Health Risk Assessment and Safety Assessment

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M. Sc. in Toxicology (Karolinska Institutet, Sweden)

RegSafe, a **consultant in regulatory toxicology and risk/safety assessment** was formed in early 2004 by **Lars Wiklund**, *Safety Assessor/Senior Toxicologist*, who previously was part of **Pharmacia World Wide Toxicology/Safety Assessment**. Altogether this provides almost 30 years' experience in chemical, pharmaceutical and cosmetics safety assessment programmes.

With this experience **RegSafe is offering expertise and businesses** related to toxicology/safety issues such as risk/safety assessments, reports or statements, toxicological advice, expert opinion and other scientific and regulatory questions.

The consultancy services and **expertise** may include searches, review and evaluation of toxicological data, and safety assessments of **pharmaceuticals** (APIs, excipients etc.), **industrial and consumer chemicals** (REACH, CLP etc.), **food additives**, **cosmetics** (ingredients, final products, EG no.: 1223/2009 and SCCS guidelines), and many other compounds or products.

Also **risk/safety assessment** and **qualification of impurities and/or degradation products in drug substances and drug products** (ICH Q3A, Q3B, Q3C, M7), including ***in silico* analyses**, and **TTC** approaches are performed.

Issues related to **cross-contamination** and **cleaning validation** during manufacturing (**health based exposure limits, PDE, shared facilities, EMA Guideline 2014**) as well as topics associated with **industrial hygiene** and **occupational exposure limits (OELs, criteria documents etc.)** are also conducted.

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RegSafe has established effective working relationships with several different organisations ranging from start-up companies, small & medium sized enterprises, small to global pharmaceutical companies, regulatory agencies, and academic institutions and universities for a variety of projects.

Teaching and training - Lectures and tutorial support within several fields of Toxicology, Regulatory Toxicology, and Risk Assessment/Safety Assessment.

For more than 30 years Lars have provided educational and training input to companies (in-house courses), academic institutions, universities (e.g. Global Master Programme in Toxicology at Karolinska Institutet) and national or international organizations, e.g. the EU-funded projects TRISK, RA-Courses and CASCADE, Swedish Academy of Pharmaceutical Sciences, e.g.: “Orienteringskurs i Toxikologi”.

Selection of completed and ongoing assignments:

- Authoring of pharmaceutical regulatory documents, i.e. Nonclinical Overviews, Expert Reports, and other regulatory toxicology and/or safety assessment reports.

- Authoring of the toxicological/safety parts of IMPDs and IBs.

- Safety assessment reports for degradation products, impurities and PGIs.

- Safety assessment reports for leakage substances from containers and packaging, e.g. from plastic materials.

- Safety assessment reports of residues/trace amounts of chemicals originating from the manufacturing process potentially present in final products.

- Preparing criteria documents for OELs and PDEs, and establishing of OELs and PDEs.

- Criteria document for tolerable daily exposure (TDE) in the laboratory work environment and other occupational settings.

- Summary of toxicological documentation and safety assessment of a new ingredients for use in topical pharmaceutical and cosmetic formulations.

- Product X - Health based exposure limit, PDE (Permitted Daily Exposure), for use in risk identification in the manufacture of different medicinal products in shared facilities.

- Preclinical toxicity studies and safety assessment strategies in drug development projects.

- Safety assessment of potential dermal exposure from components in products for monitoring of premature infants.

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