# Toxicological Risk Assessment Centre of Excellence (TRACE)

## Hazard Identification & Toxicological Risk Assessment

**Our experts provide qualitative and quantitative toxicological support specializing in product safety and occupational toxicology to pharmaceutical, biotechnology, and medical device com-panies worldwide. We offer expertise to provide solutions for compliance with global regulatory agencies and practical timelines to accommodate production process.**

### Background

Quantitative and Qualitative Health Assessments are an integral part of product development, manufacturing, and post-marketing surveillance. Product safety guidelines require establishment of safe levels for risk of cross-product contamination in multi-product facilities, E&L, mutagenic and non-mutagenic impurities, particle contamination, and volatile organic compounds. Furthermore, regulatory agencies require that excipients, degradants, contaminants, and residual solvents are present at levels that are scientifically justified and supported. To establish these safe levels, risk assessment reports are required to be performed by qualified and board-certified toxicologists.

Occupational toxicology assessments involve hazard identification and establishment of an occupational exposure limit (OEL). During early drug development stages, when information on the active pharmaceutical ingredient (API) is limited, a preliminary categorization and placement of the API into a control band can be performed by a qualified toxicologist.

### Our solutions

Intertek is a global leader in hazard identification and risk assessment by understanding the complex regulations and by providing comprehensive solutions for our clients. Total quality assured culture is key to all aspects of our work, professional training, and client relations. Our senior staff have extensive technical training, board-certification credentials, and decades of cumulative experience.

### Our core services include:

*Health-Based Exposure Limits*

- Permitted daily exposure (PDE) - establish safe limits for product contamination with other drug substances, process intermediates, residual solvents, and foreign substances
- Excipient qualification - establish safe limits for excipients
- Impurity assessment and qualification - evaluate acceptable limits for chemicals appearing as impurities in drug substance and/or formulated drug product
- Extractables and leachables assessments (drugs and medical devices) - evaluate acceptable limits for chemicals capable of leaching out of product packaging, processing components, and devices
- Volatile organic compounds assessments (medical devices) - evaluate acceptable limits for VOCs in the breathing gas pathway of medical devices and accessories
- Particle contaminant assessments -evaluate risks associated with product contaminations with foreign particles
- F-value calculation for childproof packaging - evaluate the failure criteria for child-proof packaging

*Occupational Toxicology*

- Occupational exposure banding (OEB) - categorize APIs for occupational health purposes based on toxicity and potency according to established criteria
- Occupational exposure limit (OEL) - develop scientifically valid safe limits for worker exposure to chemical substances through inhalation
- Acceptable surface limit (ASL) – develop scientifically valid safe limits for worker exposure to chemical substances from direct skin-to-surface contact

*Qualitative Assessments*

- ICH M7-compliant mutagenicity assessments – FDA- and EMA-compliant evaluation of impurities using literature and database information and in silico methods (expert- and statistical-based models), including expert review of in silico results
- Nitrosamine assessment of API and drug product - review of manufacturing process to establish potential for nitrosamine formation and/or contamination

*Research Support & Issue Resolution*

- Literature searches
- Authoring of literature reviews
- Authoring of white papers
- Authoring of expert reports

**For more information:**

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