

# PDE reports for APIs and excipients

The PDE (Permitted Daily Exposure) value is the substance-specific dose that is most unlikely to cause any adverse effects if a person is exposed to it daily over a lifetime. PDE reports are based on toxicological data and help establish safe, science-based limits for cleaning validation.

## Target Group

Pharmaceutical manufacturers producing multiple active substances in multipurpose facilities – in particular their Quality Assurance and Regulatory Affairs teams responsible for cleaning validation and GMP compliance.

## Relevant European Guidelines

- › **EMA PDE Guideline (EMA/CHMP/CVMP/SWP/169430/2012):** *Guideline on setting health based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities*
- › **ICH Guideline Q3C (R9) on Impurities:** *Guideline for Residual Solvents (EMA/CHMP/ICH/82260/2006)*
- › **VICH GL18 (R2):** *Residual Solvents in New Veterinary Medicinal Products, Active Substances and Excipients (EMA/CVMP/VICH/502/1999-Rev.2)*

## Our Service

- You will receive PDE assessments
- › in accordance with the EMA PDE guideline, in English
  - › tailored to your company
  - › prepared by experienced European ERT-certified toxicologists

## Information required for a non-binding quote

- › Name and address of the company
- › Name of the API
- › Dosage form
- › Route of application of the API or of the potential next product that is produced in the same facility (cleaning validation)

## Your non-binding quote

Request your non-binding quote for one or more PDE reports now!

[› get your quote](#)

