



# TOXI PLAN PHARMACEUTICAL SERVICES

An international team of toxicology experts

## PRE-CLINICAL EVALUATION

- Determination of **permitted daily exposure** (PDE) (ICH Q3C & Q3D).
- Determination of **occupational exposure band** (OEB) (NIOSH process).
- Risk assessment for **cross contamination** (EudraLex, EMA, GMP).
- Determination of **maximum allowable carry over** (MACO).
- **Environmental risk assessment** of active pharmaceutical ingredients (API).
- Risk assessment of a **plastic material** (USP 661.1).
- Risk assessment of an entire **packaging system** (cf. USP 661.2).
- Determination of **biocompatibility tests** (cf. USP 661.1, USP 661.2).
- Risk assessment of **extractables** (cf. USP 1663).
- Risk assessment of **leachables** (cf. USP 1664).

### EXAMPLES OF PRODUCTS EVALUATED:

Pharmaceutical products: API, Powder, Tablet, Capsule, Solution, Freeze-dried extract, etc.

Network member:



+33 (0)6 81 96 68 90

[contact@toxiplan.com](mailto:contact@toxiplan.com) / [www.toxiplan.com](http://www.toxiplan.com)

7 Rue Benjamin Franklin, Bâtiment Gauche B, ZI TRIASIS,  
31140 LAUNAGUET, FRANCE

Our R&D approvals:

