

ASSESS TOXICOLOGICAL RISK. BUILD A DEFENSIBLE SAFETY CASE.

End-to-end toxicological risk assessment of impurities, chemical constituents and extractables/leachables.

Translate chemical characterization and exposure data into scientifically justified toxicological conclusions supporting device safety and regulatory review.

YOUR CHALLENGES



TOXICOLOGICAL THRESHOLDS How to determine PDE calculations and toxicological limits for nitrosamines, elemental impurities (ICH Q3D), and mutagens (ICH M7)?



EXPOSURE & HAZARD ASSESSMENT How to evaluate patient exposure and toxicological hazards when available data are complex, incomplete or substance-specific?



NON-CLINICAL DOSSIER GAPS How to translate toxicological risk assessments (TRA) and MA Module 2.4/2.6 files into clear, traceable conclusions ?

OUR APPROACH

01 ASSESS

- Identification, toxicological profiling, and in silico screening of substance risks
- Gap analysis across ICH guidelines (Q3D, Q3C, M7), ISO 10993-1:2025, and OECD standards
- PDE calculations and strategic non-clinical testing roadmap



02 IMPLEMENT

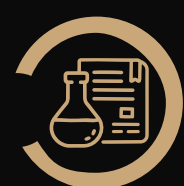
- End-to-end non-clinical study monitoring
- Evaluation of extractables/leachables, formulation stability, and biocompatibility
- Authoring of toxicological risk assessments, biowaivers, and CTD Modules 2.4 & 2.6



03 ASSURE

- Independent expert critical review and toxicological sign-off
- On-demand technical hotline for urgent authority questions and study protocols
- Direct support during Notified Body and health authority audits

YOUR BENEFITS



SCIENTIFICALLY JUSTIFIED EXPOSURE LIMITS

Toxicological thresholds and exposure limits established using transparent assumptions and appropriate scientific evidence.



CLEAR TOXICOLOGICAL CONCLUSIONS

Chemical constituents and patient exposure translated into scientifically supported conclusions on toxicological risk.



DEFENSIBLE TOXICOLOGICAL DOCUMENTATION

Traceable assessments and scientific rationales structured to support regulatory and Notified Body review.

READY TO ASSESS YOUR TOXICOLOGICAL RISKS?

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