

# THE LEADER IN GLOBAL ENGINEERING AND CONSULTING SERVICES FOR THE LIFE SCIENCES INDUSTRIES

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## TOXICOLOGICAL RISK ASSESSMENT

Product specific evaluations to help prevent product recalls and ensure patient safety; ensure worker safety; pharmaceutical cleaning limits; and an overall toxicological assessment for product development, manufacturing process, and laboratory testing.

### TOXICOLOGICAL PRODUCT ASSESSMENTS INCLUDE:

- Product characterization
  - API or product mechanism of action (MOA)
  - Pharmacokinetics – absorption, distribution, metabolism, excretion (ADME)
- Disease or ailment etiology
- Summary of pre-clinical & clinical trials (if available)
- Summary of Personal Protective Equipment (PPE) for worker safety
- Determination of manufacturing product via standard stainless-steel manufacturing vs. single use technology (SUT)
- Risk assessment of product, Health-Based Exposure Limit (HBEL)– categorization of overall toxicity and Permitted Daily Exposure (PDE,  $\mu\text{g}$  of API/day) & Occupational Exposure Limit (OEL,  $\mu\text{g}$  of API / $\text{m}^3$ ) (data permitting)
- Safety Training provided per request

### REGULATORY & GUIDANCE GOVERNANCE DOCUMENTS:

- ICH Q3C(R6)
- ICH S6(R1)
- EudraLex, Vol 4 GMP Guidelines, Part 1, Chapter 5
- EudraLex, Vol 4 GMP Guidelines, Part 1, Chapter 3
- EudraLex, Vol 4 GMP Guidelines, Annex 15
- EMA/CHMP/CVMP/SWP/169430/2012
- ISPE Baseline Guide Volume 7, Second Edition, Risk based Manufacture of Pharmaceutical Products
- Active Pharmaceutical Ingredients Committee (APIC): Guidance on Aspects of Cleaning Validation in Active Pharmaceutical Ingredient Plants.
- Technical Report No. 101: Guidance for Setting Occupational Exposure Limits: Emphasis on Data-Poor Substances

### EXAMPLES OF BIOLOGIC EVALUATIONS EXPERIENCE:

Viral Vectors:

- Adenovirus
- Adeno-associated virus (AAV)
- Lentivirus
- Poxvirus
- Baculovirus

### HOST CELL PLATFORMS:

- HEK-293
- CHO
- Sf9
- MDCK
- Vero
- C6
- ARPE-19

### EXPRESSION SYSTEMS:

- Vaccine Antigen Expression Systems
- Virus Replication Platforms
- Viruses & Vectors