PharmEng Technology

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

EXTRACTABLES & LEACHABLES (E&L) SERVICES

Extractables & Leachables (E&L) are evaluated to ensure product safety, strength, quality, or purity is not altered.

E&L are deemed a subset of impurities, & should be included in impurity evaluation, management, & control strategy within market authorization submission.

CONTACT US

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DELIVERABLES INCLUDE:

RISK MANAGEMENT FRAMEWORK

- Aid in screening & material selection for manufacturing components & container closure systems (CCS)
- Conduct Risk Assessment:
  - Risk Identification
  - Risk Analysis
  - Risk Evaluation
- Toxicology Risk Assessment addressing safety impact of individual leachable to drug product or medical device
  - Permitted Daily Exposure (PDE) calculated
  - Threshold of Toxicological Concern (TTC) applied in absence of data
  - Aid in determining Analytical Evaluation Threshold (AET)
- Risk Control
  - Risk Reduction
  - Risk Acceptance
- Risk Review

REGULATORY & GUIDANCE DOCUMENTS:

- ICH M7, "Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risks."
- ICH Q3C, "Impurities: Guideline for Residual Solvents."
- USP 1663, "Assessment of Extractables Associated with Pharmaceutical Packaging/Delivery Systems."
- USP 1664, "Assessment of Drug Product Leachables Associated with Pharmaceutical Packaging/Delivery Systems."
- ISO 10993, "Biological Evaluation of Medical Devices."
- USP 661, "Plastics Packaging Systems and Their Materials of Construction."
- USP 665, "Plastic Components and Systems Used to Manufacture Pharmaceutical Drug Substances and Products."