PHARMA SERVICES

Preliminary consultancy, project definition and management.

- OEL/OEB/ASL Assessment including engineering support for containment measures.
- PDE Assessment for Medicinal Products/Active Ingredients in shared facilities (EMA/CHMP/CVMP SWP/169430/2012/00).
- ERA for Medicinal Products for human use, as for EMEA/CHMP/SWP/4447/00, or Veterinary Use, as for VICH GL6 and VICH GL38.
- E&L (Extractables and Leachables) on finished pharma products.
- Impurity Safety Assessment (ICH Q3A, ICH Q3B and ICH M7), Genotoxicity, Toxicity and Risk Assessment.
- Elemental impurities evaluation (ICH Q3D), Genotoxicity, Toxicity and Risk Assessment in Medicinal Products for human use or veterinary use.
- Solvents evaluation (ICH Q3C), Genotoxicity, Toxicity and Risk Assessment.
- "In silico" prediction for Toxicology (DEREK Nexus), Genotoxicity (SARAH Nexus), Metabolism (METEOR Nexus); interpretation of results and Expert Report by our ERTs® (European Registered Toxicologist).
- Expert Reports & Pharmacological Evaluation
- Nitrosamines assessment

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