



Your lighthouse in  
a sea of rules

# PHARMA SERVICES



- **OEL/OEB/ASL Assessment** for all type of molecules (API, Intermediates, Reagents, ...)
- **PDE Assessment APIs** (EMA/CHMP/SWP/169430/2012/00)
- **ERA for Medicinal Products** for human use, as for EMEA/CHMP/SWP/4447/00 Rev. 1, or Veterinary Use, as for VICH GL6 and VICH GL38.
- **E&L (Extractables and Leachables)** in pharmaceutical field.
- **Toxicological Assessment of Solvents in Human Drug Products** (ICH Q3C) and **Veterinary Drug Products** (VICH GL18)
- **Toxicological Assessment of Elemental Impurities in Human Drug Products** (ICH Q3D) and **Veterinary Drug Products**
- **Toxicological Assessment of Impurities** (ICH Q3A, ICH Q3B and ICH M7)
- **“In Silico” Prediction for Toxicology** (DEREK Nexus and Leadscape for Model Applier), Mutagenecy (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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ISO 9001

BUREAU VERITAS  
Certification

