

DOUGLAS CONNECT & LEADSCOPE

ICH M7 Consulting Service

Providing European organisations outsourcing services and consulting in predictive toxicology to meet ICH M7 regulatory guidelines



EXPERIENCE

that makes a difference



Background

The new ICH M7 guidance provides a specification for the use of *in silico* models for evaluating the genotoxicity of impurities in pharmaceuticals. The guidelines support the combined use of consensus models based on statistical-based (Q)SAR and expert rule-based computational toxicology combined with an expert opinion to support a regulatory submission.

Douglas Connect and Leadscope have established a partnership providing a market leading consulting service to execute the modelling and reporting requirements of such a regulatory submission.

The regulatory-accepted Leadscope software has been developed in close collaboration with the US FDA to satisfy the requirements for the ICH M7 guidance.

Douglas Connect scientists bring a depth of expertise in computational toxicology to execute all aspects of a client project. They have lead the creation of the OpenTox platform for validated (Q)SAR model building and regulatory reporting for REACH and the ToxBank infrastructure development.

Using their expertise and the Leadscope software, Douglas Connect can provide a complete outsourced solution to satisfy ICH M7 requirements.

DETAILED

report with results

Service Components

- ▶ Evaluation of client requirements to support ICH M7-compliant (Q)SAR computational toxicology regulatory submissions
- ▶ Application of expert rule-based and statistical-based *in silico* models to generate results for client compounds
- ▶ Development of consensus models and rationale
- ▶ Provision of a chemical and biological interpretation of the results
- ▶ Preparation of an expert opinion for conflicting *in silico* results
- ▶ Provision of a detailed report to client containing results, analysis and expert opinion

“PREPARATION OF
AN EXPERT OPINION
FOR CONFLICTING
IN SILICO RESULTS”

EXPERTS

behind the project

GLENN J. MYATT

Glenn Myatt, PhD is a Chief Scientific Officer, Co-Founder of US based Leadscope Inc.

He brings many years of experience developing cheminformatics systems to support drug discovery.

Dr. Myatt received his B.Sc. in computing from Oxford Brookes University, his M.Sc. in knowledge-based systems from Heriot-Watt University Edinburgh, UK, and his PhD in chemoinformatics from the University of Leeds, UK.

His professional interests include the application of chemoinformatics to facilitate the rapid design of potent and safe drugs.

BARRY J. HARDY

Barry Hardy, PhD founded the eCheminfo and InnovationWell community activities of Douglas Connect, Switzerland.

He obtained his Ph.D. in 1990 from Syracuse University working in the area of computational chemistry, biophysics and computer-aided molecular modelling and drug design. He has developed technology solutions for internet-based conferencing, tutor-supported e-learning, laboratory automation systems and computational chemistry and informatics.

He was a National Research Fellow at the FDA Center for Biologics and Evaluation, a Hitchings-Elion Fellow at Oxford University and CEO of Virtual Environments International. Within OpenTox he has been leading the development of an open, interoperable, semantic web platform whose goal is to satisfy the needs of safety assessment through the creation of applications linking resources together for data, algorithms, models and ontologies.

ENQUIRIES AND QUOTES

ICH M7 Consulting Service

To obtain a detailed quote and agreement please contact:

Dr. Barry Hardy

E: Barry.Hardy@douglasconnect.com

T: + 41 79 755 2340

*All discussions and associated
information will be treated in
high confidence.*

douglasconnect
working communities

