

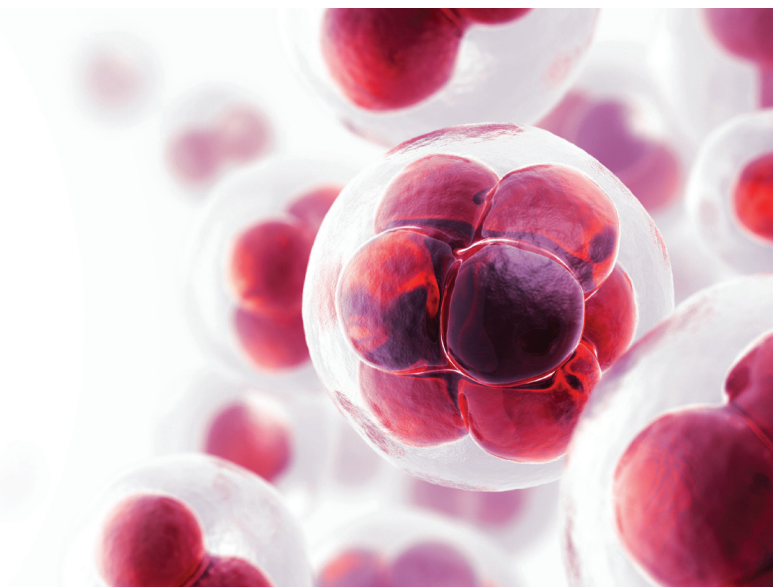
Physiologically Based Pharmacokinetic Modeling (PBPK)



Why ScitoVation for Your PBPK Modeling Needs?

PBPK modeling is a predictive tool to estimate internal target tissue concentration for a wide range of exposure conditions in animals or humans. ScitoVation offers comprehensive PBPK modeling services. Reasons to work with ScitoVation include:

- We are proficient with several PBPK modeling platforms, and have developed our own software tool for generic, life-course PBPK modeling (PLETHEM) under a partnership the US Environmental Protection Agency (EPA), with enhanced PBPK features.
- We have developed methods to link point of departure determined from in vitro toxicity assays to target tissue concentrations in vivo (q-IVIVE).
- We offer a one-stop shop because we also have an in vitro laboratory which provides input data for our PBPK models.
- ScitoVation is a reputable leader, whose work is able to withstand scientific peer review, including that of regulators.

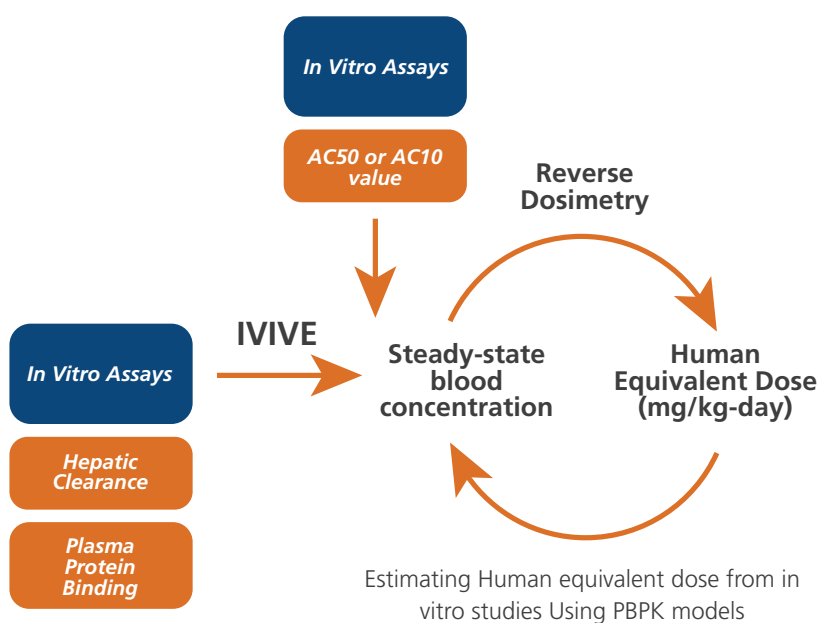


Comprehensive PBPK Modeling Services

During their lives, most humans are exposed to a wide range of chemicals from multiple sources including food, textiles, household cleaning products, cosmetics, fragrances, and medicines. Whether animal or cell-based studies are conducted to determine the dosage at which toxicity starts to occur, PBPK models can then be used to predict the equivalent doses for humans that would cause similar effect. The traditional most common use for PBPK models in risk assessment is to understand how the compound is absorbed, distributed, metabolized and excreted (ADME). Beyond the traditional ADME, using PBPK models, we have assisted clients answer questions such as:

- Inter-species extrapolation: Predicting exposure from one species to another, reducing the need to conduct studies across multiple species.
- Intra-species extrapolation: Predicting exposure for vulnerable populations such as children, the elderly or occupational exposure.

- Route-to-route extrapolation: Predicting concentration in blood or tissue from dermal exposure using oral exposure data.
- High-to-low dose extrapolation: Using high dosage exposure to predict concentration in blood and tissue for exposure at a lower dose.
- Population variability assessment: using PBPK modeling and statistical analysis such as Monte Carlo simulations to estimate variability in internal target doses across a population.
- Human biomonitoring data and epidemiological data: Estimating population daily exposure intakes that are consistent with blood or urine measures found in biomonitoring surveys.



Our Approach

- We use data from clients when available or the scientific literature
- We conduct in vitro studies to collect additional input data when necessary
- Once models are fitted, extensive analyses are conducted to validate them including sensitivity analysis to ascertain robustness of the model



- We promise to partner with you to define metrics for success at the beginning of the project and outline a clear plan to achieve them.
- We promise to meet the timeline pending receipt of client materials or approvals within the pre-agreed timeframes.
- We promise to stand behind our pricing unless there is a change in scope. Any changes in scope that affect the price will be promptly communicated and discussed as appropriate.
- We promise to perform our work with the highest level of scientific rigor and scrutiny.
- We promise that all deliverables including experimental designs, protocols, data, analyses, and reports will be reviewed before submission to the client.

CONTACT US

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