

# Accelerating the Pace of Generic Pharmaceutical Development

**The formulation team at Impax Laboratories leveraged Certara's IVIVC Toolkit for Phoenix WinNonlin to optimize generic formulations.**



## Background

Impax Laboratories is a publicly traded, specialty pharmaceutical company headquartered in the San Francisco Bay Area, California with facilities in New Jersey, Pennsylvania and Taiwan. Formed through reverse merger of the Global Pharmaceutical Corporation and Impax Pharmaceuticals, they leverage their expertise in drug delivery and formulation to develop generic and branded drugs. The generics division at Impax Labs specializes in high-value solid oral and alternative dosage form products.

## Challenge

The Impax team uses *in vitro-in vivo* correlation (IVIVC) to support formulation development. IVIVC is a predictive mathematical tool that describes the relationship between an *in vitro* property of a drug dosage form and an *in vivo* pharmacokinetic response. This biopharmaceutical tool is a surrogate for *in vivo* bioavailability and can be used to demonstrate virtual bioequivalence and support attaining regulatory biowaivers.

The Impax team wanted to spend their time developing their generics portfolio, not writing code to conduct IVIVC.

## Solution

For the past six years, the Impax generics team has been using Certara's IVIVC Toolkit™ for Phoenix® WinNonlin® on a daily basis to support formulation optimization. The IVIVC Toolkit is a software tool that creates and substantiates the Level A correlation outlined in the FDA guidance to correlate the *in vitro* dissolution profile of a dosage form with the *in vivo* pharmacokinetic (PK) profile. It can be used to predict the impact a change in formulation will have or predict the dissolution rate that is necessary to achieve a desired PK profile. The Level A IVIVC can support a biowaiver for changes in manufacturing site, raw material suppliers and minor changes in formulation.

## Challenge

The formulation team at Impax needed a user-friendly software tool to support developing IVIVC models.

## Solution

For the past six years, the Impax generics team has been using Certara's IVIVC Toolkit for Phoenix WinNonlin on a daily basis to support formulation optimization.

## Benefit

The IVIVC Toolkit's intuitive graphical user interface is easy to learn and doesn't require prior coding knowledge; it is a solution that the entire Impax formulation team can use.

## Benefit

The IVIVC Toolkit is a user-friendly solution that helps everyone on the formulation team. Its intuitive graphical user interface is easy to learn and doesn't require prior coding knowledge. In addition, the dialogue-guided wizards walk users through all the steps needed for an IVIVC, thus streamlining the workflow and reducing the likelihood of making errors.

The fact that the IVIVC Toolkit is used by the US FDA further increases their confidence in using this tool to support regulatory submissions. If FDA reviewers have any questions, they can rerun the analysis on their copy of the IVIVC Toolkit and attain the same results. Groups that use in-house developed scripts do not have this peace-of-mind regarding their submissions.

## Impact

In drug development, saving time can enhance future profitability. By using the IVIVC Toolkit for Phoenix WinNonlin, the Impax team has the flexibility and efficiency to start analyzing their data the moment it becomes available. Training new team members on this tool is simple. And, some IVIVCs can even be developed in a single day using this software. The IVIVC Toolkit is an integral tool in supporting Impax Laboratory's generic product development strategy.

## About Certara

Certara is a leading provider of decision support technology and consulting services for optimizing drug development and improving health outcomes. Certara's solutions, which span the drug development and patient care lifecycle, help increase the probability of regulatory and commercial success by using the most scientifically advanced modeling and simulation technologies and regulatory strategies. Its clients include hundreds of global biopharmaceutical companies, leading academic institutions and key regulatory agencies.

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