Simulations Plus

SCIENCE + SOFTWARE = SUCCESS

"Together, we fight the good fight to achieve high quality drug products focused on improving patient health and outcomes."

Sandra Suarez-Sharp

Vice President, Regulatory Affairs

Vision

Resolving unique, previously unsolved groundbreaking challenges involving biopharmaceutics and clinical pharmacology.

In the last several years, there are over 30 approved drug products which have been supported by an assortment of GastroPlus® modeling and simulation results, and I expect that number to increase substantially as we accelerate the qualification of sponsor data and models to streamline regulatory success.

Experience

Dr. Suarez-Sharp received her Ph.D. from the University of Florida and spent two years as a postdoctoral fellow at the University of North Carolina (Chapel Hill) before joining the U.S. FDA in 1999.

She spent time as an expert in the Office of Clinical Pharmacology, Office of Generic Drugs, and Office of Pharmaceutical Quality, where she most recently served as Master Reviewer and Scientific Advisor for the Division of Biopharmaceutics. She was actively involved in the development of several internal procedures for FDA reviewers and guidance documents for industry, and she is recognized as one of the preeminent thought leaders for Physiologically Based Biopharmaceutics Modeling (PBBM).

Her experiences reviewing numerous applications across many offices at the FDA provide her a unique perspective from which your company may now benefit.

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