



Enabling Technologies CONSORTIUM

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Enabling Technologies Consortium™ (ETC) Issues Request for Information (RFI) Regarding Development of User-Friendly Population Balance Model with Data Integration for Crystallization Development

Crystallization is an important unit operation, used as a means to isolate and purify desired chemical products. The pharmaceutical industry relies heavily on crystallizations for chemical and physical property control in the manufacturing of active pharmaceutical ingredients. The development of robust crystallization processes requires knowledge of crystallization kinetics, which will vary on a case-by-case basis. Population balance models (PBMs) have been used to determine crystallization kinetics and as tools for improving the efficiency of rational process design.

Commercial off-the-shelf software for PBMs is available from multiple suppliers, and the use of this software is increasing within the pharmaceutical industry. However, there are several opportunities to improve the current commercial PBM software in order to increase adoption of this approach. These opportunities include:

- Streamlining the data importation and transformation steps required to initialize the models;
- Automating the preprocessing steps required for model convergence;
- Increasing the incorporation of offline and online data into these models; and
- Improving the efficiency of model selection/discrimination and parameter regression.

“What makes pharmaceutical crystallization development challenging is that crystallization processes are inherently rather complex with each system being unique. PBM has the potential to be a very impactful tool because it can provide a mechanistic description of the system that, once validated, can significantly improve the efficiency of crystallization development. Unfortunately, to-date, PBM has been largely under-utilized for this application, primarily because the commercially available software packages are simply too difficult to use. Our goal is to collaborate toward the development of more user-friendly tools that can make the application of PBM an industry best practice with widespread application for crystallization development,” Aaron Cote, Ph.D. Merck & Co USA; Lead of ETC Crystallization team.

The Enabling Technologies Consortium™ would like to collaborate with a partner to develop a commercially available, user-friendly PBM tool able to integrate directly with the online PAT tools and experimental platforms, to receive raw data from various common sources in a seamless manner, to improve methods for parameter regression, and to determine the appropriate solubility expression with user-provided solubility data. As a first step in establishing this partnership, ETC has placed an open call to the vendor community by means of a “Request for Information” (RFI) through the ETC website, www.etconsortium.org. The purposes of this RFI are to solicit interest from the vendor community in collaborating on this project and to allow vendors to learn more about the technology requirements sought by ETC. This information will be used by ETC to further define this project and ultimately select a vendor to partner with through a formal “Request for Proposals” (RFP) process later this year. It is the intention of ETC that upon completion of this project, a new population balance model will have been developed and made available as a commercialized product.

We invite any vendor who may be interested in this project to participate by downloading the RFI from the ETC website and submitting a response by the August 8, 2016 deadline.

About Enabling Technologies Consortium™: (www.etconsortium.org)

The Enabling Technologies Consortium™ (ETC) is comprised of pharmaceutical and biotechnology companies collaborating on issues related to pharmaceutical chemistry, manufacturing, and control with the goal of identifying, evaluating, developing, and improving scientific tools and techniques that support the efficient development, and manufacturing of pharmaceuticals. The purpose of this consortium is to identify pro-actively high-value opportunities to deliver innovative technologies where the business case is compelling and collaboration with the broader external community is required. For more information please contact the Secretariat at info@etconsortium.org.