



Enabling Technologies CONSORTIUM™

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Enabling Technologies Consortium™ (ETC) Issues Request for Information (RFI) Regarding Technologies for the Enhancement of Process Understanding during Drying in Agitated Dryers

The Enabling Technologies Consortium™ (ETC), a consortium of pharmaceutical and biotechnology companies dedicated to collaboratively developing improved chemistry, manufacturing and control technologies for the pharmaceutical industry, is seeking information from companies on possible improvements to current drying technologies.

The drying unit operation is used extensively in the pharmaceutical industry and is a critical step in the synthesis of a drug product. Limitations in current technology constrain the development of an optimum drying protocol in the drug development process. The current state of real time data collection over the course of the drying process suffers from limitations of existing PAT tools, process measurements, and material sampling technologies. Current PAT tools cannot collect data at multiple points and suffer from equipment constraints that make it difficult to obtain a holistic picture of the heterogeneity in the drying process. Additionally, existing methodologies for scale-up or process transfer between different dryer types often result in issues with agglomeration or attrition and consequently batch failure. The current design of many dryers also does not allow for the collection of representative samples during the drying process without interrupting the process, making it difficult to discern how the powder quality attributes evolved over the course of the process.

Ultimately, the concern with the limitations in the current capabilities for real time data collection during drying is the inability to collect meaningful data for the development of closed loop control systems, model validation/verification or to pursue the design of effective scale-down equipment.

To address this need, ETC is seeking to work with companies interested in supplying equipment that can be used for PAT, process characterization, or sampling. PAT equipment should be capable of real time measurement of solvent composition, form, and particle size distribution; process measurement equipment should measure work and shear; and dryer equipment should enable automated sampling during drying in agitated dryers without breaking vacuum to allow for off-line testing. The goal of this collaborative project is joint development of instrument prototype(s) which could be used at lab and/or commercial scale and address one or more

aspects in drying technology advancement. The hope is the prototype(s) will become commercial product(s) in the future.

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: (1) solicit information and interest from the vendor community in collaborating on this project and (2) allow vendors to learn more about the technology requirements sought by ETC members. This RFI provides collective hardware and software requirements and performance criteria collected from a cross-pharmaceutical group of drying technology users. The information collected during the RFI process will be used by ETC members as part of the selection process to identify a collaborator or collaborators to develop drying technologies.

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 April 3, 2017 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.