



Enabling Technologies CONSORTIUM™

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Enabling Technologies Consortium™ (ETC) Issues Request for Information (RFI) Regarding Online Ultra-High Performance Liquid Chromatography and Probe-Based Sampling

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 companies interested in supplying a vendor-supported, portable online UHPLC, with robust, probe-based sampling.

Online liquid chromatography analysis is becoming increasingly important for studying the kinetic profiles of chemical reactions, from which valuable mechanistic information can be obtained. Historically, online sample collection was performed *via* either flow of the reaction medium through a sample loop, followed by injection, or by metered withdrawal of a defined volume flowing via a sampling tube or capillary. Both of these approaches work well for homogeneous solutions, but are not well suited to the investigation of heterogeneous reactions where solids are present or where active precipitation or crystallization is taking place. Instrumentation has been recently introduced that is capable of reliably sampling heterogeneous reactions, but its sampling capacity limits the instrument's utility for detailed kinetic profiling of reactions where frequent and extended sampling is needed.

To address this need, ETC is seeking to work with companies interested in supplying a vendor-supported system that integrates a low volume, probe-based online sampling system with a liquid chromatographic (LC) analysis capability. The integrated system should be capable of repeated automated sampling of both homogenous and heterogeneous reaction mixtures and have the ability to perform direct sample injection for LC analysis for any desired number of reaction time points. A fully integrated data management and data visualization environment is also deemed critical in the system, enabling seamless collation of sampling specifics and chromatographic results for further analysis. The goal of this collaborative project is joint development of an instrument prototype, with the hope it will become a commercial product in the future.

“Data-rich experimentation strategies, including broad deployment of Process Analytical Technologies, represent a huge opportunity for improving the process development culture throughout the pharmaceutical industry. While there are some excellent tools currently in the

marketplace tackling specific elements of direct-inject online liquid chromatography, many of these tools require the skilled hands of a seasoned practitioner to realize their full potential. Whether this is due to software, hardware, or cross-vendor integration issues, this tends to limit broad and routine deployment of online UHPLC. In this project, we are interested in partnering with one or more vendors to develop a holistic online UHPLC solution, which seamlessly integrates a full-featured, portable chromatographic system with a robust sampling platform and an intuitive software environment. This will, in turn, greatly improve the accessibility of online UHPLC for a typical experimentalist, complementing our growing arsenal of high data density tools.” Shane Grosser, Ph.D. Merck; Lead of the ETC Online UHPLC Team.

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 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 UHPLC 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 the online UHPLC with probe-based sampling system.

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 December 23, 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.