



Enabling Technologies

C O N S O R T I U M

REQUEST FOR INFORMATION

Compact HPLC Instrument

November 4, 2019

Enabling Technologies Consortium™ Request for Information

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1 Introduction

1.1 About Enabling Technologies Consortium™ (ETC)

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.

1.2 Request for Information

Publication of this Request for Information (RFI) is the first step by ETC to solicit interest in collaborating together on a compact complete HPLC instrument. The information collected during the RFI process along with subsequent interviews will be used for evaluation purposes. Depending on the responses received ETC may choose to select a collaborator solely based on their response to the RFI or may choose to refine project requirements and subsequently release a Request for Proposals (RFP) to aid in the collaborator selection process. The goal of this collaborative project is the creation of a prototype with the hope it will become a commercial product in the future.

1.3 Disclaimer

The contents and information provided in this RFI are meant to provide general information to parties interested in developing the compact HPLC instrument. The successful respondent selected by ETC at either the RFI stage or RFP stage (if applicable) will be required to execute an Agreement that will govern the terms of the project. When responding to this RFI, please note the following:

- This RFI is not an offer or a contract
- Responses submitted in response to this RFI become the property of ETC
- Respondents will not be compensated or reimbursed for any costs incurred as part of the RFI process
- If ETC receives and responds to questions from RFI respondents, ETC reserves the right to anonymize the questions and make the questions and ETC's responses available to all respondents via our website
- Responses to RFIs should contain only high-level discussions of product development efforts and should not contain trade secrets or confidential information. ETC does not make any confidentiality commitments with respect to RFI submissions but agrees not to publicly distribute the RFI responses outside the consortium or share RFI responses with other respondents.
- ETC is not obligated to contract for any of the products or services described in this RFI
- ETC reserves the right to:
 - Accept or reject any or all proposals
 - Waive any anomalies in proposals

- Negotiate with any or all bidders
- Modify or cancel this RFI at any time

1.4 RFI Contact Information

All questions and inquiries regarding this RFI should be directed to:

Ms. Alexis Myers
ETC Secretariat
c/o Drinker Biddle & Reath, LLP
1500 K St NW
Washington DC, 20005-1209
(202) 842-8800
info@etconsortium.org
<http://www.etconsortium.org/>

1.5 Anticipated Time Frames for Evaluation and Selection Process

Issue RFINovember 4, 2019
Questions on RFI dueDecember 9, 2019
Responses to RFI dueJanuary 21, 2020
Invitations sent to respondents for presentationJanuary 28, 2020
Presentation to ETC by respondentsFebruary 2020
Select Finalists for RFPMarch 2020

Please submit your response electronically to the above address. Responses received after January 21, 2020 will not benefit from full consideration and may be excluded from the selection process.

2 Project Information

2.1 Possible Project Sponsors

AbbVie, AstraZeneca, Bristol-Myers Squibb, Eli Lilly, Genentech, GlaxoSmithKline, Merck, Pfizer

2.2 Description

High performance liquid chromatography (HPLC) is a nearly universal analytical tool in organic synthesis and biochemical development laboratories. With the advent of commercially available automated sample extraction and dilution systems for heterogeneous systems (e.g. Mettler EasySampler, GlobalFIA FloPro, etc.), process development laboratories are increasingly moving towards automated analyses during synthetic route development and scale-up. Automated measurement enables unattended operation with consistent sampling at regularly scheduled intervals, increasing data density and leading to more efficient process understanding. A current limitation of the technology is related to analysis using conventional liquid chromatography systems. The chromatography system must be located proximal to the extraction and analysis or transferred over large distances. The former requirement imposes restrictions in confined spaces near the face of the laminar flow hoods where these studies are typically undertaken, and the latter approach imposes additional transfer time while increasing the risk of hold-up or carryover between successive samples. The ETC desires an integrated system (sample preparation and analysis) in a compact form factor that would enable mounting inside a lab hood. Depending on configuration, a compact system might enable “on demand” operation, due to minimal dead volume and small volume components that could quickly equilibrate prior to performing measurement.

The ETC is seeking companies interested in supplying a viable commercial compact HPLC system. This technology, combined with existing automated sample extraction and dilution systems, would enable hood-mounted on-line characterization of chemical processes during development and scale-up in pharmaceutical, commodity, and specialty chemical laboratories.

The sections below detail the system requirements as identified by a working group within the Enabling Technologies Consortium (ETC). ETC is interested in entertaining proposals from vendors regarding technologies that might be amenable to collaborative development.

2.3 Compact HPLC Instrument Requirements

2.3.1 Necessary Hardware and Software Requirements

Hardware Requirements

- A complete chromatographic system with dimensions on the order of 16" x 14" x 18" (W x H x D) for easy transport and operation within standard laboratory laminar flow hoods.
- Performance (e.g. resolution, sensitivity, analysis time) comparable to conventional bench top HPLC systems is required. A demonstration of limit of detection (LOD) approaching that of a conventional benchtop unit using a model compound is desired.
- The instrument and accessories should be powered by a single electrical service (110V/15A or 220V). Battery power is desirable for some applications, but not a requirement.
- Material of construction of wetted parts should be compatible with a wide variety of solutions and solvents used in organic synthetic process development. Although not required, inert materials for the handling of biologic materials is also desired.
- The mobile phase solvent pump must be capable of at least 400 bar pressure. A pump capable of 1000 bar is preferred.
- Minimum 2-channel gradient capability, with a desire for 3 gradient channels.
- A single- or dual- channel ultraviolet (UV) detector in the range of 210-360nm is a minimum requirement. There is a strong preference for a variable wavelength or array detector. Minimum sample rate in all cases should be compatible with fast HPLC separations (≥ 60 Hz).
- Chromatography columns should provide efficiencies comparable to typical 2.7 μm core-shell C18 columns ($\sim 250,000$ N/m). Columns should be readily available packed with a variety of commercial phases from multiple column suppliers.
- Instrument should be able to trigger remotely using contact closure or other common initiation event.
- A column compartment capable of 20-65°C temperature control is desirable.
- Facile coupling with mass spectrometry detection is also desired.

Software Requirements – User Interface

- An intuitive interface for use by non-specialists is required. Control through conventional chromatography data systems is strongly desired.
- Setup to enable a sequence of analyses (e.g. sampling interval, method parameters, number of samples, etc.) should be available in a user-friendly fashion that requires minimal training or special expertise.
- There is a requirement for simple output in a standard report format (e.g. Allotrope Foundation) to enable integration with process data management systems. Output via OPC-UA or other standard formats is desired for system integration.

Other System Requirements

- Vendor provided IQ/OQ (Installation Qualification/Operational Qualification) process.
- A migration path to GMP use must be available (i.e. 21CFR part 11)

2.3.2 Optional Hardware and Software Requirements

- Operation with an autosampler (vendor-supplied or third party) to enable standard bench-top measurements and troubleshooting would be useful.
- The ability to stack sequential analyses during real-time operation for visualization process evolution is desired, as is the capability of plotting individual species as a function of time (trend plots).

2.3.3 Availability Requirements

- Commercially available instrument, in the form of a single compact unit.
- Any requisite service on the instrument should be available globally.
- Vendor-provided, hardware and software support for both the chromatographic and sampling system is expected for the reasonable life of the product.
- Hardware, software, and firmware updates should be field deployable and available at reasonable cost following launch of the commercial technology.

2.3.4 Licensing Requirements for Commercialized Product

1. For the duration of the project with ETC (e.g., development and testing), any required software will be provided to ETC participants at no cost.
2. For the commercial product, software should be licensed to customers on a perpetual basis or subscription basis at the option of customer.
3. Software shall be available for self-hosting by (or on behalf of) customer even if the company elects to make a SaaS alternative available.
4. The company shall make available industry standard support.
5. Ownership of data generated on system resides with customer.

3 Criteria for Evaluation

The ETC will evaluate the responses to this RFI based on the vendor’s ability to:

- Provide responses reflecting a desire to participate in collaboration.
- Meet the functional, performance, and technical requirements described in this RFI as evidenced by the RFI response and presentations made to ETC.
- Provide a cost-effective solution that is compatible with the goals of the project.
- Demonstrate domain expertise and an ability to work collaboratively with the ETC in development of the Compact HPLC Instrument.
- Provide a superior level of customer service and technical support, both pre-installation and post-installation to clients.
- Discuss potential partnerships and current development efforts that show similarities to this request.
- Provide any additional capabilities that may differentiate them from other potential collaborators.

The ETC will not provide individual feedback directly to RFI respondents beyond the status of their proposal.

4 Respondent Profile *(to be completed by RFI respondent)*

Please provide information to the following:

4.1 Company/Organization Information

Company/Organization Name	
Address	
City	
State	
Country	
Zip Code	
Website	

4.2 Primary Contact Person

Name	
Title	
Email address	
Phone Number	

4.3 Company/Organization Overview

Provide a brief overview of your company/organization including number of years in business, number of employees, nature of business, description of clients, and related products developed and commercialized to date.

4.4 Parent Corporation and/or Subsidiaries

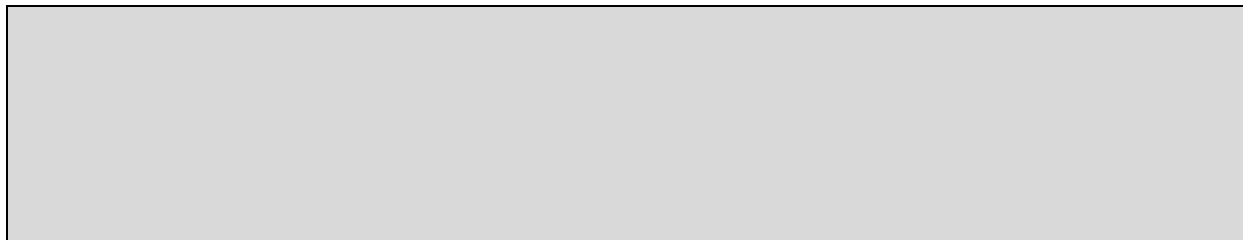
Identify any parent corporation and or subsidiaries, if appropriate.

4.5 Summary of Expertise

Give a brief description of your company/organization’s expertise in the area/field related to this RFI. Include any experience working on projects with Consortia/Associations.


4.6 Standards Certifications

List any certifications currently held, including date received, duration, and renewal date.



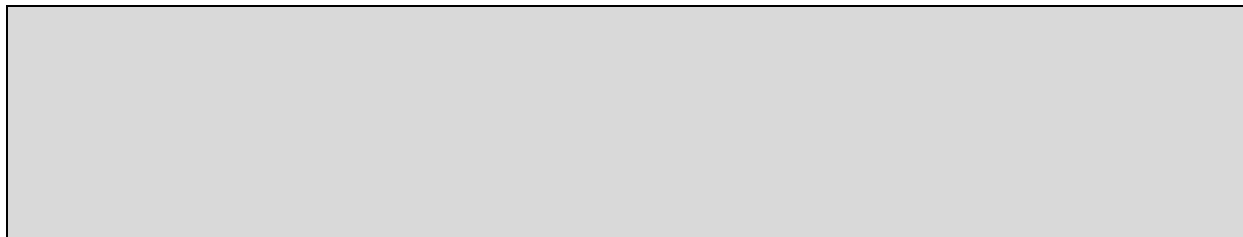
4.7 Goals and Strategic Vision

Provide a summary of your company/organization's short term and long-term goals and strategic vision.



4.8 Miscellaneous

Please enter your response to each requirement using the guidelines provided in the tables below. If additional documentation or schematics are required to respond to a particular question, please answer the question as succinctly and accurately as possible and reference supplemental attachments.



5 Company/Organization Response to RFI *(to be completed by RFI respondent)*

5.1 Proposal

5.2 Functional Requirements & Specifications

Refer to the Functional Requirements and Specifications checklist below, which summarizes the collective requirements and specifications by the member companies participating in the project.

Based upon your proposed approach to deliver a solution, provide a response to each checklist item along with comments and assign one of the following Codes to each item:

A	Current capability of existing product
B	Able to add capability as requested
C	Able to add capability with modification to ETC request
D	Unable to add capability

Feature	Requirement	Code	Vendor Comments
Hardware	A complete chromatographic system with dimensions on the order of 16" x 14" x 18" (W x H x D) for easy transport and operation within standard laboratory laminar flow hoods.		
Hardware	Performance (e.g. resolution, sensitivity, analysis time) comparable to conventional bench top HPLC systems is required. A demonstration of limit of detection (LOD) approaching that of a conventional benchtop unit using a model compound is desired.		
Hardware	The instrument and accessories should be powered by a single electrical service (110V/15A or 220V). Battery power is desirable for some applications, but not a requirement.		
Hardware	Material of construction of wetted parts should be compatible with a wide variety of solutions and solvents used in organic synthetic process development. Although not required, inert materials for the handling of biologic materials is also desired.		
Hardware	The mobile phase solvent pump must be capable of at least 400 bar pressure. A pump capable of 1000 bar is preferred.		
Hardware	Minimum 2-channel gradient capability, with a desire for 3 gradient channels.		
Hardware	A single- or dual- channel ultraviolet (UV) detector in the range of 210-360nm is a minimum requirement. There is a strong preference for a variable wavelength or array detector. Minimum sample rate in all cases should be compatible with fast HPLC separations (≥ 60 Hz).		

Hardware	Chromatography columns should provide efficiencies comparable to typical 2.7 µm core-shell C18 columns (~250,000 N/m). Columns should be readily available packed with a variety of commercial phases from multiple column suppliers.		
Hardware	Instrument should be able to trigger remotely using contact closure or other common initiation event.		
Hardware	A column compartment capable of 20-65°C temperature control is desirable.		
Hardware	Facile coupling with mass spectrometry detection is also desired.		
Software – User Interface	An intuitive interface for use by non-specialists is required. Control through conventional chromatography data systems is strongly desired.		
Software – User Interface	Setup to enable a sequence of analyses (e.g. sampling interval, method parameters, number of samples, etc.) should be available in a user-friendly fashion that requires minimal training or special expertise.		
Software – User Interface	There is a requirement for simple output in a standard report format (e.g. Allotrope Foundation) to enable integration with process data management systems. Output via OPC-UA or other standard formats is desired for system integration.		
Other	Vendor provided IQ/OQ (Installation Qualification/Operational Qualification) process.		
Other	A migration path to GMP use must be available (i.e. 21CFR part 11)		

Optional	Operation with an autosampler (vendor-supplied or third party) to enable standard bench-top measurements and troubleshooting would be useful.		
Optional	The ability to stack sequential analyses during real-time operation for visualization process evolution is desired, as is the capability of plotting individual species as a function of time (trend plots).		

5.3 Estimated Timeline

5.4 Estimated Project Cost