

REQUEST FOR INFORMATION

*Next-Generation Preparative Supercritical Fluid Chromatography Instrumentation*

July 19, 2016

Enabling Technologies Consortium

Request for Information

Table of Contents

[1. Introduction 3](#_Toc455581256)

[1.1 About Enabling Technologies Consortium™ (ETC) 3](#_Toc455581257)

[1.2 Request for Information 3](#_Toc455581258)

[1.3 Disclaimer 3](#_Toc455581259)

[1.4 RFI Contact Information 4](#_Toc455581260)

[1.5 Anticipated Time Frames for Evaluation and Selection Process 4](#_Toc455581261)

[2. Project Information 4](#_Toc455581262)

[2.1 Possible Project Sponsors 4](#_Toc455581263)

[2.2 Description 5](#_Toc455581264)

[2.3 SFC Instrument Requirements 5](#_Toc455581265)

[2.3.1 Necessary Hardware and Software Requirements 5](#_Toc455581266)

[2.3.2 Optional Hardware and Software Requirements 6](#_Toc455581267)

[2.3.3 Availability Requirements 6](#_Toc455581268)

[2.3.4 Licensing Requirements for Commercialized Product 6](#_Toc455581269)

[3. Criteria for Evaluation 6](#_Toc455581270)

[4. Respondent Profile (To be filled out by respondent) 7](#_Toc455581271)

[4.1 Company/Organization Information 7](#_Toc455581272)

[4.2 Primary Contact Person 7](#_Toc455581273)

[4.3 Company/Organization Overview 7](#_Toc455581274)

[4.4 Parent Corporation and/or Subsidiaries 8](#_Toc455581275)

[4.5 Summary of Expertise 8](#_Toc455581276)

[4.6 Standards Certifications 8](#_Toc455581277)

[4.7 Goals and Strategic Vision 8](#_Toc455581278)

[4.8 Miscellaneous 9](#_Toc455581279)

[5. Company/Organization Response to RFI 9](#_Toc455581280)

[5.1 Proposal 9](#_Toc455581281)

[5.2 Functional Requirements & Specifications 9](#_Toc455581282)

[5.2.1 Semi-prep Scale SFC Requirements 10](#_Toc455581283)

[5.2.2 Prep Scale SFC Requirements 12](#_Toc455581284)

[5.3 Estimated Timeline 13](#_Toc455581285)

[5.4 Estimated Project Cost 14](#_Toc455581286)

# Introduction

## 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.

## Request for Information

Publication of this Request for Information (RFI) is the first step by ETC to solicit interest in collaborating together on a Next-Generation Preparative Supercritical Fluid Chromatography (SFC) Instrument. The information collected during the RFI process along with subsequent interviews will be used for evaluation purposes, refinement of the subsequent Request for Proposals (RFP), and selection of respondent(s) who will be invited to submit a proposal to the future SFC Instrument RFP. The goal of this collaborative project is the creation of a prototype with the hope it will become a commercial product in the future.

## Disclaimer

The contents and information provided in this RFI are meant to provide general information to parties interested in developing the SFC Instrument. The successful respondent 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
* Proposals submitted in response to this RFI become property of ETC
* Respondents will not be compensated or reimbursed for any costs incurred as part of the RFI process
* All proposals received will remain confidential within ETC and not shared with other respondents
* ETC is not obligated to contract for any of the products and 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

## RFI Contact Information

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

Alexis Robertson

Project Coordinator

ETC Secretariat

c/o Drinker Biddle & Reath, LLP

1500 K St NW

Washington DC, 20005-1209

(202) 842-8800

[info@etconsortium.org](mailto:info@etconsortium.org)

<http://www.etconsortium.org/>

## Anticipated Time Frames for Evaluation and Selection Process (subject to change)

Issue RFI Jul 19, 2016

Questions on RFI due Aug 2, 2016

Responses to RFI due Aug 16, 2016

Invitations sent to respondents for presentation Aug 23, 2016

Presentation to ETC by respondents Aug 30 - Sep 16, 2016

Select Finalists for RFP Sep 26, 2016

***Please submit your response electronically to the above address. Responses received after August 16, 2016 will not benefit from full consideration and may be excluded from the selection process.***

# Project Information

## Possible Project Sponsors

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| AbbVie, Amgen, Biogen, Boehringer Ingelheim, Bristol-Myers Squibb, Merck & Co. (USA), and Pfizer |

## Description

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| Preparative SFC has been a preferred method for small scale purification in the pharmaceutical industry for about 15 years, since the prep SFC instrument was introduced by the now defunct Berger Instruments. Since then several vendors have entered and exited the prep SFC marketplace and a number of commercial instruments are currently available. However, these prep SFC instruments have some performance and dependability limitations, and are generally considered to be inferior to the Berger Multigram II, a ‘gold standard’ for small scale prep SFC purification that is no longer manufactured. Consequently, pharma companies interested in the planned replacement of aging instrumentation are uncertain how to proceed. In this project, desired hardware and software requirements and performance criteria collected from a cross-pharma group of SFC users will be shared with potential instrument providers, in the hope of identifying partners interested in developing, optimizing, and/or commercializing the “next-generation” of preparative SFC instrumentation collaboratively. |

## SFC Instrument Requirements

### Necessary Hardware and Software Requirements

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| There is a current need for both semi-preparative (2-3 cm i.d. columns) and preparative (>5 cm i.d. columns) scale SFC instrumentation. Requirements for each individually are listed in Section 5.2 below.  Hardware:   * Pump(s): Reliable delivery method for both compressible and non-compressible solvents at desired flowrates, isocratic and gradient control * Column temperature: Efficient column temperature regulation up to at least 60 °C * Injection: Reproducible sample introduction, no carryover * Detection: UV ; ability to add MS and up to at least one additional analog signal for both monitoring and collection * Fraction Collection: Low pressure, ventilated cabinet , no carryover * Triage: Readily available parts and easy serviceability for common wear parts (check valves, seals, injection valves, etc.) * Footprint: lab-scale setup (bench-top or cart) * CO2 recycling: available as an optional configuration * Software: User-friendly, graphical programming (visualization for fraction collection setup), on-the fly editing, stable, minimal communication errors, error logging, customizable reporting, Win 7.0 or higher operating system; availability of an application programming interface (API) to enable user customization. |

### Optional Hardware and Software Requirements

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| * Customizability: Availability of options for injection, collection, detection based on customer preference and scale. * Make-up pump: Improve recovery when using low percent modifier * Column switching valve: enable column switching without venting system, enable sample queuing on different columns |

### Availability Requirements

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| * Offering instrumentation should be commercially available * The price-point of the product should be competitive with current offerings * Vendor response time on service in less than two days. Availability of a local technician for system repair within a few days throughout US pharmaceutical laboratories. * A performance guarantee for 5-7 years would be a nice to have |

### Licensing Requirements for Commercialized Product

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| * Hardware includes all necessary licenses for use * Software licenses are perpetual based upon software version. Customers who choose to upgrade to a new software version may be subject to new software licensing fees * Ownership of data generated on system resides with customer |

# Criteria for Evaluation

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| The ETC will evaluate the responses to this RFI based on the vendor’s ability to:   * Provide response with 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 prep SFC instruments. * 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. |

# Respondent Profile (To be filled out by respondent)

Please provide information to the following:

## Company/Organization Information

|  |  |
| --- | --- |
| Company/Organization Name |  |
| Address |  |
| City |  |
| State |  |
| Country |  |
| Zip Code |  |
| Website |  |

## Primary Contact Person

|  |  |
| --- | --- |
| Name |  |
| Title |  |
| Email address |  |
| Phone Number |  |

## 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.

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## Parent Corporation and/or Subsidiaries

Identify any parent corporation and or subsidiaries, if appropriate

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## 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.

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## Standards Certifications

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

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## Goals and Strategic Vision

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

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## Miscellaneous

Provide any additional information about your company/organization you would like to provide to aid in the review of your RFI response.

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# Company/Organization Response to RFI

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.

## Proposal

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## Functional Requirements & Specifications

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

Based upon your proposed approach to deliver a solution, please address each of the features/requirements below to the extent that you can, be logically consistent with your proposal and express any caveats or qualifiers as you deem appropriate. Provide a response to each checklist item along with comments and assign one of the following Codes to each item:

|  |  |
| --- | --- |
| A | Current capability |
| B | Able to add capability as requested |
| C | Able to add capability with modification to ETC request |
| D | Unable to add capability |

### Semi-prep Scale SFC Requirements

|  |  |  |  |
| --- | --- | --- | --- |
| Feature | Semi-Prep Scale SFC Requirements | Code | Vendor Comments |
| **Typical column size** | 2-3cm x 25cm |  |  |
| **Flow rate** | 25-200mL/min @ 50% modifier |  |  |
| **Modifier Pump** | * Minimum modifier percentage of 5% across the entire flowrate range * Solvent selection valve on modifier pump allowing selection and mixing of multiple modifiers |  |  |
| **Pressure** | Programmable up to at least 200 bar |  |  |
| **Column Temp** | Efficient temperature control up to at least 60°C |  |  |
| **Injector** | * Modifier or Mixed-Stream Mode * Loop/syringe pump (0.5-10mL) * Total time for injection less than one minute * Stacked injection capability |  |  |
| **Fraction Collection** | * 6-8 fractions + waste * Low-pressure with visible GLS (allow fast visual assurance that system is operating correctly and for cleaning verification) * Separate ventilated collection cabinet to allow up to at least 2L collection vessels |  |  |
| **Method Editing** | Simple, graphical (visual), “on-the-fly” editing |  |  |
| **Fraction Collection Settings** | Point and click time point settings from saved chromatogram |  |  |
| **Fraction Collection Triggering** | * UV, MS using time, slope, and/or threshold * manual fraction collection |  |  |
| **Detection** | * UV (190-700 nm) * MS * Other (CAD, ELSD, polarimeter, CD, etc.) |  |  |
| **CO2 Recycling Option** | Available as an option |  |  |
| **GMP Qualification** | Available as an option |  |  |
| **Safety** | Shutdown triggers:   * leak detection in collection cabinet (both liquid and CO2), high pressure on CO2 and modifier pump and on column, high temp on column * Secondary containment in collection cabinet |  |  |
| **Footprint** | * Benchtop * modular components to allow flexibility in stacking * Separate collection cabinet |  |  |
| **Service** | * Response time < 2 days * local service technician * reasonably priced service contracts |  |  |
| **System Control** | * Windows 7 or higher operating system; * external PC preferred |  |  |
| **Reporting** | Customized reporting |  |  |

### Prep Scale SFC Requirements

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| --- | --- | --- | --- |
| Feature | Prep Scale SFC Requirements | Code | Vendor Comments |
| **Typical column size** | 3, 5, and 6cm x 25cm |  |  |
| **Flow rate** | 150-500 mL/min @50% modifier |  |  |
| **Modifier Pump** | * Minimum modifier percentage of 5% across the entire flowrate range * Solvent selection valve on modifier pump allowing selection and mixing of multiple modifiers |  |  |
| **Pressure** | At least up to 200 bars programmable |  |  |
| **Column Temp** | Efficient temperature control up to at least 60°C |  |  |
| **Injector** | * Modifier or Mixed-Stream Mode * Loop/syringe pump (1-25mL) * Total time for injection less than one minute * Sample loading pump (optional) * Stacked injection capability |  |  |
| **Fraction Collection** | * 4-6 fractions + waste * Low-pressure with visible GLS (allow fast visual assurance that system is operating correctly and for cleaning verification). * Separate ventilated collection cabinet to allow up to at least 5L collection vessels |  |  |
| **Method Editing** | Simple, graphical (visual), “on-the-fly” editing |  |  |
| **Fraction Collection Settings** | Point and click time point settings from saved chromatogram |  |  |
| **Fraction Collection Triggering** | * UV using time, slope, and/or threshold; * manual fraction collection |  |  |
| **Detection** | UV (190-700 nm) |  |  |
| **CO2 Recycling Option** | Yes (an optional feature with high pressure collection) |  |  |
| **GMP Qualification** | Yes |  |  |
| **Safety** | * Shutdown triggers: * leak detection in collection cabinet (both liquid and CO2), high pressure on CO2 and modifier pump and on column, high temp on column * Secondary containment in collection cabinet |  |  |
| **Footprint** | * System components on cart * Separate ventilated collection cabinet * Include option that does not require ventilated collection cabinet (for users who have existing hoods, and would like to collect into larger volume containers) |  |  |
| **Service** | * Response time < 2 days; local service technician; Reasonably priced service contracts |  |  |
| **System Control** | * Windows 7 or higher operating system; * external PC preferred |  |  |
| **Reporting** | Customized reporting |  |  |

## Estimated Timeline

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## Estimated Project Cost

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