

REQUEST FOR INFORMATION

*Development of a universally responsive and quantitative liquid chromatographic detector.*

November 6, 2020

Enabling Technologies Consortium™

Request for Information

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# 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 intended to solicit interest in collaborating on the development of a liquid chromatographic detector which is quantitative for all analyte classes. A third party that responds to this RFI may be invited to meet with ETC members to learn more about their response. It is anticipated that the information collected during the RFI will lead to the development of an RFP (Request for Proposals) with subsequent interviews which will be used for evaluation purposes, refinement of project plans, and selection of respondent(s) for collaboration. 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 development of a universally quantitative liquid chromatographic detector. In the event ETC decides to collaborate with a third party on this project, the third party will be required to execute an Agreement with ETC 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 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 RFI responses outside of ETC or share RFI responses 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 responses
  + Waive any anomalies in responses
  + 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:

Ms. Fatou Sarr

ETC Secretariat

C/o Faegre Drinker Biddle & Reath, LLP

1500 K St NW

Washington DC, 20005-1209

(202) 230-5148

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

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

## Anticipated Time Frames for RFI Process\*

Issue RFI November 6, 2020

Questions on RFI due November 30, 2020

Responses to RFI due December 18, 2020

Invitations sent to respondents for presentation *(if applicable)* Jan – Feb 2021

Presentation to ETC by respondents *(if applicable)* Feb - March 2021

Release Request For Proposals (RFP) March 2021

*\*Dates subject to change without notice*

***Please submit your response electronically to the above address. Responses received after December 18, 2020*** ***may not benefit from full consideration and may be excluded from the selection process.***

# Project Information

## Possible Project Sponsors

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| Amgen, AstraZeneca, Eli Lilly, Genentech, GlaxoSmithKline, Merck, Pfizer |

## Description

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| All liquid chromatographic (LC) detectors used for quantitative measurements exhibit response bias in some way. For example, the ubiquitous UV/Vis detector which is the industry standard will only respond to analytes with chromophores which absorb in the 190-600 nm range, and sensitivity can also be impacted by the wavelength selected for the analysis and the mobile phase properties. Additionally, UV relative response factors (RRF) for analytes within the same sample can often be quite different - requiring the synthesis of authentic reference standards and the determination of correction factors (1/RRF) to allow quantitative assay. Equally, there are known limitations with detectors utilizing mobile phase nebulization towards semi-volatile analytes and linearity of response (e.g. ELSD, CAD, MS). The only LC detector currently recognized as universally responsive, the refractive index (RI) detector, is incompatible with the gradient chromatography typically required for pharmaceutical analysis and is relatively insensitive. All other common detectors also have limitations regarding quantitation.  Members of this ETC project team have, collectively, several decades experience of working with liquid chromatography and have used or evaluated all current commercially available detectors for their ‘universal’ application with LC. While some detectors show promise, the project team feels that the requirement for unbiased detector response allowing true quantitation irrespective of analyte properties is currently unavailable. The aim of this RFI is to solicit understanding of what technologies are currently being developed within academia and/or industry with a view to either (i) partnering with the group to evaluate the instrument (ii) provide cross-industry insight into any current design or (iii) initiate the development of a new technology which meets the groups requirements.  ETC’s initial thoughts on requirements for such a detector are described in Section 2.3.1. |

## Device Requirements

### Instrumental features

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| An initial list of requirements for the LC universal detector is included in the below, categorized as ‘must haves’ and ‘wants’ (i.e. not imperative to development). This list represents a ‘first-pass’ on detector requirements; ETC would welcome the opportunity to speak with potential collaborators to understand their research in this area and refine these requirements as appropriate.  Please refer to the requirement numbering when completing Section 5.2.  **Must have**   |  |  |  | | --- | --- | --- | | **Req** | **Aspect** | **Additional comment** | | 1 | Compatible with liquid eluents | i.e. LC and resistant to common LC mobile phase additives and solvents | | 2 | Compatible with flow rates from 0.1 up to 2.0 ml/min | Ideally higher, but 2.0 ml/min as a minimum (higher) requirement | | 3 | Sampling frequency compatible with UHPLC peak widths/volumes | Range from 1 to at least 20 Hz data collection rate with an upper limit of 100 Hz | | 4 | Responds rapidly to peaks passing through detector cell | i.e. fast time constant available | | 5 | Sensitive to detection requirements typically required to comply with ICH expectations | Detection level of at least 0.02% area/area (S/N 3:1) and quantitation level at 0.05% area/area (S/N 10:1) relative to main component in sample | | 6 | Show negligible baseline drift | In line with LC-UV detector drift characteristics | | 7 | Linear response over at least 5 orders of magnitude | Ideally no limit to dynamic range | | 8 | Quantitative in terms of response factors | Response based on a (physicochemical) property common to all molecules | | 9 | Quantitative for semi-volatile analytes | ‘Semi-volatile’ definition to be agreed | | 10 | Simple to calibrate | Preferably an ‘on-board’ standard which can be changed by analyst when used/expired | | 11 | Unit cost of <$100k | Ideally less to make this a common plug-and-play detector in laboratories with cross industry appeal | | 12 | Detector response will be independent of changes in mobile phase composition | i.e. gradient compatible | | 13 | Detector response will be independent of changes in temperature | Laboratory (typically 20-35oC) or chromatographic column temperature (typically 20-80oC) | | 14 | Low background noise |  | | 15 | Detector cell will not contribute significantly to band broadening | e.g. increase of 10% dispersion (open to discussion) | | 16 | Compatible with vendors own and other chromatography data systems | Software agnostic | | 17 | Can interface with other vendors HPLC/UHPLC hardware |  | | 18 | Simple and intuitive user interface |  | | 19 | Have a physical footprint comparable with standard LC module dimensions |  | | 20 | Robust to vibration and physical knocks of those typical to an analytical laboratory |  | | 21 | Vendor can provide qualification to a level suitable to meet GMP requirements |  |   **Wants**   |  |  |  | | --- | --- | --- | | **Req** | **Aspect** | **Additional comment** | | 22 | Compatible with compressible gas eluents | i.e. SFC compatibility | | 23 | Compatible with microflow instrumentation |  | | 24 | Compatible with non-volatile mobile phase additives |  | | 25 | Non-destructive |  | | 26 | Be able to provide a measure of peak purity |  | | 27 | Be able to operate without user intervention during analysis | Minimum 48 hours unattended operation | | 28 | Maintenance free period | Operationally robust enough that there is no requirement for external engineer intervention for a minimum 6-12 months after installation | |

### Availability Requirements

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| When a project is ultimately launched, ETC anticipates the creation and availability of prototype(s) for evaluation to aid in the design of the instrument. While the ETC project team’s membership spans both Europe and the US, it is envisaged that testing will only occur within the US. Upon conclusion of the project, it is expected that a commercial version of the instrument will be available within approximately one (1) year. |

### Licensing Requirements for Commercialized Product

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| **Software**   1. Should it be necessary, any required software will be licensed to ETC participants at no cost during (i) development and (ii) a mutually agreed beta testing period. 2. Thereafter, software will be available for licensing on a perpetual basis and subscription basis at the option of ETC participants. The vendor shall make available industry standard support. 3. Software shall be available for self-hosting by (or on behalf of) the ETC participants if required. 4. Ownership of data generated on system resides with the 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. * 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 be able to provide individual feedback to RFI respondents. |

# Respondent Profile *(to be completed by RFI 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

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.

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

## RFI Response/Proposal

Please provide your RFI response below. Feel free to include any supplementary material as attachments via email when you submit your response.

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## Functional Requirements & Specifications

For each of the Device Requirements specified in Section 2.3.1, please fill out the table below. You can refer to each requirement listed in Section 2.3.1 by the “Req” number provided. For each feature of your proposed solution, please assign them one of the following Codes from the table below along with any comments you may have:

|  |  |
| --- | --- |
| 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 |

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| Feature | Requirement | Code | Vendor Comments |
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## Estimated Timeline

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## Estimated Project Cost

The overarching goal of ETC is to help bring innovative technologies to the commercial marketplace in partnership with third parties.  Aligned with that goal, participating ETC members will provide resources in the form of funding and subject matter expertise to support the development of this project.  While ETC will entertain all proposals in general when partnering with a commercial vendor, any monetary resources provided by ETC should be considered seed funding towards development with the collaborator investing as well; for academic or non-profit partnerships, any monetary contributions by ETC should be considered “Direct Cost Only” awards.  Any indirect costs by the third party are subject to negotiation and not guaranteed.

Please describe below on project costs, including not only the total project costs but also costs to be paid by ETC and any costs borne by your organization (if applicable).  All projects awarded by ETC are fixed cost engagements paid in U.S. Dollars.

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## Commercialization and Support

The overarching goal of ETC is to help bring innovative technologies to the commercial marketplace in partnership with third parties.  Aligned with that goal ETC looks to collaborate on projects which will result in products that are commercially available and supported in the marketplace.  With most projects, all commercialization rights will reside with the collaborator with ETC not assuming ownership of any intellectual property (IP) developed by the collaborator nor expecting royalties from future commercial sales.

Please describe your organization’s plans for commercialization and support of this technology following the successful conclusion of this project – be sure to limit your response to non-confidential information (see Section 1.3).  If your organization is not a commercial entity (e.g., academic or non-profit), please describe any plans related to the availability of the technology following the successful conclusion of the project.

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