

REQUEST FOR PROPOSALS

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

October 2021

Enabling Technologies Consortium™

Request for Proposals

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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 Proposal

Publication of this Request for Proposals (RFP) is intended to solicit interest in collaborating on the development of a liquid chromatographic detector which is quantitative for all analyte classes. Information and feedback from vendors collected during the [RFI phase](https://ebd118b4-5cab-49d4-92ce-fbf398e841eb.filesusr.com/ugd/d6fa33_3401a6b60445445fb8f1521f9e0c6e82.docx?dn=ETC%20RFI%20Universal%20Detection.docx) has been used in development of this RFP. The scope of this RFP is more narrow than that detailed in the original RFI. The goal of this collaborative project is identify a partner company to work with to develop a prototype instrument with the hope it will become a commercial product in the future.

## Disclaimer

The contents and information provided in this RFP are meant to provide general information to parties interested in development of a universally quantitative liquid chromatographic detector. The successful respondent will be required to execute an Agreement that will govern the terms of the project. When responding to this RFP, please note the following:

* This RFP is not an offer or a contract
* Proposals submitted in response to this RFP become property of ETC
* Respondents will not be compensated or reimbursed for any costs incurred as part of the RFP process
* If ETC receives and responds to questions from RFP 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 RFPs 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 RFP submissions but agrees not to publicly distribute RFP responses outside of ETC or share RFP responses with other respondents.
* ETC is not obligated to contract for any of the products and services described in this RFP
* ETC reserves the right to:
  + Accept or reject any or all responses/proposals
  + Waive any anomalies in responses/proposals
  + Negotiate with any or all bidders
  + Modify or cancel this RFP at any time

## RFP Contact Information

All questions and inquiries regarding this RFP 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 RFP Process\*

Issue RFP Oct 04, 2021

Questions on RFP due Nov 05, 2021

Responses to RFP due Nov 19, 2021

Invitations sent to respondents for presentation *(if applicable)* Dec 2021 – Jan 2022

Presentation to ETC by respondents *(if applicable)* Jan – Feb 2022

Project scoping and follow-up (*if applicable)* Feb – Apr 2022

*\*Dates subject to change without notice*

***Please submit your response electronically to the above address. Responses received after November 19, 2021*** ***will not benefit from full consideration and may be excluded from the selection process.***

## Project Scoping and Project Execution

ETC project sponsors will work with the selected collaborator to define the project scope and work to finalize a Statement of Work (SOW) for the project which describes project timelines, milestones, budget, deliverables, etc. Depending on the project, the scoping exercise will be conducted via email, web-meetings, and/or an in-person workshop. Following finalization of the SOW, the project will be brought forward to the ETC Board of Directors to authorize moving to execution.

Once authorized by the ETC Board of Directors, the ETC Secretariat will work with the selected collaborator to negotiate and finalize a contract between the two parties, leveraging ETC’s Development Agreement and Non-Disclosure Agreement accelerator templates. In parallel to this negotiation, the Secretariat will also work to finalize and execute our internal project Charter between participating ETC members.

## Intellectual Property

ETC acknowledges that this project, or aspects thereof, may require the use and incorporation of existing intellectual property and/or the development of new intellectual property in order to successfully complete the project.

### Existing Intellectual Property

* ETC as an organization will not engage in negotiations with the owner of any intellectual property on the respondent’s or ETC’s behalf;
* It is the responsibility of the respondent to conduct an intellectual property search and take all necessary steps to ensure their proposed project will not infringe or misappropriate any intellectual property right of a third party and/or obtain all necessary consents, assignments and licenses to provide the solution in the project proposal.

### New Intellectual Property

With most projects conducted with ETC:

* All commercialization rights will reside with the collaborator;
* ETC will not assume ownership of any intellectual property (IP) developed by the collaborator or expect royalties from future commercial sales.

# 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.  This ETC sub-group has 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 group feel that the requirement for unbiased detector response allowing true quantitation irrespective of analyte properties is currently unavailable. The aim of this RFP is to solicit proposals 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.  The application area of interest to the group for such a detector is obviously pharmaceutically relevant molecules. This will include active pharmaceutical ingredients (both small molecule and biomolecule classes), synthetic starting materials and intermediates - alongside their related impurities and degradants.  The group appreciates that development of a universal detector is potentially a long-term commitment between the company and the ETC. We envisage that the collaboration may last several years before successful delivery of the protype system and then commercial system. While an instrument may not be truly ‘universally’ we believe it will be possible to develop a system superior to those currently on the market.  The groups refined thoughts on requirements for such a detector are described in Section 2.3.1. |

## Device Requirements

### Instrumental features

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| An updated list of requirements drafted by the group for the LC universal detector is included in the table below. This list has been refined following discussions conducted during the RFI phase of this project. The group welcomes the opportunity for potential collaborators in their proposal to further refine these requirements based upon their research and expertise in this area.  Please refer to the requirement numbering in Section 5.2.   |  |  |  | | --- | --- | --- | | **Number** | **Requirement** | **Details** | | 1 | 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 | | 2 | Sensitive to detection requirements typically required to comply with ICH expectations | Detection level of at least 0.1% area/area (S/N 3:1) relative to main component in sample | | 3 | Linear response over at least 5 orders of magnitude | Ideally no limit to dynamic range | | 4 | Quantitative in terms of response factors | Response based on a (physicochemical) property common to all molecules | | 5 | Quantitative for semi-volatile analytes | ‘Semi-volatile’ definition to be agreed | | 6 | Simple to calibrate | Preferably an ‘on-board’ standard which can be changed by analyst when used/expired | | 7 | Target unit cost of <$100k | Ideally less to make this a common plug-and-play detector in laboratories with cross industry appeal | | 8 | Detector response will be independent of changes in mobile phase composition | i.e. gradient compatible | | 9 | Control and data acquisition via vendor’s own (if applicable) and other vendor’s chromatography data systems | Software and hardware agnostic. | | 10 | Reproducible results over time | Able to produce consistent results over time for the same sample.  Ability to analyse the same samples and deliver area %RSD <1-2. | |

### Availability Requirements

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| During the project, ETC anticipates the creation and availability of prototype(s) for evaluation to aid in the design of the instrument. While the group membership span both Europe and the U.S., it is envisaged that testing will only occur within the U.S.  Upon conclusion of the project, it is expected that a commercial version of the instrument will:   * Be made available as a commercial product including support within approximately 1 year. * Any requisite service on the instrument should be available globally. * Vendor-provided, hardware and software support 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. |

### Licensing Requirements for Commercialized Product

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| * Any software required to evaluate and test the instrument (e.g., to acquire data, to control the instrument, and/or to interface with existing software) will be licensed to ETC participants at no cost during (i) development and (ii) a mutually agreed beta testing period. Thereafter, software will be available for licensing on a perpetual basis or subscription basis at the option of customer. * Software shall be available for self-hosting by (or on behalf of) customer even if the collaborator elects to make a SaaS alternative available. * The collaborator shall make available industry standard support. * Ownership of data generated on system resides with customer. |

# Criteria for Evaluation

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| The ETC will evaluate the responses to this RFP based on the vendor’s ability to:   * Provide response with desire to participate in collaboration. * Demonstrate interest in commercialization of the jointly developed technology. * Meet the functional, performance, and technical requirements described in this RFP as evidenced by the RFP 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.   Please note that due to the volume of responses received, ETC only provides general updates related to the status of the review process and will not provide individualized feedback as to why a particular proposal was not selected by ETC. |

# Respondent Profile *(to be completed by RFP 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 RFP. 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 RFP (*to be completed by RFP respondent)*

## 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 (see Section 2.3.1).

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:

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| 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 received, regarding funding from ETC, please consider the following:

* Proposed budgets should be provided as **fixed-costs in US Dollars;**
* When partnering with a commercial vendor, any monetary resources provided by ETC should be viewed as seed funding to supplement the total development costs with the collaborator investing as well;
* When partnering with an academic or non-profit organization, any monetary contributions requested from ETC should be for the total project costs, inclusive of indirect costs (i.e., proposed costs should be inclusive of any indirect or other hidden costs);
* Include a payment schedule, based upon time from project start and/or milestones.

Please describe below project costs, including not only the total project costs but also costs to be paid by ETC and any costs borne by your organization.

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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;
* ETC will not assume ownership of any intellectual property (IP) developed by the collaborator or expect 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.  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. Note that for projects where there isn’t an expectation of a commercial product or service offering, (e.g., research and development project, services-only project) it is expected that each ETC member participating in this project will be provided a non-exclusive, royalty-free license to the output of the project and any new Project IP developed under this project for commercial purposes.

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