

REQUEST FOR INFORMATION

**ENABLE A LIGHT-INDUCED FLUORESCENCE-BASED ROBUST INLINE MONITORING SYSTEM for CONTINUOUS MANUFACTURING OF LOW-DOSED DRUG PRODUCT**

June 3, 2025

Enabling Technologies Consortium

Request for Proposal

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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 the first step by ETC to solicit interest in collaborating on the project titled “**Enable a light-induced fluorescence-based robust inline monitoring system for continuous manufacturing of low-dosed drug product.”** The information collected during this 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 upon its 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.

## Disclaimer

The contents and information provided in this RFI are meant to provide general information to parties interested in developing the project “**Enable a light-induced fluorescence-based robust inline monitoring system for continuous manufacturing of low-dosed drug product.”** The successful respondent selected by ETC 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 responses 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 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

## 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

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

## Anticipated Time Frames for Evaluation and Selection Process\*

Issue RFI June 3, 2025

Questions on RFI due June 23, 2025

Responses to RFI due July 11, 2025

Select Finalists for RFP August 4, 2025

*\*Dates subject to change without notice*

***Please submit your response electronically to the above address. Responses received after July 11, 2025*** ***will not benefit from full consideration and may be excluded from the selection process.***

## Project Scoping and Project Execution

Once ETC selects a respondent to collaborate with on the project, ETC project sponsors will work with the selected respondent (“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. The SOW 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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| AbbVie, Biogen, Eli Lilly, GSK, Merck & Co., Pfizer |

## Description

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| The Robust in-line Sensor project was successfully completed by Feb 2025 through the collaboration between ETC and Photon System Incorporated (PSI). The project delivered two light-induced fluorescence (LIF) prototyped units (i.e., UltraPAT 1 and 2) circulated among ETC member companies for testing and evaluation. At the end of this project, a roadshow testing was conducted, providing necessary data to illustrate the deliverables of both UltraPATs, and as well highlighting necessary areas for continuous understandings of LIF in general for pharmaceutical applications. The intent of this proposal is to seek an academic institute to help ETC further advance our understanding of the performance of both UltraPATs. *Please note, the selected academic will not be responsible for purchasing the UltraPAT units to conduct this work. ETC will coordinate with PSI to provide the UltraPAT units along with support to the selected academic for the duration of this project.*  |

## Requirements

### Project Requirements

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| Given the limited scope of the roadshow testing, certain interfering factors were not investigated. Thus, we would like to expand this proposal to those factors: * 1. The impact of excipient grades
	2. The impact of API particle size

Based upon results of the roadshow testing, the following factors need to be further investigated in order to mitigate each one’s impact on a spectroscopy method based upon the UltraPAT sensors:* 1. RPM (revolutions per minute) of the paddle in the feed frame
	2. Powder density in the feed frame
	3. Spectrometer-to-spectrometer difference on the method performance
	4. Insertion depth of UltraPAT into the powder bed in the feed frame
	5. Day-to-day variability on either UltraPAT

Partial least squares (PLS) was used as the main method calibration approach with limited preprocessing during the roadshow testing. Additional algorithms (e.g., CLS and IOT) with necessary spectral pretreatment (e.g., normalization and derivative) are needed with the intention to mitigate the impacts by these aforementioned factors and to increase the method robustness.An acceptable root mean squared error of prediction (RMSEP) will be determined based upon discussions between ETC member companies and the chosen academic institute. Such an appropriate RMSEP will be evaluated against the aforementioned interfering factors. Upon completion of the project, the selected academic will be expected to deliver the following:* Technical report of findings
* Methodology on how to counter the interfering factors mentioned above while maintaining the sensitivity of the UltraPAT
* A license to the technical report and methodology developed under this project, allowing ETC to freely use, sublicense, modify, and distribute.
* Publish at least one peer-reviewed article summarizing their findings.
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### Optional Hardware and Software Requirements

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| * Commercially available and supported software shall be used for the project.
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# Criteria for Evaluation

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| The ETC will evaluate the responses to this RFI based on the respondent’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 project.
* Provide a superior level of customer service and technical support, including tech transfer of the methodologies to clients.
* Discuss potential partnerships and current development efforts that show similarities to this RFI.
* Provide any additional capabilities that may differentiate them from other potential collaborators.

For this project, the following will also be considered during the evaluation process:* Expertise with chemometrics-based spectroscopy analysis on complex powder systems.
* Expertise with chemometric analyses beyond PCA and PLS.
* Availability of a scale-down feed frame to conduct this work.

ETC will provide general updates related to the status of the review process via email to all respondents. Respondents should reach out to the ETC Secretariat (see **Section 1.4**) via email for status updates or any questions regarding this project. * *Respondents are instructed not contact to individuals from ETC member companies seeking any information regarding this project.*

Once the ETC team has evaluated and scored all responses, the ETC Secretariat will notify each respondent via email if their submission was selected (or not selected) to progress to the next stage of our process. * *For responses not selected, due to the volume of responses and projects in the ETC portfolio ETC is unable to provide detailed, individualized feedback nor meet with respondents to discuss why their response did not move to the next stage.*
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# Respondent Profile

*(To be completed by respondent)*

Please provide information to the following:

## Company/Organization Information

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| --- | --- |
| 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

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

## Proposal

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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## 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, 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 |

| 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. *Note, the first payment due date cannot be before 90 days after the project start date.*

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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