

REQUEST FOR INFORMATION:

*Medium Throughput Personal Reactor Platform**Test*

*May 11, 2016*

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 the first step by ETC to solicit interest in collaborating together on a Medium Throughput Personal Reactor Platform. 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 Medium Throughput Personal Reactor Platform 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 Medium Throughput Personal Reactor Platform. 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
* 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

[Alexis.Robertson@dbr.com](mailto:Alexis.Robertson@dbr.com)

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

## Anticipated Time Frames for Evaluation and Selection Process

Issue RFI May 11, 2016

Questions on RFI due May 23, 2016

Responses to RFI due June 10, 2016

Invitations sent to respondents for presentation June 17, 2016

Presentation to ETC by respondents June 20-July 8, 2016

Select Finalists for RFP August 1, 2016

***Please submit your response electronically to the above address. Responses received after June 10, 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, Boehringer Ingelheim, Celgene, GSK, J&J, Merck, Pfizer |

## Description

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| There is currently no reactor platform which provides low volume, medium throughput and data rich experimentation. The currently available reactor platforms span the following two experimental regimes:   1. High volume, low throughput, easy to use and operate, with multiple Process Analytical Technologies (PATs) available 2. Low volume, high throughput, sophisticated systems requiring extensive training   The lack of a low volume, medium throughput platform has been identified by the project sponsors as a significant gap in the available technology and capabilities for the pharmaceutical industry. The industry requires an easy to use, cost-effective platform solution that will allow for automated reaction sampling with representative sampling of the solid and liquid components of slurries to enable data rich outputs with minimal compound input. The purpose of this RFI is to solicit interest from the vendor community in participating in a project to develop and create a medium throughput, low volume personal reactor platform.  This project will be conducted in collaboration with ETC and the selected vendor. Throughout the duration of this project ETC and the vendor will work together to develop the medium throughput reactor platform. ETC will supply the vendor with a comprehensive list of requirements, subject matter expertise, and funding to support this project. The vendor will supply the resources and expertise necessary to design, prototype, and ultimately manufacture the reactor platform. Upon completion of this project the medium throughput reactor platform will be realized as a prototype. It is anticipated that this technology will be made available to the scientific community as commercialized product offering by the participating vendor. |

## Medium Throughput Personal Reactor Platform Requirements

### Necessary Hardware and Software Requirements

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| 1. 8-10 reactors with 2-4 to 8-16 mL reaction volumes each    * i.e. 4x range, specific volumes to be determined by the other factors 2. Aspect ratio 2-3 : 1 (i.e. not test tubes)    * To minimize headspace volume    * Minimize loss of volatiles to the headspace or cooled upped surfaces    * Minimize contamination from trace air in the headspace    * To improve agitation    * To make it easier to load solids (separate from this system) 3. Excellent retention of solvents at their boiling points 4. Individual reactors are required to be inerted and operate with dosing and sampling under inert atmosphere 5. Overhead stirring (which can be magnetically driven) for excellent mixing without grinding solids 6. Individual temperature control and ramps -20 °C to 150 °C 7. Individual jacket and internal temperature control and monitoring 8. Representative sampling of the solid and liquid components of reaction slurries 9. One-to-many liquid dosing profiles (one to many dosing with individual profiles) 10. The reactions should be able to be scheduled for individual temperature profiles, individual sampling points, and a single liquid component to be dosed over time to each reactor with individual dosing profiles. 11. Data logging of Tr, Tj, Stirring, Dosing volume, sampling time for individual reactors is a requirement. The ability to integrate data with HPLC or other instrumentation as an option. 12. Wetted components compatible with typical process chemistry reaction conditions (no PEEK). |

### Optional Hardware and Software Requirements

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| 1. Reaction Visibility, potentially with a camera 2. Reaction Turbidity measurement 3. Disposable reactors |

### Availability Requirements

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| 1. The reactor system should be sized appropriately to fit easily within a standard laboratory fume hood, ideally with the ability to fit multiple units 2. The price-point of the product should be low enough to enable multiple purchases and deployment within a department 3. The user-facing software solution should be simple and thoughtful to enable multiple users with minimal training 4. The resulting prototype is anticipated to result in a future commercialized project 5. Service and maintenance support of the reactor system must be available for a period of no less than 5 years after commercial launch |

### Licensing Requirements for Commercialized Product

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| 1. Reaction platform hardware includes all necessary licenses for use 2. 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 3. 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 parallel reactor system. * 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

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

## 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, 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 |
| 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** |
| Number of Reactors | 8 reactors preferred, 10 reactors acceptable |  |  |
| Low-end Working Volume (mL) | 2mL is preferred, 4mL acceptable |  |  |
| High-end Working Volume (mL) | 8mL is preferred, 16 mL is acceptable (4x the low-end volume) |  |  |
| Aspect ratio (h/i.d.) | 2-3:1. Vessel shape similar to a scintillation vial and **not** a test-tube |  |  |
| Agitation/stirring | Overhead stirring (which can be magnetically driven) to provide excellent mixing without grinding of solids |  |  |
| Low Temp (°C) | -20°C Reaction temp |  |  |
| High Temp (°C) | 150°C Reaction temp |  |  |
| Temperature control and monitoring | Individual jackets with individual control, monitoring, and ramping of temperature |  |  |
| Solvent retention at/near boiling points | Accommodated by a reflux mechanism or use of sealed reactors (with appropriate pressure relief or pressure rating) |  |  |
| Inertion | Individual reactors are required to be inerted and operate with dosing and sampling under inert atmosphere |  |  |
| Sampling | Representative sampling of the solid and liquid components of reaction slurries |  |  |
| Liquid Dosing | Dosing of a single liquid to reactor profiled over time with individual profiles (i.e. One-to-many) |  |  |
| Sampling | HPLC sampling, quench, and dilution with representative sampling of the liquid and solid components of slurries is required.  Direct integration of the HPLC as an option. |  |  |
| Scheduling | The reactions should be able to be scheduled for individual temperature profiles, individual sampling points, and a single liquid component to be dosed over time to each reactor with individual dosing profiles |  |  |
| Data Capture/Logging | Data logging of Tr, Tj, Stirring, Dosing volume, sampling time for individual reactors is a requirement. The ability to integrate data with HPLC or other instrumentation as an option. |  |  |
| Wetted Material Compatibility | Wetted components compatible with typical process chemistry reaction conditions (no PEEK). |  |  |
| Reaction Visibility | **OPTIONAL** – nice to have and could potentially done with a camera |  |  |
| Reaction Turbidity | **OPTIONAL** – nice to have if easy to implement |  |  |
| Reactor Type | **OPTIONAL -** Disposable reactors |  |  |
| User Profile | Common user. Simple, easy to use, and intuitive interfaces and mechanisms |  |  |
| System Price | Price point must be low enough to enable multiple purchases |  |  |
| System Footprint | The reactor system should be sized appropriately to fit easily within a standard laboratory fume hood, ideally with the ability to fit multiple units |  |  |
| Commercial Availability | The resulting prototype is anticipated to result in a future commercialized project |  |  |
| Service and Support | Must be available for a period of no less than 5 years after commercial launch |  |  |
| Hardware Licensing | Reaction platform hardware includes all necessary licenses for use |  |  |
| Software Licensing | 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 |  |  |
| Data Ownership | Ownership of data generated on system resides with customer |  |  |

## Estimated Timeline

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## Estimated Project Cost

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