

REQUEST FOR INFORMATION

Next Generation Automated Solubility Platform

January 16, 2018

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 Next Generation Automated Solubility 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 Next Generation Automated Solubility 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 Next Generation Automated Solubility Platform. Prior to initiation of an ETC project, the vendor ultimately selected by ETC by 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
* Any questions received and responses thereto will be anonymized and made available to all respondents via our website
* All proposals received in response to this RFI will remain confidential within ETC and not shared with other respondents
* Responses to RFIs should contain only high level discussions of product development efforts and should not contain trade secrets or confidential information
* 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:

Ms. Alexis Myers

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

Issue RFI January 16, 2018

Questions on RFI due January 31, 2018

Responses to RFI due March 23, 2018

Invitations sent to respondents for presentation March 2018

Presentation to ETC by respondents May 2018

Select Finalists for RFP July 2018

***Please submit your response electronically to the above address. Responses received after March 23, 2018*** ***will not benefit from full consideration and may be excluded from the selection process.***

# Project Information

## Possible Project Sponsors

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| Amgen, AstraZeneca, Boehringer Ingelheim, Eli Lilly, Merck, Pfizer, Takeda |

## Description

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| **Problem statements**  Current high throughput solubility workflows require expensive hardware and expert users to run and are often too complicated to be used reliably as “walk up” platforms. Measuring accurate, reproducible data in solvents with highly diverse properties and over a wide range of experimental conditions can be challenging.  **Project Aims**  The aim of this project is to partner with manufacturers to develop cost effective hardware that can be operated in “walk-up” mode to deliver accurate, reproducible solubility data in highly diverse solvent systems over a wide range of experimental conditions.  While existing automation platforms have advanced capabilities, they can be non-intuitive to use and require extensive training, which often restricts their adoption and utilization to expert users. For example, reliable use of the hardware necessitates detailed knowledge of the automation software to aid design and execution of experimental methods (in contrast to a generic library of methods), allow instrument control and for data analyses/management, which often obviate walk-up operation. In comparison, it would be valuable to have platforms and associated add-on accessories that are developed with the aim of being user-friendly and intuitive, to enable reliable 'walk-up' use, including minimal training requirements.  With existing technologies and/or platforms, delivering accurate, reproducible data can be challenging in highly viscous or volatile solvents and high solids load suspensions. Errors are typically introduced during filtration and/or dilution steps and are attributed to needle clogging during aspiration or dilution errors due to inaccurate volume-based transfers and/or solvent loss due to evaporation. In addition, the need to air-dry suspensions to enable analysis of the solid residue can lead to erroneous conclusions when labile solvates or hydrates are formed. Direct and automated analysis of the solid residue in equilibrium with the saturated solution is desired.  Ultimately, the cost and complexity of current automated solubility platforms limits use to expert users within specialty automation groups. To overcome challenges with filtration and dilution of viscous, volatile or high solids load suspensions custom modifications and/or use of alternate specialty hardware is often employed. A cost-effective, user-friendly platform focused solely on reliable solubility measurement is desired. |

## Next Generation Automated Solubility Platform Requirements

### Necessary Hardware and Software Requirements

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| * **Hardware Requirements: Solids Handling**   + Integrate with solids handler to enable automated solids charging to facilitate experimentation by ‘walk-up’ user   + Capacity to perform solubility measurements in multiple (> 24) solvents or solvent mixtures with accuracy and precision; 96 well plate format is desirable * **Hardware Requirements: Liquid Handling**   + Ability to tune liquid dispenser for accuracy/precision (+/- 2%) within a range of temperatures, solvent viscosity and/or mixtures or incorporation of gravimetric measurement for assessing precision and accuracy of dispensing is also desired. * **Hardware Requirements: General**   + Material of construction for contact surfaces, especially reactor lids, add-on parts/adaptors, etc. to be compatible with range of solvents including acidic/basic solutions   + Mixing technology, i.e. stirring or vortex   + Temperature range between -20 °C to 70 °C   + Excellent solvent retention at elevated temperatures (particularly important for solvent mixtures)   + Add-on capability for analysis of solids after experiment. Technique should enable analysis of (wet) solid form in equilibrium with saturated solution (not require drying step). Add-on capabilities could include Raman, IR, XRD, etc.   + Solid/liquid separation should be efficient and accurate; sampling of supernatant via solid/liquid separating device and automated liquid handler is required. Technologies allowing filtration and dilution steps to be avoided are of interest.   + Solids/slurries retrievable at end of experiments for characterization   + Ability to measure broad range of solubility, 0.1 mg/mL – 250 mg/mL or even higher would be desirable, especially for elevated temperatures. Information on the loss of accuracy as the range expands is desired. Alternately, a desired level of accuracy and precision for a given range may be specified by the project team. * **Software Requirements**   + Data management platform that integrates experimental design and execution as well as data collection and analysis (or integrate with available systems). |

### Optional Hardware and Software Requirements

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| * Experiment size/volume flexibility: accurate solubility measurement on ~2-5mg sample size but flexible to accommodate larger, multi-injection measurements * Flexible workflow to accommodate additional studies, i.e. impurity rejection, kinetics, etc. that would fit within the mechanical footprint/operational modes of the platform * Operating temperature between -20 °C and 120°C * Gravimetric analysis (capture and record the actual mass of solids and liquids dispensed/sampled) to allow for accurate and precise dispensing and sampling * Preparation of solid residue sample for analysis |

### Availability Requirements

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| The expected output is commercially available equipment for automated solubility measurement. Expected timing is 12 months to deliver prototype. |

### Licensing Requirements for Commercialized Product

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| None |

# 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 Next Generation Automated Solubility Platform. * 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)*

## Proposal

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## Functional Requirements & Specifications

Refer to the following Functional Requirements and Specifications checklist that 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:

|  |  |
| --- | --- |
| 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 |
| Hardware Requirements: Solids Handling | Integrate with solids handler to enable automated solids charging to facilitate experimentation by ‘walk-up’ user |  |  |
| Hardware Requirements: Solids Handling | Capacity to perform solubility measurements in multiple (> 24) solvents or solvent mixtures with accuracy and precision |  |  |
| Hardware Requirements: Liquid Handling | Ability to tune liquid dispenser for accuracy/precision within a range of temperatures, solvent viscosity and/or mixtures or incorporation of gravimetric measurement for assessing precision and accuracy of dispensing is also desired. |  |  |
| Hardware Requirements: General | Material of construction for contact surfaces, especially reactor lids, add-on parts/adaptors, etc. to be compatible with range of solvents including acidic/basic solutions |  |  |
| Hardware Requirements: General | Mixing technology, i.e. stirring or vortex |  |  |
| Hardware Requirements: General | Temperature range between -20 °C to 70 °C |  |  |
| Hardware Requirements: General | Excellent solvent retention at elevated temperatures (particularly important for solvent mixtures) |  |  |
| Hardware Requirements: General | Add-on capability for analysis of solids after experiment. Technique should enable analysis of (wet) solid form in equilibrium with saturated solution (not require drying step). Add-on capabilities could include Raman, IR, XRD, etc. |  |  |
| Hardware Requirements: General | If solid/liquid separation is required for quantitative analysis, the ability to sample supernatant via solid/liquid separating device and automated liquid handler is required. Ideally, filtration and dilution steps would be avoided entirely. |  |  |
| Hardware Requirements: General | Solids/slurries retrievable at end of experiments for characterization |  |  |
| Hardware Requirements: General | Ability to measure broad range of solubility, 0.1 mg/mL – 250 mg/mL or even higher would be desirable, especially for elevated temperatures. Information on the loss of accuracy as the range expands is desired. Alternately, a desired level of accuracy and precision for a given range may be specified by the project team. |  |  |
| Software Requirements | Data management platform that integrates experimental design and execution as well as data collection and analysis (or integrate with available systems). |  |  |
| Optional Requirements | Experiment size/volume flexibility: accurate solubility measurement on ~2-5mg sample size (per well) but flexible to accommodate larger, multi-injection measurements |  |  |
| Optional Requirements | Flexible workflow to accommodate additional studies, i.e. impurity rejection, kinetics, etc. that would fit within the mechanical footprint/operational modes of the platform |  |  |
| Optional Requirements | Operating temperature between -20 °C and 120°C |  |  |
| Optional Requirements | Gravimetric analysis (capture and record the actual mass of solids and liquids dispensed/sampled) to allow for accurate and precise dispensing and sampling |  |  |

## Estimated Timeline

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## Estimated Project Cost

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