

REQUEST FOR INFORMATION

Multi-dimensional Particle Size and Shape Measurement Tool

October 30, 2017

Enabling Technologies Consortium™

Request for Information

Table of Contents

[1 Introduction 3](#_Toc490063786)

[1.1 About Enabling Technologies Consortium™ (ETC) 3](#_Toc490063787)

[1.2 Request for Information 3](#_Toc490063788)

[1.3 Disclaimer 4](#_Toc490063789)

[1.4 RFI Contact Information 5](#_Toc490063790)

[1.5 Anticipated Time Frames for Evaluation and Selection Process 5](#_Toc490063791)

[2 Project Information 6](#_Toc490063792)

[2.1 Possible Project Sponsors 6](#_Toc490063793)

[2.2 Description 6](#_Toc490063794)

[2.3 Particle Size and Shape Measurement Tool Requirements 6](#_Toc490063795)

[2.3.1 Necessary Software Requirements 6](#_Toc490063796)

[2.3.2 Optional Software Requirements 7](#_Toc490063797)

[2.3.3 Availability Requirements 7](#_Toc490063798)

[2.3.4 Licensing Requirements for Commercialized Product 8](#_Toc490063799)

[3 Criteria for Evaluation 8](#_Toc490063800)

[4 Respondent Profile *(to be completed by RFI respondent)* 9](#_Toc490063801)

[4.1 Company/Organization Information 9](#_Toc490063802)

[4.2 Primary Contact Person 9](#_Toc490063803)

[4.3 Company/Organization Overview 9](#_Toc490063804)

[4.4 Parent Corporation and/or Subsidiaries 10](#_Toc490063805)

[4.5 Summary of Expertise 10](#_Toc490063806)

[4.6 Standards Certifications 10](#_Toc490063807)

[4.7 Goals and Strategic Vision 10](#_Toc490063808)

[4.8 Miscellaneous 11](#_Toc490063809)

[5 Company/Organization Response to RFI (*to be completed by RFI respondent)* 12](#_Toc490063810)

[5.1 Proposal 12](#_Toc490063811)

[5.2 Functional Requirements & Specifications 12](#_Toc490063812)

[5.3 Estimated Timeline 13](#_Toc490063813)

[5.4 Estimated Project Cost 13](#_Toc490063814)

[6 Appendix (additional detail*)* 14](#_Toc490063815)

[6.1 Software 14](#_Toc490063816)

[6.2 Security 15](#_Toc490063817)

# 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 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 gather information on and solicit interest in collaborating on a Multi-dimensional Particle Size and Shape Measurement Tool on a future ETC project. The information collected during the RFI process will be used to inform plans for future ETC projects. As noted below, responses to this RFI should contain only high level discussions of product development efforts and should not contain trade secrets or confidential information. Respondent(s) to this RFI may be invited to submit a proposal to a future Multi-dimensional Particle Size and Shape Measurement Tool RFP.

The RFI process will serve to provide ETC members with information on project scope, timeline, and resource requirements in order for ETC to define the Project Roadmap and allow individual ETC members to meet budget allocation deadlines to support projects in 2018 and beyond.

## Disclaimer

The contents and information provided in this RFI are meant to provide general information to parties interested in developing the Multi-dimensional Particle Size and Shape Measurement Tool. If a collaborative project results from this RFI, 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
* Any questions received from potential respondents and ETC’s responses 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 this RFI should contain only high level discussions of product development efforts and should not contain trade secrets or confidential information
* Responses to this RFI may be used by ETC to inform plans for future ETC projects and associated Requests for Proposal
* 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 to this RFI
  + Waive any anomalies in proposals
  + Negotiate with any or all respondents to this RFI
  + 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 October 30, 2017

Questions on RFI due November 13, 2017

Responses to RFI due December 11, 2017

Notification of Next Steps Jan./Feb. 2018

***Please submit your response electronically to the above address. Responses received after December 11, 2017 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, AstraZeneca, Biogen, Bristol-Myers Squibb, Boehringer Ingelheim, Eli Lilly, GlaxoSmithKline, Merck, Takeda, Pfizer |

## Description

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| To improve our ability to model particle size and shape and predict downstream performance of powders, a novel tool is required to measure and provide meaningful descriptors of multidimensional particles as they form and grow.  The current state of the art equipment provides either a trending statistic (e.g. chord length) that is correlated to particle size and is a single dimension (FBRM), an image analysis routine with limited multidimensional information and poor resolution (PVM), or off-line image analysis with slurry dilution (Perdix, Canty, etc.) due to inability to collect quality images in a concentrated suspension.  This project may include the development of hardware (e.g. optics and/or interfaces) as well as software (size/shape descriptors via image analysis). |

## Multi-dimensional Particle Size and Shape Measurement Tool Requirements

### Necessary Hardware and Software Requirements

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| The tool developed should result in the ability to:   1. Measure crystals in situ real-time as they are produced from standard pharmaceutical processing (stirred tank reactors, at a minimum, with preference given to a tool that can also be used in a flow reactor) 2. Produce multidimensional statistics that can be easily understood, are relevant and meaningful to the actual size and shape of the crystals, and can be easily converted to the data required for population balance modeling. 3. Shape to be described by at least one parameter e.g. aspect ratio, and preferably two or more to give a 3D representation 4. Provide in-situ measurements in realistic systems typically seen in pharmaceutical crystallizations    1. Measure particle sizes, ideally within a range of 1 to 1000 um length in any given dimension (minimum range of 5-200 um).    2. Ability to provide a statistic related to the total number of particles per measurement volume and time    3. Make accurate measurements at realistic slurry concentrations, ideally 5-20 wt% solids.    4. Be compatible with a broad range of operating environments including temperature (-20 to 120ᵒC), pH, and organic solvents.    5. Robust to fouling or self-cleaning 5. Measure particle populations at a frequency of at least once per minute. 6. Ability to detect and evaluate morphological differences, including primary particles versus agglomerates 7. Sort based on differentiating features to create statistical distributions of multiple morphologies, shapes, and sizes descriptors that are measured (e.g. differentiation of a population of oil droplets from acicular particles within the same system)   A versatile/portable tool that can be readily moved from one crystallizer confirmation to another would be particularly attractive. |

### Optional Hardware and Software Requirements

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| Ideally the tool would have the flexibility to be applied across scales (as low as 50 mL stirred reactor) so that lab-based data could be compared to at-scale data directly. A probe-based technology is expected to be particularly suitable for such an application, though the team will be open to other approaches. It would also be strongly preferred if the measurement device were to show minimal impact of system hydrodynamics (i.e., agitation intensity) on measured particle size and shape. Full realization will be the measurement of meaningful particle descriptors that allow for modeling, strategies for morphology modification, and potentially feedback control ensuring robust delivery of materials with target attributes. |

### Availability Requirements

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| The expected output is a commercially available tool to provide in-situ, real-time particle size and shape measurement with a supporting software package  Timing for development and availability can be negotiated, but proposals that can deliver a prototype for evaluation within 1 year of project start and a commercial product within 2 years will be considered favorably. The vendor must be open to feedback on the roadmap to product delivery. |

### Licensing Requirements for Commercialized Product

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| This project is expected to result in a commercially available product. Intellectual Property will be owned by the vendor. |

# Criteria for Evaluation

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| The ETC will evaluate the responses to this RFI based on the respondent’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 Dynamically Configurable Modeling Cloud. * 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 in Section 6.2 (Appendix) that summarizes the collective requirements and specifications by the sponsors of 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 |

| Requirement | Code | Respondent Comments |
| --- | --- | --- |
| Measure crystals in situ real-time as they are produced from standard pharmaceutical processing (stirred tank reactors, at a minimum, with preference given to a tool that can also be used in a flow reactor) |  |  |
| Produce multidimensional statistics that can be easily understood, are relevant and meaningful to the actual size and shape of the crystals, and can be easily converted to the data required for population balance modeling. |  |  |
| Shape to be described by at least one parameter e.g. aspect ratio, and preferably two or more to give a 3D representation |  |  |
| Measure particle sizes, ideally within a range of 1 to 1000 um length in any given dimension (minimum range of 5-200 um) |  |  |
| Ability to provide a statistic related to the total number of particles per measurement volume and time |  |  |
| Make accurate measurements at realistic slurry concentrations, ideally 5-20 wt% solids |  |  |
| Be compatible with a broad range of operating environments including temperature (-20 to 120ᵒC), pH, and organic solvents |  |  |
| Robust to fouling or self-cleaning |  |  |
| Measure particle populations at a frequency of at least once per minute. |  |  |
| Ability to detect and evaluate morphological differences, including primary particles versus agglomerates |  |  |
| Sort based on differentiating features to create statistical distributions of multiple morphologies, shapes, and sizes descriptors that are measured (e.g. differentiation of a population of oil droplets from acicular particles within the same system) |  |  |
| Versatile/portable tool that can be readily moved from one crystallizer confirmation to another |  |  |
| **Optional -** flexibility to be applied across scales (as low as 50 mL stirred reactor) |  |  |
| ***Optional -*** measurement device shows minimal impact of system hydrodynamics (i.e., agitation intensity) on measured particle size and shape |  |  |

## Estimated Timeline

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## Estimated Project Cost

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