

REQUEST FOR PROPOSALS

*Development of a spatially resolved spectroscopy probe for application in pharmaceutical drying processes (Drying PAT)*

October 23, 2017

Enabling Technologies Consortium™

Request for Proposals

Table of Contents

[1 Introduction 3](#_Toc466624223)

[1.1 About Enabling Technologies Consortium™ (ETC) 3](#_Toc466624224)

[1.2 Request for Proposals 3](#_Toc466624225)

[1.3 Disclaimer 3](#_Toc466624226)

[1.4 RFP Contact Information 4](#_Toc466624227)

[1.5 Anticipated Time Frames for Evaluation and Selection Process 4](#_Toc466624228)

[2 Project Information 4](#_Toc466624229)

[2.1 Possible Project Sponsors 4](#_Toc466624230)

[2.2 Description 4](#_Toc466624231)

[2.3 Drying PAT Requirements 5](#_Toc466624232)

[2.3.1 Necessary Hardware and Software Requirements 5](#_Toc466624233)

[2.3.2 Optional Hardware and Software Requirements 5](#_Toc466624234)

[2.3.3 Availability Requirements 6](#_Toc466624235)

[2.3.4 Licensing Requirements for Commercialized Product 6](#_Toc466624236)

[3 Criteria for Evaluation 6](#_Toc466624237)

[4 Respondent Profile (to be completed by RFP respondent) 6](#_Toc466624238)

[4.1 Company/Organization Information 6](#_Toc466624239)

[4.2 Primary Contact Person 7](#_Toc466624240)

[4.3 Company/Organization Overview 7](#_Toc466624241)

[4.4 Parent Corporation and/or Subsidiaries 7](#_Toc466624242)

[4.5 Summary of Expertise 8](#_Toc466624243)

[4.6 Standards Certifications 8](#_Toc466624244)

[4.7 Goals and Strategic Vision 8](#_Toc466624245)

[4.8 Miscellaneous 8](#_Toc466624246)

[5 Company/Organization Response to RFP (*to be completed by RFP respondent)* 10](#_Toc466624247)

[5.1 Proposal 10](#_Toc466624248)

[5.2 Functional Requirements & Specifications 10](#_Toc466624249)

[5.3 Estimated Timeline 11](#_Toc466624250)

[5.4 Estimated Project Cost 11](#_Toc466624251)

# 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 (RFP) is intended to solicit interest in collaborating together on the development of a spatially resolved spectroscopy probe for application in pharmaceutical drying processes. The information collected during the RFP process along with any subsequent discussions, Q&A, or workshop will be used for evaluation purposes, refinement of project plans, and selection of respondent(s) for collaboration. 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 RFP are meant to provide general information to parties interested in developing a spatially resolved spectroscopy probe for application in pharmaceutical drying processes. If a collaborative project results from this RFP, 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
* 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 RFP will remain confidential within ETC and not shared with other respondents
* Responses to RFPs 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 RFP
* ETC reserves the right to:
	+ Accept or reject any or all proposals
	+ Waive any anomalies in proposals
	+ Negotiate with any or all respondents to this RFP
	+ Modify or cancel this RFP at any time

## RFP Contact Information

All questions and inquiries regarding this RFP 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

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

## Anticipated Time Frames for Evaluation and Selection Process

Issue RFP October 23, 2017

Questions on RFP due November 6, 2017

Responses to RFP due December 4, 2017

Follow up with respondents Jan./Feb. 2018

***Please submit your response electronically to the above address. Responses received after December 4, 2017*** ***will not benefit from full consideration and may be excluded from the selection process.***

# Project Information

## Possible Project Sponsors

|  |
| --- |
| AbbVie, Amgen, AstraZeneca, Boehringer Ingelheim, Bristol-Myers Squibb, Eli Lilly, Merck, Pfizer, Takeda |

##

## Description

|  |
| --- |
| To understand the drying unit operation in the pharmaceutical industry, it is desired to collect real-time data over the course of the drying process. The current state of real time data collection suffers from limitations of existing Process Analytical Technology (PAT) tools, process measurements, and/or material sampling technologies.We are seeking a project to develop PAT to monitor the drying of pharmaceutical compounds in agitated contact dryers. The project would include:* Design and development of a probe or probe-like instrument with integrated optics for the application of spatially resolved spectroscopy (e.g. IR and/or Raman) in agitated vacuum contact dryers to profile the drying process throughout the vessel
* Development of spectral analysis methods, models, and calibrations to determine solvent content, physical form, and particle size distribution across a range of conditions

The project proposal should be broken into phases including:* Design of probe(s) with feedback and revisions from participating members
* Outreach and collaboration with dryer manufacturers to integrate probe with drying vessels
* Evaluation of performance across a range of materials and conditions
* Development, calibration, and validation of data processing methods
 |

##

## Drying PAT Requirements

### Necessary Hardware and Software Requirements

|  |
| --- |
| * Probe Requirements
	+ Must be compatible with a variety of organic solvents and pharmaceutical salts (hydrochloride salts, etc.)
	+ Must be rated from full vacuum to 5 bar pressure
	+ Should have a temperature operating range of -20 °C to 100 °C
	+ Should have a thermocouple integrated
	+ Design should mitigate the risk of solids fouling on the optics (inclusion of wipers, air jets, coatings, etc.)
	+ Design should consider the presence of an agitator in the dryer (adjustable height without breaking seal and/or adjusts with agitator)
	+ Probe technology should be applicable for bench (1-5L) to commercial (1,000-10,000L) scale dryers and not require major modifications to equipment (use industry standard flange connections)
	+ Should be electrically rated for safe use in laboratories (UL or CE certification)
	+ Should have the potential for XP electrical rating (with potential 3rd party modifications) in order to use in manufacturing settings
	+ Should be capable of direct product contact use in GMP manufacturing settings (requires material of construction certifications)
	+ The respondent is expected to reach out to and collaborate with dryer equipment manufacturers to develop practical and cost effective solutions for inserting their technologies within existing manufacturing equipment.
* Data Processing Requirements
	+ A range of compound PSDs and morphologies should be evaluated
	+ A range of organic solvents should be evaluated
	+ Compounds that undergo form change should be evaluated
	+ Validation of methods with orthogonal analytical techniques should be included, demonstrating the ability to create quantitative models for solvent content, form, PSD and other physical properties
	+ Algorithms and/or data processing software will be a deliverable
	+ Integration with common plant DCS systems including data export via OPC-UA and Modbus at a minimum
	+ The respondent should indicate in their proposal strategies for validation of the developed technologies leveraging any existing partnerships and bearing in mind the constraints of working with a consortium (i.e. lack of R&D laboratories and manufacturing capabilities)
 |

###

### Optional Hardware and Software Requirements

|  |
| --- |
| * Probe Optional Requirements
	+ Multi point optics on the probe
* Data Processing Optional Requirements
	+ Graphic user interface for ease of data collection and processing
 |

### Availability Requirements

|  |
| --- |
| The final product (probe hardware and analysis methods) should be commercially available upon completion of the project. |

### Licensing Requirements for Commercialized Product

|  |
| --- |
| None. |

# Criteria for Evaluation

|  |
| --- |
| The ETC will evaluate the responses to this RFP 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 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 in development of the spatially resolved spectroscopy probe for application in pharmaceutical drying processes.
* 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 RFP respondents. |

# 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.

|  |
| --- |
|  |

##

## Parent Corporation and/or Subsidiaries

Identify any parent corporation and or subsidiaries, if appropriate.

|  |
| --- |
|  |

## 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.

|  |
| --- |
|  |

## Standards Certifications

List any certifications currently held, including date received, duration, and renewal date.

|  |
| --- |
|  |

## Goals and Strategic Vision

Provide a summary of your company/organization’s short term and long term goals and strategic vision.

|  |
| --- |
|  |

##

## 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.

|  |
| --- |
|  |

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

## Proposal

|  |
| --- |
|  |

## 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:

|  |  |
| --- | --- |
| 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 |
| Probe Requirements | Must be compatible with a variety of organic solvents and pharmaceutical salts (hydrochloride salts, etc.) |  |  |
| Must be rated from full vacuum to 5 bar pressure |  |  |
| Should have a temperature operating range of -20 °C to 100 °C |  |  |
| Should have a thermocouple integrated |  |  |
| Design should mitigate the risk of solids fouling on the optics (inclusion of wipers, air jets, coatings, etc.) |  |  |
| Design should consider the presence of an agitator in the dryer (adjustable height without breaking seal and/or adjusts with agitator) |  |  |
| Probe technology should be applicable for bench (1-5L) to commercial (1,000-10,000L) scale dryers and not require major modifications to equipment (use industry standard flange connections) |  |  |
| Should be electrically rated for safe use in laboratories (UL or CE certification) |  |  |
| Should have the potential for XP electrical rating (with potential 3rd party modifications) in order to use in manufacturing settings |  |  |
| Should be capable of direct product contact use in GMP manufacturing settings (requires material of construction certifications) |  |  |
| The respondent is expected to reach out to and collaborate with dryer equipment manufacturers to develop practical and cost effective solutions for inserting their technologies within existing manufacturing equipment.  |  |  |
| ***Optional*** - Multi point optics on the probe |  |  |
| Data Processing Requirements | A range of compound PSDs and morphologies should be evaluated |  |  |
| A range of organic solvents should be evaluated |  |  |
| Compounds that undergo form change should be evaluated |  |  |
| Validation of methods with orthogonal analytical techniques should be included, demonstrating the ability to create quantitative models for solvent content, form, PSD and other physical properties |  |  |
| Algorithms and/or data processing software will be a deliverable |  |  |
| Integration with common plant DCS systems including data export via OPC-UA and Modbus at a minimum |  |  |
| The respondent should indicate in their proposal strategies for validation of the developed technologies leveraging any existing partnerships and bearing in mind the constraints of working with a consortium (i.e. lack of R&D laboratories and manufacturing capabilities) |  |  |
|  | ***Optional*** - Graphic user interface for ease of data collection and processing |  |  |

## Estimated Timeline

|  |
| --- |
|  |

## Estimated Project Cost

|  |
| --- |
|  |