

REQUEST FOR INFORMATION

*Pharmaceutical Drying:*

*Technologies for the enhancement of process understanding during drying in agitated dryers**Test*

March 6, 2017

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. For more information about ETC, please visit the [FAQ page](http://www.etconsortium.org/faq/) on our website.

## Request for Information

Publication of this Request for Information (RFI) is the first step by ETC to solicit interest in collaborating together on a Drying PAT. 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 Pharmaceutical Drying 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 requested technologies for drying. 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 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 will not be 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

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

## Anticipated Time Frames for Evaluation and Selection Process

Issue RFI March 6, 2017

Questions on RFI due March 20, 2017

Responses to RFI due April 3, 2017

ETC RFI response debrief April 18, 2017

Invitations sent to respondents for presentation April 24, 2017

Presentation to ETC by respondents May 1 – 12, 2017

Select finalists for RFP May 23 - 30, 2017

***Please submit your response electronically to the above address. Responses received after April 3, 2017*** ***will not benefit from full consideration and may be excluded from the selection process.***

***The following times have been set for presentations to ETC by selected respondents. Please be available to present at any of these times if your response is selected:***

* May 2, 2017: 11:00 am – 12:30 pm US EDT
* May 2, 2017: 1:00 – 2:30 pm US EDT
* May 4, 2017: 9:00 – 10:30 am US EDT
* May 11, 2017: 10:00 – 11:30 am US EDT
* May 12, 2017: 11:00 am – 12:30 pm US EDT

# Project Information

## Possible Project Sponsors

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

## Description

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| 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 PAT tools, process measurements, and/or material sampling technologies.Current PAT technologies lack the capability to simultaneously measure the full contents in the dryer (e.g. generate 3D profile), suffer from probe blinding and, when required, lack of contact with solids. Furthermore, the existence of agitators, baffles and other equipment constraints make the addition of multiple probes in a drying vessel prohibitively challenging/expensive, and therefore a holistic picture of the process is generally not obtained. Also, since the wet cake during drying is heterogeneous in nature, the data collected from the probes may not be representative. In cases where off-gas analysis is done, such as by gas chromatography or mass spectrometry, the relationship between the measurements and the cake composition is indirect and the heterogeneities in the drying solids cannot be detected.Existing methodologies for scale-up and/or process transfer between different dryer types often result in issues with agglomeration and/or attrition and consequently batch failure. In such cases it would be ideal to capture process measurements such as the real-time particle size, work and shear stresses experienced by the API particles throughout the dryer during processing to enable better understanding and control of the critical process parameters. For many pharmaceutical dryers these capabilities are not readily available. Therefore, the assurance of a successful scale-up and/or process transfer to different drying equipment is empirical and often requires experimentation on full production scale.The collection of samples during the drying process for off-line analysis (e.g. particle size by laser light scattering, specific surface area, bulk density, and scanning electron microscopy for powder properties, XRPD for form, gas chromatography for solvent content analysis, etc.) is also critical and will complement real-time analysis. Unfortunately, the current design of many dryers does not allow for the collection of representative samples during the drying process without interrupting the process. When samples are collected during drying, it generally requires the material to be agitated prior to sampling which can have a detrimental impact on batch properties, especially when the sampling is done prematurely. Often the analysis of the powders cannot be done until after the powder is discharged from the drying vessel which makes it difficult to discern how the powder quality attributes evolved over the course of the process.Ultimately, the concern with the limitations in the current capabilities for real time data collection during drying is the inability to collect meaningful data for the development of closed loop control systems, model validation/verification or to pursue the design of effective scale-down equipment. For further discussion on this topic, please refer to a recent review manuscript written by the project sponsors, found in Organic Process Research & Development (**DOI:** <http://dx.doi.org/10.1021/acs.oprd.6b00406>) which is titled “The Pharmaceutical Drying Unit Operation: An Industry Perspective on Advancing the Science and Development Approach for Scale-up and Technology Transfer.” |

## Drying PAT Requirements

### Necessary Hardware and Software Requirements

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| The scope of work listed in the sections below highlights the desired future state of drying characterization. Interested parties are welcome to respond to any number of the sections below, especially if their expertise can only address certain sections or a portion of a given section. This is the first of a two phase process whose objective is to gather information on possible solutions to the above problems. Selected parties will then be called to participate in the second phase during which the system requirements will be defined and a proposal will be requested. **Section 1: PAT. The equipment of interest would be capable of real time measurement of solvent composition, form and/or particle size distribution**.* Equipment that can be used on batch sizes from ~10 g up to >100 kg suitable for contact with solvent-wet and dry powders with a mechanism to ensure the optics are clear and free from powder. Proposed equipment must be compatible with aqueous and organic solvents.
* Non-contact PAT technologies (e.g. sonar) are acceptable
* Single point as well as larger “spot” area of measurement or 3D profiling to ensure representative analysis would be required.
* Easily installed in existing dryers with minimal retrofitting.

**Section 2: Measurement of Work and Shear. These measurements would be of interest to characterize the process impacts on the particle size distribution of the powder during drying.*** Methodology for measuring work put into the powder on batch sizes from ~10 g up to >100 kg. Responses in which the equipment can only be used at lab or pilot scale are also welcome.
* Ability to “measure” shear experienced by particles along the impeller/ agitator of the dryer

**Section 3: Sampling from the Dryer at Lab and Pilot Scale**Equipment to enable automated sampling during drying in agitated dryers without breaking vacuum to allow for off-line testing. |

### Optional Hardware and Software Requirements

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| **Section 1: PAT. The equipment of interest would be capable of real time measurement of solvent composition, form and/or particle size distribution**.* Ideally a high level of penetration to allow for sub-surface analysis.
* The instrument/technique may or may not be heated and would optionally include temperature sensing to measure product temperature.
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### Availability Requirements

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| The expected output is commercially available equipment that can be used for PAT, process characterization and/or sampling. Expected timing is 12 months to deliver prototype. |

### Licensing Requirements for Commercialized Product

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| Commercially available PAT, process characterization and/or sampling equipment. IP owned by the development organization. |

# 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 Drying PAT.
* 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.

*Please note: 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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## Estimated Timeline

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## Estimated Project Cost

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