

REQUEST FOR INFORMATION

**Pharmaceutical Drying:**

**Understanding methods and models for drying kinetic modelling**

16 January 2024

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 on the project titled “**Understanding methods and models for drying kinetic modelling.”** The information collected during this process along with subsequent interviews will be used for evaluation purposes. Depending on the responses received ETC may choose to select a collaborator solely based upon its response to the RFI or may choose to refine project requirements and subsequently release a Request for Proposals (RFP) to aid in the collaborator selection process.

## Disclaimer

The contents and information provided in this RFI are meant to provide general information to parties interested in developing the project “Understanding methods and models for drying kinetic modelling**.”** The successful respondent selected by ETC 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
* Responses submitted in response to this RFI become the property of ETC
* Respondents will not be compensated or reimbursed for any costs incurred as part of the RFI process
* If ETC receives and responds to questions from RFI respondents, ETC reserves the right to anonymize the questions and make the questions and ETC’s responses available to all respondents via our website
* Responses to RFIs should contain only high-level discussions of product development efforts and should not contain trade secrets or confidential information. ETC does not make any confidentiality commitments with respect to RFI responses but agrees not to publicly distribute RFI responses outside of ETC or share RFI responses with other respondents.
* ETC is not obligated to contract for any of the products or 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. Fatou Sarr

ETC Secretariat

c/o Faegre Drinker Biddle & Reath, LLP

1500 K St NW

Washington DC, 20005-1209

202.230.5148

[info@etconsortium.org](mailto:info@etconsortium.org)

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

## Anticipated Time Frames for Evaluation and Selection Process\*

Issue RFI January 16, 2024

Questions on RFI due February 5, 2024

Responses to RFI due February 23, 2024

*\*Dates subject to change without notice*

***Please submit your response electronically to the above address. Responses received after [DATE]*** ***will not benefit from full consideration and may be excluded from the selection process.***

## Project Scoping and Project Execution

ETC project sponsors will work with the selected collaborator to define the project scope and work to finalize a Statement of Work (SOW) for the project which describes project timelines, milestones, budget, deliverables, etc. Depending on the project, the scoping exercise will be conducted via email, web-meetings, and/or an in-person workshop. Following finalization of the SOW, the project will be brought forward to the ETC Board of Directors to authorize moving to execution.

Once authorized by the ETC Board of Directors, the ETC Secretariat will work with the selected collaborator to negotiate and finalize a contract between the two parties, leveraging ETC’s Development Agreement and Non-Disclosure Agreement accelerator templates. In parallel to this negotiation, the Secretariat will also work to finalize and execute our internal project Charter between participating ETC members.

## Intellectual Property

ETC acknowledges that this project, or aspects thereof, may require the use and incorporation of existing intellectual property and/or the development of new intellectual property in order to successfully complete the project.

### Existing Intellectual Property

* ETC as an organization will not engage in negotiations with the owner of any intellectual property on the respondent’s or ETC’s behalf;
* It is the responsibility of the respondent to conduct an intellectual property search and take all necessary steps to ensure their proposed project will not infringe or misappropriate any intellectual property right of a third party and/or obtain all necessary consents, assignments and licenses to provide the solution in the project proposal.

### New Intellectual Property

With most projects conducted with ETC:

* All commercialization rights will reside with the collaborator;
* ETC will not assume ownership of any intellectual property (IP) developed by the collaborator or expect royalties from future commercial sales.

# Project Information

## Possible Project Sponsors

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| AbbVie, Amgen, AstraZeneca, Bristol Myers Squibb, Boehringer Ingelheim, Eli Lilly, Genentech, GSK, Johnson & Johnson, Merck, Novartis, Pfizer, Takeda, Zoetis |

## Description

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| Drying is a critical manufacturing step of a chemical synthesis of API with potential for great, and often detrimental, impact on API CQAs. The desired product attributes are generated and manipulated through previous unit operations to control purity, form, and powder properties. Sub-optimal drying processes can cause attrition and agglomeration through agitation due to elongated drying times, which impact these CQAs. Current drying development workflows to understand these risks rely on an experimental approach and often result in issues seen on larger scale manufacture and transfer between equipment. Modelling of drying processes offers the potential to predict these phenomena and understand the potential risks earlier in the development process. The drying of drug substance intermediates and APIs is most commonly a batch process, with a variety of vacuum contact drying equipment.  Development of an optimum drying protocol for an API involves having an in-depth understanding of the elements associated with the chemical and physical stability of the compound, the drying kinetics, and the physical properties of the isolated solids. In the pharmaceutical industry, it is critical that all three elements are considered during processing, including how they are impacted during scale-up and by the choice of equipment. Optimization of the processing parameters, with focus on one element without considering the impact on the others, can create unintended risk on the API CQAs. Often, changes that are beneficial for one are detrimental to another. For example, increasing the processing temperature or agitation rate to achieve faster drying kinetics can have a negative effect on maintaining product purity and desired physical attributes. Therefore, in addition to understanding each element, it is important to understand how each is interconnected with the other elements through the drying process parameters (e.g., temperature, agitation protocol, vacuum, dryer type) and how each is related to the API CQAs. Under ideal circumstances, the connections between the processing parameters and each drying element are fully understood and fed into the design so that the optimum drying protocol is achieved. Having this knowledge helps ensure that the drying protocol is robust and able to reliably deliver API with the desired attributes.  Models play a key role in drying process understanding, optimization and scale-up and are central to the development of appropriate process control strategies. General purpose models are needed that can reliably predict both drying times for cycle time optimization and the impact of various process parameters to the API CQAs, over a wide range of scales and equipment configurations.  An accurate kinetic model is required as the basis for any drying model. Different models exist in literature, including terms for heat transfer, mass transfer, and uniformity through the drying cake over the course of the drying process. During development of API processes, many of the terms within these models are unknown, making selecting the most appropriate model a challenge. In some scenarios, de-solvation and dehydration can occur and incorporating the kinetics of these into process models adds to the complexity.  Not knowing which model terms are required for different scenarios and which terms are most influential in predicting solvent content over time prohibits drying modelling use more widely in development and optimization. It is expected that further advances in these areas are required that will further support the development of a more robust drying model, which will allow for process optimization as well as technical transfer across different scales and equipment types. |

## Requirements

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| The scope of work listed in the sections below highlights the open questions identified by the Drying Working Group in the drying kinetic modelling area. 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: Comparison of Heat transfer only based kinetic model vs Heat AND Mass transfer based kinetic model.**   * Understanding the accuracy of these two types of models to predict wet-cake solvent content as well as solvent spatial variation over time * Ability to predict impact of agitation regime and speed on drying time and spatial variation of solvent content * Ability to optimize drying conditions (pressure, temperature, agitation regime and frequency) to minimize drying time * Ability to predict and optimize performance across different scales and dryer types * As an example, the Schlünder model and Murru models are the most frequently quoted heat transfer and heat and mass transfer models respectively.   **Section 2: Assessment of the accuracy of these above models for ‘general’ drying process compared to de-solvation and dehydration drying process.**   * Understanding of model accuracy for de-solvation or dehydration processes. * Ability to predict and optimize drying conditions whilst minimizing degree of de-solvation (of solvated compounds)   **Section 3: Review of the sensitivity of the terms included in kinetic models.**   * For the scenarios and model types detailed above, understanding sensitivity of key model parameters on predictive performance / predictive ability. * Develop simple methods to measure terms required for an accurate model, i.e., the parameters identified as key in the sensitivity analysis. * Establish typical values or ranges for parameters deemed not sensitive or hard to determine experimentally.   **Section 4: Incorporating convective drying terms in to drying kinetic modelling.**   * Ability to model different types of drying approaches (vacuum contact drying vs nitrogen blow through drying) * Ability to model drying in different types of equipment.   Suitable data sets will need to be generated for this project. As well as generating data that will support kinetic model testing, data sets should also include physical property characterization of the isolated compound, and be combined with physical and chemical stability information to give a comprehensive overview of drying.  Respondents should indicate whether they would be in a position to collect any required data to support the model development, what the proposed plan for model validation will be, and whether the required data collection and testing can be done by the respondent or would require an external partner. Any models should be demonstrated on pharmaceutically relevant compounds. |

### Availability Requirements

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| * Commercially available and supported system. * Any requisite service on the instrument should be available globally. * Vendor-provided, hardware and software support are expected for the reasonable life of the product. * Hardware, software, and firmware updates should be field deployable and available at reasonable cost following launch of the commercial technology. |

### Licensing Requirements for Commercialized Product

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| * Software will be licensed to ETC participants at no cost during (i) development and (ii) a mutually agreed beta testing period. Thereafter, software will be available for licensing on a perpetual basis or subscription basis at the option of customer. * Software shall be available for self-hosting by (or on behalf of) customer even if the collaborator elects to make a SaaS alternative available. * The collaborator shall make available industry standard support. * 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 respondent’s ability to:   * Provide responses reflecting a 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 this project. * 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 RFI. * Provide any additional capabilities that may differentiate them from other potential collaborators.   Please note that due to the volume of responses received, ETC only provides general updates related to the status of the review process and will not provide individualized feedback as to why a particular proposal was not selected by ETC. |

# Respondent Profile

*(To be completed by respondent)*

Please provide information to the following:

## Company/Organization Information

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| --- | --- |
| 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

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

## Proposal

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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## 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 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 |
| --- | --- | --- | --- |
| Comparison of Heat transfer only based kinetic model vs Heat AND Mass transfer based kinetic model. | * Understanding the accuracy of these two types of models to predict wet-cake solvent content as well as solvent spatial variation over time |  |  |
| * Ability to predict impact of agitation regime and speed on drying time and spatial variation of solvent content |  |  |
| * Ability to optimize drying conditions (pressure, temperature, agitation regime and frequency) to minimize drying time |  |  |
| * Ability to predict and optimize performance across different scales and dryer types |  |  |
| * As an example, the Schlünder model and Murru models are the most frequently quoted heat transfer and heat and mass transfer models respectively. |  |  |
| * Understanding of model accuracy for de-solvation or dehydration processes. |  |  |
| * Ability to predict and optimize drying conditions whilst minimizing degree of de-solvation (of solvated compounds) |  |  |
| Review of the sensitivity of the terms included in kinetic models. | * For the scenarios and model types detailed above, understanding sensitivity of key model parameters on predictive performance / predictive ability. |  |  |
| * Develop simple methods to measure terms required for an accurate model, i.e., the parameters identified as key in the sensitivity analysis. |  |  |
| * Establish typical values or ranges for parameters deemed not sensitive or hard to determine experimentally. |  |  |
| Incorporating convective drying terms in to drying kinetic modelling. | * Ability to model different types of drying approaches (vacuum contact drying vs nitrogen blow through drying) |  |  |
| * Ability to model drying in different types of equipment. |  |  |
| OPTIONAL | * Collect any required data to support the model development |  |  |
|  | * Proposed plan for model validation will be |  |  |
|  | * Can required data collection and testing can be done by the respondent or would require an external partner |  |  |
|  | * Demonstrate models on pharmaceutically relevant compounds. |  |  |

## Estimated Timeline

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## Estimated Project Cost

The overarching goal of ETC is to help bring innovative technologies to the commercial marketplace in partnership with third parties.  Aligned with that goal, participating ETC members will provide resources in the form of funding and subject matter expertise to support the development of this project.  While ETC will entertain all proposals received, regarding funding from ETC, please consider the following:

* Proposed budgets should be provided as **fixed-costs in US Dollars;**
* When partnering with a commercial vendor, any monetary resources provided by ETC should be viewed as seed funding to supplement the total development costs with the collaborator investing as well;
* When partnering with an academic or non-profit organization, any monetary contributions requested from ETC should be for the total project costs, inclusive of indirect costs (i.e., proposed costs should be inclusive of any indirect or other hidden costs);
* Include a payment schedule, based upon time from project start and/or milestones.

Please describe below project costs, including not only the total project costs but also costs to be paid by ETC and any costs borne by your organization.

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## Commercialization and Support

The overarching goal of ETC is to help bring innovative technologies to the commercial marketplace in partnership with third parties.  Aligned with that goal ETC looks to collaborate on projects which will result in products that are commercially available and supported in the marketplace.

* With most projects, all commercialization rights will reside with the collaborator;
* ETC will not assume ownership of any intellectual property (IP) developed by the collaborator or expect royalties from future commercial sales.

Please describe your organization’s plans for commercialization and support of this technology following the successful conclusion of this project.  If your organization is not a commercial entity (e.g., academic or non-profit), please describe any plans related to the availability of the technology following the successful conclusion of the project. Note that for projects where there isn’t an expectation of a commercial product or service offering, (e.g., research and development project, services-only project) it is expected that each ETC member participating in this project will be provided a non-exclusive, royalty-free license to the output of the project and any new Project IP developed under this project for commercial purposes.

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