

REQUEST FOR PROPOSALS

*Pharmaceutical Drying:*

*Design and manufacture of a drying scale-down laboratory kit*

July 2024

Enabling Technologies Consortium™

Request for Proposals

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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 ETC 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 Proposal

Publication of this Request for Proposal (RFP) is intended to solicit interest in collaborating together on the development of an attrition drying model for application in pharmaceutical drying processes. The information collected during the RFP process along with subsequent interviews 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 model 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 an attrition drying model for application in pharmaceutical drying processes. 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
* If ETC receives and responds to questions from RFP 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 RFPs 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 RFP submissions but agrees not to publicly distribute RFP responses outside of ETC or share RFP responses with other respondents.
* 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
	+ Modify or cancel this RFP at any time

## RFP Contact Information

All questions and inquiries regarding this RFP 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

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

## Anticipated Time Frames for Evaluation and Selection Process

Issue RFP November 8, 2024

Questions on RFP due December 9, 2024

Responses to RFP due January 17, 2025

***Please submit your response electronically to the above address. Responses received after*** **January 17, 2025** ***will not benefit from full consideration and may be excluded from the selection process.***

## Project Scoping and Project Execution

Once ETC selects a respondent to collaborate with on the project, ETC project sponsors will work with the selected respondent (“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. The SOW 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 Collaborator to negotiate and finalize a contract between ETC and the Collaborator, 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 successful completion of this project, or aspects thereof, may require the use and incorporation of existing intellectual property and/or the development of new intellectual property.

### Existing Intellectual Property

* ETC as an organization will not engage in negotiations with the owner of any intellectual property (“IP”) on the respondent’s or ETC’s behalf;
* It is the responsibility of the respondent to conduct an IP search and take all necessary steps to ensure their proposed project will not infringe or misappropriate any IP 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 IP developed by the collaborator or expect royalties from future commercial sales.

# Project Information

## Possible ETC Project Sponsors

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| GSK, AbbVie, Merck, Pfizer, Bristol Myers Squibb, Astrazeneca, Amgen |

## Description

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| Drying of pharmaceuticals is a complex separation operation that can also serve as a particle forming step. The complexity is created by the diversity of pharmaceuticals and their behavior due to the effect of drying factors such as temperature, pressure, agitation, level of liquid, scale. The effects of drying on a pharmaceutical are diverse: Breakage, attrition, agglomeration, aggregation, caking, solid form change, impurity formation etc. Reliable prediction of these behaviors at lab scale is of paramount importance, as it allows designing drying protocols that minimize risk of failure at scale, which is very costly in terms of time and finance.Currently, several drying scale-down equipment are available and enable evaluating the effect of several drying parameters on operation performance and product quality. The main parameters studied are the effect of temperature, pressure, compaction force, agitation and level of liquid. The main gap in current drying scale-down technology is the absence of a kit that allows studying the effect of compaction force and level of liquid while the wet substance is being drying. The ability to closely mimic drying at scale, should enable a more accurate prediction of drying in commercial settings, and enhance process understanding and minimize the risk of drying failure at scale.ETC is proposing to build a lab-scale filter dryer that offers the possibility to simultaneously assess the effect of compaction force and agitation on solids being dried (i.e., with various solvent content). We think that this objective can be achieved by having porous added weights with pores configured in such a way that will minimize ascending particles. A schematic of the proposed kit is shown below with suggested dimensions of main drying cell:The intent is to build a modular kit with a core part and add-ons. Example:Core unit: * Jacketed filter dryer
* Added weights
* Sight window
* Internal light
* Sampling ports for inserting probes (e.g., 4 positioned at 90o of each and placed at 2 different heights
* Interchangeable impeller
* Vertically moveable impeller
* Various mesh size filtration media
* Material of construction (stainless steel or Hastelloy)

Add-ons: * Torque measurement
* PAT (Raman, MS, Temp. probes…)
* Impellers with various configurations
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## Model requirements

### Necessary features

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| * Kit Requirements:
	+ Must be able to replicate drying behavior at lab scale (10-50 g) through commercial scale (~100 kg). This includes drying kinetics, attrition, agglomeration and form change
	+ Must be adjustable to materials with various initial properties: particle size distributions (PSD) and loss-on-drying (LOD)
	+ Must be compatible with most solvents
	+ Must have a wide range of operating conditions (Temp. , Pressure, blade type and position…)
	+ Must be adjustable to various intended commercial scales
* Data collection:
	+ Kit should offer the possibility of transient data collection (Temp. gas evolved, PSD, Torque, Form change)
	+ Kit should offer the possibility of data collection upgrades (ports for added Temp. probes, sigh windows…)
* Applicability and limitations
	+ A range of PSD and morphologies should be evaluated
	+ A range of organic solvents should be evaluated
	+ Compounds which have different behaviors (different friability levels, agglomeration tendencies, form change) should be tested.
	+ 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)
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### Availability Requirements

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| * Collaborator/Respondent to provide ETC estimate of cost of unit (once built and proved to work as intended).
* Prototype(s) of the drying scale-down kit will be available to ETC participants for testing and evaluation at no cost during (i) development and (ii) a mutually agreed beta testing period (minimum 3 years).
* The final product will be comprised of the drying scale-down kit, data collection accessories and software, and data collection readiness and necessary documentation such as risk assessments and limitations should be commercially available within a reasonable timeframe upon completion of the project.
* The final product should be offered at a discount to ETC Participants.
* User training and support will be available upon commercially release
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### Intellectual Property and Licensing Requirements for Commercialized Product

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| 1. The Collaborator shall make available industry standard support.
2. The concept/principle of the final drying scale-down kit should be in the public domain
3. Ownership of data generated on system resides with customer.
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# Criteria for Evaluation

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| The ETC will evaluate the responses to this RFP 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 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 ETC in the development and manufacture of a laboratory scale drying equipment achieving the capabilities listed in section 2.3.1.
* 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 project.
* 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.

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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 RFP. 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 RFP (*to be completed by RFP respondent)*

## Proposal

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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:

|  |  |
| --- | --- |
| 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 | Respondent Comments |
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## 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.  In general, when partnering with a respondent that is a commercial vendor, any monetary resources provided by ETC should be considered seed funding towards development with the Collaborator investing as well; for academic or non-profit partnerships, any monetary contributions by ETC should be limited to “direct costs” only.

Please describe below on 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 with ETC not assuming ownership of any intellectual property (IP) developed by the collaborator nor expecting 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.

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