

REQUEST FOR PROPOSALS

*Development and implementation of a powder feeding system to feed poor flowing materials at low rates.*

October 7, 2020

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 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 Proposal

Publication of this Request for Proposal (RFP) is intended to solicit interest in collaborating on the development of a powder feeding system to feed poor flowing materials at low rates. 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 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 development of a powder feeding system to feed poor flowing materials at low rates. 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 bidders
  + 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](about:blank)

[http://www.etconsortium.org/](about:blank)

## Anticipated Time Frames for Evaluation and Selection Process

Issue RFP October 7, 2020

Questions on RFP due October 23, 2020

Responses to RFP due November 13, 2020

Invitations sent to respondents for presentation Nov – Dec 2020

Presentation to ETC by respondents December 2020

Select collaborator for project Dec 2020 – Jan 2021

***Please submit your response electronically to the above address. Responses received after November 13, 2020*** ***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, Eli Lilly, Merck, Pfizer, Takeda |

## Description

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| Drug product continuous manufacturing often relies on multiple material feeding devices to feed the unit formula accurately and consistently into the process. An individual feeding device’s target mass flow is a function of the process total mass flow and unit formula. Maintaining the unit formula is critical to ensure product efficacy and patient safety. Therefore, the ability of the current feeding devices determines the process minimum total mass flow value. There are multiple reasons to process smaller batch sizes at low total mass flows during development and commercial manufacturing which drives the need for an individual material feeding device capable of feeding at low mass flows.  The feeding mechanism of the feeder typically involves transporting the material within its chamber and accurately metering it into the required process or a unit operation. The performance of feeding is often strongly dependent on properties of the material being fed such as bulk density, cohesiveness, flowability etc. Therefore, it is desired for the device to accurately feed materials with   * a bulk density of approximately 0.20 g/mL or less and (e.g. freeze-dried materials, aerosol materials) and/or * a flow function coefficient (FFC, measure of material flowability) of 2.0 or less. * Example materials – Cab-O-Sil silicon dioxide or lubricants (magnesium stearate or sodium stearyl fumarate) |

## Device Requirements

### Necessary features

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| * Device Requirements:   + Feed Rate – 10g/hr or less with feedback control to maintain target feed rate   + Heel – 20g maximum     - Unused material remaining in feeder after loss of feeding accuracy   + Hopper Size     - 0.5L or larger     - Minimize weight to improve scale accuracy   + Ability to be integrated into an existing continuous manufacturing line     - Communicate with an overarching control system to receive inputs and provide outputs   + Device must be cleanable/pharmaceutical grade   + Design should avoid areas where materials can be difficult to remove/clean   + Commercially dependable and suited for a GMP environment   + Materials of Construction consistent with pharmaceutical equipment * Approximate Guidelines to Assess Feeding Accuracy during Steady Operation (common cause variability):   + Long Term Accuracy of ±3% or less of target evaluated over a 1-minute period (which is ~1/3 of the system’s shortest total residence time).   + Short Term Accuracy of ±6% or less of target evaluated over a 5-second period (based on feeder control response time).   + %RSD < 3% or less over 60 second moving average   + Sampling Rate – 5 seconds or less   + Output mass flow   + Ability to ignore noisy signals |

### Availability Requirements

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| During the project, ETC anticipates the creation and availability of prototype(s) for evaluation to aid in the design of the instrument. Upon conclusion of the project, it is expected that a commercial version of the instrument will be available within approximately 2 years following project completion. |

### Licensing Requirements for Commercialized Product

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| 1. Any required software will be licensed to ETC participants at no cost during (i) development and (ii) a mutually agreed beta testing period. 2. Thereafter, software will be available for licensing on a perpetual basis and subscription basis at the option of ETC participants. The vendor shall make available industry standard support. 3. Software shall be available for self-hosting by (or on behalf of) the ETC participants even if the vendor elects to make a SaaS alternative available. 4. Ownership of data generated on system resides with customer. |

# Criteria for Evaluation

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| The ETC will evaluate the responses to this RFP based on the vendor’s ability to:   * Provide a response indicating a desire to participate in a collaboration with ETC. * 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 powder feeding devices. * 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.

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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

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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. 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.

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 |

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| --- | --- | --- | --- |
| Feature | Requirement | Code | Vendor 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.  While ETC will entertain all proposals in general when partnering with 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 considered “Direct Cost Only” awards.  Any indirect costs by the third party are subject to negotiation and not guaranteed.

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 (if applicable).  All projects awarded by ETC are fixed cost engagements paid in U.S. Dollars.

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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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