

REQUEST FOR PROPOSAL

**Co-processing Platform Technology Development**

May 4, 2023

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 Proposals

Publication of this Request for Proposals (RFP) is the first step by ETC to solicit interest in collaborating on the project titled “Co-processing Platform Technology Development**.”** 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 RFP 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 RFP are meant to provide general information to parties interested in developing the project “Co-processing Platform Technology Development**”** 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 RFP, please note the following:

* This RFP is not an offer or a contract
* Responses submitted in response to this RFP become the 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 RFP s 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 responses 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 or 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

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

## Anticipated Time Frames\*

Issue RFP May 4th, 2023

Questions on RFP due May 19th, 2023

Responses from potential collaborators due June 16th, 2023

*\*Dates subject to change without notice*

***Please submit your response electronically to the above address. Responses received after
June 16 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

|  |
| --- |
| Bristol Myers Squibb, Eli Lilly, Pfizer, Genentech, Merck, AbbVie, GSK, J&J |

## Description

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| --- |
| Feeding of the raw materials through loss-in-weight (LIW) feeders is the first unit operation in continuous manufacturing line. The critical quality attributes (CQAs) of the final product are determined by the feed rate of the individual raw materials, therefore, accurate and consistent feeding of raw materials is crucial towards success of the process to ensure product quality.1,2 Hence the active pharmaceutical ingredient (API) and excipient materials properties impacting the feeding behavior need to be well understood and controlled. There have been reports in the literature of successful demonstration of models predicting the gravimetric and volumetric feeding behavior of LIW feeders for a wide range of powder properties by establishing databases containing all the appropriate material properties from a wide selection of representative powders, and using correlations between the material properties and process behavior during feeding.3,4,5 These studies showed that feeding performance is affected by the material flow properties and bulk density.6,2 A guide for potential performance of powders in LIW feeders suggests that a flow function coefficient (FFC) measured on a shear cell or equivalent of greater than 3 is a good predictor of acceptable (i.e., predictable and reproducible gravimetric feeding) performance in a feeder.7 There is not a simple cut-off in performance at 3 but materials close to this FFC are expected to be difficult, regardless of whether they fall over or under this value.It is common for APIs to display poor flow which pose challenges for feeding. In general, crystals with lower aspect ratio are handled and processed better than more elongated particles.8 Another property that influences the flow is the particle size, and inherently the specific surface area. When the particle size is reduced to a critical average particle size of ∼30 µm for powders, flow issues are often encountered as interparticle cohesion starts to dominate over the gravitational force.9 Therefore, the most common particle engineering methods to improve powder properties are morphology and particle size modification, which are typically implemented during the API crystallization process through solvent selection, supersaturation control, seeding or milling techniques. However, there are many cases where these conventional methods fail to achieve the desired properties. Co-processing of API with excipients can significantly improve the functional properties to overcome these challenges.Co-processed APIs contain the API in addition to one or more non-covalently bonded, nonactive components (such as excipients, carrier, and additives). They differ from salts, solvates and/or co-crystals since API and nonactive component(s) do not exist in the same crystal lattice and do not always require a deﬁned stoichiometry. In a perspective paper by the Co-processed API working group supported by International Consortium for Innovation and Quality in Pharmaceutical Development (IQ), growing interest in co-processed APIs was highlighted by providing examples from industry and academia.10 There are various routes of co-processing. In the most common approach, API and nonactives are crystallized and/or precipitated in solvent-based processes and combined by various mechanisms such as agglomeration, heteronucleation, surface coating, and dispersion of API in a polymer matrix.11,12,13,14 This approach can enhance flow by modifying the particle shape, size and surface properties. Additive mediated crystallization is another route where the additives can modify the crystal morphology by adsorption of additive on crystal faces, and as a result improve the powder properties.15 In another co-processing approach, API is adsorbed on the surface or embedded or confined within the carrier particle, which can improve flow and compactability.16 The non-active components can also be added during API isolation or milling steps17 The most common method is to coat API particles with micronized or submicron nonactive components to modify surface properties and to reduce cohesive forces via dry powder coating achieved through high energy mixing. The ETC would like to seek a collaborator to generate a platform co-processing technology where API and excipients are crystallized and/or precipitated in a solvent-based process and combined via various mechanisms such as agglomeration, heteronucleation and surface coating with the goal of improving flow and bulk density of poorly flowing APIs to improve the robustness of continuous drug product manufacturing processes. The starting material choice is limited to crystalline APIs. Co-processing technologies including amorphous solid dispersions, dry coating, additive-mediated crystallization and adsorption into carrier approaches will be out of scope. **References:** 1. Engisch WE, Muzzio FJ. Method for characterization of loss-in-weight feeder equipment. Powder Technology, 2012; 228: 395-4032. Van Snick B, Holman J, Cunningham C, Kumar A, Vercruysse J, De Beer T, Remon JP, Vervaet C. Continuous direct compression as manufacturing platform for sustained release tablets. International Journal of Pharmaceutics 2017; 519 (1–2): 390-4073. Bostijn N, Dhondt J, Ryckaert A, Szabó E, Dhondt W, Van Snick B, Vanhoorne V, Vervaet C, De Beer T. A multivariate approach to predict the volumetric and gravimetric feeding behavior of a low feed rate feeder based on raw material properties. International Journal of Pharmaceutics 2019; 557: 342-3534. Van Snick B, Dhondt J, Pandelaere K, Bertels J, Mertens R, Klingeleers D, Di Pretoro G, Remon JP, Vervaet C, De Beer T, Vanhoorne V. A multivariate raw material property database to facilitate drug product development and enable in-silico design of pharmaceutical dry powder processes. International Journal of Pharmaceutics 2018; 549 (1–2): 415-4355. Wang Y, Li T, Muzzio FJ, Glasser BJ. Predicting feeder performance based on material flow properties. Powder Technology 2017; 308: 135-1486. Wang Y, O'Connor T, Li T, Ashraf M, Cruz CN. Development and applications of a material library for pharmaceutical continuous manufacturing of solid dosage forms. International Journal of Pharmaceutics 2019; 569: 1185517. 11. Barjat H, Checkley S, Chitu T, Dawson N, Farshchi A, Ferreira A, Gamble JF, Leane M, Mitchell A, Morris C, Pitt K, Storey R, Tahir F, Tobyn M. Demonstration of the Feasibility of Predicting the Flow of Pharmaceutically Relevant Powders from Particle and Bulk Physical Properties. Journal of Pharmaceutical Innovation 2021; 16: 181–1968. Podzczeck F, Mia Y. The influence of particle size and shape on the angle of internal friction and the flow factor of unlubricated and lubricated powders. Int J Pharm 1996; 144: 187-1949. Chattoraj S, Sun CC. Crystal and Particle Engineering Strategies for Improving Powder Compression and Flow Properties to Enable Continuous Tablet Manufacturing by Direct Compression. J Pharm Sci 2018; 107: 968-97410. Schenck L, Erdemir D, Saunders Gorka L, Merritt JM, Marziano I, Ho R, Lee M, Bullard J, Boukerche M, Ferguson S, Florence AJ, Khan SA, Sun CC. Recent Advances in Co-Processed APIs and Proposals for Enabling Commercialization of These Transformative Technologies. Molecular Pharmaceutics 2020; 17 (7): 2232-224411. Yazdanpanah N, Testa CJ, Perala SRK, Jensen KD, Braatz RD, Myerson AS, Trout BL. Continuous Heterogeneous Crystallization on Excipient Surfaces. Cryst. Growth Des. 2017; 17 (6): 3321– 333012. Frank D, Schenck L, Koynov A, Su Y, Li Y, Variankaval N. Optimizing Solvent Selection and Processing Conditions to Generate High Bulk-Density, Co-Precipitated Amorphous Dispersions of Posaconazole. Pharmaceutics 2021; 13(12): 201713. Erdemir D, Daftary V, Lindrud M, Buckley D, Lane G, Malsbury A, Tao J, Kopp N, Hsieh D, Nikitczuk W, Engstrom J. Design and Scale-up of a Co-processing Technology to Improve Powder Properties of Drug Substances. Org. Process Res Dev 2019; 23: 2685-269814. Erdemir D, Rosenbaum T, Chang SY, Wong B, Kientzler D, Wang S, Desai D, Kiang S. Novel Co-processing Methodology to Enable Direct Compression of a Poorly Compressible Highly Water-Soluble API for Controlled Release. Org. Process Res Dev 2018; 22 (10): 1383-139215. Kaialy W, Larhrib H, Chikwanha B, Shojaee S, Nokhodchi A. An approach to engineer paracetamol crystals by antisolvent crystallization technique in presence of various additives for direct compression. Int J Pharm 2014; 464 (1–2): 53– 6416. Sun WJ, Aburub A, Sun CC. A mesoporous silica based platform to enable tablet formulations of low dose drugs by direct compression. Int J Pharm 2018; 539 (1–2): 184– 18917. Mullarney MP, Beach LE, Dave RN, Langdon BA, Polizzi M, Blackwood DO. Applying dry powder coatings to pharmaceutical powders using a comil for improving powder flow and bulk density. Powder Technol 2011; 212 (3): 397– 402 |

## Deliverables & Requirements

### Necessary Deliverables & Requirements

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| * Develop a solvent-based process to generate co-processed API and identify appropriate isolation and drying conditions.
* Build a database of excipients suitable for the technology and their solubility in common process solvents. The purpose of the database is to enable application of the technology to wide range of APIs with different solubility behaviors.
	+ Identify minimum 5 excipients that work with the platform technology.
	+ Provide solubility of selected excipients in minimum 20 solvent systems (pure and binary) at two different temperatures. The solvent systems and temperatures will be selected in collaboration with the participating companies.
	+ The selection of excipients will be done in collaboration with participating companies to ensure qualification for use in pharmaceuticals. Excipients should be compendial. The excipients should be suitable for instant release formulations; release modifying excipients will be out of scope.
* Characterization of co-processed materials: flow by shear cell or FT4, bulk density, XRD, PSD, SEM, potency (multiple samples to confirm content uniformity), residual solvent
* Demonstrate improvement of flow and bulk density for co-processed API with respect to the starting API. The preferred level of improvement for each material will be discussed and decided in collaboration with the participating companies.
* Demonstrate polymorphic form and crystallinity of starting API does not change upon co-processing.
* If residual solvents are close to or exceeding ICH threshold after standard vacuum drying overnight, perform drying studies (such as humidified drying, effect of drying temperature and drying time, changing excipient, etc.) in order to reduce the residual solvent level.
* Demonstrate co-processed API has drug loading no less than 60 wt% and the target loading is consistently achieved.
* Demonstrate process generates no less than 90 wt% yield (with respect to input API amount) at appropriate scale.
* Demonstrate that particle size of co-processed API can be controlled to a D90 of no more than ~300 µm to prevent segregation issues during drug product processing.
* Demonstrate platform process on up to 5 different starting materials, using different combinations of excipients and solvent systems for each material.
	+ The materials will be selected in collaboration with the participating companies. The starting materials need to display cohesive nature and/or poor flow. Examples of properties for starting materials include small PSD (D90<20µm), high surface area (Surface area>5 m2/g), high aspect ratio morphology (Aspect Ratio>5) and high electrostatic charge.
* Demonstrate platform process at minimum 100 g scale for each starting material.
* Provide process scale-up strategies (such as mixing parameters, crystallization/precipitation rate) and materials properties control strategies (such as control of particle size, morphology)
 |

### Optional Deliverables & Requirements

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| * It is preferred that the platform process uses standard equipment and technology available in drug substance manufacturing plants and not require specialized equipment.
* The following tests are preferred but optional if the collaborator does not have the capability:
	+ Dissolution rate measurements for co-processed API and comparison with the input API
	+ Chemical/physical stability evaluation for co-processed API under stressed stability conditions. Conditions will be decided in collaboration with participating companies.
* Publishing the outcome of the project in a scientific journal is encouraged.
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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 responses reflecting a 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 co-processing platform technology.
* Provide a superior level of customer service and technical support.
* Discuss potential partnerships and current development efforts that show similarities to this RFP.
* 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 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)*

*We encourage all respondents to review the* [***Enabling Technologies Consortium FAQ***](https://www.etconsortium.org/_files/ugd/d6fa33_6713713d571d490ba451f348126fcc35.pdf)*to aid in the development of your response to the RFP.*

## 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 Deliverables & Requirements

Refer to the following Functional Deliverables & Requirements checklist which summarizes the collective deliverables and requirements prioritized 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 |

| Deliverables & Requirement | Code | Respondent Comments |
| --- | --- | --- |
| Develop a solvent-based process to generate co-processed API and identify appropriate isolation and drying conditions. |  |  |
| Build a database of excipients suitable for the technology and their solubility in common process solvents. The purpose of the database is to enable application of the technology to wide range of APIs with different solubility behaviors. * + Identify minimum 5 excipients that work with the platform technology.
	+ Provide solubility of selected excipients in minimum 20 solvent systems (pure and binary) at two different temperatures. The solvent systems and temperatures will be selected in collaboration with the participating companies.
	+ The selection of excipients will be done in collaboration with participating companies to ensure qualification for use in pharmaceuticals. Excipients should be compendial. The excipients should be suitable for instant release formulations; release modifying excipients will be out of scope.
 |  |  |
| Characterization of co-processed materials: flow by shear cell or FT4, bulk density, XRD, PSD, SEM, potency (multiple samples to confirm content uniformity), residual solvent |  |  |
| Demonstrate improvement of flow and bulk density for co-processed API with respect to the starting API. The preferred level of improvement for each material will be discussed and decided in collaboration with the participating companies. |  |  |
| Demonstrate polymorphic form and crystallinity of starting API does not change upon co-processing. |  |  |
| If residual solvents are close to or exceeding ICH threshold after standard vacuum drying overnight, perform drying studies (such as humidified drying, effect of drying temperature and drying time, changing excipient, etc.) in order to reduce the residual solvent level. |  |  |
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| Demonstrate co-processed API has drug loading no less than 60 wt% and the target loading is consistently achieved. |  |  |
| Demonstrate process generates no less than 90 wt% yield (with respect to input API amount) at appropriate scale. |  |  |
| Demonstrate that particle size of co-processed API can be controlled to a D90 of no more than ~300 µm to prevent segregation issues during drug product processing. |  |  |
| Demonstrate platform process on up to 5 different starting materials, using different combinations of excipients and solvent systems for each material. * + The materials will be selected in collaboration with the participating companies. The starting materials need to display cohesive nature and/or poor flow. Examples of properties for starting materials include small PSD (D90<20µm), high surface area (Surface area>5 m2/g), high aspect ratio morphology (Aspect Ratio>5) and high electrostatic charge.
 |  |  |
| Demonstrate platform process at minimum 100 g scale for each starting material. |  |  |
| Provide process scale-up strategies (such as mixing parameters, crystallization/precipitation rate) and materials properties control strategies (such as control of particle size, morphology) |  |  |
| **OPTIONAL -** It is preferred that the platform process uses standard equipment and technology available in drug substance manufacturing plants and not require specialized equipment. |  |  |
| **OPTIONAL - T**he following tests are preferred but optional if the collaborator does not have the capability:* Dissolution rate measurements for co-processed API and comparison with the input API
* Chemical/physical stability evaluation for co-processed API under stressed stability conditions. Conditions will be decided in collaboration with participating companies.
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| **OPTIONAL -** Publishing the outcome of the project in a scientific journal is encouraged. |  |  |

## 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; *Please review the* [*FAQ document*](https://www.etconsortium.org/_files/ugd/d6fa33_6713713d571d490ba451f348126fcc35.pdf)*, pages 4 through 6 for details regarding funding amounts.*
* 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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