

REQUEST FOR PROPOSALS

Organic Electrochemical Reactor

July 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 Proposals (RFP) is intended to solicit interest in collaborating together on an Organic Electrochemical Reactor. 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 developing the Organic Electrochemical Reactor. 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
* 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 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 the RFP responses outside the consortium 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. Nisha Quasba

Advisor

ETC Secretariat

C/o Faegre Drinker Biddle & Reath, LLP

1500 K St NW

Washington DC, 20005-1209

(202) 312-7045

info@etconsortium.org

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

## Anticipated Time Frames for Evaluation and Selection Process

Issue RFP July 16, 2020

Questions on RFP due August 10, 2020

Responses to RFP due August 31, 2020

Invitations sent to respondents for presentation September 2020

Presentation to ETC by respondents Sept – Oct 2020

Select collaborator for project Oct – Nov 2020

***Please submit your response electronically to the above address. Responses received after August 31, 2020*** ***will not benefit from full consideration and may be excluded from the selection process.***

# Project Information

## Possible ETC Project Sponsors

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| AbbVie, Amgen, AstraZeneca, Bristol Myers Squibb, Eli Lilly, Merck, GSK |

## Description

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| Organic electrochemical synthesis has the potential to have significant technical and economic advantages relative to traditional organic synthetic methods of pharmaceuticals. In electrochemical synthesis, the use of electrons as a reagent can enable far more efficient transformations than the use of traditional chemical reagents and can obviate the need for harsh chemicals to perform certain chemical transformations. The use of electrochemical reactions can result in safer, more cost effective processes that have less waste generation, use fewer chemicals raw materials, and result in a more streamlined chemical synthesis.A key hurdle to incorporate organic electrochemical reactions into pharmaceutical synthesis is the lack of commercially available manufacturing equipment. While manufacturing processes using organic electrochemistry do exist, these are designed to operate in a specific manufacturing facility, at a fixed scale, with bespoke reactor designs and electrode choices optimized for a specific reaction and product. For electrochemistry to gain wide interest in the pharmaceutical industry, it requires infrastructure that can support a range of reaction types, at a range of scales, and the ability to transfer a robust, scalable process from the development laboratory to the manufacturing plant. Furthermore, once this infrastructure is established, it will increase the interest in academic and industrial labs to seek new transformations that take advantage of the technology.There are a large number of variables that need to be considered in electrochemical reactor design, these include: cathode and anode material selection, undivided vs divided cells, the use of flow reactors or stirred tanks. Beyond these variables, electrochemical reaction performance will depend significantly on reactor geometry, which affects interelectrode distance, flow profile, and heat and mass transfer in the reactor. Due to the vast number of resulting reactor permutations, tech transfer of an electrochemical reaction from the development lab into a manufacturing setting may require custom builds to suit the needs of a specific reaction, or require significant process development to adapt to an existing reactor design. For these reasons, there is value in adopting a platform manufacturing-scale electrochemical reactor, as well as an equivalent scale-down system to support process development.ETC envisions that this project will consist of two phases: Phase 1 - *development of a lab scale reactor with line of sight to manufacturing scale,* and Phase 2 - *development of a manufacturing scale reactor*. Given the wide scope of this project, ETC requests a full plan to complete Phase 1, and a higher-level outline of how Phase 2 will be conducted (including budget). While ETC has provided a proposed outline of this phased approach below, respondents are encouraged to provide an alternate or modified approach as part of their proposal.Phase 1 - *development of a lab scale reactor with line of site to manufacturing scale reactor*1. Initial draft of manufacturing scale reactor and a development scale prototype based on the same design. Obtain feedback and suggested revisions from participating ETC members
2. Build a development scale reactor prototype
3. Characterization of development-scale equipment to measure key performance attributes (ETC will advise on studies to perform), specifically:
	* heat and mass transfer
	* residence time distribution
	* chemical compatibility of the system w/ key solvents & reagents at the designed temperature and pressure range
	* cell resistance

These can be determined through experimentation and/or modeling (e.g. Comsol). NOTE: The ETC contributing companies can support experimental and modeling efforts.1. Perform modifications to system as needed and complete any additional tests.
2. Availability of prototype units at different stages of the development process to be installed at on-site ETC members to conduct familiarization and trial studies with model reactions. A final prototype should be available for evaluation before proceeding to Phase 2.
3. Final agreement on the specifications and attributes of the lab scale reactor which will become the commercially available and supported solution.
4. Finalize project plan and cost for manufacturing scale reactor phase of the project (i.e, Phase 2), based upon learnings from the development of lab scale reactor. Then agreement to proceed to Phase 2

*The deliverable from Phase 1 is a commercially available lab scale reactor that can be used for process development / optimization, that can be purchased outside the terms of this agreement*Phase 2 - *development of a manufacturing scale reactor*1. Complete design of manufacturing scale reactor, with feedback and revisions from participating ETC members.
2. Build the prototype manufacturing scale reactor and perform equipment characterization.

*The deliverable from Phase 2 is a commercially available manufacturing scale reactor, that can be purchased outside the terms of this agreement**++++++++++*As described above, for this technology to be effectively utilized in a pharmaceutical setting it is important that the solution be applicable and easily transferable between the lab scale and manufacturing scale. While ETC may place more emphasis on an all-encompassing solution, proposals that only describe one scale are also welcomed.For all the proposals above respondents should provide a full plan to complete the work, including an estimated timeline with milestones, cost to ETC in US dollars, and a description of deliverables. For those proposals only focusing on one scale, respondents are strongly encouraged to describe how the transition will be made to/from each scale and any future plans for a separate project to deliver the additional capabilities upon successful completion of the initial project. |

## Organic Electrochemical Reactor Requirements

### Necessary Hardware and Software Requirements

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| The manufacturing-scale reactor will be a commercially-available system, designed with relevant safety and GMP considerations. It should include all required components (e.g. reactors, power supplies, safety equipment, etc.). It must have the following attributes:* Capable of achieving production rates for a typical organic electrochemical reaction of 0.5 to 4 moles/h (~0.5 to 1 kg/h)
* Ability to use multiple electrode materials (at minimum, metal and compressed graphite) and readily exchange electrodes. Electrodes should be easy to clean and/or replace. Expected electrode surface area needed to achieve target throughput is ~1000 - 5000 cm2 based on typical current density of 0.01 to 0.1 A/cm2)
* All wetted parts have excellent chemical compatibility for organic solvents, acids and bases.
* Ability to run continuously for extended periods of time (days) without significant intervention by operators. This includes reliable performance of electrodes, seals, etc, and ability to tolerate small amounts of solids (e.g. from electrode shedding)
* Ability to tolerate gases generated in the reactor (including H2). Gases should not accumulate in the reactor, as it would affect reactor performance.
* Identification and integration of power supply that meet power needs for the desired reaction types production rate (Up to ~20 V, and estimate ~60-200 A needed for 2.5 to 5 moles/h production).
* Safety: assured safe operation with respect to electrical hazards and other hazards common in API production (e.g. address solvent flammability hazards, presence of H2 gas, pressure build-up due to potential clogging, etc.). Safety features embedded into the power supply software, incl. safety alarms and auto shut down. Flexibility to conform to local electrical standards and requirements.
* GMP: Ability to qualify equipment in a GMP environment, including appropriate documentation and instrumentation
* Ability to control reaction temperature (e.g. -20 to +80 °C) and provide high heat transfer rates (potentially up to 400-800 W of cooling needed for 2.5 to 5 mol/h)
* Ability to tolerate moderate pressures (e.g. up to ~3 bar)
* Ability to monitor and record process parameters - process temperature, current, voltage, etc.
* Ability to control power supply and other components via PLC automation

The development-scale reactor should be an appropriately scaled-down version of the manufacturing-scale equipment. The purpose of this equipment is to perform process development ahead of a manufacturing campaign. Therefore, it should have production rates 50-100 x lower than manufacturing scale equipment. Transferring between scales should be relatively simple, requiring only a limited set of scaling rules, such as scaling for electrode surface area.* Due to the reduced size, the equipment will not be used in a GMP environment, safety requirement will be reduced
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### Optional Hardware and Software Requirements

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| * Ability to perform divided cell reactions by inserting a membrane between cathode and anode
* Ability to run power supplies and reactors with switching polarity
* For the development reactor, ability to include reference electrode into the setup
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### Availability Requirements

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| The integrated reactor setup should be commercially available to all industrial and academic facilities. In the case of customer-requested modification, the equipment producer should make an effort to accommodate such requests. |

### Licensing Requirements for Commercialized Product

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| Not applicable for this project |

# Criteria for Evaluation

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| The ETC will prioritize equipment that is simple to assemble and maintain, and limits the extent of “numbering up” numerous parallel/serial reactors to achieve the desired production rates. Beyond the requirements listed, there are no specific design limitations in the project. The ETC encourages a range of design types, including plate reactors, CSTR/tank reactors, spinning disc reactors, and any other designs that would meet the requirements.Proposals can include collaborations between equipment producers, academic labs and other third parties. ETC members can also support modeling and experimental efforts. If such support is needed, the proposals should describe the scope of support needed.Given the wide scope of this project, the ETC requests a full plan to complete Phase 1, and a higher-level outline of how Phase 2 will be conducted (including budget).The ETC will evaluate the responses to this RFP based on the vendor’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 the Organic Electrochemical Reactor.
* 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 that ETC will not be able to provide individual feedback to RFP respondents on why their proposal was not selected. |

# Respondent Profile *(to be completed by RFP 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

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| --- | --- |
| 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:

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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 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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