



## 2018 ACS GCI Pharmaceutical Roundtable Research Grant for Greener Chromatography Modalities

The ACS GCI Pharmaceutical Roundtable (Roundtable) is a partnership between the ACS Green Chemistry Institute® and pharmaceutical related corporations united by a shared commitment to integrate the principles of green chemistry and engineering into the business of drug discovery and production. Current membership includes AbbVie, Amgen, AstraZeneca, AsymChem, Bayer, Biogen, Boehringer Ingelheim, Bristol-Myers Squibb, Codexis, Gilead, Lilly, GlaxoSmithKline, Ipsen, Johnson & Johnson, Merck, Pharmaron, Novartis, Pfizer, Roche, Sanofi, Takeda, WuXi App, and ACS GCI.

The ACS GCI Pharmaceutical Roundtable is seeking a 1 year R&D commitment to assist the Roundtable's biopharma initiative. The focus of the R&D will be reducing the process mass intensity of chromatography operations. Projects should focus on reducing water consumption, resin usage, and/or chemical usage in monoclonal antibody purification. Novel technologies to replace chromatography unit operations will be considered. Proposals are invited from public and private institutions of higher education worldwide. This collaborative project is intended for a student within the selected Principal Investigator's research group. One grant is planned to be awarded and the total award is limited to \$50,000 for a grant period of 12 months. Interested PI's are required to provide a written proposal describing the investigator's capability to carry out the Roundtable's proposed research. Deadline for receipt of proposals is **July 15, 2018**. All submissions must be emailed to [gcipr@acs.org](mailto:gcipr@acs.org). The Principal Investigator with the selected proposal will be notified by **September 1, 2018**. It is expected that research will commence in the principal investigator's lab by October 2018 and last approximately 12 months.

### Requirements for Submission

Proposals will only be accepted from public and private institutions of higher education. The grant is not limited to institutions in the United States. Proposals must be submitted by email to [gcipr@acs.org](mailto:gcipr@acs.org) through the appropriate institutional office for external funding. For international submissions, if there is no comparable office, submit a pdf of a letter signed by an appropriate university official recognizing the terms of the grant.

### Detailed Project Description

The GCIPR recently benchmarked the process mass intensity (PMI) of monoclonal antibody (mAb) production, which accounts for water, raw material and consumable usage across all unit operations, and found that chromatography operations account for 62% of water consumption for the entire process. Water use intensity was shown to correlate with the number of chromatography steps used in the process (benchmarked processes varied between 2 and 4 chromatography steps). Chromatography operations also accounted for 55% of the raw materials (salts, buffers, etc) used to manufacture a mAb. The GCIPR is seeking proposals that can reduce material intensity (water, raw materials, and/or consumables) in chromatography operations within the following parameters:

- Ease of implementation into current mAb processing schemes
- Analytical methods that provide in-line parameter monitoring or detection
- Continuous processing methods
- Optimization of buffer utilization (e.g., minimum volumes for equilibration, etc)
- Optimization of chromatography cleaning strategies
- Single-use technologies and novel applications of these technologies (e.g., multi-operation usage, etc)

### **Project Goal**

Provide novel chromatography methodologies that are widely applicable in mAb processing, which optimize material consumption (water, raw materials and/or consumables) as compared to typical three column purification platform.

### **Project Timeline**

It is expected that one year of research support will be sufficient to provide progress toward intended goals.

### **Proposal Format** (Maximum 3 pages as described below + CVs)

All of the information below must be submitted as a single PDF file. All components described in sections A, B, and C must be included in the same PDF file to assure the proposal is reviewed in its entirety.

#### A) Title Page (1 page, 12 pt font, 1-inch margins)

1. Project Title:
2. Principal Investigator:
3. Title / Position(s):
4. Telephone Number(s):
5. Fax Number(s):
6. Postal Mailing Address:
7. E-Mail Address:
8. Research Group website:

#### B) Proposed Plan of Work (2 pages, 12 pt font, 1-inch margins)

1. Summarize the student's (undergraduate, graduate student and /or postdoc) capabilities to perform the Roundtable's proposed work.
2. Brief description of the PI's research facilities.
3. Proposed milestone deliveries (primary project and side project) with brief description of the manner in which the researcher intends to achieve them.
4. The PI should list any existing background intellectual property and/or collaborations they are aware of that might limit the freedom to operate any of the results arising from any research funded by ACS GCI. The priority of the Roundtable is to encourage research utilizing reaction conditions that are commercially available with the freedom to use.
5. References (Does not count toward your page limit.)

- C) Curriculum Vitae of Project Team Members: Please submit a two page curriculum vitae of all project team members. (Does not count toward your page limit.)

Any proposals selected for funding will then be required to submit the following:

1. Detailed Project Timeline
2. Detailed Estimated Budget: The total amount requested would include all direct costs, student assistantships, etc. The total award is limited to \$50,000 for a grant period of up to 12 months.
  - a. Institutional overhead costs (indirect costs) are prohibited.
  - b. Funding would start in October 2018, or later as agreed between the Principal Investigator and the Roundtable.
  - c. Post-doctoral associate salary and benefits are supported.
  - d. Graduate student stipend and benefits are supported. Proposals for support of advanced graduate students are highly favored.
  - e. PI salary supplements will not be supported.
  - f. Laboratory supplies and instrument use charges are supported.
  - g. No funds may be allocated for travel, equipment purchase or repair, or administrative support.
3. Current funding list for the PI including title of grant award, agency, award amount and duration.
4. Listing of any existing background intellectual property and/or collaborations that might limit the freedom to operate any of the results arising from any research funded by ACS GCI.

### **Report Requirements**

- As a collaborative research project, the Roundtable will work closely with the principal investigator and student(s) to provide industrial direction, when appropriate, in a manner that respects the independence of the researcher/student.
  - Progress updates are due at 1 month intervals from initiation of research and discussed in arranged teleconferences.
  - Updates are to include research milestones/significant outcomes, summary of progress to date noting any deviations from the proposal, and research plans for upcoming months.
- A final comprehensive report including research outcomes and final budget is due one month after the end of the grant period.
  - The report must be submitted as an Adobe PDF document electronically to [gcipr@acs.org](mailto:gcipr@acs.org). The report will be shared with the member companies of the Roundtable.
  - The content of the report will be targeted for publication in a peer review technical journal within six months of the conclusion of the research. As a collaborative research project, the paper will be written by the principal investigator and student(s) performing the work, with the Roundtable as co-authors.

### **Intellectual Property, Publication Acknowledgement, and Terms of the Grant**

- The primary purpose of this grant is to publish research to make information publicly available.

- Every patent, United States or foreign, that results from research funded (in part or in its entirety) by the ACS GCI Pharmaceutical Roundtable Grant shall be immediately dedicated to the public, royalty free.
- Publication of results is expected within 6 months of work completion.
- Each publication prepared in connection with the ACS GCI Pharmaceutical Roundtable Grant shall make acknowledgement to the ACS GCI Pharmaceutical Roundtable Research Grant, in the following manner. “Acknowledgement is made to the ACS GCI Pharmaceutical Roundtable Grant for support (or partial support) of this research.”
- Acceptance of a Roundtable Grant will be conditioned upon agreement by the grantee institution that in the event the principal investigator is unable for any reason to conduct the research proposed, the funds, if previously paid by the Roundtable, shall, upon demand, be returned in full to the Roundtable, and further, that in the event the PI is unable for any reason to continue with the research after it has commenced, this grant shall be terminated forthwith and the unexpended and unencumbered balance of any funds theretofore advanced shall be returned to the Roundtable.
- The grantee institution, by acceptance of this grant, provides assurance that support normally provided by the institution for research of the faculty member will not be diminished.
- Applicants may have only one research grant with the ACS GCI Pharmaceutical Roundtable at a time. In order to close a grant, the required reports must be received and approved by the ACS GCI Pharmaceutical Roundtable.

**For additional information:**

Website: [www.acs.org/gcipharmaroundtable](http://www.acs.org/gcipharmaroundtable)

Email: [gcipr@acs.org](mailto:gcipr@acs.org)