

Request for Information (RFI)

Introduction:

This is a Request for Information (RFI) only and does not constitute a commitment, implied or otherwise, that Colorado State University (CSU) or CSU Ventures (CSUV) will take procurement action in this matter. Further, neither CSU nor CSUV will be responsible for any cost incurred in furnishing this information.

CSU recognizes the importance of manufacturing in the enablement of translational stage medical research. CSU is constructing an 8,400 ft² cGMP (current good manufacturing practices) manufacturing building (RIC-GMP) that is part of a greater life science complex it is establishing in Ft. Collins, CO. Furthermore CSU anticipates interest by life science companies and contract manufacturing entities in the utilization of this facility upon its completion in March 2010. CSU's vision is to establish a relationship with a private enterprise that will enhance CSU's capability in life science research and product development, providing a unique opportunity for the partner to succeed in its contract manufacturing business plan. As a result, strategic planning and interaction with interested private sector enterprises is required prior to opening of the facility.

This RFI is being used to gather market data for CSU to make strategic decisions about engaging private-sector companies in the utilization of space in its new life science complex, in particular the new RIC-GMP facility.

CSU is interested in identifying whether organizations have the requisite resources, knowledge, and interest in entering into a binding lease agreement for occupancy and utilization of the RIC-GMP. Utilization of the RIC-GMP would also include items such as move in expenses and routine operational costs not included in the lease (regulated medical waste disposal, equipment maintenance fees on equipment not owned by CSU, etc.). In addition, potential organizations should be in a position to outline a business plan that achieves sustained revenue generation to support the recurring lease payments.

CSU will use the results of this RFI to determine interest that may lead to selection of specific organizations to receive a follow up RFP and/or enter directly into lease discussions. The RIC-GMP building will be directly leased ('exclusive') to the eligible recipient organizations under the authority provided to the real estate office of Colorado State Research Foundation (CSURF) by CSU. The organization that ultimately enters into the lease with CSURF will be responsible for all costs of the lease agreement.

Background:

CSU has a long history in life science research that encompasses many scientific disciplines engaged in fundamental and applied research. In particular CSU has domestic and international recognition as a leader in infectious disease, animal cancer and veterinary medicine (appendix 1- CSU-BioMedicine.pdf).

A major emphasis at CSU is translational-stage research wherein studies are performed to improve the utility of basic research discoveries as a means to address global healthcare needs. Key to the ability to perform these studies is the availability of study materials such as new active ingredients (e.g. therapeutics, biomarkers), and/or new drug products or diagnostics. The studies performed in the translational phase require access to quantities, in excess of research bench quantity and of a quality that matches the study requirement (GLP and non-GLP). Most often this will be the first time a tangible quantity of new material has ever been generated. It is CSU's position that an external private business entity experienced in contract cGMP manufacture of clinical-grade therapeutics will augment the universities existing capability by expanding its reach, expertise, capacity and freedom to operate.

CSU's capability in the life sciences includes a newly established supercluster model in the areas of infectious disease and animal cancer research. The supercluster model and research capability is considered a key benefit. The rationale behind this anticipated benefit is the interaction with the supercluster research faculty and their associated enterprise organizations MicroRx and NeoTrex. These two organizations are part of CSU Ventures, a 501c3 organization, which is a division of the CSU Research Foundation (CSURF). Dr. Joseph Guiles (J & J, Sanofi, Replidyne) and Dr. Terry Opgenorth (Abbott Labs), MicroRx and NeoTrex's two leaders respectively, have a combined 40 years of pharmaceutical research and management experience. MicroRx and NeoTrex work with the superclusters and research faculty in identifying new sponsored research opportunities with particular emphasis on increasing collaboration with the private sector, grants, out licensing and creation of startup companies. MicroRx and NeoTrex, at no cost to the leasing organization, will provide information on potential grant or sponsored research opportunities and contract opportunities through their extensive pharma/biotech business connections. Operationally, MicroRx is the building manager for RIC-GMP and the associated RIC business incubator (2nd floor of RIC). CSU is the property owner and the real estate office of CSURF is the leasing agent.

The location of the RIC-GMP facility provides unique access to the capabilities of the Infectious Disease Research Center (IDRC) which includes >100 researchers and research faculty with specialized capability (e.g. BSL-3/select agent research). A major part of the IDRC is the NIH/NIAID-funded RMRCE (Rocky Mountain Regional Center of Excellence) which includes three core work groups with specialized capability in research areas that include animal models, genomics/proteomics, and biomolecule manufacturing. In 2007, CSU opened the NIH/NIAID and CSU-funded Rocky Mountain Regional Biocontainment Laboratory (RBL) which complements similar infectious disease research already underway at the CDC facility and the USDA laboratory on the Foothills Campus as well as at the university's existing Bioenvironmental Research Building (BRB) and its Arthropod-borne and Infectious Diseases Laboratory (AIDL).

The RIC-GMP complements the pre-existing cGMP facility housed within the Regional Biocontainment Lab (RBL). The RBL-GMP facility is operated by a small university employed workgroup titled BioMarc. BioMarc and the RBL-GMP are funded through grants obtained by the Rocky Mountain Regional Center of Excellence (RMRCE). The RBL-GMP facility and BioMarc have capability in small-scale cGMP of BSL-2 and BSL-3 biomolecules and aseptic fill and finish. CSURF and CSU expect complimentary interaction between the RBL-GMP facility and BioMarc, and anticipate potential synergy between these capabilities.

Figure 1. RIC-GMP

Physical Characteristics of the RIC-GMP Facility include:

8,400 square foot facility	Steam Sterilization (Clean Steam)
Loading Dock	Gas system (CO ₂ , N ₂ , Air, Special)
Shipping/Receiving/Warehousing Rooms	WFI system
Refrigerated Storage	Vacuum System
Clean Rooms (ISO class 7 & 8)	Process Waste System
QC Room	BMS & UPS
Offices & Meeting room (furnished)	Process/Decontamination
Ethernet & Phone wiring throughout	Select Fixed Equipment (list tbd)

Services Provided

Secure gaited facility	Facilities & Maintenance
Access to full CSU library	Access to RIC-Incubator lease space
Maintenance of Biosafety cabinets & fixed equipment (installed by CSU)	Business Development (MicroRx & NeoTrex)

Research Innovation Center (RIC-Incubator)

In April 2010 businesses and university scientists in northern Colorado will soon occupy a state-of-the-art facility that fosters private and public sector collaboration in the pursuit of new products to treat and diagnose important unmet medical needs. The RIC-Incubator (figure 2) will house faculty and researchers as well as private-sector research & development companies. The top floor will serve as a biotechnology incubator, fostering startup and established companies to conduct life science R & D and associated business operations. The facility will be built to safety standards (BSL-2) that allow scientists to conduct life science research that addresses important public health concerns.



Figure 2. RIC-Incubator(foreground), RIC-GMP (background))

Building Highlights

56,222 Square-Feet (ft²) (whole building)

24-Hour Key Card Access

Incubator Space (2nd floor)

- Total Area : 17,000sqft
- Total Office Area: 1,700sqft, 12 Offices
- Total Lab Area: 7,500sqft, 21 Labs - 220, 300, & 600 SF
- Total Common Area: 7,800sqft
- BSL-2 design

Services Provided

- Flexible lab space with movable benches
- Access to full CSU library services
- BMS & UPS
- Front lobby entrance with check-in desk
- Biosafety and chemical fume hoods with annual inspection & maintenance
- Private office space
- Loading Dock
- High-speed wired and wireless internet access
- Telephone access
- Furnished conference rooms

CSU is developing a lease estimate for the RIC-GMP building. The lease rate will include triple net (utilities, taxes, insurance) but will not include medical waste disposal costs or equipment maintenance costs for equipment not provided with the facility. The lease rate will be based on comparable construction quality and be competitive with space found in other regional science parks (e.g. Fitzsimmons Life Science, adjacent to University of Colorado-Anschutz Medical Campus). Wherein a ballpark price for lab/technical space is \$24/ft² and non-lab space is \$18/ft². It should be noted that the extent and duration of the lease will impact the lease discussion.

The estimate is subject to change. It does not take into account special measures that may be required in specific situations such as start up costs that may encompass unanticipated equipment and systems.

Special Considerations:

There is a limited quantity of support staff that can provide services to assist in the move in and start up operations.

Responding to this RFI:

Each organizations responding to this RFI must be an established business entity, authorized to transact business in the state of Colorado, or with the demonstrated ability and intent to become a registered business entity prior to submitting a proposal in an RFP.

RFI responses must include:

- Name of the primary point of contact for the response
- Full legal name of the entity that is responding or that anticipates it may respond to an RFP that results from this RFI;
- Type of business entity (e.g., corporation, partnership, etc.) and jurisdiction(s) in which the entity is organized and has a principal place of business;
- Description of the entity, its mission, nature of its business, size, locations, etc.;
- Date that the business entity was formed and general historical information about its businesses
- A brief summary (300 word limit) description of previous relevant experience in cGMP manufacture of drug products and/or diagnostics (e.g. technical expertise, IND/NDA/ANDA filings, FDA inspections)

RFI Questions:

1. Would your organization be interested in leasing the RIC-GMP space? For what general type of projects and purpose?
2. Please explain your organization's approach to committing (and, if necessary, raising) the funds necessary for entering into a binding lease agreement for utilization of the RIC-GMP.
 - a. What would be the proposed source(s) of funding?
 - b. What is the estimated amount of time needed to raise sufficient funds?
3. Please explain your organization's outcome on profit and loss with contract manufacturing business model.
 - a. Historical examples
 - b. Projected business for 2010-2011.
4. The RIC-GMP is a new facility and will require suitable understanding of the validation and commissioning process to successfully start up manufacturing operations. Please provide your organization's capabilities to appropriately understand and navigate this operational aspect.
5. What are the benefits to CSU to entering into lease agreement for the RIC-GMP facility with your organization? In your response, please identify:
 - a. How you would use the facility in collaboration with CSU's life science community; in particular; interactions with the enterprise units MicroRx & NeoTrex, and the BioMarc group that operates the RBL-GMP facility

Respondents should also include the following in an Appendix in as much detail as reasonably possible:

- Mission Statement
- Organizational Chart
- Accreditation or other relevant credential
- Budget and Resources profile including staffing plan for first two years

Please note that RFI responses including the Appendix must not exceed 25 pages in length. Use single-spaced, 12-point, Times New Roman font.

Authorized file formats include: Adobe Acrobat versions 6 - 8 (.pdf) Microsoft Word versions 2000 – 2007 (.doc) and Microsoft Excel versions 2000 – 2003 (.xls)

Response Submission Deadline:

Responses to this RFI must be submitted no later than August 31, 2009. RFI submissions will be accepted as email attachments only. All Responses must be sent to microrx@colostate.edu with "RIC-GMP RFI Response" in the subject line. An email confirmation of receipt from CSU will be sent within a one-week period to the designated point of contact.

Point of Contact for Inquiries and Submissions:

Inquiries regarding this proposal may be directed to MicroRx, 3195 Rampart Road, Fort Collins, CO 80523-1690, (970)491-8582, (970)491-8707 fax or electronic mail to microrx@colostate.edu with "SSP RFI Inquiry" in the subject line.

This RFI may also be found electronically at the MicroRx homepage www.microrx.org

CONFIDENTIALITY:

MicroRx will hold proprietary information obtained in response to the RFI as confidential, and unless provided for herein, will not disclose it to a third party. In the event that MicroRx or an affiliated entity is required by law, such as the Colorado Open Records Law (C.R.S. § 24-72-203 *et seq.*), to disclose any information, MicroRx will give prompt written notice of such requirement and permit you to intervene in any relevant proceedings to protect your interests.

DISCLAIMER:

This RFI contains limited information about the RIC-GMP facility, and general information regarding CSURF, CSU Ventures, Inc., MicroRx, NeoTrex, and CSU. This RFI does not purport to contain all relevant information, and interested parties should conduct their own investigation and analysis regarding the accuracy, reliability and completeness of the information contained herein. Neither MicroRx, NeoTrex, CSU Ventures, Inc., CSURF, nor CSU make any representation or warranty and shall have no liability under any statute, rule or regulation as to the accuracy, reliability or completeness of the RFI. In addition, the information contained herein and the stated plans for the RIC-GMP facility are subject to change at any time. This RFI is not a contract, offer, or invitation to any other party. The terms of any future relationship with and the rights of any third party with respect to this project would be set out in separate agreements. MicroRx reserves the right to respond or not respond, for any reason or no reason, to the information submitted by an interested party.