INFECTIOUS DISEASE RESEARCH CENTER

BIOMARC BIOPHARMACEUTICALS FILL-FINISH FACILITY PROJECT SUMMARY

FOR PRELIMINARY BOARD OF GOVERNOR’S APPROVAL

JANUARY 2021
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1. Existing conditions

BioMARC is a nonprofit CMO owned and operated by CSU, and was created to translate and produce biopharmaceutical products for non-clinical, clinical, and commercial use under Biosafety Level 3 (BSL-3) and BSL-2 containment (including spore former containment) and Select Agent (SA) biosecurity conditions. BioMARC operates the cGMP Pharmaceutical Manufacturing Facility at the Infectious Disease Research Center (IDRC) on the Foothills Campus.

2. Opportunity

BioMARC envisions expanding their operations into a fill and finish suite that is capable of producing stable liquid and lyophilized drug products. This new 14,000-15,000 gsf facility will consist of open shell space with MEP systems to support phased installation of premanufactured clean room and BSL 3 laboratory environments. These “pods” can be configured to user specifications to support pharmaceutical manufacturing processes for drug products for clinical trials. There is ample land and utility service at the IDRC to construct the facility adjacent to the CGMP building.
3. Impact

This new 14,000-15,000 gsf SF facility will allow BioMARC to provide additional services to customers and become globally recognized as a leader in formulating and manufacturing difficult-to-produce new human and animal drug products for clinical trials. It will pave the way for manufacturing medicines of the future such as antibody-drug conjugates, nanoparticles and bio-similars. In April 2019 the Infectious Disease Research Center was honored as the winner of the Colorado Manufacturing Awards (CMAs) for 2019 Bioscience/Medical Manufacturer of the Year. The selection of the IDRC was made on the basis of its program of work in supporting the development and manufacture of diagnostics, therapeutics and vaccine products on behalf of government, academic and private sector organizations carried out under the BioMARC operation. The current COVID 19 outbreak has emphasized that the ability to produce large quantities of vaccines in a cost-effective manner is and will continue to be vital.
4. Space Needs

A preliminary space program is shown below:

<table>
<thead>
<tr>
<th>Space Type</th>
<th>gsf</th>
<th>notes</th>
<th>Estimated cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Premanufactured metal building</td>
<td>14,369</td>
<td>Allows for installation of up to 3 pods and support space</td>
<td>5,750,000</td>
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<tr>
<td>Support space</td>
<td>2000</td>
<td>Reception, office, conference, restrooms and shower facilities- included in overall building gsf</td>
<td>950,000</td>
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<tr>
<td>POD 1</td>
<td>5000</td>
<td>Included in overall building gsf</td>
<td>9,000,000</td>
</tr>
<tr>
<td><strong>Total gsf</strong></td>
<td>14369</td>
<td></td>
<td><strong>15,700,000</strong></td>
</tr>
</tbody>
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5. Cost

Facilities Management provided a detailed cost estimate for this project, based on recent costs of premanufactured buildings and preliminary information from a supplier of premanufactured clean room and BSL 3 laboratory environments. Current cost estimate for the IDRC Biopharmaceuticals Building is $15-$20M, depending on when project is approved. Funding is anticipated to be from donors and/or grants.