Adenoviral Reference Material Working Group
Bid Submission Form – Purified Formulated Bulk Virus Reference Material
Production and Release Testing Donation
RFP 5.0

Item for Submission

Production and release testing of an Ad5 Wild-type Virus Bulk Reference Material in final formulation ready to be vialed. The bidder will also provide a Certificate of Analysis summarizing characterization as called for below. The intended lot size for the reference material is to enough bulk for vialing of 4500 to 5000 x 0.5 mL vials at 2 to 5 x 10^{11} particles/mL, or equivalent to approximately 1.3 x 10^{15} total particles after release. The bulk material should be delivered in at least 4 aliquots.

General Requirements for Bidding

Reference material will need to be produced under conditions equivalent to CGMP. Virus bank and cell bank vials used for reference material production will be supplied from other bid activities in this process. Indicate your minimum requirements / concerns for acceptance of these materials (cell bank vials and viral bank vials) if not addressed by characterization called for RFP 4.0. The bid should indicate the amount of time required from receipt of the cell bank vials and viral bank vials for the production and release of the purified, formulated bulk reference material.

The institution will need to provide a brief statement describing the proposed method for production and purification of the reference material bulk, including proposed container configuration. The institution should include their proposed specifications, including information on the proposed test methods, and proposed Certificate of Analysis addressing the following points:

- Identity
- Purity
- Provisional Particle concentration
- Functional activity (such as infectivity)
- Sterility (USP or 21CFR610.12)
- Mycoplasma
- Endotoxin
- In vitro adventitious viral agents or equivalent
- AAV

And where applicable

- Bovine virus – Certificate of Analysis (raw material or final vial test) (per 9CFR113.47)
- Porcine parvovirus – Certificate of Analysis (raw material trypsin or final vial test)
The proposal should include details of the proposed method/container for shipping to ensure integrity of the bulk material upon arrival at the vialing facility. The proposal should also include instructions regarding how the material is to be dispensed. Examples are “the material will be shipped at 2-8°C and should be dispensed before freezing,” or, “the material will be shipped frozen; it should be thawed under the following conditions (supplied) and then should be dispensed and then frozen.”

In addition to these specific documentation requirements, each institution should include a brief statement describing their experience and capacity to perform this activity and a description of the facility in which the work will be performed. The facility description should address procedures to ensure segregation during viral bulk reference material production and purification.

It is expected that the final documentation package made available with the formulated bulk would include copies of the completed batch records used for production.

**Documentation Requirements**

Documentation should include detailed information on a proposed final formulation, which should not be solely PBS (phosphate buffered saline)-based nor should it contain protein. This information should include supporting data indicating the formulation’s ability to provide stability for storage of Adenovirus at ≤-55°C. The formulation information should also indicate compatibility with biological and chemical characterization methods. The working group will determine the final formulation used.

The bid should include a description of the proposed cell and viral culture, harvest, and purification methods along with the proposed specifications, test methods, and proposed Certificate of Analysis.

The proposal should include details of the proposed method/container for shipping the formulated bulk reference material to the vialing facility.
Please complete the following fields:

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<th>Contact Information – RFP 5.0</th>
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<tr>
<td><strong>Contact Individual:</strong></td>
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<td><strong>Institution:</strong></td>
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**Purified Formulated Bulk Virus Reference Material Production and Release Testing**

**Donation – RFP 5.0**

Indicate Propagation Method:  
- [ ] Suspension  
- [ ] Adherent

Please indicate if your institution is also submitting proposals for the other activities:

- [ ] Donation of Cell Bank
- [ ] Donation of Ad5 Wild-type Virus
- [ ] Ad5 Wild-type Virus Bank Production
- [ ] Donation of Repository Services
- [ ] Vialing of Ad5 Wild-type Reference Material
- [ ] Donation of Supplies/Other Services

Please attach:  
- Proposed Certificate of Analysis, specifications, and test methods
- Proposed method for production and purification
- Proposed Formulation Information
- Institution Capability Statement
- Information on shipping

Purified Bulk Reference Material Form, RFP 5.0

February 7, 2001

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Submit this completed form and all attached information for receipt by February 28, 2001 to the address below. Electronic submissions are encouraged. Final decisions will be communicated by or about March 31, 2001. Please note that all information submitted will be publicly available. Please do not mark any information confidential, as we cannot honor that request. Please also include an estimate of cost and market value of donated goods and services.

Williamsburg BioProcessing Foundation  
Attn: Adenovirus Reference Material Working Group  
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Norfolk, VA 23508  

PH: 757-423-8823  
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