

**AAV Reference Material Working Group
Bid Submission Form
Vialing and Freezing Donation, RFP 4.0**

This Request for Proposal is for Vialing and Freezing of an Adeno-Associated Virus Reference Material (AAVRM) bulk that will be provided in its final formulation. Bulk should provide enough material to fill 5000 to 10,000 vials at 0.5 mL with approximately 2×10^{11} particles/mL. Vials are intended to be stored at less than minus 55 C until shipped under appropriate conditions to the designated repositories. Bidder will include the sterility test for the vials as part of the bid, and will ship the material using temp tales.

General Requirements for Bidding

Finishing activities must be done under documentation equivalent to those for cGMP operation. Institutions will need to provide evidence of their experience in finishing purified adeno-associated virus or other similar biologics, and provide detail about their facility and its capabilities. The facility description should address procedures that ensure segregation during filling of the reference material.

The purified, formulated adeno-associated virus reference material will be supplied from other bid activities in this process, and will be accompanied by minimum handling instructions. Indicate your minimum requirements or concerns for acceptance of this material. The bid should indicate the amount of time required from receipt of the purified, formulated bulk reference material until completion of vialing, freezing, and sterility testing of the final containers.

The proposal should include details of the proposed method and container for shipping that will ensure integrity of the vialled reference material upon arrival at the repository facility.

Documentation Requirements

Documentation should include detailed information about the proposed container/closure system(s). Information should also be provided on the maximum number of vials that can be filled at one time; the amount of time for filling the proposed number of vials; and handling and storing of bulk before and during fill.

The proposal should address the following issues:

- Container/closure system's ability to provide stability for storage of adeno-associated virus at $<-55^{\circ}\text{C}$ and the specified virus concentration
- If filling is to be staged in a specific number of vials, information regarding the institution's limitations and how the institution proposes to address these limitations

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- If documentation and practices equivalent to cGMP are not employed, what other data can be provided to support fill (e.g., media fill using the proposed container/closure)
- Environmental monitoring program—It is expected that the Batch Records used for the filling procedure and the environmental monitoring data collected will be made available.

The proposal should contain the proposed method for sterility testing of the vialled reference material and details related to proposed shipping of adeno-associated virus reference material vials to the designated repositories.

Please complete the following fields:

Contact Information – RFP 6.0

Individual:

Institution:

Address:

Phone Number:

Email Address:

Vialing and Freezing Donation Information – RFP 6.0

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

Donation of Supplies/Other Services

Please attach:

1. Procedure for Vialing
2. Proposed Container/Closure Information
3. Institution Capability Statement
4. Media Fill or Other Validation Information as available
5. Information on shipping

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Submit this completed form and all attached information for receipt **by Friday, February 25, 2005**, to the address below.

Williamsburg BioProcessing Foundation
Attn: Adeno-Associated Virus Reference Material Working Group
P.O. Box 1229
Virginia Beach, VA 23451
phone: 757-423-8823 fax: 757-423-2065
e-mail: referencematerial@wilbio.com

Electronic submissions are encouraged.

Please note that all information submitted will be publicly available. Please do not mark any information confidential, as we cannot honor that request.

Please estimate the cost and market value of donated goods and services.



*Final decisions will be communicated by or about **Friday, February 25, 2005**.*