

Request for Information (RFI): Aseptic fill of a recombinant virus for clinical trials
6/24/2013

Notice Number:

RFI13-153

Key Dates:

Release Date: June 24, 2013

Responses Due: Responses will be accepted as long as this RFI is posted

Related Announcements:

None

Issued By:

SAIC-Frederick, Inc.
Frederick National Laboratory for Cancer Research
P.O. Box B
Frederick, MD 21702

Overview

The Frederick National Laboratory for Cancer Research (FNLCR, <http://ncifrederick.cancer.gov/>) a national laboratory operated by SAIC-Frederic under a contract from the National Cancer Institute (NCI) is seeking information to gain feedback, comments, and novel ideas to perform an aseptic fill of a recombinant virus for clinical trials formulation (designated as a BL2 agent) which was approved under the NCI Experimental Therapeutics Project (NEXT). The batch size would encompass on the order of 5000 vials containing 0.5 mL of liquid product, to be stored and shipped at -80 degrees C.

The bulk viral product will be produced, tested and released by the Biopharmaceutical Development Program (BDP) at their Frederick, Maryland facility, subject to characterization testing, prior to transport to the vialing contractor for performance of the final fill.

All vialled product will be returned to the BDP, along with all supporting documentation, and the BDP will be solely responsible for testing and release of the final vialled product.

This project is intended to support the potentially ongoing production of a promising cancer agent presently in phase I and being readied for phase II clinical trials, and the scope of these trials may widen depending on the results observed.

- The current filling process will need to be adapted to the contractor's equipment and GMP documentation will need to be prepared to use in the actual filling process.
- Fill of a clinical batch based on #1 above following cGMPs suitable for human clinical trials would then be executed. It is anticipated that the drug products described in this RFI will be processed under Good Manufacturing Practice (GMP) guidelines.

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Information Requested

SAIC-Frederick requests your input supplying consumable supplies and equipment to carry out the tasks noted below:

1. Studies, if required, to develop a process for performing a 5000-6000 vial fill of the bulk product without having a deleterious effect on that product.
2. Vialing of clinical product
 - i. The ability to prepare draft manufacturing batch records for preparation of: drug product that include all the steps used to manufacture the drug product, any in process testing (before and after filtration assays, appearance, etc., fill checks for volume, membrane bubble point following filtration, etc.), vial stoppering, sealing, inspection and labeling.
 - ii. For response purposes to this RFI, assume batch sizes of 5000-6000 vials of injectable liquid product at a fill volume of 0.5 mL in a 3 mL vial.

The respondent's capability for storage of the drug products at the labeled temperature until shipping instructions are provided.

3. If certain tasks or tests are not carried out in house, list the organizations that will carry out those functions, the basis for their selection and audit history of those organizations.

Note: Do not include any proprietary information

If you are willing to do so, please indicate your primary affiliation/role from the categories listed below:

- Academia (basic or clinical research)
- Small Business
- Pharmaceutical/Biotechnology Industry
- Federal Government
- State Government
- Healthcare Professional organization
- Integrative Medicine Professional organization;
- Patient Advocacy Group;
- Country; and
- Other (briefly define).

How to submit a response

Please submit detailed and concise responses.

Responses should be returned to:

Calvin Proffitt

Manager, Subcontracts

proffittch@mail.nih.gov

Attached Documents (Microsoft Word.doc or Adobe Acrobat.pdf files)

Inquiries

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Inquiries regarding this RFI should be directed to:

Calvin Proffitt

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