

AGENDA

Adenovirus Reference Material Working Group Meeting

March 22, 2001

8:30 – 3:30 PM

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|----|---|---|
| 1. | Introductions and Practical Matters (Keith Carson, Estuardo Aguilar-Cordova, Beth Hutchins)
Rules and Directives for the Meeting | 15 min |
| 2. | Overview of submitted RFPs (Keith Carson, Stephanie Simek)
Summary Table
Any RFPs not electronically posted?
Supplies and other services category (RFP 3.0) | 15 min |
| 3. | RFP 1.0, Cell Bank Donation
Brief review of submissions
FDA recommendation for RFP
Discussion
Decision | 15 min |
| 4. | RFP 2.0, Viral Material Donation
Brief review of submissions
FDA recommendation for RFP
Discussion
Decision | 15 min |
| 5. | RFP 4.0, Viral Bank Production and Testing Donation
Brief review of submissions
FDA recommendation for RFP
Discussion
Decision | 45 min |
| | | <i>15 min BREAK</i> |
| 6. | RFP 5.0, Purified Formulated Bulk Virus Reference Material Production and Release Testing Donation
Brief review of submissions
FDA recommendation for RFP
Discussion
Decision | 45 min |
| 7. | RFP 6.0, Vialing and Freezing Donation
Brief review of submissions
FDA recommendation for RFP
Discussion
Decision | 45 min |
| | | <i>30 min Working LUNCH w/Short Break</i> |
| 8. | RFP 7.0, Donation of Repository Services
Brief review of submissions
FDA recommendation for RFP
Discussion
Decision | 45 min |

9. New RFP's: 1 ½ hrs
 RFP 8.0, Participation in Establishing Particle Concentration of Adenovirus Reference Material
 RFP 9.0, Participation in Establishing Infectious Titer of Adenovirus Reference Material

These will be discussed together. There are two proposals for handling this aspect of characterization.

Proposal #1 (FDA)

- At least 6 testing laboratories participate
- Each testing laboratory will test standard for virus particle count and infectivity
- All 6 labs will test virus particles by OD260 nm method
- Infectivity assay will be done by Plaque assay using one agreed upon cell line
- Each testing lab can submit other assay for VP and infectivity with SOPs

Proposal #2

- At least 6 testing laboratories participate for particle count
- At least 6 testing laboratories participate for infectious titer determination
- Laboratories do not have to do both
- Particle count:
 - All 6 labs will test virus particles by same OD260 nm method/SDS
 - Labs also propose to perform other methods to establish particle number, submitting detailed information on the SOP for the method. Purpose is to establish particle count via orthogonal approach. Methods could include PN via RP-HPLC, AE-HPLC, EM, DNA Pico Green, DNA qPCR, etc. Can establish a better extinction coefficient for the OD260 nm assay with this approach.
- Infectivity assay:
 - All 6 labs will test virus particles by same method using 1 cell line. SOP to be provided.
 - All 6 labs to perform NAS titer calculation to determine infectious titer.
 - Each testing lab can submit other assay data for infectivity with detailed SOPs.

SHORT BREAK?

10. Last RFP's 45 min
 RFP 10.0, Participation in Establishing Other Characteristics of Adenovirus Reference Material
 RFP 11.0, Participation in Stability Study of Adenovirus Reference Material
11. Timeline for Actions: 15 min
 New RFPs drafted
 New RFPs reviewed by email
 New RFPs finalized
 New RFPs posting date
 Deadline for new RFPs
 Notifying Awards of RFPs
12. Next meeting? ASGT?