AGENDA

Adenovirus Reference Material Working Group Meeting
March 22, 2001
8:30 – 3:30 PM

1. Introductions and Practical Matters (Keith Carson, Estuardo Aguilar-Cordova, Beth Hutchins) 15 min
   Rules and Directives for the Meeting

2. Overview of submitted RFPs (Keith Carson, Stephanie Simek) 15 min
   Summary Table
   Any RFPs not electronically posted?
   Supplies and other services category (RFP 3.0)

3. RFP 1.0, Cell Bank Donation 15 min
   Brief review of submissions
   FDA recommendation for RFP
   Discussion
   Decision

4. RFP 2.0, Viral Material Donation 15 min
   Brief review of submissions
   FDA recommendation for RFP
   Discussion
   Decision

5. RFP 4.0, Viral Bank Production and Testing Donation 45 min
   Brief review of submissions
   FDA recommendation for RFP
   Discussion
   Decision

   15 min BREAK

6. RFP 5.0, Purified Formulated Bulk Virus Reference Material Production and Release Testing Donation 45 min
   Brief review of submissions
   FDA recommendation for RFP
   Discussion
   Decision

7. RFP 6.0, Vialing and Freezing Donation 45 min
   Brief review of submissions
   FDA recommendation for RFP
   Discussion
   Decision

   30 min Working LUNCH w/Short Break

8. RFP 7.0, Donation of Repository Services 45 min
   Brief review of submissions
   FDA recommendation for RFP
   Discussion
   Decision
9. New RFP’s:  
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  
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:  
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?