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**Subject:** Results of ARMWG vote & June-6 meeting info/agenda

**Importance:** High  
All:

**The vote results are below. There are 2 issues to address to complete the assignment of particle concentration and infectious titer, and we will do so at the June-6 meeting of the ARMWG.**

[a] Determine the number of significant figures to assign each measurement.

For both particle concentration and for infectious titer it has been suggested that 1 significant figure be used.

This would mean the particle concentration is assigned as  $5.8 \times 10^{11}$  particles per mL.

[b] The method of statistical analysis of the infectious titer and the assignment of infectious titer must be discussed again as there is not complete agreement on how to arrive at the infectious titer assignment from the data set collected. In particular there is confusion or concern about how the variance reported for the infectious titer should be applied to its use. Additionally the number of significant figures needs to be determined, possibly before the statistical method is applied.

Here is the summary of the vote on the assignment of particle concentration and infectious titer:

[1] It is proposed that the label claim for the **particle concentration** of the Adenovirus Reference Material be assigned as  $5.825 \times 10^{11}$  particles per mL, based on the FDA's recommendation.

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**YES (AGREE) 19 (8 are qualified Y)                      NO (DISAGREE) 2 (both qualified)**  
**ABSTAIN 5**

*The 8 qualified yes votes; Yes but only if the number of significant figures is reduced*

*The 2 qualified no votes; No because not agree with number of significant figures in assignment.*

*Abstentions from either not having participated in this assay or in deference to other experts.*

[2] It is proposed that the label claim for the **infectious titer** of the Adenovirus Reference Material be based on the Maximum Likelihood method of analysis and be assigned as  $7.37 \times 10^{10}$  Infectious Units per mL, based on the FDA's recommendation. The Maximum Likelihood method of analysis examines all raw data and has the least bias. Information on this method is contained in the Statistician's Report

**YES (AGREE) 15 (5 are qualified Y)                      NO (DISAGREE) 4 (2 qualified)**  
**ABSTAIN 5**

*The 5 qualified yes votes: Yes but only if the number of significant figures is reduced.*

*The 4 qualified no votes: 2 are no because not agree with the number of significant figures used.*

*2 are no because not agree with the statistical analysis applied.*

*Abstentions from either not having participated in this assay or in deference to other experts.*

**JUNE-6 2002 Meeting of ARMWG:**  
**Where: Hynes Convention Center (site of ASGT), Boston**  
**Room 103**  
**When: 12:30 to 1:30 PM ET**  
**Lunch will be provided to attendees of ARMWG. RSVP IS REQUIRED BY MAY-24.**  
**Teleconferencing will be available. RSVP is required to receive the phone-in number.**  
**RSVP BY MAY-24.**

**June 6 ARMWG Meeting AGENDA:**

1-FDA's view of how the assigned p/mL and IU/mL will be used by those using the ARM to validate sponsor's internal reference materials. (See attachment which contains Dr. Simek's presentation to PhRMA on use.)

**2-Assignment of Particle Concentration**

- a-Determine number of significant figures
- b- Vote on assignment of particle concentration

**3-Assignment of Infectious Titer**

- a-Determine number of significant figures
- b-Application of statistical methods (15 min limit for discussion)
  - including how to report the variance
- c-Vote on action

Possible actions:

[1] With new number of significant figures, apply statistical method “x”, then

email vote of confirm infectious titer assignment within assigned timeline.

[2] With new number of significant figures, vote to assign infectious titer as  $7.4 \times 10^{10}$

Infectious Units per mL plus variance per discussion.

4-Update on analysis of highly chromogenic material noted in some ARMWG vials

(Gallagher/Sublett)

5-Update on long term stability testing of 1503 (Sugarman)

6-Determine next meeting, action steps, and manuscript/other writing assignments and timelines.

It is unlikely we will have the time to discuss:

Proposal for release of ARM lot numbers 1504, 1505, and 1506.

However a straw man proposal will be handed out for ARMWG members to consider.

-B.



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