

May 3-4, 2005  
ACPS  
Hilda F. Scharen

**Summary Minutes of the  
Advisory Committee for Pharmaceutical Science  
May 3-4, 2005**

## ERRATA

Correcting the voting record for the answers to Questions for Topic #1 and Topic #3 of the Questions to the Committee

**Questions to the Committee:**

*Topic #1*

**Are the tactical steps outlined consistent with the QbD goals we seek to achieve?**

*The Committee agreed with the outlined tactical steps and the members felt that this is one additional step in moving towards Quality by Design while moving to Desired State. The members expressed some concerns with the current dissolution tests that are used, as the dissolution specifications are not tailored to specific scenarios and there is substantial variability with the methodology. In addition, the Committee felt that in light of the complexity in understanding this system, the proposed approach will lead to a mechanistic understanding of the manufacturing process and the relationship of the process and product. The members agreed to adopt and move forward with the tactical plan and the proposed steps to be incorporated in the recommendations.*

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*Topic #3*

**Does the ACPS support the creation of a subcommittee under ACPS to develop the criteria and the process for review of OPS research programs?**

*The members agreed with the concept of creating a subcommittee under the Advisory Committee for Pharmaceutical Science in order to review the Office of Pharmaceutical Science research programs. The Committee unanimously endorsed the recommendation for the creation of this subcommittee under the main Advisory Committee for Pharmaceutical Science.*

Yes: 11  
No: 0  
Abstain: 0