

1 MINUTES OF THE TELECONFERENCE  
2 OF THE PQRI PSD MASS BALANCE WORKING GROUP ON  
3 4 June 2003

4 **I. PARTICIPANTS**

Terry Tougas (Boehringer Ingelheim), Chair	Lana Lyapustina (IPAC-RS)
Dave Christopher (Schering-Plough)	Jolyon Mitchell (Trudell Medical)
Paul Curry (USP Aerosols Expert Committee)	Brian Rogers (FDA)
Bill Doub (FDA)	Helen Strickland (GlaxoSmithKline)
Ken Furnkranz (FDA)	Bruce Wyka (Schering-Plough)

5 **II. OPENING**

6 Dr. Tougas opened the teleconference and welcomed the participants. He proposed the  
7 following as main objectives for the teleconference: (i) to discuss practical aspects of the CI  
8 variability study; (ii) to review the preliminary results of the APSD/MB Failure Causes Survey;  
9 and (iii) to agree on next steps. The participants approved the proposed agenda.

10 The Working Group discussed and approved the draft minutes of the teleconferences  
11 held on 3 April and 14 May.

12 **III. DISCUSSION**

13 *CI Variability Study: Practical Considerations*

14 Ms. Strickland and Mr. Christopher summarized for the participants the resource and  
15 time requirements for the CI variability study, based on the statistical split-plot design  
16 approved by the Working Group previously. The study preferably should be done on several  
17 (e.g., 4) types of products, using the test method approved for each product. It would be  
18 necessary to have 27 canisters from a single batch of each product. Each laboratory performing  
19 the experiment must have 3 identical Anderson Cascade Impactors (ACI) and 3 analysts trained  
20 in the method, working in concert over 9 days.

21 The participants discussed how volunteers for the CI variability study could be found  
22 and noted the following:

- 23 • The study need not be performed at a lab or on a product associated with the  
24 Working Group members.
- 25 • Since the study must be done on an approved product using approved methods, it  
26 would be most efficient if a pharmaceutical company conducted the study using its  
27 own product(s), method(s), facilities and analysts. The identity of the product and  
28 company may remain undisclosed.
- 29 • Potentially, an FDA lab or CROs could be asked to perform the study; however, the  
30 necessary training and method transfer would require additional resources and time.

- 31           • The batch that is volunteered for the study could be chosen judiciously (*e.g.*, a small  
32           or near-expiry batch), so as to minimize the risks of negative repercussions for the  
33           companies that would volunteer to conduct the study.
- 34           • The Working Group should explore the possibility that PQRI create a “safe harbor”  
35           for prospective research by PQRI Working Groups on marketed products.
- 36           • The NGI consortium did not have to deal with regulatory issues because NGI testing  
37           was not an official method for the tested products. It was also mainly performed in  
38           Europe.

39           The participants also discussed whether it would be possible and practical to create and  
40           test a “dummy” product, since the focus is on the performance of the ACI and not on the  
41           product. However, the Working Group concluded that formulating a stable product, and  
42           developing and validating appropriate methods for it, would require substantial investment.

43           *Preliminary Results of the MB/APSD Failure Cause Survey*

44           The participants briefly discussed the preliminary compilation of the MB/APSD Failure  
45           Causes Survey results. Several members agreed to review the results in more detail and to  
46           prepare a summary and conclusions for discussion by the full Working Group at the next  
47           teleconference. Some slides on this topic may be prepared for presentation at the PQRI  
48           Workshop but will not be included in the Workshop binder because there is not sufficient time  
49           for the full Working Group to review the additional slides before the slides are due to the  
50           Workshop organizers for publishing.

51           This small discussion group will hold a separate teleconference to discuss the survey  
52           results. Prior to that teleconference, Dr. Mitchell will analyze and summarize the answers to  
53           question 2.9 of the survey, Dr. Curry – answers to Part I, Mr. Wyka – answers to Part II except  
54           question 2.9. Ms. Strickland would help prepare graphical summaries. Other assignments  
55           would be discussed by email.

56           **IV. AGREED ACTIONS**

- 57           • Ms. Strickland and Mr. Christopher will finalize a written summary of resource and  
58           time requirements for the CI variability study. This summary will be used to  
59           approach pharmaceutical companies with a request to volunteer products and  
60           resources for the study.
- 61           • The Working Group’s presentation at the PQRI Workshop will include a request for  
62           companies to volunteer for the study.
- 63           • Dr. Mitchell, Dr. Curry, Dr. Doub, Dr. Furnkranz, Ms. Strickland and Mr. Wyka will  
64           review in more detail the results of the MB/APSD Failure Cause Survey and prepare  
65           a summary for discussion at the next teleconference of the Working Group. They  
66           will also draft several slides on this topic, which could be added to the presentation  
67           at the PQRI Workshop. A teleconference of this discussion group will be scheduled  
68           via email.

- 69           • The main messages and details of the Working Group's presentation at the PQRI  
70           Workshop will be discussed at the next teleconference.

71   **V.    NEXT TELECONFERENCE / MEETING**

72           The next teleconference of the PQRI PSD Mass Balance Working Group was scheduled  
73           via email for Wednesday, 23 July, 11:00 AM Eastern Time.

74           A face-to-face meeting of the Working Group in conjunction with the PQRI Workshop  
75           was scheduled via email for Tuesday, 5 August, 3:00-4:00 PM.

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*Finalized on 23 July 2003*