

1 MINUTES OF THE TELECONFERENCE
2 OF THE PQRI PSD MASS BALANCE WORKING GROUP ON
3 19 December 2002

4 **I. PARTICIPANTS**

Terry Tougas (Boehringer Ingelheim), Chair
Dave Christopher (Schering-Plough)
Paul Curry (Boehringer Ingelheim)
Bill Doub (FDA)
Martin Lavery (Aventis)
Lana Lyapustina (IPAC-RS)
Jolyon Mitchell (Trudell Medical)
Brian Rogers (FDA)
Bruce Wyka (Schering-Plough)

5 **II. OPENING**

6 Dr. Tougas opened the meeting and welcomed the participants. The participants
7 approved the following objectives of the teleconference: (i) to finalize and approve the Good
8 Cascade Impactor Practices (GCIP) paper for submission to the Journal of Aerosol Medicine, (ii)
9 to finalize and approve the initiation of the survey on Mass Balance Failure Causes, and (iii) to
10 update on progress of statistical design for CI method variability study.

11 The Working Group finalized the draft minutes of the 8 November teleconference.

12 **III. DISCUSSION**

13 Dr. Mitchell reviewed final changes to the previous draft of GCIP (version dated 8
14 November). He explained that the changes were made in response to comments received
15 during the review by the PQRI Drug Product Technical Committee, PQRI Member
16 Organizations, and PQRI Steering Committee.

17 The participants reviewed page-by-page the final GCIP draft (version dated 15
18 December) and agreed on several minor editorial revisions. During this review, the participants
19 discussed the role of checklists in the overall system of strong management oversight, analyst
20 training and compliance control. The Working Group members approved the submission of the
21 finalized GCIP to the Journal of Aerosol Medicine.

22 The Working Group reviewed the final draft of the questionnaire on mass balance
23 failure causes (version dated 8 November 2002). The draft has been reviewed by the PQRI Drug
24 Product Technical Committee, Member Organizations, and Steering Committee. No
25 substantive changes have been proposed. The Working Group approved the initiation of the
26 survey.

27 Mr. Christopher reviewed the status of designing a study of CI method variability
28 components. He explained that he and Ms. Strickland are doing simulations to estimate
29 whether the previously presented statistical design would have enough power to separate out
30 the highly variable components such as the analyst variability. Based on the simulation results,
31 the statistical design will be adjusted, *e.g.*, the analyst and day/time conditions may need to be
32 combined and treated as one component. After the required data structure is determined by the
33 Working Group, the next steps such as data gathering will be considered.

34 **IV. AGREED ACTIONS**

- 35 • Dr. Mitchell will submit the finalized GCIP paper to the Journal of Aerosol
36 Medicine.¹
- 37 • Mr. Christopher and Ms. Strickland will continue simulations to determine optimal
38 design of the Cascade Impactor Method Variability Study.
- 39 • The finalized questionnaire on Mass Balance Failure Causes will be forwarded to Ms.
40 Gantt for posting on the PQRI website.²

41 **V. NEXT TELECONFERENCE/MEETING**

42 The next teleconference of the PQRI PSD Mass Balance Working Group is scheduled for
43 **Friday, 24 January 2003, at 10:00 AM EST**. The main objective of this teleconference will be to
44 review considerations for design of the Cascade Impactor Method Variability Study.

45 *Finalized on 24 January 2003*

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¹ Following the teleconference, the issue of the check list was re-visited separately.

² Pending the finalization of the GCIP paper.