

1 MINUTES OF THE TELECONFERENCE
2 OF THE PQRI PSD MASS BALANCE WORKING GROUP ON
3 24 January 2003

4 **I. PARTICIPANTS**

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

5 **II. OPENING**

6 Dr. Tougas welcomed the teleconference participants. The participants agreed on the
7 following objectives for the teleconference: (i) to discuss final changes and approve the Good
8 Cascade Impactor Practices (GCIP) paper for submission to the Journal of Aerosol Medicine, (ii)
9 to discuss the survey of Mass Balance failure causes, (iii) to update on statistical design for CI
10 method variability study; (iv) to discuss preparations for the PQRI Workshop on 3-4 April; and
11 (v) to discuss the AAPS Workshop on Particle Size Analysis on 30 April-2 May 2003.

12 The Working Group approved the draft minutes of the 19 December teleconference.

13 **III. DISCUSSION**

14 Dr. Tougas explained that after the 19 December teleconference, Dr. Rogers expressed
15 reservations related to the issue of checklists. Since then the issue was discussed with Dr.
16 Poochikian, and the latest language proposed by Dr. Poochikian was circulated to the Working
17 Group before this teleconference. The participants reviewed the new text, and approved it
18 unanimously with the following two changes: *"The investigation of analyst-related errors would be*
19 *facilitated if the analyst follows and initials a step-wise checklist to confirm to the extent possible the*
20 *correct performance of procedural steps and use of appropriate (~~correct~~) equipment."* The paper was
21 unanimously approved for submission to the Journal of Aerosol Medicine.

22 The Working Group discussed the timing of the survey on MB failure causes. They
23 agreed that after the GCIP paper has been submitted for publication, the survey should be
24 initiated, accompanied by the final version of the GCIP paper. The responses should be due by
25 15 March 2003. The survey results will be discussed by the Working Group at the next face-to-
26 face meeting, which will be held in conjunction with the PQRI Workshop scheduled for 3-4

27 April. The plans for the Working Group's meeting will be finalized when the PQRI Workshop's
28 agenda is available. The preliminary program for the Workshop is currently posted at
29 <http://www.pqri.org/events/workshops/imagespdfs/workshop.pdf>.

30 Ms. Strickland and Mr. Christopher explained that they need to investigate further the
31 statistical design of the CI variability study, to ensure that it has the capability to answer the
32 questions posed by the Working Group. The statisticians will present their findings by the end
33 of February, for discussion at the Working Group's next teleconference.

34 The Working Group discussed plans for a presentation at the PQRI Workshop on 3-4
35 April. They agreed that the draft slides on the Working Group's activities would be prepared
36 by Mr. Christopher, Dr. Curry, Dr. Mitchell, Dr. Rogers, Ms. Strickland, Dr. Tougas, and Mr.
37 Wyka. The talk would be delivered by Dr. Tougas, perhaps in combination with one or two
38 other Working Group members, depending on the time allotted to the PSD discussion at the
39 Workshop. The Working Group will discuss this in more detail at a future teleconference.

40 The participants also discussed the AAPS Workshop on Particle Size Analysis, co-
41 sponsored by FDA, PQRI and USP, to be held in Arlington, VA on 30 April - 2 May. A
42 preliminary program is posted at <http://aaps.org/meetings/particlesize/imagespdfs/PS.pdf>.

43 **IV. AGREED**

- 44 • Dr. Mitchell will submit the GCIP paper as finalized on this teleconference to the
45 Journal of Aerosol Medicine.
- 46 • The due-date for responses to the questionnaire on MB failure causes will be 15
47 March 2003. The questionnaire and GCIP paper will be forwarded to Ms. Gantt for
48 posting on the PQRI website.
- 49 • Mr. Christopher and Ms. Strickland will continue investigation of the statistical
50 design and report their findings at the next teleconference of the Working Group.
- 51 • The following Working Group members will prepare a summary of the MB failure
52 survey results: Dr. Mitchell, Dr. Rogers, Ms. Strickland and Dr. Tougas.
- 53 • The Working Group will hold a face-to-face meeting in conjunction with the PQRI
54 Workshop on 3-4 April 2003. The exact date/location will be determined when a
55 detailed agenda for the Workshop is available.
- 56 • The following members will participate in drafting presentations on the Working
57 Group's activities for the PQRI Workshop: Mr. Christopher, Dr. Curry, Dr. Mitchell,
58 Dr. Rogers, Ms. Strickland, Dr. Tougas and Mr. Wyka. Dr. Lyapustina will assist in
59 and coordinate the preparation of the slides. The draft presentations will be
60 reviewed and discussed by the full Working Group at a future teleconference.

61 **V. NEXT TELECONFERENCE/MEETING**

62 The next teleconference of the PQRI PSD Mass Balance Working Group is scheduled for
63 **Monday, 3 March 2003, at 10:00 AM EST.**

64 *Finalized on 3 March 2003*