

1 **Minutes of the Teleconference**
2 **of the PQRI PSD Mass Balance Working Group**
3 **on 22 September 2005**

4 **I. PARTICIPANTS**

Terry Tougas (BI) <i>Co-Chair</i>	Ken Furnkranz (FDA)
Bruce Wyka (Schering-Plough) <i>Co-Chair</i>	Lana Lyapustina (IPAC-RS)
Dave Christopher (Schering-Plough)	Jolyon Mitchell (Trudell Medical)
Paul Curry (Solvay)	Helen Strickland (GSK)

5 **II. OPENING**

6 Mr. Wyka opened the teleconference and welcomed the participants. Dr. Lyapustina read the
7 antitrust admonition. The participants reviewed and approved the proposed objectives of the
8 teleconference, which were: (i) to review updates; (ii) to comment on the draft slides for DPTC;
9 (iii) to discuss recent invitations to meetings; (iv) to report on status of the 6 April minutes; and
10 (iv) to agree on next steps.

11 **III. DISCUSSION**

12 Dr. Tougas reviewed recent comments of the PQRI Steering Committee pertaining to the Mass
13 Balance Working Group. He noted that Ms. Winkle requested a briefing; the Working Group
14 agreed that the slides being prepared for the DPTC could serve as a basis for such a
15 presentation, supplemented with an executive summary.

16 Mr. Furnkranz recommended that in all the upcoming presentations and publications, the
17 original concept discussed in this Working Group be emphasized, namely that the main
18 problem lies in the use of CI Mass Balance as a product specification (rather than a run
19 qualification). The other participants strongly supported this proposal. Dr. Mitchell clarified
20 that the other, and separate, problem has to do with the specification limits.

21 The Working Group discussed invitations to present on the issues related to cascade impaction,
22 mass balance and specifications at the following meetings:

- 23 • Inhalation Technology Focus Group (AAPS) meeting
24 (<http://www.rddonline.com/industry/AAPS%20ITFG.pdf>);
- 25 • IPAC-RS Conference 2006 (<http://www.ipacrs.com/conf2006.html>); and
- 26 • Respiratory Drug Delivery Conference
27 (<http://www.rddonline.com/conferences/rdd10.asp>).

28 It was agreed that a decision about potential presentations should be made based on further
29 information about these meetings.

30 Mr. Wyka reported that he is still waiting for response from Dr. Lostritto regarding the revised
31 draft minutes of the 6 April 2005 meeting of the Working Group.

32 The participants reviewed the draft slides for the upcoming DPTC meeting page-by-page and
33 made a number of revisions reflected in the new version of the draft slides.

34 **IV. AGREEMENTS**

35 • Mr. Wyka will co-present with Dr. Tougas during the contact with Ms. Winkle.
36 Discussion slides and the executive summary should be drafted by 3 October. Dr.
37 Mitchell will assist in selecting material for presentation to Ms. Winkle.

38 • Both the slides and technical paper should emphasize the concept discussed earlier
39 during this Working Group's formation and initial meetings, namely that the Mass
40 Balance measurement obtained from Cascade Impaction tests is not appropriate as a
41 product specification but might have value as a 'run qualification'.

42 • Dr. Curry will recommend to ITFG that updates be included at the end of the 30
43 September meeting.

44 • Mr. Wyka will contact Dr. Peter Byron to clarify his plans for RDD X.

45 • Ms. Strickland will co-present the statistical slides with Mr. Wyka during the 4
46 November DPTC meeting.

47 • The slides as revised on this teleconference will be circulated by email for further
48 comment.

49 **V. NEXT TELECONFERENCE/MEETING**

50 The next teleconference will be scheduled by email.

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Finalized on 20 October 2005