

1 **Minutes of the Teleconference**
2 **of the PQRI PSD Mass Balance Working Group**
3 **on 10 June 2005**

4 **I. PARTICIPANTS**

Terry Tougas (BI) <i>Co-Chair</i>	Bill Doub (FDA)
Bruce Wyka (Schering-Plough) <i>Co-Chair</i>	Craig Dunbar (Alkermes)
Mary Devlin Capizzi (IPAC-RS)	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. Ms. Capizzi gave
7 an antitrust admonition. The participants reviewed the proposed objectives of the
8 teleconference, which were: (i) to update on the DPTC discussions regarding this Working
9 Group; and (ii) to agree on next steps.

10 **III. DISCUSSION**

11 Mr. Wyka and Dr. Tougas reported on the recommendations of the PQRI Steering
12 Committee (SC) and Drug Product Technical Committee (DPTC), as summarized below:

- 13 • On a previous teleconference, the SC recommended that both points of view regarding
14 Mass Balance be presented to the DPTC for an in-depth technical discussion. One
15 presentation would be prepared by Drs. Lostritto, Rogers and Poochikian, and the other
16 by the remaining Working Group members. Ms. Helen Winkle committed to explain
17 the SC decision to Dr. Lostritto and his subgroup.
- 18 • At the 8 June meeting, DPTC agreed that these presentations should be made during its
19 September meeting. Drs. Tougas and Poochikian would be involved in the preparation
20 of the respective presentations but will not themselves be presenting. Each presentation
21 should describe the proposal and explain how the proposal meets the objectives and
22 goals of the originally approved Workplan. The outcome of the DPTC technical
23 discussion would be reported to the SC.

24 In response to questions, Dr. Tougas confirmed that the original Workplan was
25 approved by all, and there was an agreement that the issue of Mass Balance needed to be
26 addressed; the agreed focus of work being two-fold: (1) the appropriate role of the MB
27 measurement in the overall system of quality control; and (2) the appropriate limits for MB.
28 The Workplan did not pre-suppose any particular position.

29 Dr. Tougas also clarified that he had listed several options for the Steering Committee's
30 consideration, including (i) going forward with the remaining MB WG, completing the work
31 and submitting recommendations; (ii) preparing a paper with the remaining MB WG; and (iii)

32 stopping all work in the MB WG. He also mentioned to the SC that an industry paper on this
33 issue would be prepared even if the PQRI work was stopped. Dr. Mitchell reiterated that it
34 would be important to state the problem in scientific terms and explain the two different
35 approaches in a peer-reviewed publication.

36 All participants on the teleconference were comfortable with this plan and agreed to
37 proceed. It was suggested that the September presentation for DPTC would follow the outline
38 of the paper that has been proposed at the April meeting and subsequently started by the
39 drafting group.

40 At the conclusion of the teleconference, several participants commented that they are
41 pleased that the dialogue on MB continues and that the group is still moving ahead. One
42 participant commended the group for getting things done.

43 **IV. AGREEMENTS**

- 44 • Dr. Lyapustina will circulate an outline of the paper with assignments before the next
45 teleconference of the drafting group.
- 46 • Ms. Strickland will provide OC curves for comparing the November 2004 and April 2005
47 proposals.

48 **V. NEXT TELECONFERENCE/MEETING**

49 A teleconference will be scheduled via email, for mid-July.
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Finalized 13 July 2005