

MINUTES OF THE TELECONFERENCE
OF THE PQRI PSD MASS BALANCE WORKING GROUP ON
8 November 2002

I. PARTICIPANTS

Terry Tougas (Boehringer Ingelheim), Chair	Martin Lavery (Aventis)
Dave Chritopher (Schering-Plough)	Lana Lyapustina (IPAC-RS)
Paul Curry (Boehringer Ingelheim)	Jolyon Mitchell (Trudell Medical)
Bill Doub (FDA)	Brian Rogers (FDA)
Ken Furnkranz (FDA)	Helen Strickland (GlaxoSmithKline)
Sylvia Gantt (PQRI)	Bruce Wyka (Schering-Plough)

II. OPENING

Dr. Tougas opened the meeting and welcomed the participants. He explained that the objectives of the teleconference are: (i) to review and discuss proposed revisions to the "Good Cascade Impactor Practices" (GCIP) paper, (ii) to review and discuss proposed revisions to the Mass Balance Failure Causes Questionnaire, and (iii) to agree on next steps. The participants agreed that an update on the experimental design would be discussed at the next teleconference.

III. DISCUSSION

The participants reviewed the latest version of the GCIP draft page by page, and discussed all proposed revisions.

The Working Group discussed the topic of check lists and agreed that even though check lists might be useful in certain situations as part of a larger compliance program, they also have inherent limitations.

The Working Group also reviewed and discussed minor revisions proposed for the Mass Balance Failure Causes Questionnaire. They set the deadline for data submissions at 1 March 2003.

The participants agreed that once the revisions approved on the teleconference are incorporated in both documents, the drafts should be forwarded for review and approval to the DPTC and SC.

IV. AGREED ACTIONS

- A revised version of the GCIP paper and the Mass Balance Questionnaire will be forwarded to Ms. Gantt for distribution to the DPTC and SC, for their comments and approval.

28 **V. NEXT TELECONFERENCE/MEETINGS**

29 The next teleconference of the PQRI PSD Mass Balance Working Group is scheduled for
30 **Thursday, 19 December, 2002, at 10:00 AM EST.** The main objectives of this teleconference
31 will be (i) to discuss final revisions and approve the GCIP paper for submission to the *Journal of*
32 *Aerosol Medicine*, (ii) to discuss final revisions and approve the initiation of the survey on Mass
33 Balance Failure Causes, and (iii) to consider experimental design issues.

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Finalized on 19 December 2002