

MINUTES OF THE TELECONFERENCE
OF THE DISCUSSION GROUP OF THE
PQRI PSD MASS BALANCE WORKING GROUP ON
2 JULY 2003

I. PARTICIPANTS

Jolyon Mitchell (Trudell Medical), Moderator
Paul Curry (USP AEC)
Ken Furnkranz (FDA)
Lana Lyapustina (IPAC-RS)
Helen Strickland (GSK)
Bruce Wyka (Schering-Plough)

II. OPENING

Dr. Mitchell proposed the following main objectives for the teleconference: (i) to review results of the recent survey on causes of MB and APSD failures; (ii) to discuss whether and how the Excel spreadsheet summary should be revised; and (iii) to discuss what information from the survey should be communicated at the upcoming PQRI Workshop.

III. DISCUSSION

The participants discussed the results of the survey on causes of MB and APSD failures and noted that:

- No obvious trends or patterns were raised by any of the participants as a result of the initial examination of the survey results. One observation was that the responses appear to be "bimodal" with respect to failure frequencies. Some laboratories experience MB failures often, others do not. It was suggested that, at least in some instances, a lack of reported MB failures could be due to the absence of MB specifications.
- In some instances, the cause of the failure was clearly identified, in others it was not.
- Two issues in particular were highlighted as reasons for MB/APSD failures: coating to minimize particle bouncing and electrostatic effects.
- Particle bouncing has emerged as an issue even for the NGI, e.g., as reported in the poster by Dr. Byron's group at a recent ISAM meeting. Similar observations were made in other laboratories.
- About half of the responses note a use of some type of a check list. It was speculated that in the other half of the cases, very detailed, thorough procedures and instructions are followed to perform the approved method, even if such instructions are not arranged in the check list format.

- Newer nebulizer-type, breath-actuated systems should be considered in a class of their own, distinct from MDIs and DPIs.
- Of the 14 received responses, 13 answered the posed questions and could be used for further analysis. The 14th response presented a general argument and may be difficult to use for the purposes of this survey directly.

IV. AGREED ACTIONS

- Dr. Mitchell will prepare a distillation of the survey results in a PowerPoint format.
- Each member of this Discussion Group will email thoughts and impressions of the main messages from the survey.
- Ms. Strickland will prepare a graphical summary of the survey's information, in particular, a summary of descriptions of the operations (in Part I of the survey).
- The printed version of the slides for the PQRI Workshop will not contain a summary of the survey results (due to lack of time prior to the 14 July deadline for the slides' submission to the publishers), but the actual slides presented at the Workshop may have such a summary, which will be discussed at the teleconference of the full Working Group on 23 July.

V. NEXT TELECONFERENCE/MEETINGS

The next teleconference of this Discussion Group is scheduled for Thursday, 17 July, at 2:00 PM U.S. Eastern Time.

Finalized on 17 July 2003