

MINUTES
Drug Product Technical Committee
Tuesday - March 11, 2003

Telephone Conference

Attendees List

AAPS/Industry Representatives

Sidney Goldstein, Chairman-GPhA
Jeffrey Blumenstein-IPAC-RS
Robert Dana-PDA
Shawn Dressman-USP
Chris Moreton-IPEC
Richard Poska-PhRMA
Russell Somma-ISPE

FDA Representatives

Guiragos Poochikian-CDER/ONDC

Guests

David Christopher-PSD-PCWG
Thomas Garcia-BUWG
Daniel Malinowski-C/CSWG
Prof. Fernando Muzzio-BUWG
Lee Nagao-IPAC-RS
Daniel Norwood-L&EWG

Absentees

Lorraine Calitri-CHPA
Sylvia Gantt-PQRI
Devinder Gill-CDER/OGD
Lana Lyapustina-IPAC-RS
Terry Tougas-PSD-MBWG
Rajendra Uppoor-CDER/OPS

Approval of Minutes

The minutes of December 18, 2002 were approved and will be posted on the PQRI web site.

Blend Uniformity Working Group Status

Professor Fernando Muzzio (Rutgers/BUWG) presented his pre-proposal entitled "Effective Methods for Achieving Blend Uniformity" Those present submitted their questions and comments. Comments will also be requested from the DPTC members who could not attend but have a copy of the proposal. Comments received will be reviewed and action considered at the next DPTC meeting.

Tom Garcia reviewed the proposed agenda for the BUWG Workshop which is tentatively scheduled for September 2003.

Container/Closure Systems Working Group Status

Chris Moreton (DPTC Liaison) reported that the working group is in the process of defining package equivalence based on MVTR equivalence. This activity will lead to the development of a white paper with technical rationale to justify the use of MVTR/unit to assess container/closure system equivalence.

The group was also informed that the PACPAC draft guidance is currently under review by the agency.

PDS Profile Comparisons Working Group Status

Statistical calculations and simulations investigating null distributions, robustness of the chi-square method, and what-if-scenarios are underway. The chi-square analysis still looks promising. However, based on results from our initial evaluation we may find through future simulations that for certain CI configurations with fewer numbers of stages that the chi-square method may be less robust and have less applicability.

PDS Mass Balance Working Group Status

The final version of the draft publication entitled "Consideration for the Development and Practice of Cascade Impaction Testing Including a Mass Balance Failure Tree" has been submitted to the Journal of Aerosol Medicine on 1-24-03.. Experiments will be conducted to determine: cascade

impaction (CI) method variability (as opposed to product variability) and relative contribution to CI overall variability by analyst, apparatus, day/time and product.

Data mining to assess compliance with the 85%-115% LCMB specification in the CMC guidance (MDI/DPI, Nasal) is in progress.

Leachables/Extractables Working Group Status

Chemists have started controlled extraction studies on elastomer and plastic test articles of known formulation. Initial extractions and analyses were performed at BI, Monarch and Cardinal labs. Initial experiments are meant to collect qualitative results from the various extraction and analyses procedures. The group plans to use the qualitative information to identify a single extraction technique/method, which will then be optimized and used for collection of quantitative information.

The working group toxicologists are revising and refining their threshold justification document. The justification proposes a qualification threshold of 5 ug/day, derived from consideration of safety limits for non-carcinogenic compounds. The justification proposes a toxicological concern threshold of 0.06ug/day, derived from consideration of safety limits for carcinogenic compounds.

Miscellaneous Items

The PQRI April Work Shop's program was discussed.

The approved "Policy & Procedures for Review and Approval of PQRI Publications" will be circulated to the group.

The next DPTC meeting is scheduled for Wednesday, May 14, 2003