

Drug Product Technical Committee Summary Meeting Minutes
June 11, 2007
11:00 am – 12:00 pm

Call in Information:
1-866-570-1041
295845# conference code

Admonition Statement

DPTC Chair reviewed admonition statement for the benefit of all members.

Agenda

Agenda was accepted as presented.

Work Group Updates

Stability Shelf Life-

- May face to face meeting finalized the work plan which is currently in review with DPTC and SC. Deadline for comments extended to June 15, 2007.
- Subgroups are getting started on their work (i.e., data warehouse, CMC, etc.)
- UNL rep presented poster of WGs mission to the Statistician's Meeting in Muncie, IN in late May 2007. Very well received by attendees
- FDA participation being secured. Official process for adding a member to the WG will need to be followed once it is decided who the FDA rep will be.
- Next face to face meeting set for September 2007 at Boehringer in CT.
- Question asked: Is the WG defining terms such as "shelf life" and "expiry date" for layman's usage? This is being addressed in an upcoming publication. In addition, WG stated that a Glossary is being formulated to deal with some of those terms to get everyone on the same page.

Specification Design WG- no report given

Excipients WG-

- Working on finalizing the position paper which is out for review with DPTC and SC. Deadline for comments is June 18, 2007. Refinements are currently taking place.
- Telecon on June 21 should incorporate all the final comments and disclaimers
- Once finalized on the 21st, submit to *Pharm Tech* for publication by June 28th

Profile Comparison WG –

- Submitted final report to *Pharm Tech*; waiting for editorial comments
- After publication will explore if follow up activity is needed for the WG

Container Closure WG –

- About to start 2nd study

- Completed multi-unit testing and creating summary report for review. Report should be ready for DPTC within the next month or so
- Protocol for unit dose screening in the process of being reviewed; PDA still has outstanding comments which should be received by June 13, 2007
- MVTR protocol is a preliminary study to define blister protocol
- Comments addressed during meeting:
 - Recommend that they use experience gained from previous study
 - WG advised they are doing so
 - Clarity of plan reference the multiple polymers being used
 - Use of 1 gram of silica gel in size 0 capsule questioned.
 - Silica gel is compressed tablet; sizing issue was addressed by WG
- Need to add one row to clarify # cavities
 - WG clarified the chart and will relook at numbers used
 - 5 cards of 6 cavities each for total of 30 cavities necessary
- 14 day duration of test – is it sufficient time frame?
 - WG stated actual test is carried out over 6 months
 - Need to show that in the table to clarify issue
- Compressed silica gel vs. loose silica gel usage?
 - WG advised that no significant difference between compressed and loose on these tests

Leachables & Extractables WG –

- Finished course in Chicago with 40-50 attendees
- Registration is now open for Basel and San Diego courses
- Article in Toxicological Sciences Journal (reprints being ordered by PQRI)
- Next article is in the works and so is the book under the Wiley contract
- PDA supported proposal re **Reporting and Qualification Thresholds for Leachables in Parenteral and Ophthalmic Drug Products** has been approved by the SC to move forward, and with no objections noted on the DPTC it is also approved to move forward
 - Next step is to get a Work Group populated following PQRI procedure. Nominations must go through and be approved by the TC. Therefore, an official search will begin for nominees. FDA will work with them to find FDA representation for the WG
 - Next step will be for the WG to establish their work plan.

Other Business

Issues from the May 31, 2007 SC meeting:

- Procedure being refined and documented for TCs and WGs to be populated. Basically all nominations must come through the Member organization

primary representative to the appropriate committee for their review and decision. TCs will be populated by the SC and WGs will be populated by their TC.

- *PQRI to send a copy of the email with the letter which outlines the restructuring to all DPTC members. Action accomplished on June 11, 2007.*

Adjournment

There being no further comments from any of the attendees, the meeting was adjourned at 11:55 am.