

1 **Minutes of the DPTC Teleconference**
2 **on 5 April 2007**

3 ***Opening***

4 At the beginning of the teleconference, the following admonition was read: “Our
5 discussions today are subject to the anti-trust guidance applicable in the U.S. and E.U.
6 Nothing discussed at this meeting is intended to restrict the individual decision-making of
7 any member company or to represent an agreement to coordinate marketing or sales
8 conduct. Those participating in this meeting are instructed to avoid discussion of
9 competitively sensitive subjects, including, but not limited to, confidential marketing,
10 sales, and pricing information.”

11 ***SC Update***

12 The PQRI SC Chair explained the planned re-structuring of the PQRI Technical
13 Committees addressing drug product and drug substance issues. In order to align the
14 PQRI work with the current FDA paradigm, a new Technical Committee will be formed,
15 which will be focused on Development issues and will replace the DPTC and DSTC.
16 The date when the new structure becomes effective has not been set yet. The current
17 Working Groups and the MTC, BTC will not be affected by the restructuring.

18 The SC will oversee the staffing of the Development TC, which will be based on
19 technical skills, and will aim to bring together specialists from all areas that are important
20 to QbD development, e.g., pharmaceutical formulation, statistics, excipients, materials,
21 analytical methods, physical characterization, etc. (The DPTC and DSTC Chairs are
22 identifying the desired complete skill set.) There were some questions regarding the
23 make up and working arrangements for the new committee. The SC is preparing a
24 communication about this re-organization and plans to circulate it to all member
25 organizations in the coming weeks.

26 ***New Project***

27 A new project proposal based on the past L&E WG work has been circulated to the
28 DPTC members before the teleconference. The project is aimed at extending the L&E
29 threshold approach to parenteral products (e.g., ophthalmics and injectables). Since it can
30 use some of the learnings from the previous WG, especially regarding the PQRI process,
31 the proposed anticipated timeline is shorter. Involvement of parenterals manufacturers
32 and their suppliers is considered to be of high priority. Harmonization with USP
33 (especially regarding chapter <381>) will also be sought. The PDA Science Advisory
34 Board has already reviewed and approved the proposal.

35 ***Leachables and Extractables***

36 The second “Best Practices” training course will take place in Chicago, IL next week.
37 Registration has already reached the target number. A European training course is being
38 planned for September in Basel. A West-Coast course has not been considered yet.

39 The Working Group’s article in the *Toxicological Sciences* will be appearing shortly.
40 The preparation of a book for Wiley publishers is underway. The book will address
41 toxicological qualification and development process for leachables and extractables in
42 inhalation products. The Chairs of the Toxicology and Chemistry subteams of the L&E
43 WG are serving as editors.

44 ***Container Closure Working Group***

45 The 90-day data collection has been completed and forwarded to the WG statistician for
46 analysis. The protocol for unit-does (blisters) screening experiments will be forwarded to
47 the DPTC for review within the next month.

48 The WG would like to present its information and findings to date to the FDA through an
49 informal meeting, because companies’ efforts to apply MVTR concepts using current
50 regulations had met with only intermittent success. The DPTC FDA representative stated
51 that the Agency in general supports the theoretical basis of MVTR but would like to see
52 and discuss data at the meeting.

53 ***Profile Comparisons***

54 The Working Group’s “final report” manuscript has been submitted to the SC for review
55 and approval. The WG expects to submit the paper to the *AAPS PharmSciTech* in May.

56 ***Excipients***

57 The WG held a successful meeting with FDA on March 26. The meeting participants
58 discussed the terminology of the “flow” control process appropriate for continuous (365
59 days-a-year) manufacturing. The WG also plans to address terminology in 21 CFR
60 211.84, e.g., to add the word “measurement” because with modern techniques, adequate
61 control could be achieved through in-line/on-line measurements and not only through
62 lab-bench tests.

63 The meeting minutes will be provided to the DPTC after finalization, and the meeting
64 outcomes will be discussed in more detail on a future DPTC teleconference.

65 ***Specifications Design and Life Cycle Management***

66 No update was available.

