

1 **Minutes of the DPTC Teleconference**
2 **on 27 September 2006**

3 **ATTENDEES**

4 Terry Tougas, *Chair* (Boehringer Ingelheim)
5 Clyde Anthony (USP)
6 David Christopher (Schering-Plough), by phone
7 Bob Dana (PDA)
8 Frank Holcombe (FDA), by phone
9 Lana Lyapustina (IPAC-RS)
10 Lee Nagao (IPAC-RS), by phone
11 Rich Poska (Abbot), by phone
12 Raj Uppoor (FDA), by phone
13 Bob Wiens (Lilly), by phone
14 Bruce Wyka (Schering-Plough), by phone

15 ***Absentees***

16 Tony Amann (GPhA)
17 Sylvia Gantt (PQRI)
18 Michael Golden (GlaxoSmithKline)
19 Dan Malinowski (Pfizer)
20 Chris Moreton (Idenix Pharmaceuticals)
21 Dan Norwood (Boehringer Ingelheim)
22 Nakissa Sadrieh (FDA)
23 Vilayat Sayeed (FDA)
24 Jim Schwenke (BI)
25 Russel Somma (IPS)
26 Bill Williams (University of Texas)

27 **EXECUTIVE SUMMARY**

- 28 • The process for submitting the L&E Recommendations to FDA and making them available
29 to the public will be discussed by the SC.
- 30 • Information about the upcoming Excipients Workshop will be provided for further
31 dissemination through PQRI member organizations.
- 32 • Clyde Anthony will serve as a liaison to the Specifications Design & Life Cycle Management
33 WG, and as a first step will coordinate review of candidates from the DPTC side.
- 34 • The Profile Comparisons WG should consider presentations and seminars in order to
35 publicize its work and explain approaches and conclusions both to the Agency and industry.
- 36 • The Stability & Shelf Life WG should discuss and make recommendations to DPTC
37 regarding membership.

- 38 • At the next teleconference, the DPTC will consider a succession plan for the Committee's
39 leadership and membership.

40 **DISCUSSION**

41 *Opening*

42 Dr. Tougas opened the meeting and read the antitrust admonition: "Our discussions today are
43 subject to the anti-trust guidance applicable in the U.S. and E.U. Nothing discussed at this
44 meeting is intended to restrict the individual decision-making of any member company or to
45 represent an agreement to coordinate marketing or sales conduct. Those participating in this
46 meeting are instructed to avoid discussion of competitively sensitive subjects, including, but
47 not limited to, confidential marketing, sales, and pricing information."

48 The proposed objectives of the meeting were to discuss updates on all Working Groups and
49 new projects.

50 *Leachables and Extractables*

51 Dr. Nagao provided an update on the L&E WG, and the Committee discussed it, as follows:

- 52 • The L&E Recommendations have been endorsed by the Steering Committee (SC) and
53 now will be forwarded to the FDA.
- 54 – At its upcoming meeting, the SC will discuss an appropriate process for submitting
55 the document formally to FDA so that it is widely available to all reviewers.
56 (Participation by FDA staff on a WG, TC or SC is not sufficient for this purpose).
57 One possibility would be to submit the Recommendation to the FDA Dockets.
- 58 – In addition, a strategy for publicizing this PQRI success, and ways for a making this
59 document widely available to the public will be discussed by the SC. Posting the
60 Recommendations on the PQRI website could be one of the first steps in this process.
- 61 – The FDA representatives on DPTC supported the need for a formal submission and
62 indicated no preference whether the public availability of the Recommendations
63 occurs before or after submission to FDA.
- 64 • The L&E Training Course held in Washington, DC, on 9/20-21, was successful both
65 financially and in the level of interest it generated among the participants.
- 66 – The registration maxed out at 80 based on the room's capacity, and there was a
67 waiting list. The Working Group will be discussing potential additional courses to
68 accommodate the need and interest expressed by this community. Among attendees
69 were representatives of supplier and pharma companies, including non-inhalation
70 companies, and several participants from overseas.
- 71 – Most of the attendees stayed through the entire 2-day course, and actively participated
72 even in the Q&A session on the afternoon of the 2nd day. An initial review of the

73 Evaluations of the Training Course (completed by over 50% of the participants)
74 indicated an eagerness on behalf of the attendees to implement the Recommendations
75 at their companies.

76 – The Working Group will be preparing a summary of the Training Course.

77 • The draft of the toxicological & safety publication is ready. The Working Group is
78 additionally looking into sources for publishing its Best Practices.

79 • The contract for a book with Wiley publishers is being reviewed by PQRI attorneys. At
80 the request of one of the members, Dr. Tougas agreed to keep the DPTC informed of the
81 SC and Board decisions on this topic. Dr. Nagao confirmed that this project will be
82 proposed as a new work item to the DPTC, separate from the roll-out and publicizing of
83 the Recommendations.

84 The DPTC thanked the L&E WG for their work.

85 *Excipients*

86 Mr. Wiens provided an update on the Excipients WG, and the DPTC discussed it, as follows:

87 • The Working Group's article had been published in the September issue of
88 *Pharmaceutical Technology*.

89 (<http://www.pharmtech.com/pharmtech/article/articleDetail.jsp?id=371142>).

90 • A full report on the Excipients survey has been distributed to the DPTC, with editorial
91 changes included. The report will be added to the binders for the upcoming Excipients
92 Workshop.

93 • Dr. Uppoor publicized the WG's work through the Agency and publicized the upcoming
94 workshop on CDER's website (<http://www.fda.gov/cder/workshop.htm>, in the "CDER
95 calendar" menu).

96 • Registrations for the Excipients workshop are growing in number, albeit slower than
97 desired, and with few excipient suppliers so far. Information about the workshop has
98 already been circulated through PQRI, FDA, USP and IPEC channels. In addition, Mr.
99 Dana offered to disseminate appropriate information through PDA. Dr. Tougas agreed to
100 ask SC members to promote attendance at the workshop through all PQRI member
101 organizations. It was suggested that printed materials be considered for future
102 workshops, and promotional strategy be discussed with ECAS.

103 • The Working Group plans to prepare Proceedings of the Workshop, which will include:

104 – a summary of all findings;

105 – changes in regulatory environment;

106 – efficient company strategies and best practices.

107 The DPTC thanked the Excipients WG and encouraged a concentrated effort to publicize this
108 important work.

109 ***Specifications Design and Life Cycle Management***

110 Dr. Tougas reminded the participants that this is a joint WG with the Manufacturing
111 Technical Committee (MTC). Mr. Dana, who participates in the MTC, clarified that the WG
112 is waiting for nominations from the DPTC but otherwise is ready to start work. Dr. Anthony
113 agreed to serve as a liaison to that WG and as a first step to coordinate the review of CVs of
114 candidates. Dr. Lyapustina agreed to coordinate the voting process.

115 Dr. Upoor mentioned that some of the Agency staff had concerns with the proposal. Dr.
116 Tougas reminded all that the Work Plan had already been reviewed and approved by DPTC,
117 MTC and the Steering Committee. The DPTC encouraged Dr. Upoor to submit any
118 concerns to the WG as soon as possible.

119 ***Profile Comparisons***

120 Mr. Christopher reported that the Working Group's Interim Report had been revised per
121 reviewers' comments and re-submitted to AAPS PharmSciTech. The Final Report is
122 expected to be ready for the DPTC review by the end of October. The Report will not be
123 recommending any specific test for regulatory use but rather will be highlighting areas where
124 the chi-square ratio test is or is not sufficient.

125 The Final Report might be ready for submission to the AAPS PharmSciTech by the end of
126 2006, after which the WG could be sunset. The DPTC encouraged the WG to consider ways
127 to publicize its work more broadly and to explain its approaches and conclusions both to the
128 Agency and industry.

129 ***Mass Balance***

130 Mr. Wyka reported that the technical paper has been finalized and would be submitted to the
131 Journal of Aerosol Medicine this week. Dr. Tougas reported that the proposed language for a
132 guidance has been submitted to the SC Chair, and a process for formal submission to FDA
133 would be further discussed by the SC.

134 ***Stability & Shelf Life***

135 Dr. Tougas reported that the Proposal had been approved by the Steering Committee and
136 several nominations have already been received for this WG. The current co-chair for
137 statistics is Dr. Jim Schwenke, and a co-chair for CMC is being sought. Mr. Christopher
138 added that PhRMA CMC Statistics group is interested in participating in this work. He also
139 encouraged potential FDA involvement.

140 Dr. Tougas further explained that the WG aims to address issues of setting specifications and
141 shelf life based on the same stability data; and plans to correct technical methods used for
142 estimating shelf life.

143 The participants also discussed that the Center sets specifications based on averages while
144 the field applies those specifications to individual values.

145 The DPTC advised that the existing core WG should consider its needs (e.g., number of
146 participants, their qualifications and field of expertise) and make a recommendation to the
147 DPTC regarding membership.

148 *New Projects*

149 Dr. Tougas invited DPTC members to think about and propose new projects. He mentioned
150 that a proposal to examine approaches for exploratory INDs might be coming to the DPTC in
151 the future.

152 *Succession Plan*

153 Dr. Tougas suggested that DPTC consider a plan for ensuring orderly succession of
154 leadership and membership of the Committee, e.g., term of service, process for selecting new
155 chair or vice chair, etc. The participants agreed to discuss these issues at the next
156 teleconference. They emphasized that the discussion would benefit from confirmation of
157 FDA's continued commitment to PQRI.

158 *Container Closure Working Group*

159 (Post-meeting communication from Dan Malinowski)

- 160 • Ron Forster from Amgen was endorsed by the DPTC as a C/C WG member.
- 161 • Packaging for the multi-unit container MVTR screening study should occur the first week
162 in October.
- 163 • MVTR Testing will be performed at 4 company labs (Abbott, Merck, Pfizer, Sanofi-
164 Aventis)
- 165 • Next step is to finalize single-unit (blister) container packaging and testing protocol.

166 **NEXT MEETING/TELECONFERENCE**

167 The next DPTC teleconference is scheduled for 23 October, Monday, at 10:00 AM ET .

168 Finalized on 19 October 2006