

1 **Minutes of the DPTC Teleconference**
2 **on 31 March 2006**

3 **ATTENDEES**

4 Terry Tougas, *Chair* (Boehringer Ingelheim, IPAC-RS)
5 Clyde Anthony (USP)
6 David Christopher (Schering-Plough, IPAC-RS)
7 Bob Dana (PDA)
8 Michael Golden (GlaxoSmithKline, IPAC-RS)
9 Lana Lyapustina (IPAC-RS Secretariat)
10 Dan Malinowski (Pfizer, PhRMA)
11 Chris Moreton (Idenix Pharmaceuticals, IPEC)
12 Dan Norwood (Boehringer Ingelheim, IPAC-RS)
13 Lee Nagao (IPAC-RS Secretariat)
14 Rich Poska (Abbot, PhRMA)
15 Robert Seevers (Lilly, PhRMA)
16 Russel Somma (IPS, ISPE)
17 Raj Uppoor (FDA)
18 Phyllis Walsh (Schering-Plough, IPEC)
19 Bob Wiens (Lilly, IPEC)
20 Bruce Wyka (Schering-Plough, IPAC-RS)

21 ***Absentees***

22 Tony Amann (GPhA)
23 Frank Holcombe (FDA)
24 Nakissa Sadrieh (FDA)
25 Vilayat Sayeed (FDA)
26 Bill Williams (University of Texas, AAPS)

27 **EXECUTIVE SUMMARY**

28 Working Group updates have been discussed.

29 The next DPTC meeting will primarily be focused on possible new projects.

30 **DISCUSSION**

31 ***Opening***

32 Dr. Tougas opened the meeting and read the antitrust admonition: “Our discussions today are
33 subject to the anti-trust guidance applicable in the U.S. and E.U. Nothing discussed at this
34 meeting is intended to restrict the individual decision-making of any member company or to
35 represent an agreement to coordinate marketing or sales conduct. Those participating in this

36 meeting are instructed to avoid discussion of competitively sensitive subjects, including, but
37 not limited to, confidential marketing, sales, and pricing information.”

38 The proposed objectives of the teleconference were to review updates from the Working
39 Groups and to consider possible new projects. Due to limited time, the discussion of new
40 projects was postponed until the next DPTC meeting.

41 ***Leachables and Extractables***

42 Dr. Norwood reported that FDA had agreed that the Leachables and Extractables
43 Recommendations document could be moved forward. The Working Group had also
44 received comments from the L&E Workshop participants. The Working Group would be
45 meeting the following week to discuss these comments. Dr. Tougas suggested that the same
46 process be followed for handling the comments as was used for the Blend Uniformity
47 document. Dr. Uppoor agreed to help with identifying that process. A revised L&E
48 Recommendations document would be provided to the DPTC in the near future.

49 Dr. Norwood further reported that a presentation at the Society of Toxicology Symposium
50 had generated a good panel discussion, and the Working Group has been invited to prepare a
51 review article on the topic. Dr. Nagao added that a member of the Working Group, Diane
52 Paskiet, has been invited to make a presentation at another upcoming conference; however
53 she would not disclose any new information that had not already been discussed at the PQRI
54 L&E Workshop. The DPTC members had no objection to these plans.

55 ***RFID***

56 Dr. Seevers reported that the revised RFID paper had been circulated to the Steering
57 Committee and upon the SC approval it would be submitted for publication to
58 Pharmaceutical Technology.

59 Dr. Uppoor mentioned the March 6-7, 2006 RFID Workshop and Vendor Exhibition, where
60 much relevant information had been shared; he also pointed to two commercial products that
61 had already started using RFID tags. Dr. Seevers noted that for those two products,
62 authentication issues had been the main driver. Dr. Poska asked about the cost-benefit of
63 using RFIDs and pointed out that 3-D RFID tags rather than 2-D tags are likely to be used in
64 the future. Dr. Seevers added that RFIDs could not be used on vials with metal crimps or
65 with aqueous formulations, which would include all biologics.

66 The Working Group thanked Dr. Seevers for his efforts on this topic.

67 ***Container Closure System***

68 Mr. Malinowski explained that since mid-2005, FDA’s representative on the Working Group
69 had been Susan Sach, and she clarified the status of the PACPAC document submitted to
70 FDA in 2004. Due to FDA’s recent re-structuring, the PACPAC guidance – which had been
71 the original focus of this PQRI Working Group – had been given low priority by the OPS

72 CC. Nevertheless, there are still some activities this Working Group needs to complete, such
73 as studies of moisture vapor transition rates; possible revision of the method or development
74 of a new method. For the MVTR study, Dennis Sandell (AstraZeneca) would be contacting
75 the Working Group regarding a representation and potential help with laboratory resources.

76 Mr. Malinowski indicated that a revised Workplan for this Working Group would be
77 provided to the DPTC by the end of April.

78 Dr. Uppoor (and later Dr. Holcombe) clarified that in the past, all CMC-related guidances
79 had been prepared by the CMC Coordinating Committee (CMC CC) within the Office of
80 Pharmaceutical Science (OPS), and which included Directors from the Office of New Drug
81 Chemistry (ONDC) and Office of Generic Drugs (OGD) as primary members and the Office
82 Directors or designates serving as co-chairs. With the expansion and reorganization of OPS,
83 the CMC CC role has been incorporated into the OPS level OPS CC, comprised of Directors
84 of all OPS offices. The new Coordinating Committee is emphasizing science - and risk-
85 based approaches (including recent ICH guidances) and re-prioritizing guidances
86 accordingly.

87 *Profile Comparisons*

88 Mr. Christopher reported that the WG has started preparing its Final Report, which would be
89 submitted to FDA and to a peer-reviewed journal for publication. The Interim Report paper
90 had been revised and resubmitted to the Journal of Aerosol Medicine.

91 Dr. Uppoor mentioned a recent approval of a generic nasal spray, indicating that droplet size
92 distribution problems were successfully resolved there. Dr. Tougas noted however that nasal
93 products are different from the pulmonary drugs, which are the focus of this Working Group.

94 Mr. Christopher confirmed that the Working Group stays on track with its plan to complete
95 all active work by mid-2006.

96 *Excipients*

97 Mr. Wiens said that only one set of comments on the Working Group's draft report had been
98 received to date, and he encouraged all DPTC members to forward any other comments as
99 soon as possible.

100 Dr. Uppoor asked about the purpose of the proposed Excipients Workshop because he felt
101 FDA had already addressed all main issues, such as acceptance of skip-lot testing, of PAT,
102 and of compendial methods. He also said that a recent Federal Register notice gave the
103 Agency regulatory discretion for situations when specification limits are broadened.

104 Ms Walsh and other participants noted that there are still many questions about best ways to
105 control quality of excipients and addressing them would be very important. Dr. Moreton
106 added that at least one supplier has stopped using USP NF designations for their excipients
107 and there is a risk that this may continue. These problems should be discussed openly with all

108 interested parties, such as at a PQRI Workshop. He explained that these are not so much
109 science issues as regulatory, quality and legal issues.

110 It was agreed that Dr. Uppoor, Ms. Walsh and Mr. Wiens will continue in-depth discussion
111 of this topic separately.

112 ***Mass Balance***

113 Mr. Wyka reminded the Committee that at the November 4, 2005 joint meeting of the Mass
114 Balance Working Group and the DPTC, it was proposed that consensus language be drafted
115 for the guidance, addressing the issue of Mass Balance. At a recent teleconference such
116 language was discussed and apparently agreed, but after the teleconference some
117 disagreements re-surfaced. Subsequently, FDA managers indicated that (i) the Agency
118 representatives should not be involved in creating this language that would be proposed by
119 the PQRI Working Group to the Agency, and that (ii) proscriptive, specification-oriented
120 language would be contrary to the Quality by Design initiatives.

121 Mr. Wyka said that the Working Group would consider these recent directions from the
122 Agency and would discuss what to submit to the Agency as the output of this PQRI activity,
123 and how to proceed with the draft paper that had been reviewed by the DPTC.

124 **NEXT MEETING/TELECONFERENCE**

125 To be confirmed by email.

126

Finalized on 10 May 2006