

Summary Minutes of the MTC Teleconference
Thursday, 08 December 2011
9:00 AM - 11:00 AM ET

Teleconference Information:
1-866-570-1041
Passcode: 544861

Welcome/roll call

Antitrust Statement was read by the Vice Chair.

Minutes approval – Minutes accepted as amended and posted on website

Review of actions from November meeting and updates–

* Spec Design- Member received one comment. **Action Item:** He will make adjustments to the doc and get it ready for publication. The original paper will be ready for MTC members to see a highlighted copy on Dec. 16th and then have until Jan. 5th to make comments for changes. He will highlight those items in track changes that he believes need a second look as things have changed in the industry since this paper was originally written. The full paper should then be ready for posting on the PQRI website following the Jan. 12th MTC telcon and approval.

* Transdermals- The Board approved the \$3,000 fee for Open Access and the paper is now in the publication process. The paper should be ready for posting by the end of December if all goes according to plan. Chair is waiting for the final galley from the publisher.

* Excipient Variability – no report. Member advised that Univ. of Maryland has announced a new project in this topic area and that NIPTE is conducting work on this topic for the FDA. **Action Item:** Members will try to get this moving again. Perhaps new energy will be needed to keep this moving forward.

* IR/MR SUPAC Update – MTC Chair sent draft of work plan out to MTC members. Comments should be sent directly to her by no later than Jan. 5th so that hopefully she can make changes prior to the Jan. 12th telecom.

* Process Drift Workshop – no ideas were sent to FDA member. **Action Item:** He will arrange for a meeting with planning committee to try to create a skeleton agenda so that we can prepare a draft budget for SC/Board consideration. We need financial information in order to have discussions with the SC and Board about co-sponsorships and financing of the workshop. They will work to have something in place as a framework by the Feb. 9th MTC meeting.

* Steering Committee/Board Report – nothing to report as the next meeting is set for Dec. 20th

* Ideas for new WGs –none at this time

* 2012 TC Meeting Schedule – all are at 9:00- 11:00 AM ET

- 12 Jan
- 09 Feb
- 08 Mar
- 12 Apr
- 10 May
- 14 June
- 12 July
- 08 Aug – ask Chair to check date to make sure it is on other than a Thursday?
- 13 Sep
- 11 Oct

- 08 Nov
- 13 Dec

* No other business to report. Meeting adjourned at 10:15 am.