

MEETING MINUTES

AAPS – Manufacturing, Engineering, Quality, Focus Group (MEQ-FG)

Date: June 9, 2005

Time: 3:00-4:00 p.m. (ET)

Location: Teleconference

Facilitator: MikeYelvig, Chair, MEQ FG

Document Originator: Mike Yelvig

Objective: First kick-of meeting of MEQ Focus Group

Meeting Minutes:

1.This was the first meeting of the Manufacturing, engineering, Quality (MEQ) Focus Group. The meeting attendees were, Mukund (Mike) Yelvig, Chair MEQ FG (MY, Wyeth), Parimal Desai (PD, Wyeth), Joe Mattia (JM, Wyeth), Hoshang Unvala (HU, Bayer), John Engelhart (JE, Organon), Kathy Ulman (KU, Dow-Corning), Sharmista Chatterjee (SC, Forest). The meeting agenda and other details of the FG are attached with these minutes.

2.MY provided the background information which led to the formation of MEQ FG. The AAPS Executive committee approved the formation of MEQ FG in April 2005. At the start of the FG there were 75 members signed up (current membership is 90). The main focus of the group is to address the needs of manufacturing, engineering and quality areas in the industry and regulatory bodies. The currently circulated goals and objective document need to be further enhanced as the FG evolves. All members were requested to send their comments to MY ASAP.

3. One of the objectives of the FG is to suggest programming ideas to AAPS. HU outlined various types of programming ideas for AAPS meetings. He suggested that this FG might consider such as Hot Topic, symposiums, Workshops, Round Table Discussions. He also informed on the AAPS-FDA sponsored forthcoming workshop on QbD in Oct 2005.

4. The list of ideas generated for future meetings is attached .It was discussed that any programming idea for 2005 AAPS annual meeting is a stretch goal due to the lack of lead-time. PD suggested that Quality by Design is an important evolving subject and industry needs to understand clearly what it means and how to implement. Continuing on this discussion, he suggested that a workshop at Puerto Rico, which is the main hub of pharmaceutical manufacturing be held in Feb/March 2006. CA and JM suggested that at this workshop not only QbyD but also topics on API manufacturing, Packaging Design and Manufacturing Execution systems (MES) could be included. MY was asked to follow-up with PT section chair on this proposal.

(PMN: MY followed up on this suggestion and as AAPS needs at least 12 month lead time for any workshop idea, it was felt that this idea be pursued for end of 2006 or early 2007. However PAT FG is in the process of preparing a proposal for PAT workshop in late 2006. PAT workshop chairperson Leslie Hawley had contacted MY for possible joint collaboration for this workshop.

MY along with SC, HU and JE are currently working with PAT FG in the proposal for a cluster workshop for 2006. Certain subjects of interest to MEQ FG such as Case studies in QbyD,

QbyD in API development are being considered for this workshop. Further details of this workshop will be communicated to members thru the minutes of PAT FG)

5. The meeting adjourned with a vote of thanks to all attendees. The minutes will be posted on the AAPS-MEQ-FG web page for the benefit of all members.

ENCL:Meeting Agenda

AGENDA
AAPS – Manufacturing Engineering and Quality (MEQ) Focus Group
Leadership Group Meeting

Date: June 9, 2005

Time: 02:00-3:30 p.m. (ET)

Location: Teleconference

Call In Number: 1-877-213-9444, Pass code 331549

Facilitator: Mike Yelvigi

Objective: Discuss MEQ Goals and Program Ideas for 2005/2006.

Agenda Items:

1. Introductions
2. Current Goals and Structure of MEQ...Mike Yelvigi
 - a. Steering Committee Members for each section
 - b. Future meetings and procedures
3. Program Ideas for 2005/2006
 - a. AAPS Future meetings and dates ...H. Unvala
 - b. Discussion on various topics...All

Suggested Program Ideas for Discussion (list compiled with inputs from you)

Quality system Framework-Quality system and Risk Management
Drug Batch Release
Investigations
Vendor Certification Programmes

Use of Inline analytics for Pharma manufacturing
Application of Continuous processing
Use of Predictive tools in scale-up of unit operations

API Technology Transfer
Process Validation of API
Management of Outsourcing for API

Master Batch Records Administration

