

May 28, 2006

In accordance with the suggestion of the MGCC, the leadership of the Process Development, MEQ and PAT focus groups discussed the scope and remit of our focus groups. The scope of interest of the three focus groups is outlined in the attached diagram. Although there would be more than one way to group common areas of interest's verses separate endeavors the message is still the same in that the three FG have unique responsibilities and should maintain a separate identity. Further justification is provided below.

Given our common goal of developing, registering and manufacturing quality products, there is a common interface among the three groups and areas of overlap between groups; this shared interface is in fact conducive to developing joint programming for addressing common areas of interest among the three focus groups. The leadership (steering committee) of the focus groups is committed to doing so and this is reflected in programs being developed for the 2006 and 2007 annual and cluster meetings.

However, there are clearly delineated areas that are of primary interest to the membership of each focus group and only peripherally of interest to the other two groups. Examples of these are vendor qualification, supply chain consolidation, facility design and quality systems – topics of primary interest to the MEQ membership. These specific interests also determine the interface of the three focus groups with other focus groups within and outside the PT section, as well as with external organizations. Thus, the Process Development focus group maintains close programming links with formulation focus group and PDD and Regulatory sciences section while the PAT focus group is closely aligned with APQ and the MEQ focus group maintains a strong link with ISPE.

The leadership of the three focus groups is of the opinion that our respective constituencies, i.e., focus group members, are best served by retaining this focus and addressing programming needs both in the specific and general areas of interest. The latter is best addressed through collaborative programming and the former in symposia, roundtables and workshops that are targeted primarily toward the focus group membership. We will be updating our websites with this information and also communicating the charter of the focus groups to our membership.

We thank the MGCC for their thorough review and we do greatly appreciate the renewed focus on the focus groups. Please feel free to contact us if you require further information or clarification.

Sincerely,

Vidya Swaminathan, PDFG

Mike Yelvigi, MEQ

Chris Watts, PAT

OVERLAP & DIFFERENCES IN EACH FG MISSION / VISION

