Experiences of the Blend Uniformity Working Group

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Positive Experiences

• Blend Uniformity Workshop (September 2000)
  – Defined the problems associated with blend uniformity testing
  – Facilitated drafting our recommendation for addressing blend uniformity
• Drafted a recommendation to resolve blend uniformity issues
  – Currently posted for public comment
Positive Experiences

• The BUWG effectively provided a forum to openly discuss the blend uniformity concerns from industry, academia and FDA perspectives
  – Participants considered the concerns of both the FDA and pharmaceutical industry
  – BUWG’s recommendation identified a potential solution to address & resolve everyone’s concerns

• Trust and a good rapport developed between the group members
Positive Experiences

• Satisfying to see the FDA being open to drafting scientifically based regulations driven by the BUWG’s work and proposal
  – Refreshing attitude

• Empowerment of the group based on the expertise and experience of the people in the working group helped accelerate progress
Positive Experiences

• Interactions with Ajaz Hussain
  – Committed to see us succeed
  – Provide leadership and clarity to the group
  – What was the impact of his influence within the FDA?

• Opportunity for working group members to co-author publications

• Networking/contacts/friendships gained
Areas for Improvement

• Keep the science separated from the bureaucracy
  – Beware of hidden agendas

• The goal was vague at first
  – General feeling we needed to respond to the OGD draft, but we were too cautious in the early days
  – Spent our energy preparing for the public meeting, and then lost some momentum for a while
Areas for Improvement

• Better alignment in the goals and objectives for the Working Groups and Steering Committee
  – Guidance from the Steering Committee was not always clear
  – Disconnect in the direction we were headed and thought was proper vs. where SC wanted us to go
  – Empowerment of the working groups to address scientific issues
    • We are the “experts” in our respective areas
Areas for Improvement

• Freeing up the working groups from having to deal with some of the administrative functions associated with PQRI
  – Working group members are primarily scientists with little experience in writing contracts
  – Need standard procedures to award contracts
  – Need assistance to assure that we are meeting not only the scientific requirements, but also the legal requirements when we award a contract
Areas for Improvement

• Engagement of all members to actively participate on the working group
  – Convey the time commitment & work expectations to potential candidates when initially populating the working groups or replacing members

• Balanced representation from both brand and generic sides of the industry
  – With one exception, consistent generic representation was a problem