



The Product Quality Research Institute (PQRI) was established in August 1999 to provide a neutral forum for industry, academia and FDA to address pharmaceutical product quality issues of mutual interest. One of the first decisions made by the PQRI Steering Committee was to address Industry concerns with various aspects of the FDA draft “Guidance for Industry, ANDA’s: Blend Uniformity Analysis” (August 1999). Under the leadership of Dr. Tom Garcia (Pfizer) the PQRI Blend Uniformity Working Group labored to articulate the specific Industry and FDA issues with the guidance, developed a work plan to address each issue, evaluated data provided by industry and available in the literature and jointly agreed upon a recommendation that was submitted to FDA for consideration. The Agency reviewed the initial recommendation and raised several issues for the working group to address before it could be accepted. The Group met with the FDA reviewers and successfully responded to their concerns. The final recommendation has been accepted by the Agency and the guidance is incorporating the points made therein. It should also be noted that the PQRI recommendation was reviewed and accepted by the Pharmaceutical Sciences Advisory Committee.

The effort of the Blend Uniformity Working Group was significant for several reasons. First, the group members had to learn how to work together as scientific experts rather than representatives of industry, academia or the FDA. Secondly, this was the first project to move through PQRI and there were many administrative and procedural issues that had to be addressed which had not been anticipated. The group provided the Institute with a testing ground in which to establish its operating principles. Lastly, this project provided both Industry and FDA with proof of principle that the PQRI concept is viable and that FDA would indeed accept and act on a PQRI recommendation.

The cover letters to the initial and revised recommendations and the final recommendation are being published to share the work done by the Working Group with the general public. The work of the group is not completed, however. Their next step is to conduct a workshop to share with industry and the Agency how the recommendation can be implemented.

PQRI currently is sponsoring 12 other working groups. We welcome the opportunity to provide this unique forum to address product quality issues and invite all interested parties to participate in the PQRI effort.