

Desired Professional Qualifications for Membership in the PQRI-PODP Leachables and Extractables Working Group

- Background in the development and registration of pharmaceutical products, especially injectable, parenteral, ophthalmic, and/or transdermal drug products. Areas specifically desired include: Analytical Chemistry, Toxicology/Risk Assessment/Qualification, Manufacturing/Quality Control, Packaging, Statistics, and Regulatory Affairs.
- Recognized expertise in leachables and extractables, with particular emphasis on injectables, parenterals, ophthalmics, and/or transdermal drug products.
- Demonstrated record of scientific accomplishment and achievement, as evidenced by (for example) publications, presentations, memberships, active participation in scientific organizations and scientific meetings, etc.
- Commitment and ability to meet the administrative requirements of the group, including attendance at face-to-face meetings, participation in teleconferences, performance of assigned tasks and completion of key deliverables within mutually accepted time lines. These commitments could include up to 4 face-to-face meetings and 12 teleconferences per year. Active, sustained participation in the group's efforts is a firm requirement.
- Ability and organizational support to provide additional technical assistance to the Working Group is desired. This could include laboratory support of the Group's objectives (case study), and providing materials for study (i.e. test articles).
- Ability to effectively operate in a team environment, leveraging one's organizational viewpoints and responsibilities to drive towards consensus in pursuit and timely attainment of the Working Group's Mission and Objectives.