

PQRI Group 2 meeting 2 (4-27-01 teleconference)

A very rough roster of attendees (see the teleconference log for better accuracy?)

Frank Etzler, Pascal Toma, Michael Van Ort (not here, Chuck Ekhart), Hullahalli Parsanna, Ron Mueller, Joe Stowall, Eric Duffy, Rick Bruce, John Bauer, Nallahaperumal Chidambaram (FDA), Rob Lyon, Sylvia Gantt, Bernie Olsen, Sharon Snorek

1. Meeting Discussion Products

1.1 Instruments Polled

1.2 Recommendations









1.2.1 Look @ sample under microscope first!

1.2.2 How do we characterize Shape?

1.3 Design and conduct a Round Robin to examine: How good does the technology match what we consider to be ideal?

1.3.1 What specifications would be robust enough to regulate?





1.3.2 What demonstration trials could be used as Standards?

-  Idealized sample test set
-  sample type & source
-  sample matrix
-  morphology
-  Real Life Formulation sample set
-  sample type & source
-  sample matrix
-  morphology

1.3.3 How do we fund the demo tests?

 \$20 -- 70K

1.3.4 Who does the demos?

-  contract labs?
-  instrument manufacturer applications
- labs**
-  universities
-  pharma companies

1.4 Holding a Mini Conference

1.4.1 Size (Limited to PQRI (152))


1.4.2 Timescale

 **mid-November**
 **1-day, 6-7 speakers**

1.4.3 Location (**Greater DC Area**)

 **FDA**
 **AAPS**
 **U. MD**






» See also: : University MD Ultra Structure

 **NIST**

» See also: : M. Postek

1.4.4 options

A) Technical conference speaker (honoraria)

 **Terry Allen**
 **R. Muller**
 **W. Mehnert**
 **others**
 **M. Postek**

» See also: : University MD Ultra Structure
» See also: : NIST







 **University MD Ultra Structure**

» See also: : M. Postek
» See also: : U. MD

 **Peter York**
 **Strauss**

B) Invited Instrument Manufacturers (free)

1.4.5 Funding/ hosts

 **PhARMA**
 **Companies**
 **ACS**
 **Division of Colloid & Surface Chemistry**
 **AAPS**
 **Standing discussion groups**

- ✍ IWPCS
- ✍ AAPS Special Topics Meeting
- ✍ ArdenHouse
- ✍ Colloid & SS Symposium (Usually meets in June)
- ✍ MST Conferences
- ✍ Eastern Analytical Symposium

2. Homework list (to be done post meeting ASAP by each member (except where specified))

2.1 Each member reprioritize, delete or add to these items & rank importance (To be used to clarify thinking about standardizing instruments)

2.1.1 What are the characteristics of an ideal particle sizing instrument?

- ✍ Results should be reproducible over time and between instruments.
- ✍ Algorithm for converting instrument signal to spherical diameter should be well described.
- ✍ Resolution should be known.
- ✍ Instrument should be able to correctly measure the relative populations of particles in bimodal or multimodal particle size distributions.

✍ Instruments should display a linear response to the increase in the population of particles in a given size interval.

- ✍ Particle dispersion energy should be variable and known.
- ✍ Results should not be affected by the presence of particles outside the analysis window.

2.1.2 Problems with Status Quo

- ✍ Dispersion energy of various instruments unknown.
- ✍ Linear responses to population changes not always tested.
- ✍ Ability to measure the relative populations in multimodal distributions often unknown.
- ✍ Effect of polydispersity on instrument performance unknown
- ✍ Fraunhofer instruments not always used in a manner with ISO standards.
- ✍ Unclear how to apply Mie optical model can be applied to birefringent materials.
- ✍ Manufacturer/software version dependence unknown.
- ✍ Fraunhofer may exhibit non-linear responses to population changes.
- ✍ Relative performance of various instruments unknown

- 2.1.3 Defining measurement dimension**
- 2.2 FDA members will translate the idealized paradigms into language useful for regulations**
- 2.3 Add to the List of mini-conference speakers**
- 2.4 Contribute to the PSA Decision tree**
 - 2.4.1 tablets**
 - 2.4.2 inhalation**
 - 2.4.3 parenterals**
 - 2.4.4 suspensions**
- 3. Next teleconf. 3rd week in May on Friday PM 5/18**
- 4. Working Agenda**