**Regulated Bioanalysis Interest Group ASMS 2012 Workshop Report**

**Presiding: Steve Lowes and Gary Schultz**

**Estimated Attendees: 150 people**

**Summary**

The workshop was well attended and focused on three areas:

1) High resolution accurate mass application to regulated bioanalysis
2) Current status of regulated bioanalysis global harmonization initiatives
3) Tiered approaches to bioanalytical methods

After opening comments on the background of the interest group and the membership survey that drove the agenda for the workshop, Dr. Gary Schultz opened the first topic on the agenda. The second and third topics were initiated by Dr. Steve Lowes with short slide decks and then each topic was revisited in a question and answer session for all attendees.

Significant discussion ensued around the HRMS topic with reference made to the session preceding the workshop that was dedicated to the same area. Dr. Walter Korfmacher made comment to the encouraging future of the techniques that have evolved out of drug discovery applications. In many respects HRMS should be considered as any other detector for LC separations. Emphasis was made that we should consistently reference the technique as HRAMS where "A" stands for accuracy. Other discussion focused on opinions regarding biggest barriers to entry for HRAMS in support of regulated bioanalytical assays, and whether instruments are already ready to address the practical world. Consensus was that triple quads are a hard act to follow but most seem to accept that there is a role for the HRAMS in regulated bioanalysis and this role can be expected to grow with advancement in hardware, software and general acceptance of the technique.

The current status of regulatory harmonization as it pertains to bioanalytical method validation was presented from the perspective of the Global Bioanalysis Consortium progress. Brief discussion was had around the new timelines and understanding that much needs to coordinate with the release of the new FDA BMV draft guidance anticipated later this year.

Further discussion then centered on the tiered approach to bioanalysis topic. This generated the typical spectrum of comments about needing to do what is scientifically appropriate versus needing to do what is necessary to pass regulatory inspection. This can quickly become a heated debate although it remained constructive in this workshop. Several progressive opinions were expressed. The take away conclusion was that much additional discussion within the bioanalytical community and with the regulators is required before a common understanding can evolve into consistent practice.

The attendance alone at this workshop suggested that there is significant number of ASMS members interested in regulated bioanalysis. The workshop concluded with a reminder to send suggestions for next year's workshop agenda and format to Steve Lowes at steve.lowes@quintiles.com or to Fabio Garofolo at fgarofolo@algopharm.com