Adaptation and Impact

Adaptation and Impact. These two words represent key concepts that the Global Bioanalysis Consortium (GBC) has embodied during the past two years. As the GBC's message of harmonized science-based bioanalytical guidelines has spread and become accepted, the GBC Steering Committee and Harmonization Teams have recognized that the environment in which we work continues to change.

Recent presentations by US, EU, Canadian, Japanese, Brazilian and Chinese regulatory authorities have noted that the message for harmonized practices has been heard and is being taken into account as each revises or writes its regulations. It was gratifying to see that the work of the GBC is having Impact.

While the Steering committee has been promoting the harmonization message, 20 Harmonization Teams have been diligently working to develop specific science-based recommendations that cover all aspects of bioanalysis using nearly any technology (LC-MS/MS, ligand-binding, AMS, ICP-MS, etc.). Last week the Steering Committee and Harmonization Team leaders met and reviewed the progress made to date in generating recommendations. In addition to the well-thought out and scientific recommendations presented, the in-depth review also clearly demonstrated the commitment and impact that collaborating scientists from around the globe can have when working together. The Teams left the meeting with clear expectations on what is needed to complete their recommendations and release them in June to the global bioanalytical scientific, quality assurance and regulatory communities.

After a period of open global review, the GBC plan had been to have a conference in September where the bioanalytical scientific, quality assurance and regulatory communities could discuss the recommendations and generally agree on them. However, the US FDA has indicated that a draft revision of its Bioanalytical Method Validation Guidance would be released for comment this summer and that a joint FDA-AAPS Crystal City Workshop would be held on the revisions has caused the GBC to reconsider its plans and adapt to the new reality. The GBC Steering Committee and Harmonization Team Leaders recognize that their efforts to date must be released, debated and finalized in time for them to be used and have impact in responding to the revised FDA Guidance. To achieve that, the Harmonization teams have been asked to ensure their efforts deliver workable recommendations by June, a clear agreement that regional meetings need to whenever possible leverage more in-depth discussions on the HT recommendations, and the Steering Committee has evaluated its options with regard to the planned meeting in The Netherlands.

Many factors went into the assessment on the place and timing of a GBC global meeting, including timing relative to the revised guidance, timing relative to other regional meetings, travel costs for participants for both the Crystal City meeting and GBC conference, and the need for the Harmonization Team recommendations to be included in the discussions. After deliberations, our plan has changed to having the GBC conference in the Washington DC area the two days prior to the FDA-AAPS Crystal City Conference. Because there is not now, nor expected to be any warning on the release of the FDA's draft revised guidance, planning the dates for these two meetings by their respective organizations cannot be made. However, the GBC is committed to ensuring the global bioanalytical community can complete its deliberations in time to influence the FDA and will as quickly as possible after the Guidance is released announce the dates and location of the GBC meeting.

We recognize that these changes will make it difficult for some to attend, but by minimizing the travel costs, we feel the greatest number of scientists will be able to meet in consideration of the HT recommendations. For those not able to attend, we hope that the regional meetings provide an opportunity to debate the recommendations such that the regional representatives may carry your message to the global conference.

In closing, we wish to assure the community that it is not our intent to use the GBC conference as a platform for discussing the FDA revised Guidance, but to maintain a focus on the science-based recommendations that can be agreed upon as a global platform for bioanalysis, and thereby use that consensus to carry the message into the Crystal City meeting.

Sincerely,

The Global Bioanalysis Steering Committee

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