GLOBAL BIOANALYSIS CONSORTIUM

Update on the GBC activities

Michaela Golob on behalf of GBC
at 5rd EBF Open Symposium
November 16th 2012 - Barcelona - Spain
Mission Statement

Create an all inclusive **Global Bioanalysis Consortium** (GBC) consisting of represented scientific associations with world wide influence to merge existing or emerging bioanalytical guidance to create one, **unified consensus document** that can be presented to the regulatory bodies/health authorities in various countries.
GBC Organisation overview

GBC SC

Scientific Leadership Team (GBC-SLT)

A:
Harmonization teams focusing on topics which apply for both chromatography based assays and Ligand Binding Assays
(All molecules)

S:
Harmonization teams focusing on topics which apply for Chromatography based assays
(Small molecules)

L:
Harmonization teams focusing on topics which apply for Ligand Binding Assays
(Large molecules)
Harmonization Teams

All Topics Common to all molecules

- A1 Scope and regulations
- A3 Method Transfer, partial/cross validations
- A5 Sample Management
- A7 Repeat analysis and ISR
- A9 Analytical Instrument Qualification
- A11 Biomarkers

A2 Tiered approaches for method validation

- A4 Reference standards and reagents
- A6 Stability
- A8 Documentation
- A10 New Frontiers

L1 Large molecule specific run acceptance

- L2 Large molecule specific assay operation
- L3 Assay formats
- L4 Reagents and their Stability
- L5 Automation practices in LM bioanalysis
- L6 Immunogenicity effect on Pk

L Large Molecule

- S1 Small molecule specific run acceptance
- S2 Small molecule specific assay operation
- S3 Chromatographic Run Quality Assessment

S Small Molecule (Chromatographic Assays)

Global Bioanalysis Consortium
On harmonization of bioanalytical guidance
### SC Sponsorship of Harmonization Teams

<table>
<thead>
<tr>
<th>Team Leaders</th>
<th>SC Sponsor</th>
<th>Team Leaders</th>
<th>SC Sponsor</th>
</tr>
</thead>
</table>
| A1: Surendra Bansal | Philip Timmerman  
EBF, Europe | L1: Marian Kelley  
EBF, Europe | Michaela Golob  
EBF, Europe |
| A2: Steve Lowes | Daniel Tang  
BBDS & SBDS, CBF, Asia Pacific | L2: Lauren Stevenson  
CVC, N America | Fabio Garofolo  
CVC, N America |
| A4: Joseph Bower | Shinobu Kudoh  
JBF, Asia Pacific | L3: Sherri Dudal  
CVC, N America | Binodh DeSilva  
AAPS, N America |
| A6: Nico van den Merbel | | L4: Lindsay King | |
| A11: Russ Weiner | | L5: Scott Davis | |
| | | L6: Jeff Sailstad | |
| A3: Ray Briggs | Peter van Amsterdam  
EBF, Europe | A9: Chad Briscoe  
ACBio, L America | Rafael Barrientos  
ACBio, L America |
| A5: Mike Redrup | Shrinivas Savale  
APA-India, Asia Pacific | A10: Bob Bethem/Chad Ray | Mark Arnold  
AAPS, N America |
| A7: Eric Fluhler | | S1: Douglas Fast | |
| A8: Tom Verhaeghe | | S2: Eric Woolf | |
| | | S3: Stuart McDougall | |
Original GBC plan

Start up phase

HT- L identification

HT identification

HT working on content working close with SLT

SLT f-2-f Consolidation and joint discussion of all topics in preparation of Global Meeting

Global Meeting
3-day Conference in Noordwijk-Amsterdam (NL) in week of Sept. 24, 2012

Identified regional meetings
- Invite 4-5 HT to present the progress of their teams and to share.
- Present high level progress on other topics and Get input

Other regional meetings
FDA plan/communication to release draft of updated Guidance in summer. As follow up, AAPS/FDA will organize a 5\textsuperscript{th} Crystal City meeting (CC-V) in Washington DC area within 90 days of draft Guidance release.

Impact on GBC global meeting:
- CC-V and GBC global meeting involve the same audience separated potentially by only few weeks or months.
- Travel restrictions in industry will limit delegates to travel to two similar meetings in 2 different regions.
- Attendance to CC-V may be prioritized by industry over GBC global meeting.
- By connecting the GBC global meeting in time and place, GBC and delegates can participate in both meetings:
  - Provide consolidated feedback to and get input from the global community on draft GBC recommendations (= original intent of GBC global meeting)
  - At the CC-V meeting, share this consolidated GBC as input into the FDA draft Guidance (= impact as per GBC Mission & Vision)
Changed way forward

Continued slide iterations, based on HT team meetings and input form the regions

**HT-L/SC F2F**
San Antonio (Tx)
Consolidation and joint discussion of all topics in preparation of Global Meeting

**draft slides**
Consolidation of slides from all HTs from SA (Tx) on GBC website

‘**Recommendation Slides’**
on GBC website for all to read, in preparation of Global Meeting

**GBC Global Meeting**

**Crystal City V**
max. 90 days after release of draft FDA Guidance.

**Intensify** consolidation and consultation from teams and from regional meetings, building on slides presented at HT-L in San Antonio

2012

March

April

e.o. June

**Global Bioanalysis Consortium**
On harmonization of bioanalytical guidance
Welcome to the website of the Global Bioanalysis Consortium (GBC)

Our Mission:
The Global Bioanalysis Consortium (GBC) is a world wide organisation consisting of representatives of scientific associations with the mission to harmonize and merge existing or emerging bioanalytical guidances to create one, unified consensus document that can be presented to the regulatory bodies/health authorities in various countries.

Our Goals and Objectives:
To bring together stakeholders from the pharmaceutical industry, contract research organizations and academia to share current understanding of bioanalysis guidelines, identify differences in these guidelines or differences in the interpretation or application thereof to routine regulated bioanalysis. To come forward with recommendations to Health Authorities and regulatory bodies worldwide on globally agreed best practices for Bioanalytical Method Validation (BMV) and application of such methods/technologies to the analysis of drugs of all molecular sizes in support of clinical and nonclinical studies.

Disclaimer

The views expressed on this website are those of the Global Bioanalysis Consortium and do not necessarily reflect the representative affiliation or company's position on the subject.
A discussion group was formed on LinkedIn, to enable bioanalytical scientists where people - world wide – to interact with the GBC Harmonisation teams. Membership is open to all bioanalysts, regulators and QA specialists.

Link on the GBC webpage:
Webinars

Limited number of Webinars are planned to present and interactively discuss Harmonisation Team Recommendations following template of EBF post conference event later today.

Webinars will be announced via GBC web-page as well as the EBF newsletter.
Publication strategy

GBC is closed to publication, awaiting final input of EBF post conference event and webinars.

In view of uncertainty of date of GBC conference, GBC is preparing publication asap. Discussion and fine tuning ongoing in GBC-SC, in consultation with HT-L.
Updates from GBC-Harmonisation Teams

Post conference event: 14:00 – 16:00

The aim of this post-conference event is to present Harmonisation Teams recommendations and to gather input from the community, especially on topics that are still under discussion.