



GLOBAL BIOANALYSIS CONSORTIUM

Update on the GBC activities

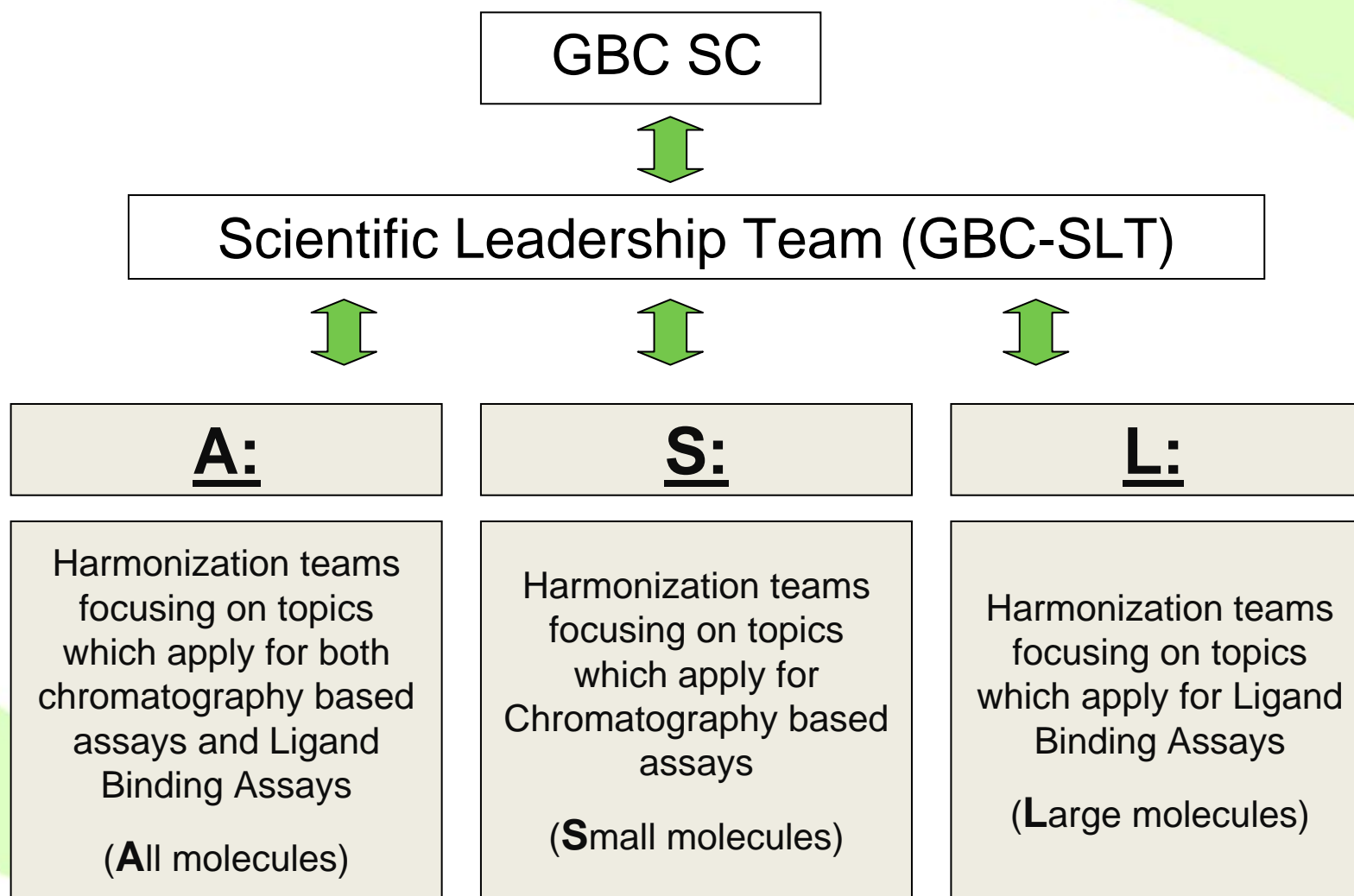
Michaela Golob on behalf of GBC
at 5rd EBF Open Symposium
November 16th 2012 - Barcelona - Spain



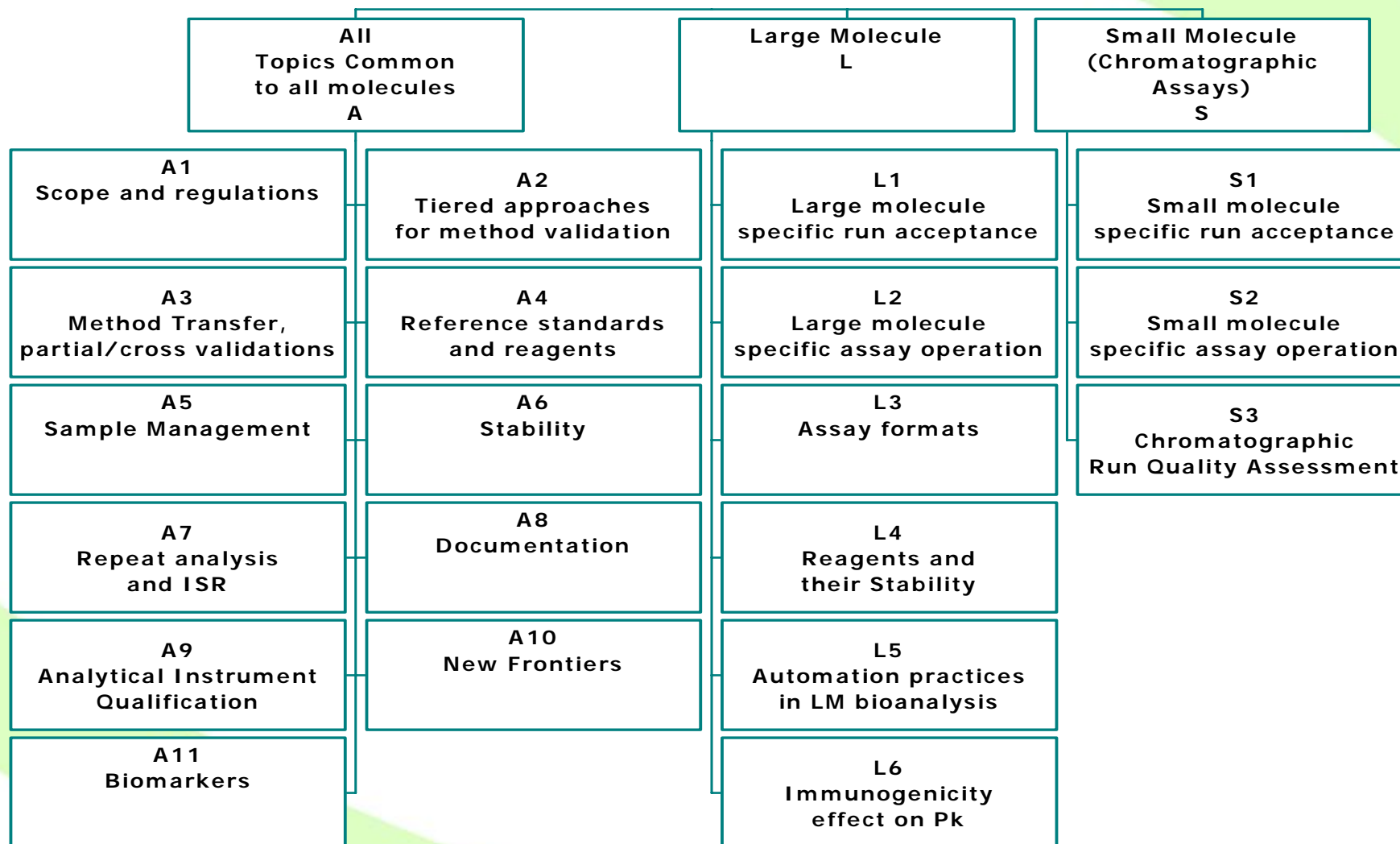
Mission Statement

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



Harmonization Teams

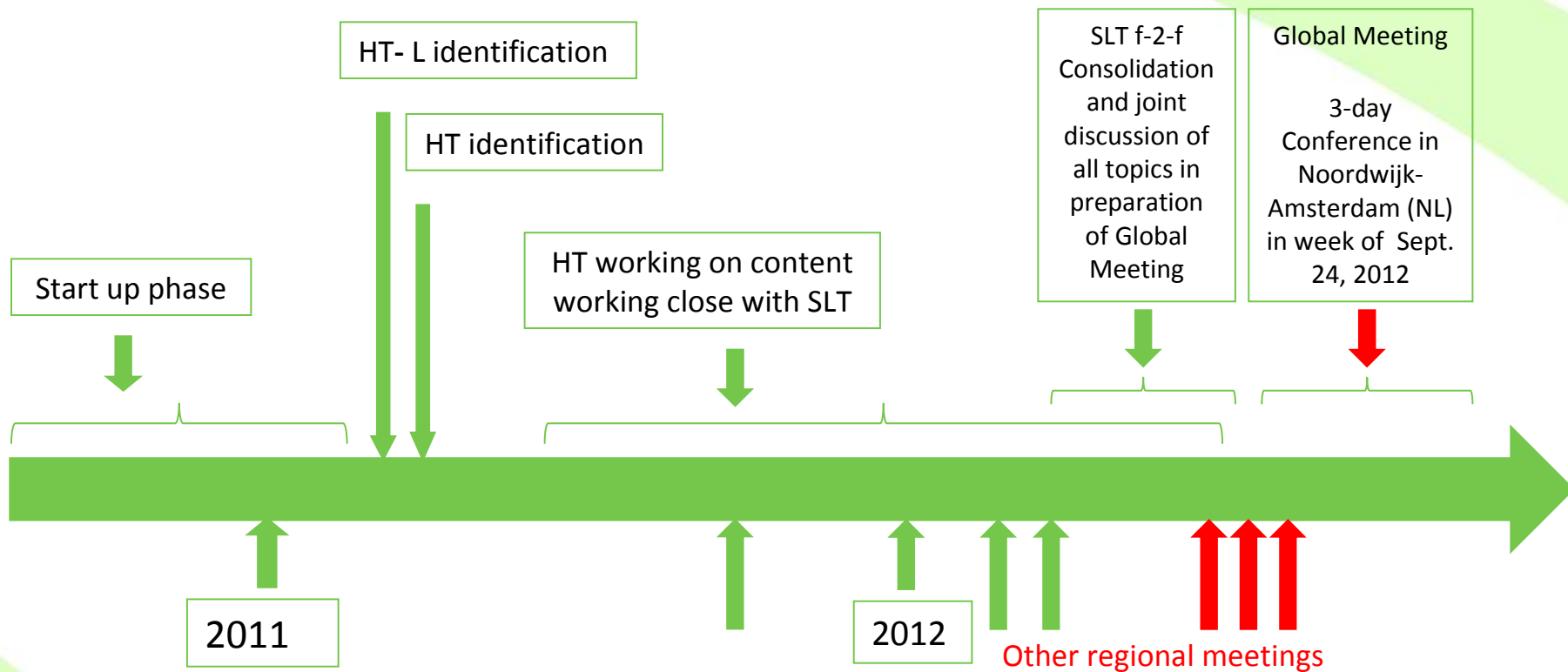


SC Sponsorship of Harmonization Teams

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

Original GBC plan

↓ : Done
↓ : Planned



- 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



What triggered the change?

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 As follow up, AAPS/FDA will organize a 5th Crystal City meeting (CC-V) in Washington DC area within 90 days of draft Guidance release.

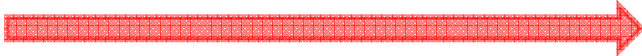
Impact on GBC global meeting:

- 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

 : Done
 : Planned

Continued slide iterations, based on HT team meetings and input from 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.

March

April

e.o. June

exact date unknown today

2012



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

↑
APAC
CPSA
e.o.
April

↑
LA
ACBio
mid
May

↑
NA
NBC
mid
May

↑
EU
EBF
mid
June

↑
US
LoL
e.o.
July

↑
APAC
JBF
mid
Aug.

↑
AAPS
AM
Mid
Oct.


↑
EU
EBF
mid
Nov.

Global Bioanalysis Consortium

http://www.globalbioanalysisconsortium.org/index/

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Global Bioanalysis Consortium

On harmonization of bioanalytical guidance

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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.

Go to "http://www.globalbioanalysisconsortium.org/Harmonizationteams/"

LinkedIn Discussion group

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:](#)

Join the discussions on bioanalytical method validation with fellow scientists and GBC Harmonization Team members and leads!

The Global Bioanalysis Consortium has created a group in the LinkedIn environment to enable the bioanalytical scientists - world wide - to interact with the GBC Harmonization Teams.

Membership is open to all bioanalysts, regulators and QA specialists.

To join go to: [GBC - Global Bioanalysis Consortium | LinkedIn](#)

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.