GLOBAL BIOANALYSIS CONSORTIUM

Regulated Bioanalysis - A Proposed Global Harmonization Process

Harmonization team tasks, scope, interdependencies and deliverable

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: 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.

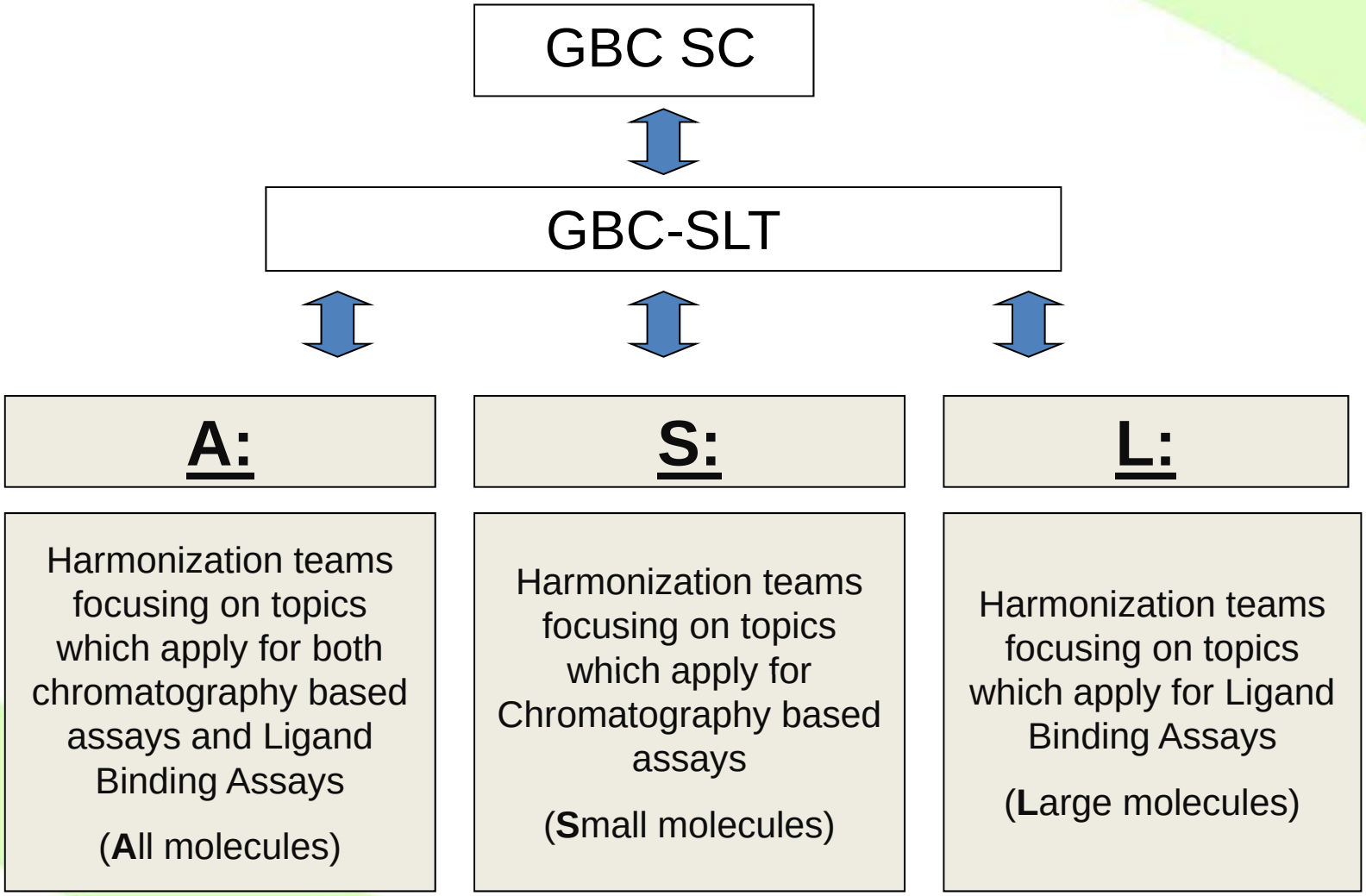
GBC: Goals and Objectives

- To invite relevant stakeholders, from industry, academia, Health Authorities and regulatory bodies, to jointly discuss the GBC recommendations at a **global conference(s)** in order to achieve globally agreed guidelines on bioanalysis.

- Going forward, to serve as a **pivot point** on the continued harmonized interpretation and/or updates of globally agreed guidelines.

Which Harmonization Teams?

Overview



Objective of the HT Lead

Objective of HT-L

- Remove concepts of company or region from thinking - you're leading a global effort
- Facilitate discussion, don't push personal agenda

Teams are to develop science-based best practices

- Recognize that consensus may not be possible. People with different views will spark vigorous discussion.
- Prevent bullying by the loudest voice.
- Recognize that some governments may have regulations that are outdated or inconsistent with a science-based approach. Be prepared to defend proposals that conflict with existing regulations.

80:20 Rule

- Not all items within the Scope of the Team need to be redone, in fact 80% may already have industry-regulatory consensus

Role of Team leader

Select team members

- from application list
- from different regions
- look for thought leaders; people who have published, spoken or previously been involved in topic at workshops

Evaluate Scope with team

- Is everything presented appropriate to team?
- Is anything missing?
- Ensure there is clarity within team on Scope
- Finalize Scope and meet with GBC EC and other team leaders to review and evaluate overlap or points of contact for resolution of individual team

Inform GBC SC and other Team leads of progress

- seek counsel and input as needed

Team activities 1/3

Keep minutes

- Utilize a team member to record minutes
- Distribute and permit team to comment
- Ensure agreement prior to finalizing

Compile regional information on regulations and practices related to the Teams scope

- Understand current (global) regulatory environment on assigned topic
- Consider both Existing guidelines and anticipated or emerging guidelines
- Use GBC website as starting point
- Dissect out the regulations related to your topic (see also next slide)
  - Understand and discuss areas of difference in interpretation – provide clarification
  - Acknowledge consensus (probably 80%)
  - Focus on missing, unclear of conflicting guidelines (maybe 20%)
- Share regulations with other Team leaders/Teams

Team activities 2/3

Based on commonality, filter scope list to those that are fully agreed to, generally agreed to, and those with no agreement.

- For those that are agreed to, write science-based language as proposed position
- For those that are generally agreed to, discuss differences and develop science-based position, write science-based language as proposed position
- For those that are not generally agreed to, prioritize the list to enable discussion on those with the greatest impact to the bioanalytical community
  - Have internal team discussions and where possible, develop recommendations
  - Where no consensus is achieved, provide arguments on both sides
  - Utilize GBC EC and other team leaders for input
- Team members should reach back to regional organizations for input
  - Query regional organization membership on positions on a topic(s), use surveys if time permits. Coordinate across Teams, regional memberships will lose interest if frequently bombarded with requests.

Team activities 3/3

Proposals

- Write proposals in a clear and concise manner that are suitable for publication, include references to existing literature and regulations
  - As noted above, where proposal conflicts with existing regulations, additional details and discussion may be needed
- Create slide deck for communication of proposals that go into greater depth and may contain data
  - This will be foundation of presentation at international meeting
- Where no consensus is achieved, provide arguments on both sides

Proposed logistics of team meetings

HT

- Team members are committed to attend HT-meetings (TCs).
- The team is mindful of time zone challenges, 'difficult hours' rotate equally amongst the team members.
- Frequency at discretion of HT, but sufficient progress needs to be visible

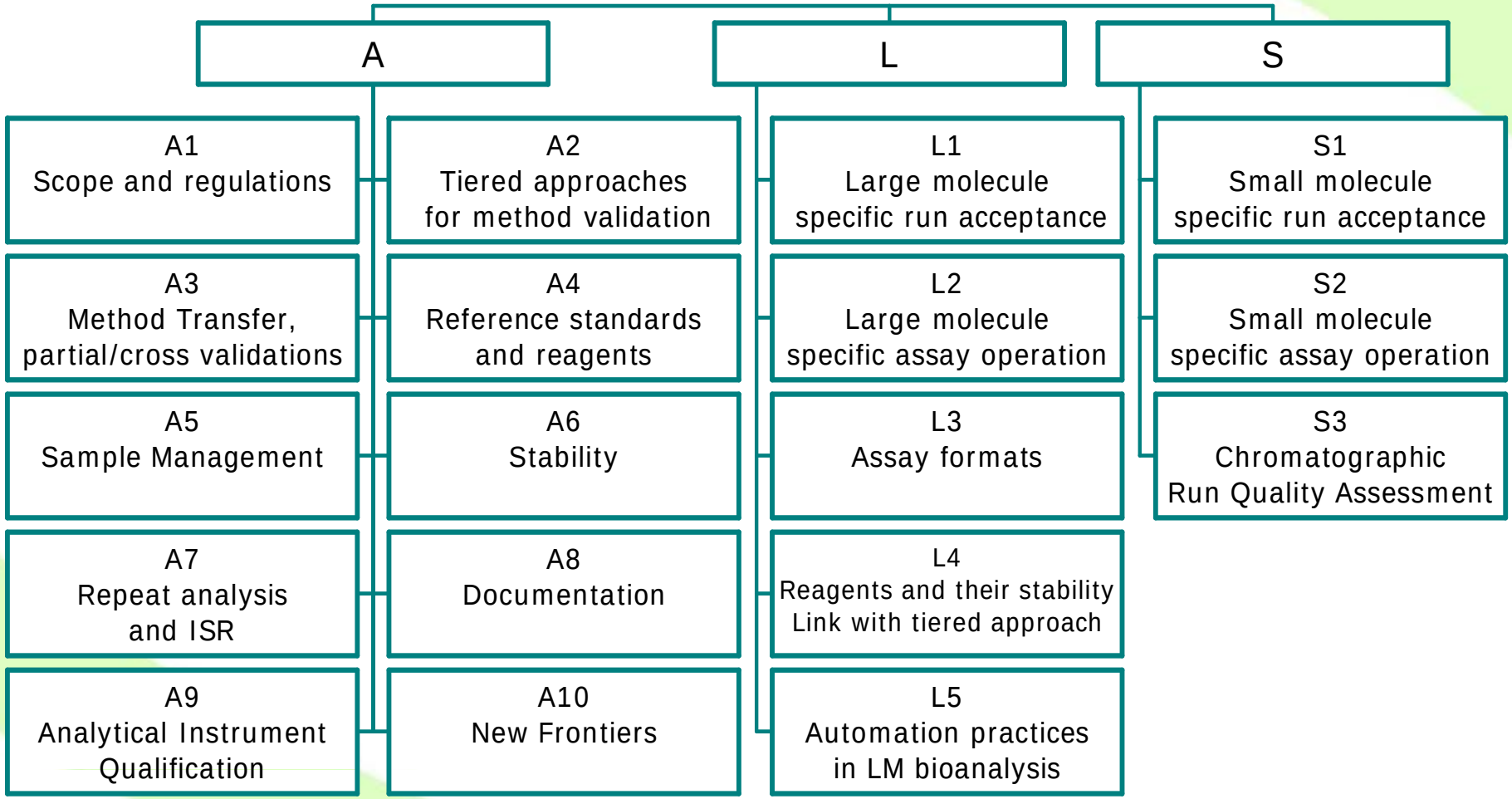
HT interactions within SLT

- Provide FB to SLT at least every 2 months
- Escalate issues, hurdles or potential duplication/conflicts with other teams asap to other HT-L or SC asap

Progress thus far (April 21, 2011)

- Communication regarding the GBC and the mission and scope has been done world wide
- The SC consists of representatives from all major regions of the world (NA, EU, APAC, LA)
- The HT leads have been selected by the SC
- The invitation letter to the HT leads will be sent this week and a teleconference is scheduled for the week after
- The timeline for the selection of HT members will be done shortly

Which Harmonization Teams ?



A1: Scope and regulations (EXAMPLE)

Team members:

Team lead

- Name – region – e-mail

Other members

- Name – region – e-mail
- Name – region – e-mail
- Name – region – e-mail
- Name – region – e-mail
- Name – region – e-mail
- Name – region – e-mail
- Name – region – e-mail
- Name – region – e-mail

In scope

- Scope and regulations (GxPs) for bioanalytical validation and samples analysis
- Glossary

Interdependencies with other teams – if any

- Scope and regulations (GxPs) for bioanalytical validation and samples analysis
- Glossary

Out of scope

- Scope and regulations (GxPs) for bioanalytical validation and samples analysis
- Glossary

L1: Large molecule specific run acceptance (EXAMPLE)

Team members:

Team lead

- Name - region - email

Other members

- Name – region – e-mail
- Name – region – e-mail
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In scope

- Non Linearity of the standard curves
- Assay range (ELISA vs. MSD)
- Accuracy, precision, total error
- Appropriate calibration curve and QC ranges (during validation and for study specific)
- Selection of regression analysis
- Individual runs and overall run acceptance during validation
- Individual runs acceptance during samples analysis

Interdependencies with other teams – if any

- S1

Out of scope