



# GLOBAL BIOANALYSIS CONSORTIUM

## Regulated Bioanalysis A Proposed Global Harmonization Process

Mark Arnold for the GBC  
CPSA October 2011

# Agenda

Review GBC structure

Harmonization Teams' Activities



**Global Bioanalysis Consortium**

On harmonization of bioanalytical guidance

# Organization Chart

**Steering Committee (GBC-SC)**



**Scientific Leadership Team (GBC-SLT)**



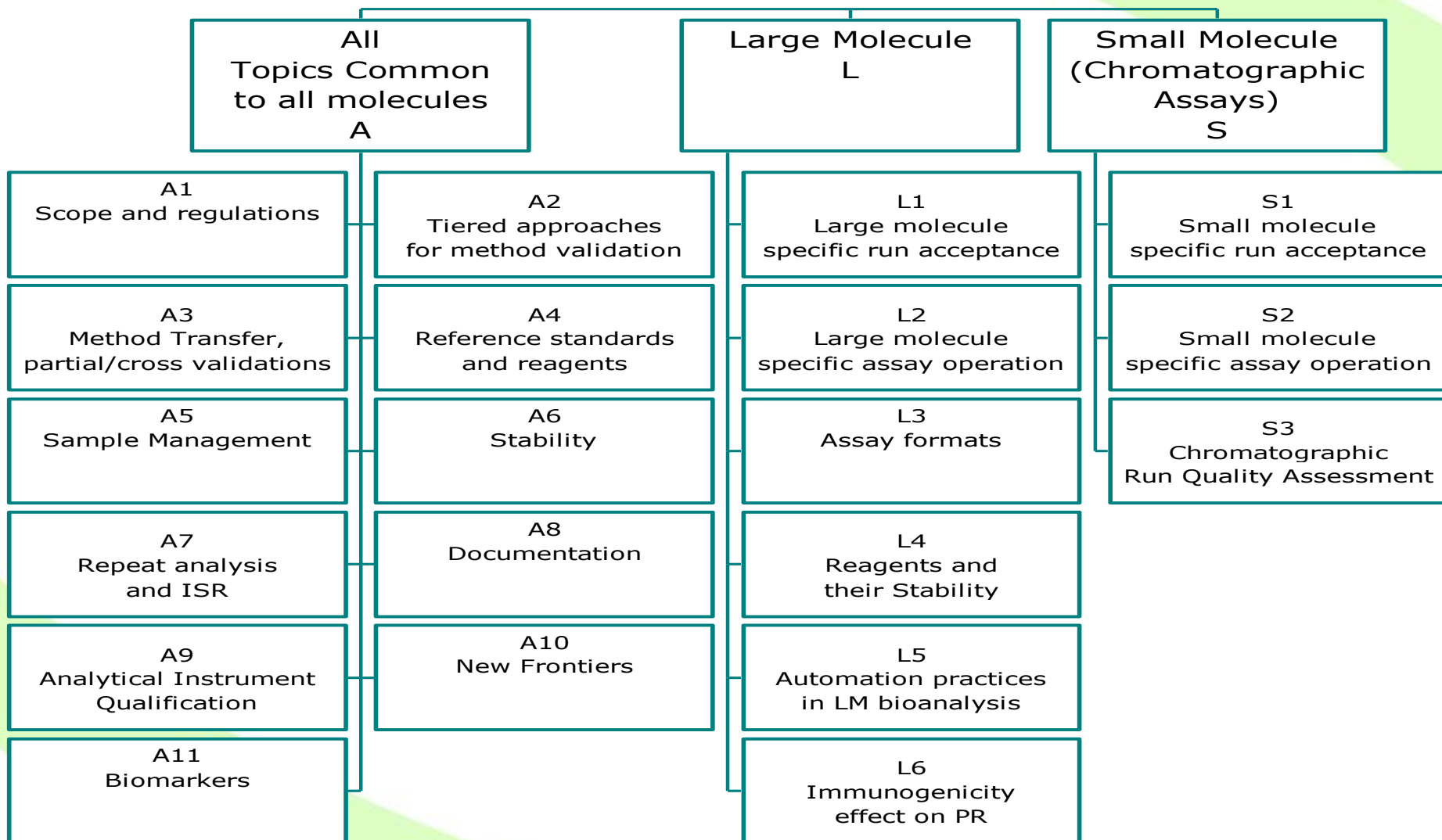
**Harmonization  
Team # 1**

**Harmonization  
Team # 2**



**Harmonization  
Team # 'n'**

# Active Harmonization Teams



# Operating committees: HT-L

**A1: Surendra Bansal**

**A2: Steve Lowes**

**A3: Ray Briggs**

**A4: Joseph Bower**

**A5: Mike Redrup**

**A6: Nico van den Merbel**

**A7: Eric Fluhler**

**A8: Tom Verhaeghe**

**A9: Chad Brisco**

**A10: Bob Bethem**

**A11: Howard Hill**

**L1: Marian Kelley**

**L2: Lauren Stevenson**

**L3: Sherri Dudal**

**L4: Lindsay King**

**L5: Han Gunn**

**L6: Jeff Sailstadt**

**S1: Douglas Fast**

**S2: Eric Woolf**

**S3: Stuart McDougall**

Team Leaders

A1: Surendra Bansal  
A2: Steve Lowes  
A4: Joseph Bower  
A6: Nico van den Merbel  
A11: Howard Hill

SC Sponsor

Philip Timmerman  
Daniel Tang  
Shinobu Kudoh

Team Leaders

L1: Marian Kelley  
L2: Lauren Stevenson  
L3: Sherri Dudal  
L4: Lindsay King  
L5: Han Gunn  
L6: Jeff Sailstad

SC Sponsor

Michaela Golub  
Fabio Garofolo  
Binodh DeSilva

A3: Ray Briggs  
A5: Mike Redrup  
A7: Eric Fluhler  
A8: Tom Verhaeghe

Peter van Amsterdam  
Shrinivas Savale

A9: Chad Brisco  
A10: Bob Bethem  
S1: Douglas Fast  
S2: Eric Woolf  
S3: Stuart McDougall

Rafael Barrientos  
Mark Arnold

# Harmonization Team Objectives

## HT Leaders Objectives

- Remove concepts of company or region from your thinking - you're leading a global effort.
- Facilitate discussion, don't push your 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. Allow and stimulate less extrovert people to share their opinion and experience
- Recognize that some governments /regions may have regulations that are outdated or inconsistent with a science-based approach.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 e.g. 80% may already have industry-regulatory consensus

# HT activities - 1 of 3

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

- Share regulations with other Team
- A lot of prework has been done by various SC members as part of their presentations at international conferences – please check the GBC website.

## **Evaluate scope list to those that are fully**

- agreed to
- generally agreed to
- those with no agreement.

**The GBC SC believes that for many (if not all) topics, 80% of the items will be generally agreed to with only 20% in the latter two categories.**



# HT activities - 2 of 3

- 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.

# HT activities – 3 of 3

## Proposals and outcome

- 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
  - This will be foundation of publications in international journals
  - Note: timing of publications in relation to international meeting tbd by SC
- Where no consensus is achieved, provide arguments on both sides

# S2: Small molecule specific assay operation

## Team members:

### Team lead

- Eric Woolf – NA – [woolf@merck.com](mailto:woolf@merck.com)

### Other members

- Abhishek Sharma– AP – [abhishek.sharma@advinus.com](mailto:abhishek.sharma@advinus.com)
- Barbara Duncan – NA – [barbara.a.duncan@pfizer.com](mailto:barbara.a.duncan@pfizer.com)
- Berthold Lausecker– EU – [berthold.lausecker@crs-group.de](mailto:berthold.lausecker@crs-group.de)
- Gabriel Marcelín – LA – [gabmarcelin@pharmometrica.com.mx](mailto:gabmarcelin@pharmometrica.com.mx)
- Kazutaka Togashi– AP – [k.togashi@scas.co.jp](mailto:k.togashi@scas.co.jp)
- Miguel Vago- LA - [mvago@raffo.com.ar](mailto:mvago@raffo.com.ar)
- Pat Bennett– NA – [patrick.bennett@thermofisher.com](mailto:patrick.bennett@thermofisher.com)
- Ravi Kumar Trivedi – AP – [ravi.trivedi@syngeneintl.com](mailto:ravi.trivedi@syngeneintl.com)
- Roger Hayes– AP – [roger.hayes@cetero.com](mailto:roger.hayes@cetero.com)
- Steve White- EU - [Stephen.A.White@gsk.com](mailto:Stephen.A.White@gsk.com)

## Interdependencies with other teams:

Sample reinjection – Team A6 (re: stability)

API Salt / Counter-ion changes – Team A6 (re: stability)

System Equilibration – Team A9 (re: system suitability)

## In scope

- Carryover and contamination
  - methodology to assess
  - acceptance criteria
  - impact of sample analysis sequence
- Sensitivity
  - “One off” std. curve range changes
- Specificity - selectivity
  - impact of co. meds/metabolites
- Matrix Effects
  - assessment methodology
  - effect of hemolyzed/hyperlipidemic plasma
- Recovery
  - assessment methodology & acceptance criteria
- IS evaluation
  - addition methodology
  - response variability assessment & acceptance criteria
- System equilibration
  - use of study samples
- Sample reinjections
- Reporting of failed runs
- Impact of salt form/counter ion changes of analyte
- Preparation of calibrators – organic solvent content

## Out of scope

- stability criteria

# New insights developed at GBC-SC meetings

Desire for increased engagement, input and contribution from the different regions

- The current team dynamics and composition may not sufficiently engage current non contributors in the broader scientific community
- Open discussion

Desire to provide opportunity for regular updates on GBC progress in an open format

- The current process may lead to a significant period of 'radio silence'
- Prevent that all GBC-proposals come as one avalanche at the global meeting, which may be too much to manage if not previewed
- Provide regulators a chance to get better understanding of activities of GBC



# Proposal - How?

Shift GBC Global meeting from Q2 to Q3 2012.

Use appropriate 2011-2012 regional meetings in all 4 regions (best attended and most affordable in each region, >1x region?) to give a flavor of the progress we are making.

- If the regional meeting can accommodate, include a GBC session in those meetings to provide update and allow input
- Invite 4-5 topic HT-L (or a regional representative from those teams) to present the progress of their teams and to share.
- Stimulate HT-SC(s) to present high level progress on other topics, with input from other HT
- Engage with meeting organizers how to optimize GBC visibility during the meeting
- Publish outcome as a rapid communication to ensure all regions connect (GBC website or “Bioanalysis”)
- Inviting organizations to provide travel assistance



# Potential win-win

- Connect GBC better with the regions
  - Reconnection with supporting organizations as our day to day supporters
  - All regions get expanded opportunity to be involved
- Engage and inform a broader scientific community in advance of the global meeting
  - Allow BA community to comment within the comfort zone of their region
  - Allow BA community to comment to their regional organizations
- Provide the opportunity to publish a summary of thinking in advance of the global meeting
  - Allow participants to know what's coming
  - Be more engaged in the global meeting and not be caught by surprise
- Create visibility, recognition and connectivity in regions
  - for HT-L and HT members
  - for SC members
- Create flexibility to present on topics in need of influencing current thinking of regulators or on emerging guidelines

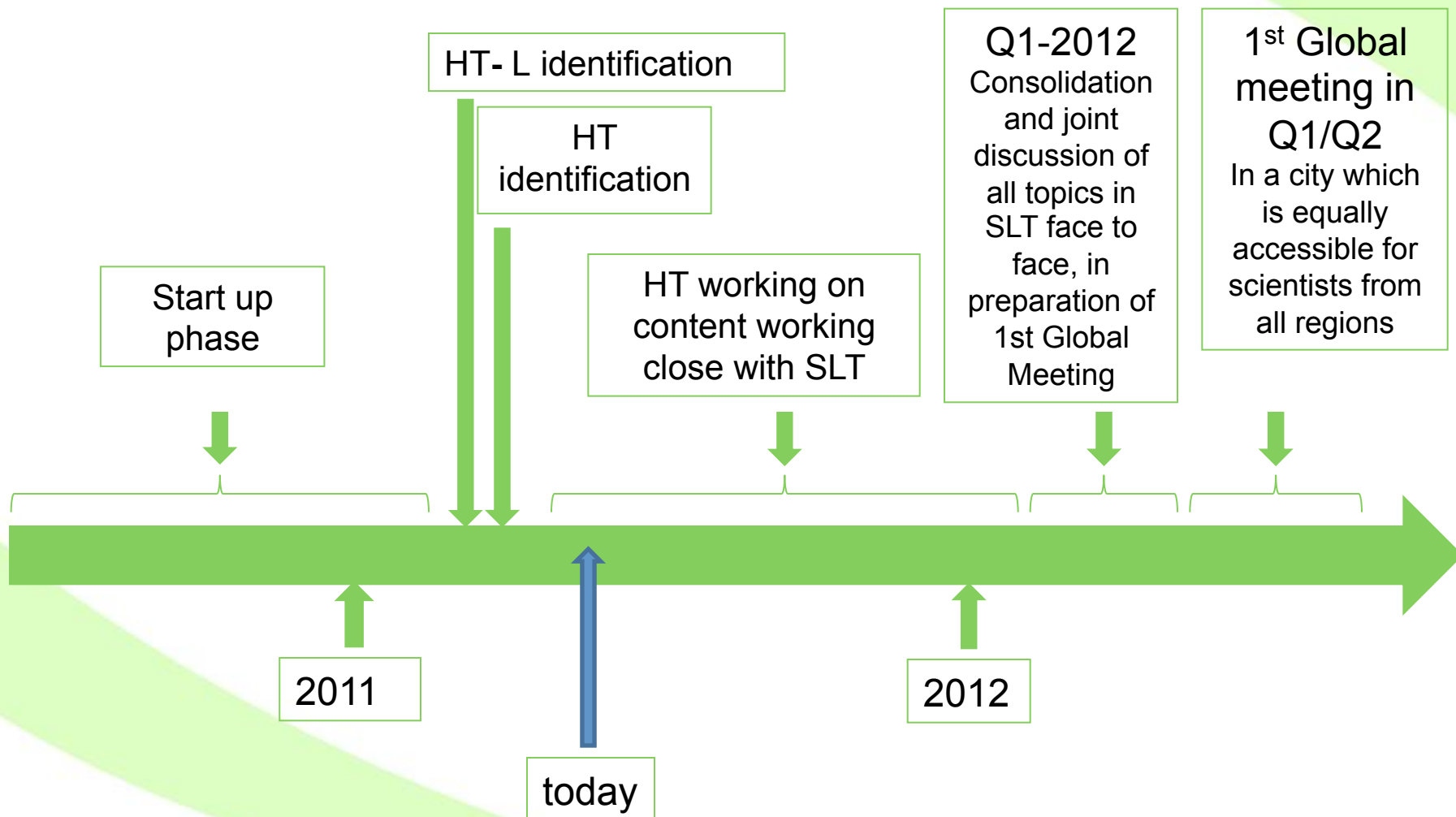
# In practice

## Identified meetings qualifying for inclusion GBC session

- Fit with respect to timing
- Fit with respect to willingness of organizers to include GBC session
- Meetings potentially qualifying – further discussion with meeting organizers needed
  - **NA:**
    - Oct 2011: AAPS Washington USA
    - March 2012: 6th WRIB-CVG – San Antonio - USA
    - May 2012: NBC San Diego USA
    - May 2012: ASMS –Vancouver Canada YES
    - July 2012: Land O'Lakes- Winconsin- USA
    - Sept 2012 - APA- Boston- USA
    - Other regional meetings (e.g., DVDMG)
  - **EU:**
    - Nov 2011: EBF - organizers agree on inclusion of session
    - May/June 2012: EBF Focus meeting - organizers agree on inclusion of session
    - Other regional meetings (e.g., Fabian, FrenchGLP,..)
  - **APAC:**
    - Feb 2012: JBF Japan
    - Feb 2012: APA India
    - **2<sup>nd</sup> APBC-CVG China**
    - Other regional meetings
  - **LA:**
    - ACBio will be planned, targeted in May2012
    - Other regional meetings



# Proposed way forward - OLD





# Proposed way forward - NEW

