GBC and current global situation of BMV guidelines

BMV guideline history

1992 US FDA/AAPS discussed validation

2001 US FDA issued Guidance for Industry (Bioanalytical method validation).

2007 US FDA/AAPS discussed again and issued a white paper
Introduction of ISR

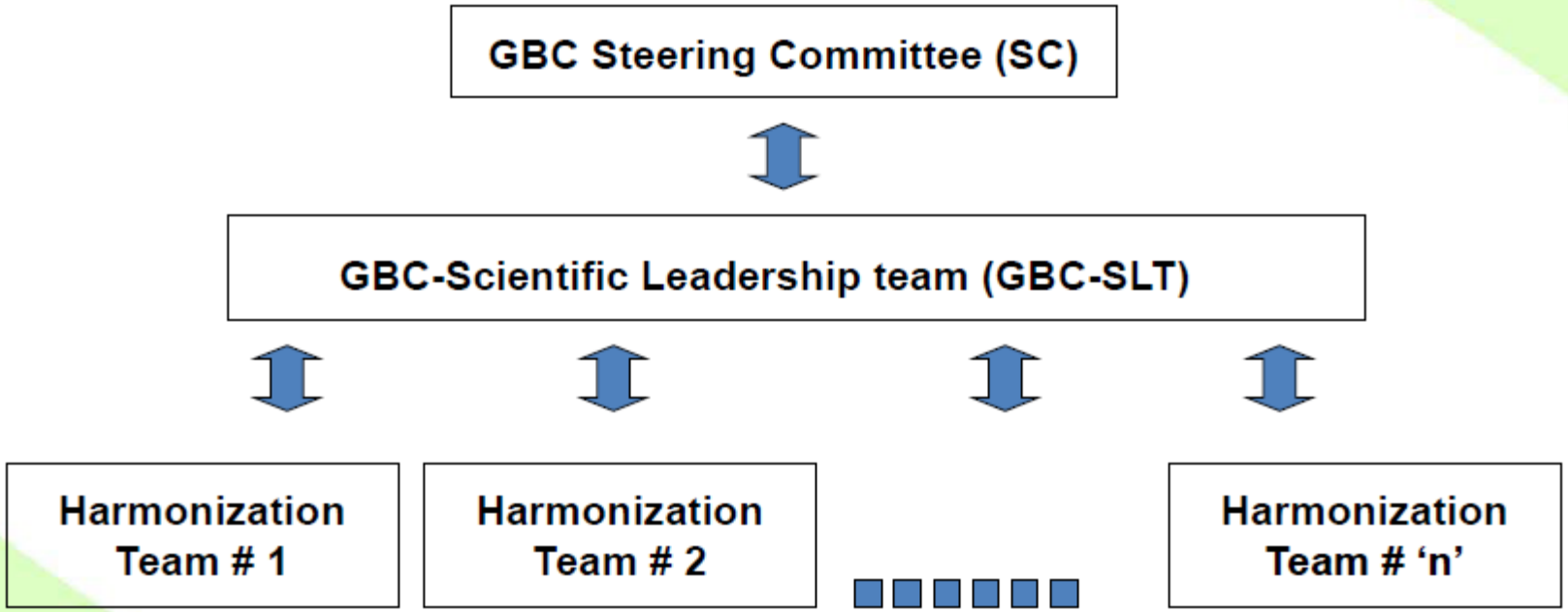
2009 EMA made draft Guideline on Validation of Bioanalytical Methods.

2010 Global Bioanalysis Consortium（GBC）

GBC: introduction

- In April, 2010, consensus to start in CVG (Canadian group) workshop
- Region : global (not only US/EU but also Latin America and Asia Pacific)
- Type of studies : Small/large molecule, nonclinical/clinical
- To create one, unified consensus document that can be presented to the regulatory bodies/health authorities in various countries
- Participants: volunteers from industries

GBC: how to organize?



Details on next slides

Operating committees: Summary

GBC Steering Committee (GBC-SC)

- Participation: based on balanced representation from all (4) regions
- Role:
  - Build/coordinating GBC as organization (2010: together with founding members)
  - Facilitate and coordinate
  - represent of GBC to outside world

GBC Scientific Leadership Team (GBC-SLT)

- Participation: based on scientific expertise and anticipated contribution
- Role:
  - Coordinate HT interactions and provide input as needed
  - Provide scientific leadership to facilitate progress
  - Ensure HTs work in concert and don't derail

Harmonization teams (HT)

- Participation: based on scientific expertise and contribution
- Role:
  - Prepare proposals, blending (emerging) science, existing and emerging guidelines, on a harmonized way forward on the specific harmonization topic assigned to the team
  - Propose draft harmonized proposals to GBC-SLT
  - Present harmonized proposal at the GBC conference

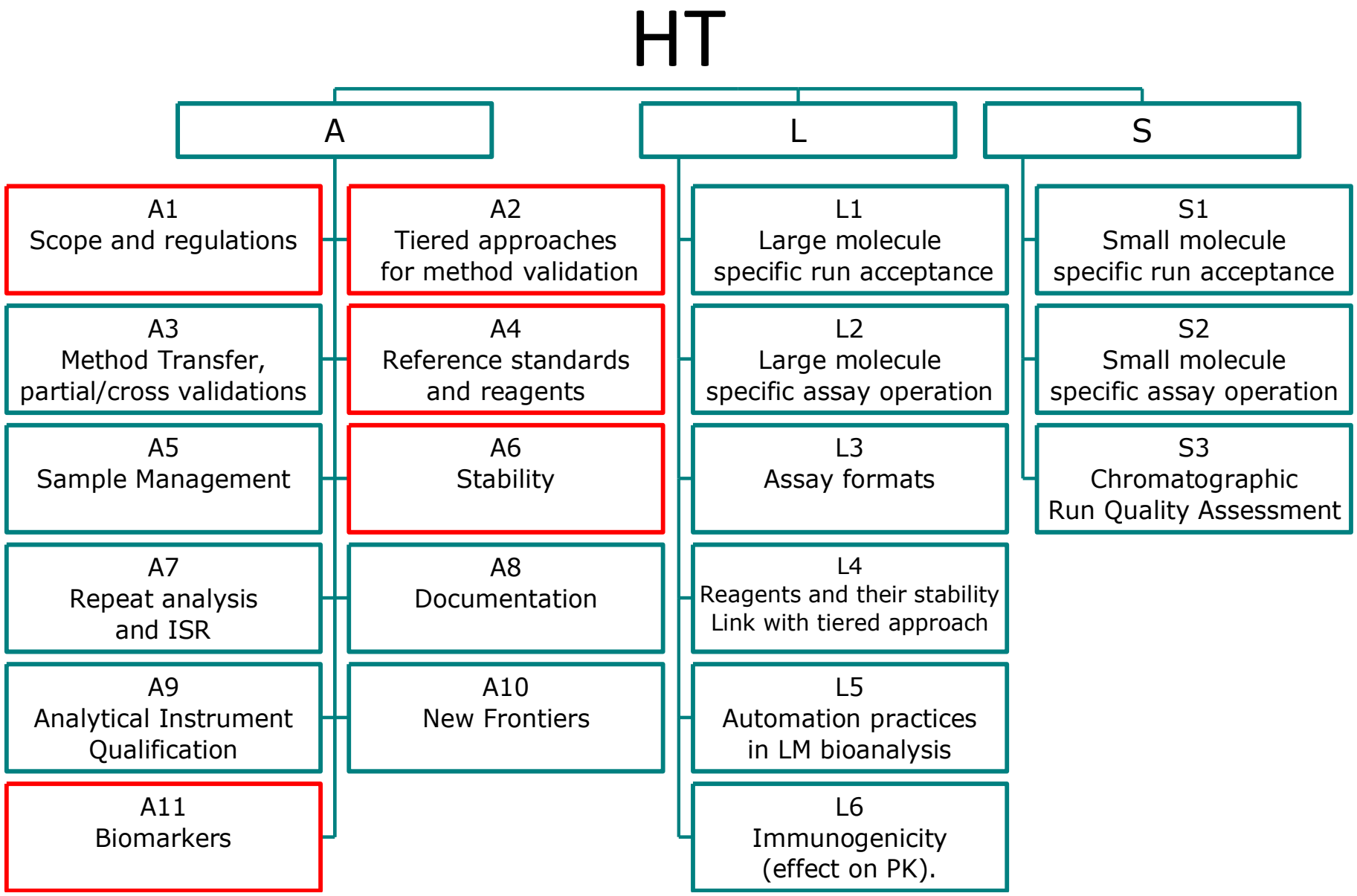
SC member list

North America
(US + Canada)
- Binodh DeSilva (AAPS, US)
- Mark Arnold (AAPS , US)
- Fabio Garofolo (CVG , Canada)

Latin America
(South America + Mexico)
- Rafael Barrientos (AcBio, Brazil)

Asia Pacific
(Asia + Pacific area)
- Tatsuo Kurokawa (JBF, Japan)
- Daniel Tang (SBDG&BBDG, China)
- Shrinivas Savale (APA-India, India)

Europe
(Europe + Africa/Middle East)
- Peter van Amsterdam (EBF, EU)
- Philip Timmerman (EBF, EU)
- Michaela Golob (EBF, EU)


HT
A
L
S
A1
Scope and regulations
A2
Tiered approaches
for method validation
A3
Method Transfer,
partial/cross validations
A4
Reference standards
and reagents
A5
Sample Management
A6
Stability
A7
Repeat analysis
and ISR
A8
Documentation
A9
Analytical Instrument
Qualification
A10
New Frontiers
A11
Biomarkers
L1
Large molecule
specific run acceptance
L2
Large molecule
specific assay operation
L3
Assay formats
L4
Reagents and their stability
Link with tiered approach
L5
Automation practices
in LM bioanalysis
L6
Immunogenicity
(effect on PK).
S1
Small molecule
specific run acceptance
S2
Small molecule
specific assay operation
S3
Chromatographic
Run Quality Assessment

Interaction between SC and HT-L

SC sponsors HTs and interact with HT-Ls.

SC	HT-L
Tatsuo/Philip/Daniel	A1, A2, A4, A6, A11
Peter/Shrinivas	A3, A7, A8
Mark/Rafael	A9, A10, S1, S2, S3
Michaela/Binodh/Fabio	L1 to L6

All SC and all HT-L forms SLT (Scientific Leadership Team).

GBC activities

2010 Apr	Consensus to start
	Start of SC invitation (APAC etc)
	HT-L/member application (global)
2011 Apr	HT-L selection by SC
	Start of HT member selection by HT-L
2011 Jun	Scientific discussion started in some HTs

Back-up

GBC HT-L
All molecules

• A1	Scope and Regulations	Surendra Bansal (FM)	(Hofmann-La Roche)
• A2	Tiered approaches for method validation	Steve Lowes (FM)	(Advion)
• A3	Method transfer, partial/cross validations	Ray Briggs	(Analytical Biosystem)
• A4	Reference standards and reagents	Joseph Bower	(Covance)
• A5	Sample Management	Mike Redrup	(Quotient Bioresearch)
• A6	Stability	Nico van de Merbel	(PRA International)
• A7	Repeat analysis and ISR	Eric Fluhler	(Pfizer)
• A8	Documentation	Tom Verhaeghe	(J&J)
• A9	Analytical instrument qualification	Chad Briscoe	(PRA International)
• A10	New Frontiers	Robert Benthem	(AstraZeneca)
• A11	Biomarkers	Howard Hill	(Huntingdon Life Sciences)
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GBC HT-L
Large/small molecules

- **Large Molecules / Ligand Binding**
- L1 Large molecule specific run acceptance — Marian Kelley (MKelley Consulting)
- L2 Large molecule specific assay operation — Lauren Stevenson (Biogen Idec)
- L3 Assay formats — Sherri Dudal (Novartis)
- L4 Reagents and their stability — Lindsay King (Pfizer)
- L5 Automation practices in LM bioanalysis — Han Gunn (Amgen)
- L6 Immunogenicity - Effect on PK — Jeff Sailstad (Sailstad and Associates Inc.)
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- **Small Molecules / Chromatographic Assays**
- S1 Small molecule specific run acceptance — Doug Fast (FM) (Covance)
- S2 Small molecule specific assay operation — Eric Woolf (FM) (Merck)
- S3 Chromatographic run quality assessment — Stuart McDougall (Covance)