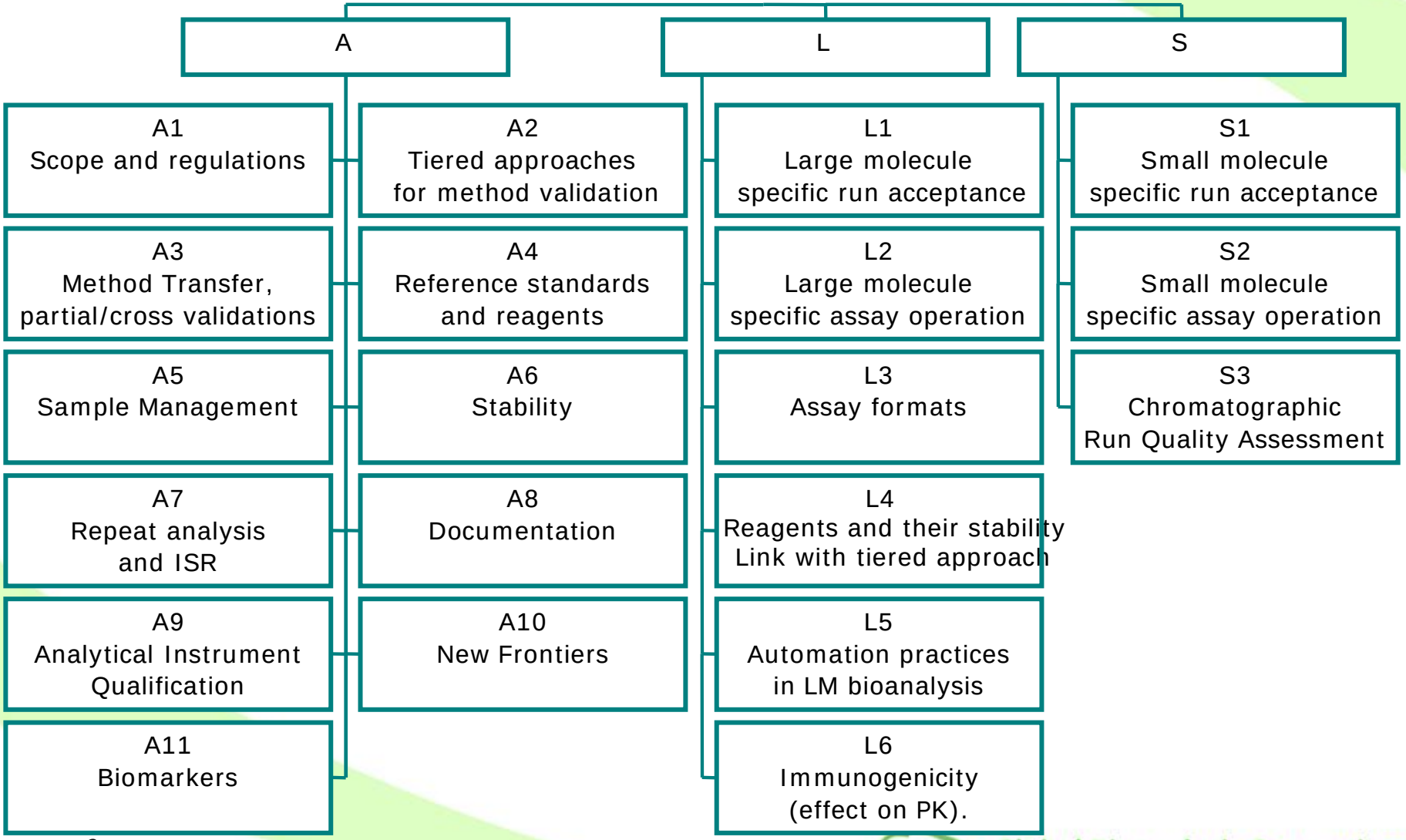
GLOBAL BIOANALYSIS CONSORTIUM

Brief update

Shrinivas Savale for GBC
at APA India 2012
Feb 2012, Ahmedabad, India

Global Bioanalysis Consortium
On harmonization of bioanalytical guidance

Which Harmonization Teams ?



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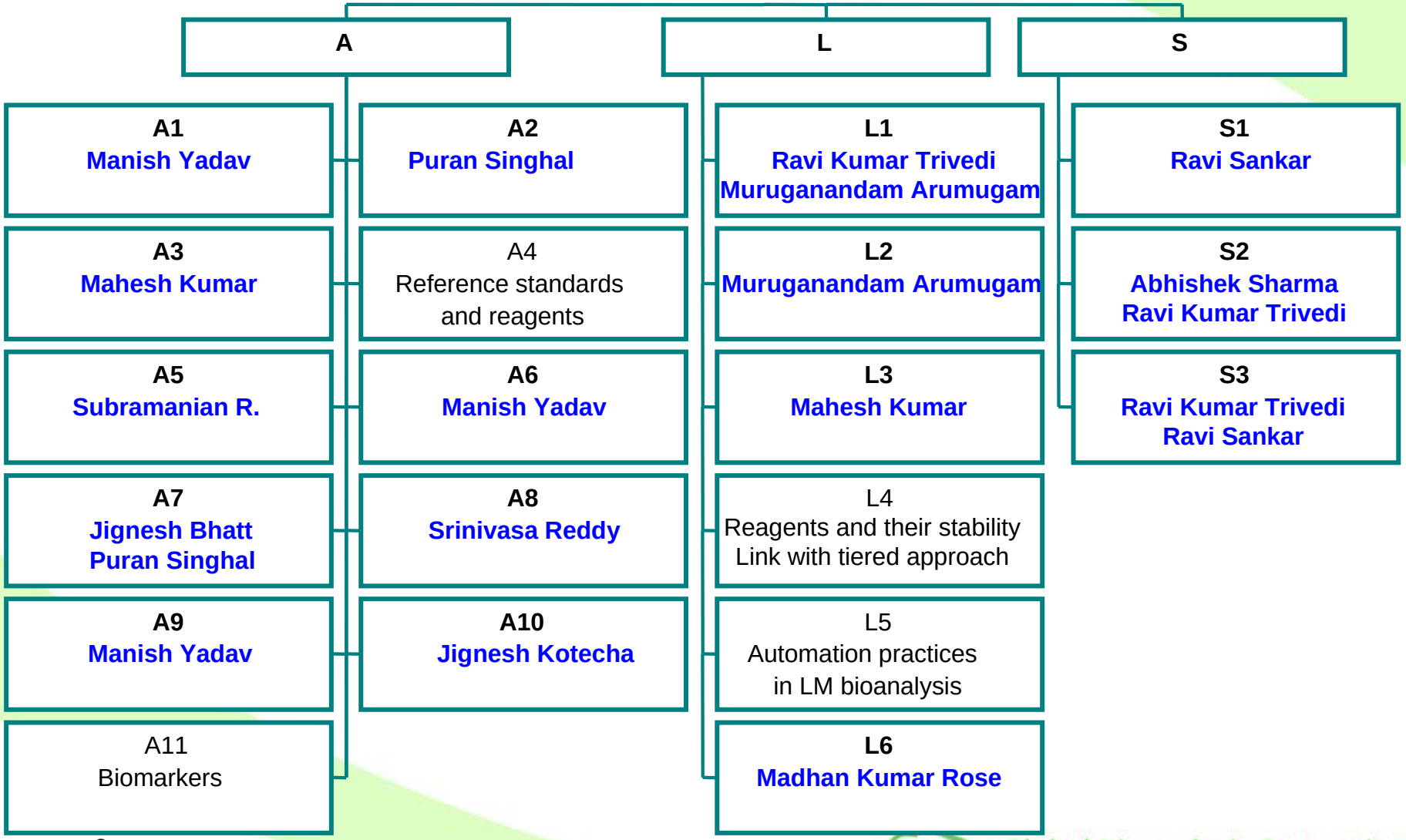
Indian representation at GBC



Updates on

A1: Scope and Regulations

Manish Yadav

Global Bioanalysis Consortium

On harmonization of bioanalytical guidance

A1: Scope and Regulations

Team members:

Team lead

• Surendra Bansal	NA

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Other members

• Dafong Zhong	APAC
• Martin Ullmann	NA
• Krzysztof Selinger	NA
• **Manish Yadav**	**APAC**
• Tomoko Arakawa	APAC
• John Smeraglia	EU
• Myriam Salvadori	LA
• Jim Hulse	NA

In scope

- Scope and regulations for bioanalytical method validation and samples analysis
- Extent of validation before analysis of samples
  - Consider Validation a continuum process
- Glossary

Interdependencies with other teams

- A2 Tiered approach for method validation
- All teams for glossary

Out of scope

- Biomarkers: Possibly include them as fit for purpose
- Immunogenicity within or out of scope?
  - Depends if large molecule HT is..

Current status

Drafted scope for performing bioanalytical work.

- Worked on the scope and regulations for bioanalytical method validation and samples analysis
- Considered Validation as a continuum process (need to interact with team A2 for tiered approach to include the tiered approach within the scope for bioanalytical work)
- Drafted glossary from existing FDA and EMA documents. Additional terms to be added from other regulatory documents or from bioanalytical community, as necessary.

Next steps

- Interact with team A2 for tiered approach to include the tiered approach within the scope for bioanalytical work
- Send draft glossary to all HTs for their input
- Provide current summary to GBC HTs in March 2012 and take input
- Finalize by August 2012 to prepare for the GBC global meeting

Updates on

A7: Repeat analysis and ISR

Puran Singhal

Global Bioanalysis Consortium

On harmonization of bioanalytical guidance

A7: Repeat analysis and ISR

Team members:

Team lead

- Eric Fluhler NA

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Other members

- Ajai Chaudhary NA
- Bernard Jeanbaptiste EU
- Dafong Zhong APAC
- Faye Vazvaei NA
- Jignesh Bhatt APAC
- **Puran Singhal APAC**
- Theo de Boer EU
- Wenkui Li NA
- Oscar Alderetr LA
- Vinícius Rezende LA
- Masahiro Taniguchi APAC
- Petra Vinck EU

In scope

Repeat analysis:

- Repeats for analytical reasons
- PK repeats (Including pre-dose concentrations)
- Single analyte repeat in multi-analyte assays
- Reinjection <-> Reanalysis
- Decision trees
- Acceptance criteria
- Failure and Investigation

ISR:

- Multiple analytes & endogenous compounds
- Timing of ISR analyses
- Sample selection
- Number / percentage of ISR samples
- Types of studies
- Acceptance criteria
- Failure and Investigation
- Large molecule considerations

Interdependencies with other teams:

- Stability Team – Stability of incurred samples

Out of scope

- Run acceptance criteria, including IS response variability/issues

Current status

- Sub-teams formed to address guidance around:
  1. Repeat analysis (RA)
  2. Incurred sample reanalysis (ISR)
  3. Failures and investigations
- Sub-teams 1 & 2 have been meeting throughout Q3-Q4 2011 and established recommended principles to be applied for their topics
- Sub-team 3 initiated activities in December 2011 and is working on establishing recommendations
- Full team has reviewed output from teams 1 & 2 and provided feedback to teams.
- Verbiage drafted for guidance around classical aspects of RA and ISR

Next steps

- Continue sub-team 3 efforts on “failure and investigations”
- Establish communication with Stability team (incurred sample stability)
- Prepare preliminary slide deck for March meeting
- Obtain SC feedback on positions
- Progress sub-team output to final draft for publication
- Prepare for global meeting overview