



# **GBC HT-L6**

## **Immunogenicity – Effect on PK**

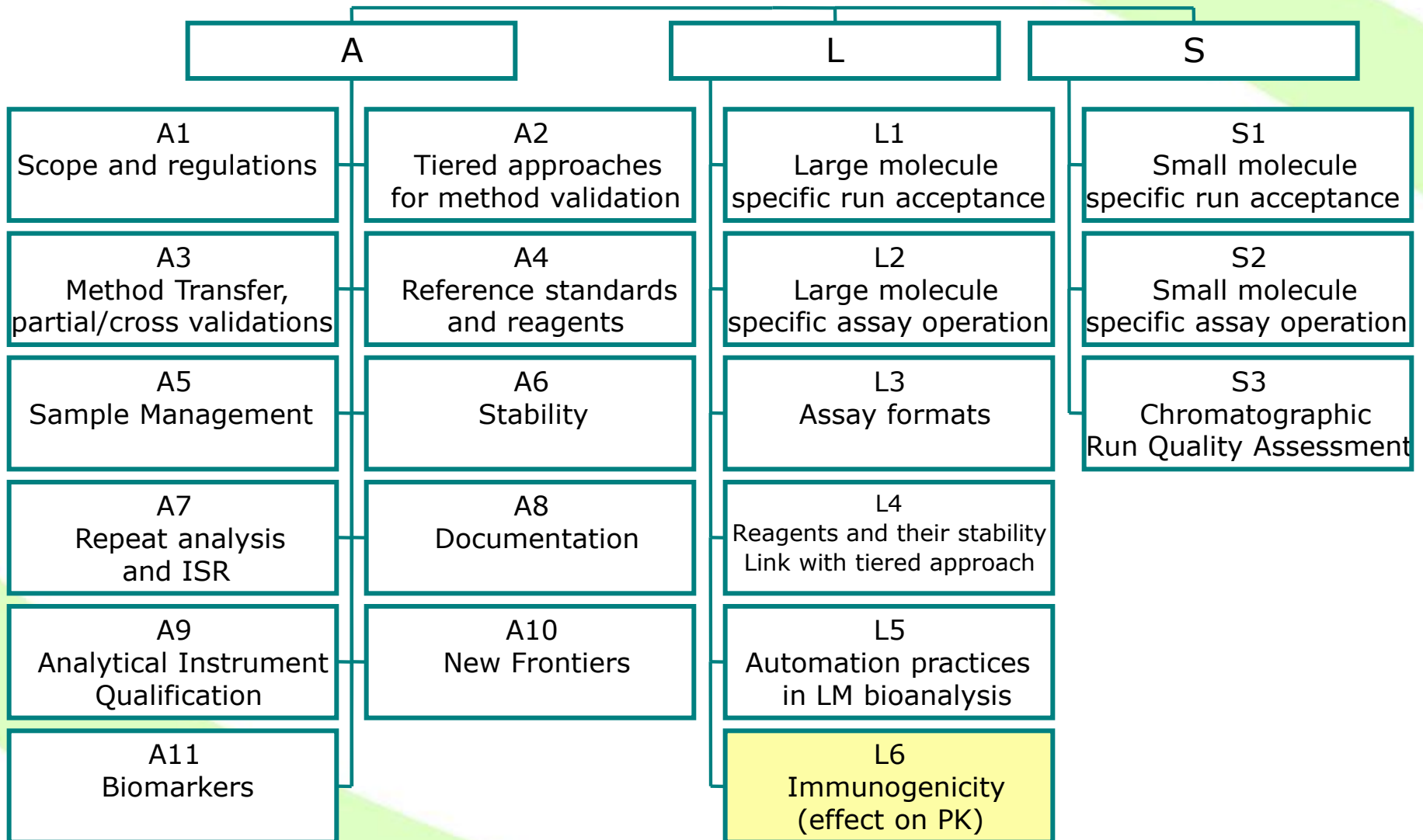
**Current Status November 2011**

**Michaela Golob on behalf of the L6 Team**



**Global Bioanalysis Consortium**  
On harmonization of bioanalytical guidance

# GBC - Harmonization Teams



# Harmonization Team L6

## Team lead

•Jeff Sailstad – US  
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## Other members:

Adrienne Clement Egan	US
Boris Gorovits	US
Heather Myler	US
Jason (Jay) Wustner	US
Lakshmi Amaravadi	US
Lei Tang	US
Renuka Pillutla	US
Shobha Purushothama	US
Joleen White	US
Madhan Kumar Rose	India
Sonehara from SCAS	Japan
	EU

# L6: Anti-drug antibody (ADA) Interference of PK Assessments

## Scope

**ADA can alter the pharmacokinetics of a therapeutic as well as interfere with the analytical methods or assays used to determine the pharmacokinetics.**

- **ways to separate true alterations of pharmacokinetics from artificial changes by interference in the analytical method.**
- **consideration will be provided on various assay formats and relative susceptibility to ADA interference.**
- **case studies where analytical interference was suspected, either confirmed or shown not to be an issue.**

# L6: Anti-drug antibody (ADA) Interference of PK Assessments

## Goal

- provide guidance on the factors to consider in assigning the magnitude of ADA impact on pharmacokinetics
- rank those factors

**ADA interference can impact the interpretation PK data throughout a development program therefore our scope will include pre-clinical and clinical applications.**

# L6: Anti-drug antibody (ADA) Interference of PK Assessments

**Interdependencies with other teams – if any**

–Link with tiered approach

**Out of scope:**

- **Immunogenicity Assessment**
- **Cut point analysis**
- **Screening assay**
- **Confirmatory assay**
- **Nab assay**

# L6 starting point

**AAPS annual meeting 2010:**

**Session on “Influence of Immunogenicity on PK assessment”**

**Summary report published in Bioanalysis (2011):**

**“Understanding the Mitigating Impact of Immunogenicity on pharmacokinetic assays”**

**Joleen White, Michaela Golob and Jeff Sailstad**

**<http://www.future-science.com/doi/pdfplus/10.4155/bio.11.162>**



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# Current status

- **Brainstorming**
- **Case studies are being presented and discussed**
- **Dropbox has been set up to share papers and other documentation.**
- **A process map is being prepared to help guide the development of a white paper.**