GLOBAL BIOANALYSIS CONSORTIUM

Regulated Bioanalysis - A Proposed Global Harmonization Process

presented on behalf of GBC

at

SQA 2011
March 29th 2011 - San Antonio -USA
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.
**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.
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.
2008-2009:

• Loose discussions in multiple BA communities contemplating on the need and added value of harmonized BA guidelines

Dec. 2009 - EBF Conference (Barcelona, Spain)

• Formal request for harmonization from Bioanalytical community
• Acknowledgement by Regulatory Agencies present (FDA & EMA)
• Discussion among international pharmaceutical scientific organizations with a strong stake in bioanalysis: AAPS, APA, CVG and EBF
• Request Health Authorities to initiate a harmonization process
  • Offer support to Health Authorities for such a process
  • Letter sent to FDA and EMA in February 2010
• Publication as Open letter in April 2010 issue of Bioanalysis
• Entertain initial idea of forming a Global Bioanalysis Consortium
Request for Global Harmonization of the Guidance for Bioanalytical Method Validation and Sample Analysis

Open letter to the bioanalytical community. Sent to the US FDA/European Medicines Agency in February 2010

The 2001 US FDA Bioanalytical Method Validation (BMV) guidance document has been widely accepted and adopted by the bioanalytical community worldwide. As such, it has become the cornerstone of regulated bioanalytical laboratory procedure. In recent years, clarifications to these FDA guidelines and subsequent enhancements were discussed at North American- and European-hosted meetings and conferences. The outcome of these meetings, published in White Papers, conference reports or recommendations, are currently being implemented in many bioanalytical laboratories around the world. Nevertheless, differences in expectations or interpretation of the guidelines from individual auditors/inspectors or regional health authorities are a growing concern for the bioanalytical community.

Further globalization of the pharmaceutical industry is also impacting the bioanalytical community. Bioanalytical labs are booming in regions outside the EU and North America, and regional authorities are looking to accommodate this growth or being confronted with the lack of guidance within their own regulations. Consequently, this creates a stimulus for these countries/regions to
Apr. 2010 – 4th CVG Workshop (Montreal, Canada)

- Consensus reached among panelists, 5 regulatory agencies and international attendees on how to proceed with the Global Harmonization of Bioanalytical Guidances: institution of a Global Bioanalytical Consortium

- Agreement on the main characteristic of a Global Bioanalytical Guidance:
  - Should be science driven
  - Should include rationale behind each requirement to prevent “box checking”
  - Should look at global picture, not local issues
  - Should NOT be a prescriptive guidance
  - Must get buy-in from all the countries
Operating Committees

GBC Steering Committee (GBC-SC)
• Participation with balanced representation from all (4) regions
• Members from organizations which represent the regional BA community
• Balanced membership to cover LBA and chromatographic assays

GBC Scientific Leadership Team (GBC-SLT)
• Participation based on scientific expertise and contribution
• Members = SC + FM + HL-L
  
  *Steering Committee, Founding members (FM) and Harmonization Team Leads (HT-L)*

Harmonization teams (HT)
• Participation based on scientific expertise and contribution
• HT = HT-lead + HT-members
Operating committees:

GBC Steering Committee (GBC-SC)
- Build/coordinate GBC as organization
- Facilitates and coordinates
- Represent GBC in outside world

GBC Scientific Leadership Team (GBC-SLT)
- 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)
- Prepare proposals, blending (emerging) science, existing and emerging guidelines, on a harmonized way forward on all topic assigned to the team
- Propose draft harmonized proposals to GBC-SLT
- Present harmonized proposal at the GBC conference
## Operating committees: GBC-SC

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<thead>
<tr>
<th>North America (US + Canada)</th>
<th>Asia Pacific (Asia + Pacific area)</th>
<th>Latin America (South America + Mexico)</th>
<th>Europe (Europe + Africa/Middle East)</th>
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<tr>
<td>• Mark Arnold (AAPS)</td>
<td>• Tatsuo Kurokawa (JBDG)</td>
<td>• Rafael Barrientos (AcBio)</td>
<td>• Peter van Amsterdam (EBF)</td>
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<td>• Binodh DeSilva (AAPS)</td>
<td>• Shrinivas Savale (APA-India)</td>
<td>• Fabio Garofolo (CVG)</td>
<td>• Michaela Golob (EBF)</td>
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<td>• Fabio Garofolo (CVG)</td>
<td>• Daniel Tang (SBDG&amp;BBDG)</td>
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<td>• Philip Timmerman (EBF)</td>
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</table>

Global Bioanalysis Consortium
On harmonization of bioanalytical guidance
Operating committees: **GBC-SC**

**Roles and Responsibilities of the GBC-SC**

- **Coordinate** the GBC process of a global BMV harmonization strategy.
- **Organize** and register GBC as an independent entity unless association with reputed existing organization is in the best interest of GBC.
- **Financial** responsibility for overseeing finances and filings.
- **Oversight** and co-ordinate the GBC-SLT and facilitate conflict resolution.
- **Communicate** or facilitate communication of the GBC progress to global community.
- **Represent** or facilitate representation of GBC at international and regional meetings.
- **Dialogue** with Health Authorities/regulatory agencies on behalf of GBC.
- **Organize** international meetings/conferences for harmonization / globalization.
- **Interact** with and appraise other interested BA and related groups having interest in GBC.
- **Report back** to GBC-Scientific Leadership Team.
- **Sponsor** of selection of HT teams.
Roles and Responsibilities of HT-L

• Leads the a specific HT

• Identifies team members for his/her team (preferably from multiple regions and recruited via application forms)

• Responsible for organizing regular HT meetings (agenda/timing) and ensuring meeting minutes are available.

• Connects with GBC-SLT to report back on progress or get input.

• Connects with other HT leads in case of overlapping discussions
Where are we now – March 2011

- Create **awareness and get input** at international Bioanalysis meetings in all regions

### Done

- **LoL**
- **APA Baltimore**
- **CPSA**
- **AAPS New Orleans**
- **EBF Barcelona**
- **CVG APAC Shanghai**
- **APA-India**

### Planned Ongoing

- Get broader **consensus** on process from industry
- Finalize identification of harmonization team topics (Q1 2011)
  - HT to start working
- Reach out to **health authorities/regulatory** agencies to create awareness and reach agreement on process - ongoing
Proposed way forward

2011

HT-L identification

HT identification

1st Global meeting in Q1/Q2
In a city which is equally accessible for scientists from all regions

2012

Start up phase
Which Harmonization Teams?  
Overview

GBC SC

GBC-SLT

A: Harmonization teams focusing on topics which apply for both chromatography based assays and Ligand Binding Assays (All molecules)

S: Harmonization teams focusing on topics which apply for Chromatography based assays (Small molecules)

L: Harmonization teams focusing on topics which apply for Ligand Binding Assays (Large molecules)
Which Harmonization Teams?

A1 Scope and regulations
A3 Method Transfer, partial/cross validations
A5 Sample Management
A7 Repeat analysis and ISR
A9 Analytical Instrument Qualification

A2 Tiered approaches for method validation
A4 Reference standards and reagents
A6 Stability
A8 Documentation
A10 New Frontiers

Biomarkers others

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

S1 Small molecule specific run acceptance
S2 Small molecule specific assay operation
S3 Chromatographic Run Quality Assessment

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Examples of Consensus Topics

Basic 6 principles of Method Validation

- Accuracy, Precision, Sensitivity, Selectivity, Stability and Reproducibility (ISR)
  - Overall design of the validation experiments
  - Run acceptance criteria: 4/6/15(20) or 4/6/20(25) Rules

Principles of Incurred sample reanalysis

Fundamentals of what goes into a bioanalytical report

- For MV or sample analysis
- Recent debate around the report generation process and finalization
Topics Requiring Consensus Building

Examples

**Within current Method Validation guidance**
- Tiered approaches to metabolites
- Statistical approaches vs. fixed number (e.g. 4/6/15 rule)
- Analyte stability experiments
- Scientific investigations
- Method transfer and cross-validations
- Internal standard criteria

**Other developments**
- Challenge of LBA vs. chromatographic assays
- Will regulatory language accommodate emerging technologies? – chromatographic and LBA
- Accommodating biomarker assays
- New technologies or other evolving issues
Harmonization team activities?
An example: Harmonization team **A6 - Stability**

**Scope:**
- Reference standards and reagent stability
- Process stability established during validation
- Stability in matrix
- Co-formulated and co-administered drugs
- Whole blood and tissue stability
- Stability at the sample collection time
- Degradation vs. stability vs. solubility loss vs. absorptive loss

**Proposed discussion points:**
Understand and discuss areas of difference in interpretation – provide clarification
- Understand current (global) regulatory environment on assigned topic
  - Consider both Existing guidelines and anticipated or emerging guidelines
- Acknowledge consensus (probably 80%)
- Focus on missing, unclear of conflicting guidelines (maybe 20%)

**Moving forward:**
- Team to have regular TCs
- Team to give feedback to SLT at regular intervals or BA community as appropriate
- Team to present outcome at GBC conference
A1: Scope and regulations

**Team members:**

**Team lead**
- Name – region – e-mail

**Other members**
- Name – region – e-mail
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**In scope**
- Scope and regulations (GxPs) for bioanalytical validation and samples analysis
- Glossary

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**Interdependencies with other teams – if any**
- Scope and regulations (GxPs) for bioanalytical validation and samples analysis
- Glossary

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**Out of scope**
- Scope and regulations (GxPs) for bioanalytical validation and samples analysis
- Glossary

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Global Bioanalysis Consortium
On harmonization of bioanalytical guidance
## A2: Tiered approaches for method validation

### Team members:

**Team lead**
- Name – region – e-mail

**Other members**
- Name – region – e-mail
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### In scope

- Definitions of screening, qualification in relation to validation, applicable for
  - Validation/qualification of assays for tissues
  - Tiered approach for metabolites quantification
  - Biomarker assay qualification/validation
- Stability assessment in tiered approach (blood, tissue, urine, metabolites, biomarkers – as applicable..)

### Out of scope

### Interdependencies with other teams – if any

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On harmonization of bioanalytical guidance
A3 Method Transfer, partial and cross validation

Team members:
Team lead
• Name – region – e-mail

Other members
• Name – region – e-mail
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In scope
– Life cycle of a method after first full validation or relation with other validated methods.
  – Partial validation
  – Method transfer
  – Cross validation
– Definitions of method transfer, partial and cross validations
– Recommendation on when to perform method transfer, partial and cross validations
– Recommendations of which experiments are desirable for each proposed steps after full validation

Interdependencies with other teams – if any
– A6

Out of scope

Global Bioanalysis Consortium
On harmonization of bioanalytical guidance
# A4: Reference standards and reagents

## Team members:

### Team lead
- Name – region – e-mail

### Other members
- Name – region – e-mail
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## In scope
- Reference standards used for drugs, metabolites and internal standards – Purity certification and COA
- Preparation of stock solutions, calibration standards and QCs

## Interdependencies with other teams – if any
- A2

## Out of scope
A5: Sample Management

**Team members:**

**Team lead**
- Name – region – e-mail

**Other members**
- Name – region – e-mail
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**In scope**
- All aspects of sample management from collection to disposition - Cold chain management
  - Collection, handling and storage at clinical/animal lab
  - Storage and shipment from clinical/animal lab to CL or analytical lab
  - Pre analysis storage at analytical lab
  - Post analysis storage or shipment
  - Disposal or archiving/banking

**Interdependencies with other teams – if any**
- A6

**Out of scope**
**A6: Stability**

**Team members:**

**Team lead**
- Name – region – e-mail

**Other members**
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**In scope**
- Stability in relation to validated methods
- Reference standards and reagent stability
- Process stability established during validation
- Stability in matrix
- Co-formulated drugs, co-administered drugs
- Whole blood and tissue stability for validated methods
- Stability at the sample collection - A6
- Degradation vs. stability vs. solubility loss vs. absorptive loss

**Interdependencies with other teams – if any**
- A2
- A3
- A5

**Out of scope**
- Stability assessment in tiered approach (blood, tissue, urine, metabolites, biomarkers – as applicable..) – A3
A7: Repeat analysis and ISR

Team members:

Team lead
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Other members
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In scope
– Repeats for analytical reasons
– PK repeats
– ISR
– Incl. recommendation on single analyte repeat in multi-analyte assay

Interdependencies with other teams – if any

Out of scope
# A8: Documentation

<table>
<thead>
<tr>
<th>Team members:</th>
<th>In scope</th>
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</table>
| **Team lead** | - Definitions of different report types  
- Documentation of method development  
- Method Validation reports  
- Study reports  
- Failure investigation and documentation  
- Documentation at analytical site  
- Raw data definitions data (electronic and paper) including notebook records, instrument use and maintenance records  
- Archiving |
| • Name – region – e-mail | |

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A9: Analytical Instrument Qualification

**Team members:**

**Team lead**
- Name – region – e-mail

**Other members**
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**In scope**
- Software Validation
- Instrument qualification based on instrument categories
- System suitability
- Instrument decommissioning

**Interdependencies with other teams – if any**
- A1

**Out of scope**
A10: New Frontiers

Team members:

**Team lead**
- Name – region – e-mail

**Other members**
- Name – region – e-mail
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In scope
- Understand analogies with established techniques and need for regulatory recommendation vs. need for increased scientific validation prior to recommending regulations, i.e. new techniques already applied in regulatory context (peptide PK/TK with LC-MS/MS)
- Examples are, but not limited to
  - Micro-sampling (includes DBS)
  - Alternate technologies (AMS, ICPMS)
  - Large molecules analysis by new technologies

Out of scope

Interdependencies with other teams – if any
- A1

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On harmonization of bioanalytical guidance
A10: New Frontiers – biomarkers?

**Team members:**

**Team lead**
- Name – region – e-mail

**Other members**
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**In scope**

**Interdependencies with other teams – if any**
- A1

**Out of scope**
### A10: New Frontiers – others?

<table>
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<th>Team members:</th>
<th>In scope</th>
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<th>Out of scope</th>
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# L1: Large molecule specific run acceptance

## Team members:

**Team lead**
- Name – region – e-mail

**Other members**
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## In scope
- Linearity, 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
# L2: Large molecule specific assay operation

## Team members:

**Team lead**
- Name – region – e-mail

**Other members**
- Name – region – e-mail
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## In scope

## Out of scope

## Interdependencies with other teams – if any

## Out of scope
## L3: Assay formats

**Team members:**

**Team lead**
- Name – region – e-mail

**Other members**
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### In scope

### Out of scope

**Interdependencies with other teams – if any**

**Out of scope**
L4: Reagents and their stability

Team members:

Team lead
- Name – region – e-mail

Other members
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In scope

Interdependencies with other teams – if any

Link with tiered approach

Out of scope
## L5: Automation practices in LM bioanalysis

**Team members:**

**Team lead**
- Name – region – e-mail

**Other members**
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**In scope**

**Interdependencies with other teams – if any**

**Link with tiered approach**

**Out of scope**

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On harmonization of bioanalytical guidance
L6: Immunogenicity

Team members:

Team lead
• Name – region – e-mail

Other members
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Interdependencies with other teams – if any

Link with tiered approach

In scope

Out of scope
# S1: Small molecule specific run acceptance

## Team members:

**Team lead**
- Name – region – e-mail

**Other members**
- Name – region – e-mail
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## In scope

- Linearity, Accuracy, Precision
- Appropriate calibration curve and QC ranges (during validation and for study specific)
- Selection of regression analysis (linear vs. best fit)
- Individual runs and overall run acceptance during validation
- Individual runs acceptance during samples analysis

## Interdependencies with other teams – if any

- L1

## Out of scope


S1: Small molecule specific assay operation

**Team members:**

**Team lead**
- Name – region – e-mail

**Other members**
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**In scope**
- Carryover and contamination
- Sensitivity
- Specificity - selectivity
- Matrix Effects
- Recovery
- IS evaluation

**Interdependencies with other teams – if any**

**Out of scope**
S3: Chromatographic Run Quality Assessment

Team members:

Team lead
• Name – region – e-mail

Other members
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In scope
– Chromatographic resolution and peak shape
– Noise signal
– Peak integration algorithms and manual integrations
– Other quality parameters potentially needed for recommendation, e.g.:
  – Changes in slopes during study

Interdependencies with other teams – if any

Out of scope
HT-L
• Registration for HT-L closed on **Feb. 21st 2011**.

HT members
• HT-L will identify their team based on level of expertise the candidates have with the topic of the specific team.
• Candidates for HT membership can make themselves known by submitting the registration form to:
  – apply@globalbioanalysisconsortium.org
  – Identifying the team they volunteer to join
Acknowledgment

- Mark Arnold (AAPS) – SC & FM
- Peter van Amsterdam (EBF) – SC & FM
- Surendra Bansal (AAPS) - FM
- Rafael Barrientos (AcBio) - SC
- Binodh DeSilva (AAPS) - SC
- Douglas Fast (BSAT) - FM
- Fabio Garofolo (CVG) – SC & FM
- Michaela Golob (EBF) – SC
- Tatsuo Kurokawa (JBDG) – SC
- Steve Lowes (AAPS) - FM
- Shrinivas Savale (APA-India) - SC
- Daniel Tang (SBDG&BBDG) - SC
- Philip Timmerman (EBF) – SC & FM
- Eric Woolf (BSAT) - FM