GLOBAL BIOANALYSIS CONSORTIUM

Regulated Bioanalysis - A Proposed Global Harmonization Process

Presented by Peter van Amsterdam for GBC
At 2010 FABIAN – Doping opnieuw geanalyseerd
Utrecht, 4 Nov 2010

Global Bioanalysis Consortium
On harmonization of bioanalytical guidance

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.

GBC: 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.

GBC: 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.

GBC: History

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

GBC: History *(cntd)*

Dec. 2009 - EBF Conference

OPEN LETTER

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

Philip Timmerman, MSc
Website: www.european bioanalysisforum.eu/

EBF

Steve Lowes, PhD
Website: www.aaps pharmaceutica.com

aaps

Douglas M Fast, PhD
Website: www.applied pharmaceuticalanalysis.org

APPLIED PHARMACEUTICAL ANALYSIS

Fabio Garofolo, PhD
Website: www.canadianlcms group.com

CVG

GBC: History *(cntd)*

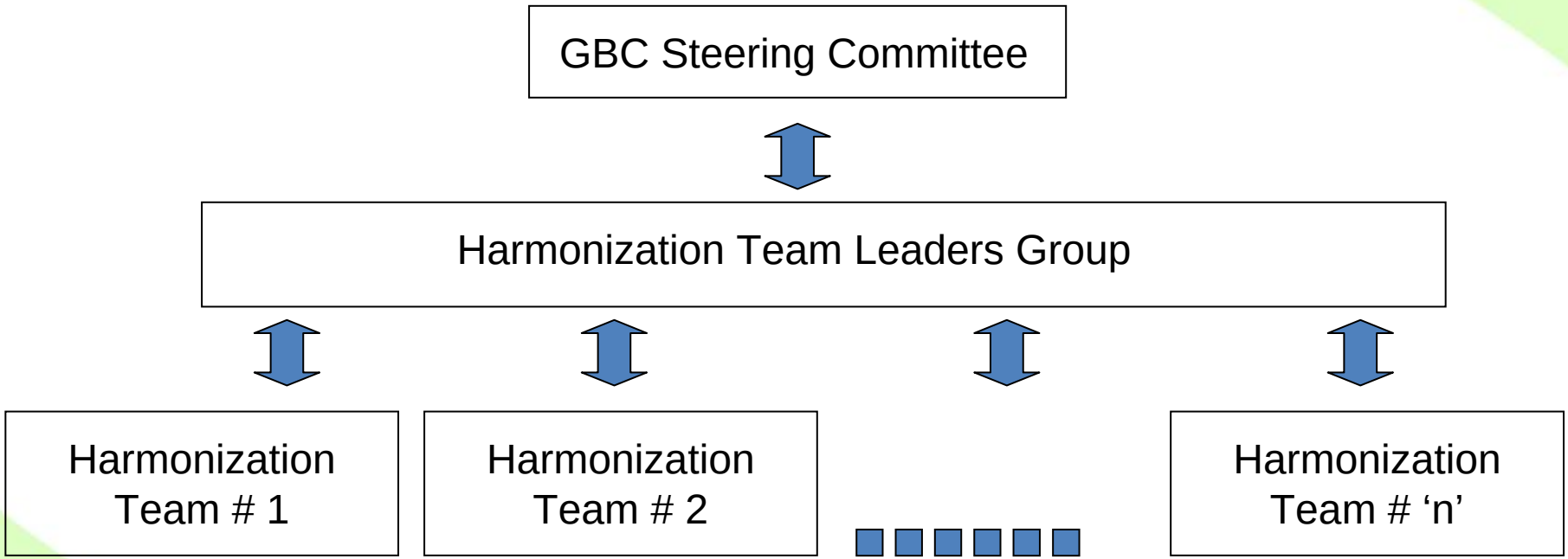
Apr. 2010 - CVG Workshop (Montreal, Canada)

– 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**

GBC: how to organize?



GBC Steering Committee (SC)

Roles and Responsibilities of SC

- **Coordinate** the GBC process of supporting a global BMV harmonizing strategy
- **Connect** and support the harmonization teams (via team lead)
- **Communicate** GBC progress to global community
- **Represent** GBC at international meetings
- **Dialogue** with Health Authorities/regulatory agencies on behalf of GBC
- **Organize** harmonization through international meetings/conferences
- **Interact** with and appraise other interested bodies of GBC progress e.g. organizational support and quality assurance groups
- **Ensure**
    - Global participation in harmonization teams
    - Representation of both biologics and small molecule analytical representatives in harmonization teams

GBC Steering Committee (SC) *(cntd)*

Notes:

- SC do not own content of harmonization discussion, but can act as a **sounding board**
- SC ensures that **large and small molecule** bioanalysis be fully represented in process
- Size of SC will be kept minimal, but all regions are represented in SC
- Currently **4 regions** are identified:
  - North America (NA)
  - Latin America (LA)
  - Europe (EU)
  - Asia-Pacific (APAC)

Steering Committee (as per 10-2010)

North America

- Binodh DeSilva
- Fabio Garofolo
- Mark Arnold

Latin America

- Rafael Barrientos

Asia Pacific

- Daniel Tang
- 2nd SC member being identified

Europe

- Peter van Amsterdam
- Philip Timmerman

Harmonization Teams

Roles and Responsibilities of HT

- **Engage on discussing** different subtopics in preparation of harmonization meeting(s)
- Team consists of a **team lead** and subject matter experts from multiple regions
- Team members engage to discuss and share experience in support of harmonization and best practice. By focusing on content in detail, will come forward with a **recommendation**, reached by consensus, to be presented at Global Harmonization meeting(s).
- Will include all technologies during assessment, but may defer some in favor of earlier enacted recommendations for those more broadly used.

Harmonization Teams

Roles and Responsibilities of HT

- Each team focuses on the their **defined topics**, but is mindful of potential **overlaps** and will discuss these with the other teams (via team lead)

- Teams report back on content and progress (via team lead) to SC to allow SC oversight of progress or identify potential roadblocks/contradictions

- Membership to more than 1 team can be beneficial and is endorsed, but membership is limited to 3 teams

Harmonization Team Leads

Roles and Responsibilities of HT leads

•Leads the HT working on a specific method validation or sample analysis topic

- Identifies team members for his/her team

- Profile of HT members
  - Selected team members should be **experienced in the topic**
  - **No region can be excluded** unless the region elects not to be involved
  - No region can have >50% of team members.
  - Size of teams can vary (advice: 5-10 members, depending on the topic)

Harmonization Team Leads *(cntd)*

Roles and Responsibilities of HT leads

- **Organizes** the HT meetings (agenda/timing) and ensures meeting minutes are available.
- **Connects** with SC to report back on progress or get input from SC.
- **Connects** with other HT leads in case of overlapping discussions

Selection process for HT Leads and Members

HT Leads

- SC will identify the HT leads based on level of expertise the candidates have with the topic of the specific team.
- The principle is to be selective rather than restrictive.
  - Candidates for HT leads can make themselves known by submitting the registration form to:
    - apply@globalbioanalysisconsortium.org
    - Identifying the team they volunteer to lead

Team members

- HT leads 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(s) they volunteer be a member of

Selection process *(cntd)*

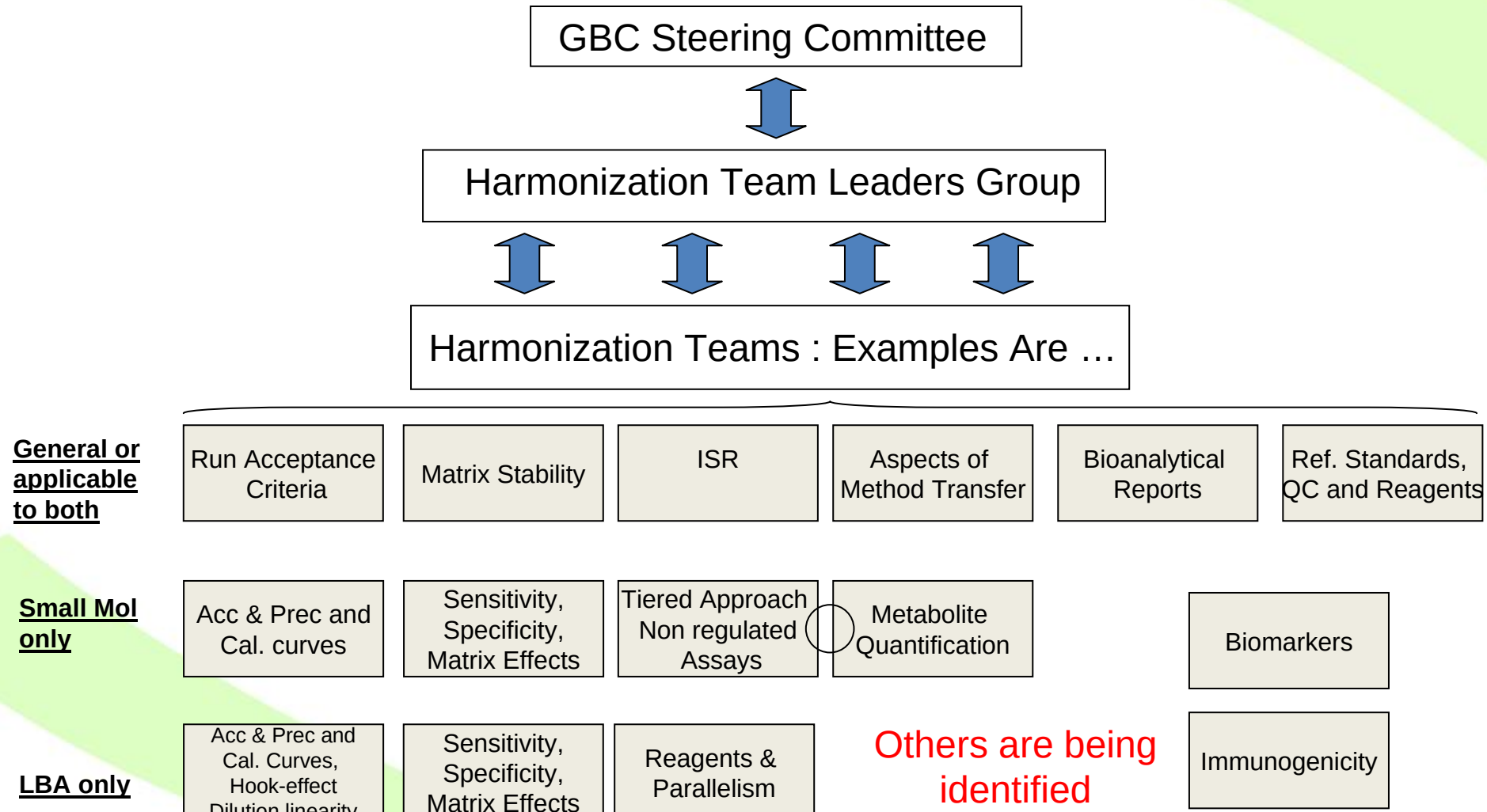
Registration form available from GBC website

- http://www.globalbioanalysisconsortium.org

Registration Form seeks input on:

- Name
- Organization
- Region you will represent
- Experience
  - Small vs Large molecule analysis (or both)
  - Years
- Interest
  - Lead an HT (commit to the time, effort and travel)
  - Participate in a HT
  - Which teams are you interested in

Which Harmonization Teams?



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Proposed way forward

2010 (Jan. 2011 included):

- Steering Committee to agree on GBC charter
- Monthly teleconferences to build GBC (founding members plus new members of SC)
- Identify **regional bioanalytical organizations** (NA, SA, EU, APAC - ongoing) and identify representative SC member
- Identify harmonization team (HT) lead and HT members
- Create **awareness** at international Bioanalysis meetings in all regions
  - LOL (NA) *(done)*
  - CVG-CRO (NA) *(done)*
  - APA-BSAT (NA) *(done)*
  - EBF-CRO (EU) *(done)*
  - CPSA (NA) *(done)*
  - FABIAN (EU)

Proposed way forward *(cntd)*

2010 (Jan. 2011 included):

- Get **input** at regional key meetings to **reach agreement**
  - AAPS/PSWC/FIP (NA)
  - EBF (EU)
  - CVG-Asia Pacific (APAC)
  - TBD (SA)

- Get broader consensus on process from industry

- Finalize identification of harmonization team topics (Jan 2011)

- Reach out to **health authorities/regulatory** agencies to create awareness and reach agreement on process

- Create GBC website and e-mail address (*done*)
- http://www.globalbioanalysisconsortium.org
- info@globalbioanalysisconsortium.org

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Proposed way forward *(cntd)*

2011 (from Feb. onwards):

- Finalize identification and assignment of experts to SC (founding members replaced by SC), HT leads and HT members (Q1-2011)
- Start discussion in Harmonization Teams
- SC and HT leads work together and interact to prepare **global harmonization meeting** at globally accepted venue
  - SC to identify date and venue
  - current target date: Q1-2012
- Continue to update industry to maintain **consensus** on process
- Give regular feedback in meetings (SC) /web page

Acknowledgment

GBC founding team members:

- Peter van Amsterdam (Abbott, for EBF)
- Mark Arnold (BMS, for AAPS)
- Surendra Bansal (Roche, for AAPS)
- Douglas Fast (Covance, for BSAT)
- Fabio Garofolo (Algorithme Pharma, for CVG)
- Steve Lowes (Advion, for AAPS)
- Philip Timmerman (J&J, for EBF)
- Eric Woolf (Merck, for AAPS)