

AAPS Perspective on Global Bioanalytical Harmonization

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Agenda

Introduction

Activities at November's FIP Pharmaceutical Sciences World Congress in association with the AAPS National meeting

- ◆ **Symposium**
- ◆ **Open Forum**

AAPS Organization – Support Activities

FIP-AAPS Symposium: Bioanalytical Procedures and Regulation - Towards Global Harmonization

Monday Afternoon 15Nov2010

- **Eric Woolf – Regulated Bioanalysis in Support of Global Drug Registration Applications – An Industry Perspective**
- **Howard Hill – Bioanalytical Methods Validation, Evolving Sensitivities in the Global Workspace**
- **C.T. Viswanathan – A US Regulatory Perspective on harmonizing Bioanalytical Regulations**
- **Olivier Le Blaye – An EU Regulatory Perspective on Bioanalytical Harmonization**
- **Ariadna Barra- ANVISA Perspective on Global Bioanalytical Harmonization: ANVIDSA Guidelines – Support of Submission in Brazil and CRO's Certification**

FIP-AAPS Symposium: Bioanalytical Procedures and Regulation - Towards Global Harmonization

Observations:

- ◆ Differences in regulations create challenges to provide single comprehensive bioanalytical filing packages
- ◆ Sometimes, flexibility is lacking during review process
- ◆ Still many topics that are covered in guidance that are not prescriptive and open to interpretation
- ◆ Future guidance should not be prescriptive but remain flexible to support emerging technologies

FIP-AAPS Symposium: Bioanalytical Procedures and Regulation - Towards Global Harmonization

Observations:

- ◆ C.T. Viswanathan supports science-based internationally harmonized regulations
- ◆ Olivier LeBlaye noted EMA reviewers and auditors are seeing the same problems during their audits that the FDA has seen
 - Resulting in similar concerns *and requirements* to achieve data quality
- ◆ FDA and EMA will be sharing their draft guidance to create the opportunity for alignment
- ◆ Ariadna Barra - Brazil is rewriting their guidelines and will be taking into account aspects and concerns from other regions guidance

FIP-AAPS Open Forum: Open Forum

Thursday Afternoon 18Nov10

- **Surendra Bansal – Introduction**
- **Vinod Shah – FIP – A Historical Assessment of the Development of Bioanalytical Technologies in the Regulated and Unregulated Environment**
- **Michael Berntgen – EMA – European Perspective of Scientific Guidelines Development**
- **C.T. Viswanathan - FDA - Globalization Issues**
- **Steven Lowes - Current Update on Standardization of Global Bioanalytical Practices**
- **Open Discussion**

FIP-AAPS Open Forum: Open Forum Participants

Participants demonstrated a global presence.

Region	Pharma	CRO	Academic	Regulators	Total
ROW	10	3	5	1	19
US	44	20	8	1	73
Total	54	23	13	2	92

FIP-AAPS Open Forum: Open Forum

Observations:

- Suggestion that GBC operate under another organization (e.g., FIP or ICH)
- Confidentiality Agreement between FDA and EMA to collaborate on regulations
 - ◆ Will share draft of bioanalytical regulations
 - ◆ Will look to harmonize recommended practices and prevent conflicting approaches prior to release

FIP-AAPS Open Forum: Open Forum

Observations:

- **Suggested criteria for GBC credibility**
 - ◆ **Representative and Inclusive**
 - ◆ **International**
 - ◆ **Unify on science and practicality**

Possibility of ICH documents also surfaced

- ◆ **Beyond US, EU and Japan, other country's expert groups can also provide input.**
- ◆ **ICH documents may take a very long time.**

AAPS Support & Involvement

Bioanalytical Focus Group (BFG)

- ◆ Not limited to small molecule and chromatographic assay focus
- ◆ Organized under the APQ Section

Ligand-Binding Assay Bioanalytical Focus Group (LBABFG)

- ◆ Large molecule and immuno-assay focus
- ◆ Organized under the BIOTECH Section

AAPS Support & Involvement

Both the BFG and LBABFG, as well as their sponsoring sections support the objectives of global bioanalytical harmonization

- ◆ **Provided representatives to SC of GBC**
 - **Binodh DeSilva for the LBABFG**
 - **Mark Arnold for the BFG**
- ◆ **LBABFG wants to ensure that immunoassay issues and representation are present in Teams and deliberations**

AAPS Support & Involvement

AAPS Executive Council

- ◆ Fully supports the objectives of GBC and efforts for collaboration with other pharmaceutical associations
- ◆ Provided a \$5000 travel stipend to each Focus Group to send their representative to GBC activities
- ◆ Asked for quarterly updates of progress

AAPS Support & Involvement

Notes from the BFG members meeting

- ◆ Would like fully membership vote on representative to SC of GBC
- ◆ Concern that SC has one, possibly two, large molecule scientists
 - Noted that SC is not driving content, will be at HTs
- ◆ Want communication on process and progress
 - BFG homepage links
 - Discussion forum threads for each Harmonization Team
 - Updates
 - Seek input from scientific community
- ◆ Collaborate with other NA bioanalytically focused organizations – Land O'Lakes, BSAT-APA, CPSA, etc.

Other US organizations interested in GBC

Applied Pharmaceutical Analysis (Boston Society)

Land O'Lakes Bioanalytical (University of Wisconsin sponsored)

Chemical & Pharmaceutical Structure Analysis (CPSA)

- ◆ 2010 meetings for these organizations have discussed global harmonization and the formation of GBC
 - Well received, widely and energetically discussed

Summary

AAPS and its members support global harmonization of bioanalytical regulations

- ◆ Recognize the need and value
- ◆ Ready to dive in

Regulatory Community is noting:

- ◆ Common problems with bioanalytical data quality
- ◆ The need for collaboration to achieve harmonization

Key message

Practical science-based approaches