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
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
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
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- FDA and EMA will be sharing their draft guidance to create the opportunity for alignment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
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.

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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
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
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*