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AAPS Connection

American Association of Pharmaceutical Scientists June 2015

CRYSTAL CITY VI: AAPS WORKSHOP ON BIOANALYTICAL METHOD VALIDATION FOR BIOMARKERS BY LC-MS AND LBA

September 28–29, 2015
Renaissance Baltimore Harborplace Hotel
Baltimore

With the growing focus on Translational Research and the use of biomarkers to drive drug development and approvals, biomarkers have become a significant area of research within the pharmaceutical industry. However, until the FDA's 2013 draft guidance on Bioanalytical Method Validation included consideration of biomarker assays using LC-MS and LBA, biomarker assays were created, validated and used without standards of performance. This resulted in the FDA receiving data substantiating claims of efficacy and safety that it could not rely on to back those claims. Thus, the extension of the BMV to cover biomarkers was made and subsequently was discussed at Crystal City V (CCV) in 2013. As the first forum for industry-Agency discussion, it was recognized that it was an initial discussion, and more in-depth and extensive discussion around the general issues of biomarker measurements (*e.g.*, endogenous levels) and the specific technology strengths and weaknesses would be needed. Two years after CCV and after growing publications and discussions within the bioanalytical community, the time is right to hold a 2-day workshop to address regulated biomarkers used to support new therapeutic labeling claims. The Workshop will permit a broader and more in-depth discussion on the parts of industry and Agency, as well as international regulators, with specific learnings for each, with an ultimate goal of providing a Workshop Report that will serve as the basis of LC-MS and LBA biomarker assays performance.

Goals and Objectives

Provide a more robust discussion of the issues related to biomarkers that are of concern to the FDA and Industry:

- General challenges with biomarkers—endogenous levels (no 'blank matrix'), for protein markers lack of appropriate reference standards.
- Continue the CCV dialogue on Category 1 vs 2 assays, and comparison of Qualitative Assay, Relative Quantitative Assay, Definitive Quantitative Assay with respect to successful and unsuccessful approaches used for LBA and LC-MS assays.

With the growth of LC-MS for biomarkers, previous concepts proposed in an industry white paper (Lee *et al.* 2006) are not appropriate and an appropriate operating construct is needed.

For more information, please visit www.aaps.org/CCVI

AAPS WORKSHOP ON CHALLENGES IN ASSESSMENT OF NON BIOLOGICAL COMPLEX DRUG SIMILARITY AND THE CONSEQUENCES IN PRACTICE

September 28–29, 2015
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How do you evaluate the comparability/similarity of a generic version (follow on) to an innovator drug product that is a complex mixture of structures and cannot be fully characterized by analytical means, where it is not known what specific characteristics relate to clinically relevant outcomes, and

where the product quality depends on a tightly controlled process of manufacturing? Examples of such complex drugs can be found in the group of biologicals, and the non-biological complex drugs (NBCDs), such as the families of liposomes, glatiramoids, iron-carbohydrate complexes, bumin-cytostatic complexes and emulsions. Often these NBCDs are also members of the family of nanomedicines and upcoming associated nanosimilars provide similar challenges. And how do we evaluate the design space of drug products where no two batches of the drug product are exactly the same, not only quantitatively, but also qualitatively?

Goals and Objectives

- To inform the participants on the differences between small molecule generics and similar/follow on versions of (non) biological complex drugs (the science and the regulatory implications).
- To identify the outstanding challenges in the assessment of complex drug similarity and consequences for interchangeability of products.
- To identify differences and commonalities in the behavior of biologicals and (different) NBCD families.
- To engage the relevant stakeholders in a science based discussion and exchange experiences on this topic between industrial, academic and regulatory scientists.
- To report afterwards in the *The AAPS journal* on potential ways moving forward in this complex drugs arena and to lay the foundation for a globally aligned regulatory policy.

For more information, please visit www.aaps.org/Challenges

AAPS members receive discounts on all AAPS meetings attendance.

Look for the AAPS Member Benefits logo in all AAPS publications and webpages.

UPCOMING AAPS MEETINGS

www.aaps.org/meetings/

October 24, 2015

CRS/AAPS Joint Workshop on Formulation, Processing, and Testing of Functionally Coated Multiparticulates
Orange County Convention Center, Orlando, Fla.

October 25, 2015

AAPS Workshop on Nanotechnology in Personalized Medicine
Orange County Convention Center, Orlando, Fla.

October 24–25, 2015
AAPS Workshop on Dosing Recommendations in Subpopulations: Leveraging and Applying Existing Knowledge
Orange County Convention Center, Orlando, Fla.

October 25, 2015
AAPS Workshop on the Totality of Evidence in Biosimilar Development Programs: Current Multidisciplinary Perspectives
Orange County Convention Center, Orlando, Fla.

October 25–29, 2015
2015 AAPS Annual Meeting and Exposition
Orange County Convention Center, Orlando, Fla.

Also check out the AAPS webinars by visiting www.aaps.org/webinars/

AAPS/WEBSEDGE PARTNERSHIP

AAPS is partnering with the international film and broadcasting company, WebsEdge, to bring AAPS TV to the 2015 Annual Meeting and Exposition from October 25–29 in Orlando.

AAPS TV will be an onsite conference television channel featuring a new episode daily, screened around the venue, as well as on a dedicated television channel in selected guest hotel rooms and online.

This venture serves to raise the visibility of the hard work of pharmaceutical sciences and to provide an opportunity to learn about leading edge research and development that is advancing drugs and drug delivery systems.

Each daily program has two features: "Thought Leadership" and "Conference News." Thought Leadership pieces are 5-min sponsored film segments highlighting major programs and activities underway in the field. Conference News is a daily program of Annual Meeting highlights, featuring "behind the scenes" interviews, coverage of conference events, and reactions to the day from attendees.

WebsEdge will be reaching out to organizations and agencies to describe the "Thought Leadership" program and seek their engagement in creating the 5-min documentary-style films highlighting particular aspects of their project work.

There are a limited number of places available for the 5-min films. If you would like to explore having a film featured in the program, please contact the following WebsEdge's director of sales, Mark Rose, at mark@websedge.com.

To view a selection of news highlights and featured films from similar programs produced by WebsEdge please visit http://www.websedge.com/videos/education/#/

2015 ANNUAL MEETING AND EXPOSITION CAREER FAIR

Mark your calendar now for your job search at our upcoming 2015 AAPS Career Fair held in conjunction with the 2015 AAPS Annual Meeting and Exposition from October 25–29 at the Orange County Convention Center in Orlando, Fla. The Career Fair begins Sunday night October 25 through Tuesday afternoon, October 27.

For more information, please visit www.aaps.org/AMcareerfair/

AAPS Connection
2107 Wilson Blvd., Suite 700, Arlington, Va. 22201-3042
Ph: +1.703.243.2800
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