

EMEA Draft Guideline on Validation of Bioanalytical Methods

April 15-16 • 2010 • Sheraton Hotel Brussels • Brussels • Belgium



Place Rogier3, BE-1210 Brussels, Belgium
 Phone +32 2 2243111

The Workshop will open on Thursday, April 15, 2010, at 09:00, and it closes on Friday, April 16, 2010, at 14:30.

Scope & Aim

The European Medicines Agency (EMA) Committee for Human Medicinal Products (CHMP) released, as result of a gap analysis, a concept paper on the “Need of a Guideline for the Validation of Bioanalytical Methods” in December 2008. All interested parties were invited to provide input by the end of March 2009. Having collected and collated all input, the CHMP subcommittee released a Draft Guideline in November 2009, which is now in the cycle of consultation, until the end of May 2010, i.e. for final comments.

The aim of this Workshop is to discuss the current scientific knowledge in the area of bioanalysis, the regulatory requirements and their subsequent translation into the work in the bioanalytical laboratory. Examples of topics to be discussed include the GLP-status of the process of method validation; acceptance criteria of methods to be used in the area of chromatography based and ligand-binding based assays; incurred sample

reproducibility (ISR; study sample reanalysis for PK purposes; and re-integration, to list only a few).

The intention of this Workshop is to give scientists from industry and academia, managers and representatives of company regulatory functions the opportunity to discuss the new regulation with representative from regulatory authorities in Europe. Input for the Workshop Programme includes comments submitted to the organisers in the run-up phase to the event. All participants are invited to present their views and suggestions, based on own experience, during the discussion, and to support these proposals by experimental data.

Although the forthcoming guidance will be new for the area of the European Union, it is not built from the very beginning. The Federal Drug Administration (FDA), as the regulatory agency in the USA, started in the early 1990ies with conferences and workshops on bioanalytical method validation and study sample analysis resulting in the current “Guidance for Industry – Bioanalytical Method Validation”, as of 2001. As there was no other regulatory guidance outside the USA available, this has been widely used and accepted as standard by the global bioanalytical community. Now, after being close to 10 years in use – and a number of white papers – it will be updated.

Preliminary Programme

Thursday, April 15, 2010			
Time		Chair (Organisers)	Co-chair (EMEA)
09:00	Welcome and Introduction	<i>Erich Brendel</i>	<i>Jan Welink</i>
09:15	Including goals, objectives and structure of the workshop	<i>Berthold Lausecker</i> <i>Christoph Siethoff</i>	<i>Olivier Le Blaye</i> <i>Jérôme Barré</i>
09:15	Plenary Background, including legal basis and regulatory needs	<i>Erich Brendel</i>	<i>Jan Welink</i>
10:15	CHMP Working Party Representative (20 min, Jan Welink) EBF representative (20 min, Berthold Lausecker) EUFEPS representative (20 min, Erich Brendel)		
10:15	Coffee-Break		
10:45	Session I – General Aspects on Validation of Bioanalytical Methods	<i>Christoph Siethoff</i>	<i>Jérôme Barré</i>
12:45	Reference standards, integration of chromatography based and ligand-binding based assays, stability testing, assay precision and accuracy testing, full validation, partial validation, cross validation EBF-EUFEPS position (10 min) Up to 4 Presentations (each 10 min) Open discussion (60 min)		
12:45	Lunch Break		
13:45	Session II – Method Validation of Chromatography Based Assays (Small Molecules)	<i>Berthold Lausecker</i>	<i>Jan Welink</i>
15:45	Matrix effect selectivity LLOQ determination CHMP problem statement (10 min) EBF-EUFEPS position (10 min) Up to 4 Presentations (each 10 min) Open discussion (60 min)		
15:45	Coffee Break		
16:15	Session III – Method Validation of Assays for Ligand Binding Based Assays (Large Molecules)	<i>Margarete Brudny-Klöppel</i>	<i>Jan Welink</i>
18:15	Parallelism and dilution integrity, LLOQ determination, selectivity testing CHMP problem statement (10 min) EBF-EUFEPS position (10 min) Up to 4 Presentations (each 10 min) Open discussion (60 min)		
Reception			

Friday, April 16, 2010			
Time		Chair (Organisers)	Co-chair (EMEA)
09:00	Session IV (1) – Analysis of Study Samples	<i>Gabriele Rohde</i>	<i>Olivier Le Blaye</i>
10:30	Incurred Sample Reanalysis, Reanalysis of study samples, Integration, Acceptance criteria, Multi-analyte assays, Sequence design, Carry-over assessment, Assay range changes CHMP problem statement (10 min) EBF-EUFEPS position (10 min) Up to 3 Presentations (each 10 min) Open discussion (40 min)		
10:30	Coffee-Break		
11:00	Session IV (2) – Analysis of Study Samples	<i>Gabriele Rohde</i>	<i>Olivier Le Blaye</i>
12:30	Study Report, Assay Report CHMP problem statement (10 min) EBF-EUFEPS position (10 min) Up to 3 Presentations (each 10 min) Open discussion (40 min)		
12:30	Lunch Break		
13:45	Wrap-up and Closing Remarks	<i>Erich Brendel,</i> <i>Berthold Lausecker,</i> <i>Christoph Siethoff</i>	<i>Jan Welink,</i> <i>Olivier Le Blaye,</i> <i>Jerome Barré</i>
15:45			
Workshop Facilitators			
Moderators: Howard Hill & Kamal Midha			
Rapporteur: Henning Blume			

Who should attend?

The Workshop is organised as an open plenary discussion forum to meet the requirements and expectations of professionals from the generic and the research based industry, CROs, academia and regulatory agencies. Department heads, project managers, bioanalytical scientists and consultants in R&D, in regulatory affairs, pharmacokinetics, clinical studies, and biostatistics and so forth should attend in order to contribute with their experience with the scientists from European regulatory agencies. All delegates are invited to contribute actively to the scientific discussions and to support the process toward science driven regulations.

Open Discussion Forum Sessions and Leadership

Each one of the three-hour forum discussion sessions, will be co-chaired by one representative of EBF, EMEA and EUFEPS, normally, and start with a thirty-minutes background presentation on the chapter topics to be discussed. Other additional presentations will also be inserted.

Call for Commentaries (10 minutes presentations)

In order to stimulate discussions, the Organising Committee is inviting registered delegates to provide commentaries in 10 minutes session specific presentations. The presentations should provide the view of the presenter and/or its organisation on which behalf she/he is presenting and should preferentially be data based. Presentations will be selected, on the basis of the abstract, as will for what session the presentation will be accepted. These presentations are strongly limited to 10 minutes each. No commercial advertisement will be allowed.

Please submit your abstract, of no more than 200 words, and your full address, by March 22, 2010, to the Organising Committee at: eufeps@congrax.com indicating the name of the workshop (EBF & EUFEPS Workshop on EMEA Draft Guideline on Validation of Bioanalytical Methods).

The acceptance of your presentation will be communicated by March 29, 2010. Accepted presentations should be sent, in common Microsoft Office format applications as Power Point, Excel or Word, to: eufeps@congrax.com as well, by April 6, 2010.

Conference Co-chairs

Dr. Erich Brendel, Bayer Schering Pharma, Berlin, Germany (also EUFEPS BABP Network)
Dr. Berthold Lausecker, F. Hoffmann-La Roche, Basel, Switzerland (also EBF)
Dr. Christoph Siethoff, Swiss BioQuant, Reinach, Switzerland (also CROs)

Workshop Leaders and Contributors

Jérôme Barré, Centre Hospitalier Intercommunal, Créteil, France
Henning Blume, Socratec R&D, Oberursel, Germany
Erich Brendel, Bayer Schering Pharma AG, Wuppertal, Germany
Margarete Brudny-Kloeppe, Bayer Schering Pharma AG, Berlin, Germany
Howard Hill, Huntington Life Science, Huntington, United Kingdom
Berthold Lausecker, F. Hoffmann-La Roche Ltd, Basel, Switzerland
Olivier Le Blaye, AFSSAPS, Saint Denis, France
Kamal Midha, University of Saskatchewan, Saskatoon, Canada and FIP, The Hague, The Netherlands
Gabriele Rohde, Bayer Schering Pharma AG; Wuppertal, Germany
Christoph Siethoff, Swiss BioQuant AG, Basel, Switzerland
Jan Welink, The Medicines Evaluation Board (MEB), The Hague, The Netherlands

Registration and Accommodation

Please click here to Register for the EBF-EUFEPS Workshop on the EMEA Draft Guideline on Validation of Bioanalytical Methods

For room reservations at the venue or nearby hotel, please make direct contacts with the reservation departments of, for example:

Sheraton Hotel Brussels

Tel + 32 2 2243111

Email reservations.brussels@sheraton.com

www <http://www.starwoodhotels.com/sheraton/index.html>

Thon Hotel Brussels City Centre

Tel + 32 2 2051511

Email brusselcitycentre@thonhotels.be

www <http://www.thonhotels.be/brusselcitycentre>

For workshop leaders and contributors, a number of rooms have been blocked at the Sheraton Hotel Brussels (see Online Registration Form).

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Dr. Berthold Lausecker, F. Hoffmann-La Roche, Basel, Switzerland (also EBF)
Dr. Christoph Siethoff, Swiss BioQuant, Reinach, Switzerland (also CROs)

Plan to join!

Consult the EBF Website or EUFEPS Online for updates!
EBF – European Bioanalysis Forum
Email europeanbioanalysisforum@gmail.com
EBF Website www.europeanbioanalysisforum.eu

Organised by the
EBF – The European Bioanalysis Forum and
EUFEPS – European Federation for Pharmaceutical Sciences



EUFEPS Secretariat
Veddesta Business Center
SE-175 72 Järfälla (Stockholm) Sweden
Phone +46 8 50582040
Fax +46 8 4113217
Email conferences@eufeps.org
Website www.eufeps.org

EBF
– European Bioanalysis Forum
Email europeanbioanalysisforum@gmail.com
Website www.europeanbioanalysisforum.eu

