ECA
European Compliance Academy

Bio Production Forum 2013

The new GMP Annex 2

Biological APIs and Medicinal Products

19 -20 June 2013, Copenhagen, Denmark

HIGHLIGHTS:

- Changes in Part A general chapters
- Requirements of Part B – modern products
- Quality Assurance in Biotechnology - the practicalities and why it's different
- GMP implementation for advanced cell and cell-based products
- GMP in early phases – Requirements during development with focus on process-related items and analytics
- Annex 2 and its application to the manufacture of biological active substances

FROM AUTHORITIES

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This conference is supported by:

LMU Ludwig-Maximilians-Universität München · Cilag · Universiteit Leiden · MERCK · Roche

This conference is supported by

The University of Munich, Germany / Chair for Pharmaceutical Technology and Biopharmaceutics at the Department of Pharmacy-Center for Drug Research

The Center for Drug Research is dedicated to training in all areas of pharmaceutical technology for undergraduate and graduate students and to research in the field of parenteral dosage forms, colloidal systems and has a specific focus on protein drug formulations. The Center conducts research projects with a number of biotech drugs Further research topics are drug delivery systems for topical delivery as well as systemic depot forms and targeting approaches using nano-scaled technologies. Process technologies in the area of freeze drying, spray drying, nanoparticle and liposome formulation etc. are applied and further developed.

Schweizerische Gesellschaft der Pharmazeutischen Wissenschaften (SGPhW) / Swiss Society of Pharmaceutical Sciences (SAPhS)

The society promotes as a principal goal Pharmaceutical Sciences in Switzerland. For this purpose the society has assumed the function of an academy pursuing the following mission:

- Unifying and coaching the national and regional societies linked to the discipline of Pharmaceutical Sciences
- Promotion of national and international scientific contacts and of cooperations with other scientific societies and academies
- Public promotion of Pharmaceutical Sciences
- Promotion of the communication of eminent pharmaceutical findings and realizations in science, research, development, industry, health care and public society
- To award distinguished persons for their merits in Pharmaceutical Science

Cilag AG

Founded in 1936 in Schaffhausen, Switzerland, CILAG's creative and innovative approach has resulted in the continuous introduction of new products, processes and technologies. Today, the company is a worldwide strategic development, launch and production center of APIs (active pharmaceutical ingredients) and drug products within the Johnson & Johnson Pharmaceuticals Group, the world's most comprehensive and broadly based manufacturer of health care products, as well as a provider of related services, for the consumer, pharmaceutical and professional markets.

University of Leiden

Leiden University is the oldest university in the Netherlands. It was founded in February 1575, as a gift from William of Orange to the citizens of Leiden who had withstood a long siege by the Spaniards In Leiden there are approximately 17,000 students and 4,000 staff members. The University consists of nine faculties, a School of Management and a School of Education. The University houses faculties of Archaeology, Arts, Creative and Performing Arts, Law, LUMC (Leiden University Medical Center), Mathematics and Natural Sciences, Philosophy, Social and Behavioural Sciences, and Theology.

Merck Serono

Merck Serono is the division for innovative prescription pharmaceuticals of Merck KGaA, Darmstadt, Germany, a global pharmaceutical and chemical company. Headquartered in Geneva, Switzerland, Merck Serono discovers, develops, manufactures and markets innovative small molecules and biopharmaceuticals to help patients with unmet medical needs. In the United States and Canada, EMD Serono operates through separately incorporated affiliates. For more information, please visit www.merckserono.com or www.merck.de.

Roche

Roche is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world's largest biotech company with differentiated medicines in oncology, virology, inflammation, metabolism and CNS. Roche is the world leader in in-vitro diagnostics, tissue-based cancer diagnostics and a pioneer in diabetes management. The personalised healthcare strategy aims at providing medicines and diagnostic tools for improvements in the health, quality of life and survival of patients.

Bio Production Forum

The new GMP Annex 2

19-20 June 2013, Copenhagen, Denmark

Objectives

This conference will provide information about the changes in the Annex 2 and the impact of these changes on biopharmaceutical development and manufacturing. Expert speakers from authorities, industry and laboratories with experiences on different types of biopharmaceuticals, e.g. vaccines, gene therapeutics ATMP, will present their experiences on implementation of the Annex 2. They show you the regulatory requirements as well as practical approaches to realize GMP standards in biopharmaceutical development and manufacturing companies. It will be a unique chance to discuss the different points of view with speakers and colleagues.

Background

On 31 January 2013, the new Annex 2 of the EU GMP Guide becomes effective. In the review period of about five years the volume increased from 5 to 32 pages. The revised version shows comprehensive modifications and additions in comparison with the last version. The tremendous developments in the area of biopharmaceutical products - especially the developments in the area of transgenic products and Advanced Therapy Medicinal Products (ATMP) - urgently required a review. The first significant modification already becomes obvious in the name of this Annex. In its 2004 version it only comprised "Biological Medicinal Products", while the new version now also covers "Biological Active Substances".

To take into consideration the diversity of biological products the new Annex 2 is separated in two parts. Part A comprises the general requirements relative issues like Personnel, Premises and Equipment, Starting and Raw Materials, Production and more.

Part B of the revised Annex 2 covers the special requirements with regard to the origin or respectively to the type of product. The following groups are addressed:

1. Animal sourced products
2. Allergen products - materials manufactured by extraction from natural sources as well as by recombinant DNA technology
3. Animal Immunosera products
4. Vaccines
5. Recombinant products
6. Monoclonal antibody products
7. Transgenic animal products
8. Transgenic plant products
9. Gene therapy products
10. Somatic and xenogeneic cell therapy products and tissue engineered products

The new Annex 2 necessitates for many companies and institutes to review their existing quality system to evaluate whether additional measures are necessary.

Target Audience

Responsible persons from biopharmaceutical industry, laboratory, research institutions and authorities who are involved in

- Quality Control
- Quality Assurance
- Regulatory Affairs
- Research and Development
- Audits and Inspections

Programme

GMP Requirements for Biopharmaceuticals, Annex 2 Part A (General Guidance) - An Inspector's view

- New requirements from revised Annex 2
- Scope of the revised Annex 2
- Regulatory expectations on
  - personnel
  - premises
  - equipment
  - production
- Common issues during GMP inspections of biopharmaceutical manufacturing sites
- Examples of typical observations

DR DANIEL MÜLLER, *GMP Inspectorate Tübingen, Germany*

Quality Assurance in Biotechnology - the practicalities and why it's different

- Challenges facing the implementation of GMP quality
- Required thought processes
- Ways of approaching the subject

DR PAUL STOCKBRIDGE, *Stockbridge Biopharm Consulting*

Expectation of a licensing Agency

- Guideline on Process Validation
- EU Inspection Trends
- New Trends in Manufacturing and Controls: PAT, QbD, Starting materials,
- QbD Submissions related inspections - Experiences

STEFFEN GROSS, *Paul-Ehrlich Institut, German Federal Agency for Vaccines and Biomedicines*

How to manage the inherent variability of biotechnological products – Implementation of annex 2 in vaccine manufacturing

- Under one roof: The challenges of multi-product facilities
- Clean and safe: Handling infectious agents under GMP
- Next one please: Change over principles in campaign-based vaccine manufacturing

DR JOCHEN PROBST, *IDT Biologika*

Impact of Annex 2 on ATMP – Regulatory View

- Overview: The ATMP Landscape
- Interface: Where does GMP for cell-based products start?
- Manufacturing: Does the revised Annex 2 provide new tools for ATMPs?
- Observations: Common deficiencies in clinical trial applications and inspections

RALF SANZENBACHER, *Paul-Ehrlich Institut, German Federal Agency for Vaccines and Biomedicines*

GMP Implementation for advanced cell and cell based products

- Technical requirements and clean room concept
- Validation : cleaning, aseptic processing and process validation
- Qualification of clean room personnel

DR CHRISTOPH PETER, *Apceth*

Integration of Annex 2 principles into multiproduct monoclonal antibody drug substance facility design and start up

- Design considerations for Annex 2
- Incorporation of multiproduct elements
- Facility Qualification
- Facility Start-up and Process Validation

TO BE NAMED

GMP in early phases – Requirements during development with focus on process-related items and analytics

- Process development in the new Annex 2 environment
- Analytical tools to control process development in early stages
- Quality control during clinical development

DR MARKUS FIDO, *VelaLabs*

Continuous Process Verification – a new level of interaction between dossier evaluation activities and GMP activities (inspections)"
STEFFEN GROSS, ***Paul-Ehrlich Institut, German Federal Agency for Vaccines and Biomedicines***

Annex 2 and its application to the manufacture of biopharmaceutical active substances
- Cell Banking
- Supplier qualification and material management
- Implementation

DR OLWEN BIRCH, ***Lonza***

Special requirements on protein analytics related to Annex 2
- Analytical method design for in-process control & product release
- Biological assays and potency determination
- Compliance with other legal requirements and Guidelines

DI KLAUS HAJSZAN, ***VelaLabs***

Speakers

DR OLWEN BIRCH, LONZA, SWITZERLAND
Olwen is a biochemist with over 20 years of experience in the biopharmaceutical industry. For the last 13 years she has worked in Quality Assurance and is currently Head of Quality Systems at Lonza's Visp site, with responsibility for regulatory inspections, audits and compliance.

DR STEFFEN GROSS,SCIENTIFIC ASSESSOR AND LABORATORY HEAD, PAUL-EHRLICH-INSTITUT, GERMANY, AGENCY FOR VACCINES AND BIOMEDICINES
Steffen Groß pursued a PhD degree at Max Planck Research Unit Molecular Cell Biology Jena, Germany. Today, he is Deputy Head of the Section Monoclonal and Polyclonal Antibodies, Laboratory Head and Scientific Assessor (Quality, Pre-clinic) at the Paul-Ehrlich Institute.

DR MARKUS FIDO, VELA, AUSTRIA
Markus Fido is CEO and Founder of Vela Laboratories, were he is responsible for Finance & Controlling Regulatory Affairs & Quality Operations. Before that he was Head Quality Control at Igeneon / Aphton Biopharma AG where he was in charge for all QC aspects of pre-clinical and clinical projects such as stability studies, specifications, method validation, and product release. Prior he was working as a Group Leader of Immunology and Product Development at Biomin GmbH, Head Biochemical Control at Baxter AG and Head Quality Operations at Octapharma GmbH. His focus is GMP/GCP concerns during the development of Biopharmaceuticals, Biosimilars and Biologics. He holds a Ph.D. in biochemistry and molecular microbiology from the Technical University in Graz (Austria).

DR DANIEL MÜLLER, GMP INSPECTOR, LOCAL GOVERNMENT TÜBINGEN, GERMANY
Daniel Müller studied Pharmacy at the University of Wuerzburg, followed by doctorate. He started working in the pharmaceutical industry in 1998. Among other positions he served as a Qualified Person of large volume parenterals. In 2001 he joined a German inspectorate at Tübingen. Since that time he has been working as a GMP Inspector with focus on biotechnological active ingredients and sterile drug products.

DR CHRISTOPH PETER, HEAD OF PRODUCTION, APCETH GMBH & CO. KG, GERMANY
Christoph Peter studied Biology at the University of Heidelberg with focus on molecular- and cell-biology. After finishing his PhD at the MPI for medical Research in Heidelberg, he worked as a postdoctoral fellow at Stanford University, CA, USA. From 2008 until 2012 he was working for apceth, a biotech start up company located in Munich, as head of manufacturing for cell based medicinal products. Since January 2012 he is holding the position of Head of Quality Management at apceth.

Speakers

DR JOCHEN PROBST, IDT BIOLOGIKA GMBH, GERMANY
Jochen Probst studied Biology at the University of Tübingen. After completing his PhD in 2005 he joined the biotech company CureVac GmbH in Tübingen where he held different positions in preclinical research and development as well as in vaccine manufacturing. He was substantially involved in achieving regulatory approval for first in man clinical trials of an entirely new vaccine technology based on messenger RNA in Europe and the US. In 2012 he joined IDT Biologika GmbH in Dessau-Rosslau. As Senior Compliance Manager Quality Unit Vaccines he is heading the quality assurance of the vaccine manufacturing business of the company.

KLAUS HAJSZAN, VELA LABORATORIES, AUSTRIA.
He studied Bioengineering / Quality Management in Vienna. He is Head of Quality Control at Vela Laboratories and responsible for planning, controlling and statistical analysis of method validation and for the coordination of analytical method transfer

DR RALF SANZENBACHER, PAUL-EHRLICH-INSTITUT, GERMAN AGENCY FOR VACCINES AND BIOMEDICINES
Dr Ralf Sanzenbacher works at the Section of Somatic Cell Therapy and Tissue Engineering at the Paul-Ehrlich-Institut. He is an expert for quality and preclinical aspects within the scope of manufacturing license, clinical trials and marketing authorisation.

DR PAUL STOCKBRIDGE, STOCKBRIDGE BIOPHARM CONSULTING, UNITED KINGDOM
Dr Stockbridge spent 23 years with Eli Lilly, initially in fermentation development and then in quality assurance where he became a Q.P. and Q.A. Advisor for biotechnology projects for which he travelled globally. He then moved to a Head of Quality Operations role with Aventis Pharma before being appointed to the role of Corporate Quality Director for Cobra Biomanufacturing Plc. After over 7 years with Cobra he is now providing independent consulting and training services for the steriles, aseptic and biotechnology industries. Paul has a degree in biology, a PhD in fermentation, is an EU Qualified Person and is a Fellow of the U.K. Society of Biology.

DR GÜNTER WAXENECKER, AGES PHARMMED, AUSTRIA
Günter Waxenecker studied Food science and Biotechnology at the University of Agricultural Sciences in Vienna; Started in Research at Novartis Research Institute in Vienna, later in R&D for Igeneon and finally Intercell; Held various positions as Postdoc, Project Leader and Program Manager; Now working as Assessor (Expert Biologics) at AGES PharmMed (Austrian Competent Authority) involved in assessment of clinical trial applications and as EMEA expert assessing products submitted for marketing authorization under the EMEA centralized procedure. Additionally assessor for national and central (EMEA) Scientific Advice procedures.

Social Event

On 19 June you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

Conference language

The official conference language will be English.

About CONCEPT HEIDELBERG

Founded in 1978, CONCEPT HEIDELBERG is the leading organiser of seminars on pharmaceutical production, quality control, quality assurance and GMP in Europe. This year more than 240 events will be organised by CONCEPT HEIDELBERG. ECA has entrusted CONCEPT HEIDELBERG with the organisation of its events.

GMP Certification Programme

This conference is recognised within the GMP Certification Programme Module "Biotech Manager". By attending selected seminars, the participant can acquire an additional certificate. We offer the following modules:

- Validation Manager (ECA)
- QA Manager (ECA)
- API (Production) Manager (ECA)
- Quality Control Manager (ECA)
- Pharmaceutical Engineering/Production Manager (ECA)
- Computer Validation Manager (ECA)
- Regulatory Affairs Manager (ECA)
- Microbiological Laboratory Manager (ECA)
- Sterile Production Manager (ECA)
- Pharmaceutical Development Manager (ECA)
- Biotech Manager (ECA)

On the internet at www.gmp-compliance.org you will find a text explaining which seminars are recognised for which certificates. Or you send an e-mail to info@gmp-compliance.org or a fax to +49-6221- 84 44 64 with the request for information about the GMP Certification Programme. We will then send you our brochure on the topic.

What Is ECA?

The European Compliance Academy (ECA) is an independent educational organisation chaired by a Scientific Advisory Board with members of the pharmaceutical industry and regulatory authorities. The ECA will provide support to the Pharmaceutical Industry and Regulators to promote the move towards a harmonised set of GMP and regulatory guidelines by providing information and interpretation of new or updated guidances.

What Are the Benefits of ECA?

First benefit: During the membership, you enjoy a 200 EUR discount on the regular participation fee of any European Conference organised by ECA in co-operation with CONCEPT HEIDELBERG.

Second benefit: The GMP Guideline Manager Software with a large number of guidelines, e.g. EC Directives, FDA Guidelines, ICH Guidelines, will be forwarded to you when you are using your membership for a conference registration.

How Do You Become Member of ECA?

By participating in one of the European Compliance Conferences or Courses marked with ECA, you will automatically become a member of ECA for two years – free of charge. There are no obligations for the member! Conferences and Education Courses organised by ECA will be realised in co-operation with CONCEPT HEIDELBERG. More information about ECA can be obtained on the Website www.gmp-compliance.org.

Special offer with Lufthansa – discounted travel for Bio Production Forum attendees

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As an ECA course or conference attendee, you will receive **up to 20% discounted travel fares** (according to availability). And as Lufthansa German Airlines offers a comprehensive global route network linking major cities around the world you will most likely be able to benefit from these special prices and conditions.

And this is how it works: Once you registered for a course or conference you will receive a link together with your registration confirmation. Opening that link will take you to the Mobility Partner Program website where you can enter a code in the "Access to Event Booking" area you will also receive. This will take you into an online booking platform that will automatically calculate the discount offered or provide you with an even better offer if another promotional fare is available.

We look forward to welcoming at one of our next events – and we already wish you a pleasant flight!

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.bio-conference.org

Date
Wednesday, 19 June 2013, 09.00 – 18.00 h
(Registration and coffee 08.30 – 09.00 h)
Thursday, 20 June 2013, 09.00 – 16.00 h

Venue
Radisson Blu Scandinavia Hotel
Amager Boulevard 70
2300 Copenhagen S, Denmark
Tel +45 33 96 50 00
Or
00 800 3333 3333
Fax +45 33 96 55 55

Fees
ECA Members € 1,590.-*
APIC Members € 1,690.-* (does not include ECA Membership)
Non-ECA Members € 1,790.-*
EU GMP Inspectorates € 895.-*
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on both days and all refreshments. VAT is reclaimable.

* per delegate plus VAT

Registration
Via the attached reservation form, by e-mail or by fax message. Or you register online at www.bio-conference.org.

Accommodation
CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form when you have registered for the event. Please use this form for your room reservation to receive the specially negotiated room rate for the duration of your stay. Reservation should be made directly with the hotel. Early reservation is recommended.

Organisation and Contact
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Reservation Form (Please complete in full)

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The new GMP Annex 2 – Bio Production Forum 2013
Copenhagen, Denmark, 19 – 20 June 2013

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1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees: Cancellation
- until 2 weeks prior to the conference 10 %,
- until 1 weeks prior to the conference 50 %
- within 1 week prior to the conference 100 %.

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