CELS®

Workshop

Securing Quality in Bioanalysis and Production

25 November 2009

Stockholm, Sweden

At the meeting you get

A regulatory up-date on biologicals production

Quality by Design as viewed by medical products agencies and the EMEA PAT team

Analysis of product variants and refinement of process design

Data management with a focus on quality assurance

A general discussion on: Optimal resource allocation in quality assessment and control

Technology presentations:

QCM based analysis of product attributes such as glycosylation dependent interaction

Meeting up with regulatory requirements within Cleaning validation

Durability of polymeric materials

CEFFORT®

Workshop
Securing Quality in Bioanalysis and Production

25 November 2009

Venue: Stockholmsmässan locality B9 (in parallell with BiotechForum, ScanLab and The Annual General Meeting of The Swedish Society of Medicine)

Overview Programme

09.30 - 10.00	**Registration with coffee/tea**
10.00 - 10.20	**Welcome - Intention with this meeting** (Gunnar Hörnsten, CEFFORT AB)
Plenary program:	
10.20 - 10.50	**Regulatory and Quality Considerations for Development of Biopharmaceuticals** (Karin Sewerin, BioPharmaLinx AB)
10.55 - 11.25	**Quality by Design as viewed by medical products agencies** (Mats Welin, Medical Products Agency and the EMEA PAT team)
11.30 - 11.45	Short break
11.50 - 12.20	**Analysis of product variants** (Per Edebrink, Recipharm Biologics AB)
12.25 - 12.55	**A real-time, continuous flow QCM-based biosensor** (Alexander Kovacs, Attana AB)
13.00 - 14.00	Lunch and networking
14.00 - 14.30	**Accelerated ageing and lifetime prediction** (Ignacy Jakubowicz, SP Technical Research Institute of Sweden)
14.35 - 15.05	**Essentials in set-up of cleaning validation** (Stefan Olsson, Ecolab)
15.10 - 15.25	Coffee
15.30 - 16.00	**From the creation of the Human Protein Atlas to business growth by IT-based PDM/PLM tools** (Erik Björling, Filoprocess AB)
16.05 - 16.45	**Discussion on Optimal resource allocation in quality assessment and control** (chaired by Sven Petrén)
16.45 - 16.50	**Suggestion to a CEFFORT®: A collaboration on** Best practices, demands from regulatory authorities, quality attributes and price for quality assessment based on advanced bioanalysis.
16.50 - 17.00	**Discussion and Closing remarks**
17.00	**Drinks**

The intention with this meeting
(Gunnar Hörnsten, CEO, CEFFORT AB)

Abstract: A key ambition is to support our members in the strengthening of their international competitiveness. This is done e.g. through collaboration on best practices, quality attributes and price for quality assessment in advanced bioanalysis. At this meeting the general question how demands from regulatory authorities should be translated into in-house resources is disseminated?

Regulatory and Quality Considerations for Development of Biopharmaceuticals
(Karin Sewerin, BioPharmaLinx AB)

Abstract: Biopharmaceutical products are complex molecules, and are a result of a complex process all the way from design to the production. The regulatory requirements and control of manufacturing process and product to be used in clinical trials in preparation for registration will be discussed. Expectations on quality of material to be used in phase 1, as well as risks associated with biological materials and how to ensure to reduce the risks to the patients will be presented. Can quality systems and reduced testing associated with QbD (Quality by Design) be applied to biological products and a biotech process, or is the process still the product in the word of biologicals?

Quality by Design as viewed by medical products agencies (Mats Welin, Swedish Medical Products Agency)

Abstract: ICH Q8, Q9 and Q10 have introduced a new paradigm for control of medicinal products including biologicals. The development will be more science based and will result in a control strategy which is more focused on what is critical for the product in terms of quality, safety and efficacy. Even if it is expected that the control strategy will change with the introduction, the degree of control should not be less. The expectations from the regulatory agencies on aspects to be covered in a QbD application will be discussed.

Analysis of product variants
(Per Edebrink, Recipharm Biologics AB)

Abstract: Biologics are indeed challenging products and the manufacturing is a complex process that typically involves refinement throughout all phases, from early discovery to post-approval and marketing. The reasons to change manufacturing process are many, e.g. higher yields, higher purity, increased stability, scale-up or change of manufacturing facilities. Changes introduced into the process may alter the structural attributes of the product, for example by changing the post-translational modification profiles. This may lead to altered biological effects of the product and thus possibly affecting the efficacy or safety of the product.
It is required to characterise the physico-chemical properties of the product in order to assess the risks associated with any major change to the process. Analytical tools and examples of post-translational modification profiling will be discussed during the presentation.

A real-time, continuous flow QCM-based biosensor
(Alexander Kovacs, Global Product Manager, Attana AB)

Abstract: This presentation will discuss the applications of the Attana's label-free and real-time analysis technology to address the current market needs for high quality and cost-efficient analysis of molecular interactions. The presentation will show 2 case studies. The first showing how to use the technology to speed up clonal selection and expression analysis and the second one of development of a biopharmaceutical and the usages of Attana's biosensors in the preclinical process for quality control, selection, inter species interaction and control of glycosylation dependent interactions.

Accelerated ageing and lifetime prediction
(Ignacy Jakubowicz, SP Technical Research Institute of Sweden)

Abstract: The constantly increasing use of polymers in various technological environments presents an important challenge to the polymer technologists concerning development of new materials and products and to scientists in providing a scientific basis for understanding the degradation phenomena and ultimately to controlling them. Questions associated with performance, cost, durability and environmental effects are closely related to each other and must be answered before the industry and the consumers can adopt new materials. There are two fundamentally different approaches to modelling the durability of materials: empirical approach that attempts to describe mathematically "what has happened" and predictive approach which is based on a mathematical assessment of the effects of dependent and independent variables and the subsequent refinement of the prediction based on experimental data. Accelerated ageing tests and extrapolation of test results constitute the predictive approach.

Essentials in set-up of cleaning validation
(Stefan Olsson, Ecolab)

Abstract: This presentation will discuss cleaning validation requirements as stipulated by regulatory frameworks and possible means of approaching such project practically. Given various types of manufacturing; small molecules and large; biomolecules, various conditions of cleaning are to be considered. Herein, process equipment, development of analytical methods and validation of these, degradation identification, acceptance criteria and acceptance limits of cleaning agents, protocol development and cleaning SOP. I will pinpoint essentials e.g. preparation work; documentation, written cleaning validation plan and a rational supporting the analytical methods and limits defined etc. Finally some words on the maintenance phase and issues like monitoring, revalidation and change control.

From the creation of the Human Protein Atlas to business growth by IT-based PDM/PLM tools (Erik Björling, Filoprocess AB)

Abstract: This presentation will describe how a large and labour intensive academic biotechnology project was taken from paper notes via Microsoft Excel to a database-based software system. During the course of curation and standardization of the production processes, the overall production rate of the project was increased 30 times! Experience, lessons learned and good practice will be presented with focus on quality assurance. The presentation will also cover general definitions and approaches to PDM/PLM (Product Data Management/Product Lifecycle Management). IT should be an enabler for business growth through improved productivity and secured quality in the field of bioanalysis and production.

Workshop organiser
CELS Network www.ceffort.org

Gunnar Hörnsten, CEO
CEFFORT AB

Persons:

Gunnar Hörnsten has more than 25 years of experience within Biotechnology. He has established and coordinated/managed Networks and larger R&D programmes involving many participants (total exceeding 150) on the Nordic market since 1994. With a PhD from Linköping Institute of Technology and 14 years experience from the Swedish Industry Institute Sector, he has worked cross-diciplinary within Life Sciences. His speciality area involves analytics within Microbiology and Biotechnology in which he holds an associate professorship (docent). Founder of Hörnstens Analytica in 1992. Founder and CEO of CEFFORT AB in 2009.

Karin Sewerin is a Sr. Consultant at BioPharmaLinx AB working with quality strategy and regulatory advice for development and registration of Biopharmaceuticals. She has over 25 years of industrial experience from Kabi-Pharmacia and AstraZeneca in Sweden and Genentech in USA. Karin has worked with development and validation of analytical methods for in process control and release testing for products in clinical trials and for registration. She has also worked with process validation, process characterization, technology transfers for clinical and marketed products, and definition and development of Quality by Design for Biotechnology derived products in industrial and regulatory groups. She holds a PhD in Pharmaceutical Biochemistry at the University of Uppsala, Sweden.

Dr **Per Edebrink** is Principal Scientist at Recipharm Biologics AB, a Contract Development and Manufacturing Organisation (CDMO) in the Recipharm group. He finished his PhD in Organic Chemistry at Stockholm University, Sweden in 1995. Afterwards he joined AstraZeneca where he held positions as team manager and Associate principal scientist within pharmaceutical and analytical research and development. With a background in mass spectrometry, protein and carbohydrate chemistry he is responsible for the characterisation and comparability of protein products at Recipharm Biologics.

Erik Björling was, during 2003-2009, Director of Infomatics for the Human Proteome Resource program at the Royal Institute of Technology (KTH) in Stockholm. As such, he was responsible for the development of all IT-tools and the creation of the public Human Protein Atlas (www.proteinatlas.org). Erik Björling has a PhD in Biotechnology from the Royal Institute of Technology (KTH) and a MSc in Software Engineering from Blekinge Institute of Technology, and has a wide IT-experience through delivery of IT-solutions in several different domains, such as retail business, armed forces, stock

exchange, finance and biotechnology. Erik Björling now works as project manager and IT-architect at FiloProcess AB (www.filoprocess.se). FiloProcess is a consultancy firm specialized in the areas of Product Data Management (PDM) and Product Lifecycle Management (PLM). FiloProcess delivers a wide range of services and products to companies in order to measure, analyse, improve and secure their business processes through efficient utilization of IT-tools.

Mats Welin is a pharmacist by training and is working as a senior Expert at the Medical Products Agency dealing with quality assessment of biological products and normative work within the field. He has also been involved in regulatory discussions on regulations relating to biologicals at EU level. He is a member of the CHMP subgroups on biologicals, the Biological Working party, and on QbD related issues, The EMEA PAT team. He is also a member of the ICH Quality implementation working group aimed at advising how the new principles should be introduced globally in a harmonised way.

Dr **Alexander Kovacs** is Global Product Manager at Attana AB (Stockholm, Sweden). He has a background in academic research at Karolinska Institutet (Stockholm, Sweden) and Oxford University (UK). His research involves genetics and systems biology within the field of cardiovascular medicine, with a special focus on inflammation and immunological processes in vitro as well as in vivo. Dr Kovacs also has a broad experience involving entrepreneurial enterprises and start-up companies.

Associate professor **Ignacy Jakubowicz** is R&D Manager at the Polymer Technology Department at SP Technical Research Institute of Sweden. He finished his PhD in Physical Chemistry at the University of Gothenburg/Sweden in 1985 and afterwards he joined SP. An essential part of his scientific work comprises degradation, stabilisation and lifetime technology of polymeric materials, polymer nanocomposites and biodegradable materials.

Stefan Olsson has 22 years experience in cleaning technology, BSc in chemical engineering. Work for Ecolab, a US based company specializing in cleaning and disinfection technology covering various markets. Previous positions; R&D, Quality and Environmental Management, Application technology Food, Sales in pharmaceutical market, and currently responsible for Regulatory and Technical Affairs in Division Healthcare Nordic of Ecolab.

Dr **Sven Petrén** has nearly 20 years of experience at different positions within Biotech Drug Development, including positions as both project leader and group manager. His work has mainly focused on characterisation, analysis and formulation of proteins/peptides and he has also been a member of the biotech expert group at EFPIA and was involved in the development of international guidance documents, e.g ICH guidelines.

Suggestion to a CEFFORT®: A collaboration on best practices, demands from regulatory authorities, quality attributes and price for quality assessment based on advanced bioanalysis. (Gunnar Hörnsten, CEFFORT AB)

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Binding Registration

Securing Quality in Bioanalysis and Production

Discount price for members of *CEFFORTs in Life Sciences**

early registration (before 091106)	600 SEK/person
final registration deadline 091120	950 SEK/person

Non-members of *CEFFORTs in Life Sciences**

early registration (before 091106)	1 950 SEK per person
final registration deadline 091120	2 450 SEK per person

See www.ceffort.org for information on membership

*VAT (25 %) will be added for Swedish participants and participants without international VAT registration number.

Send an email with the information below to:

registration@ceffort.org

Needed information:

- Company/University/Organisation
- Name, email, telephone and address of Participant
- International VAT reg. number (non-swedish participant)

Please: specify which meeting that you register to!

Confirmation of Meeting and Registration (Disclaimer)
In case the meeting is moved to a different venue, cancelled or postponed, an email will be sent to the participants on the day after the final registration date. The organisers takes no responsibility for travel or other costs in the case an unconfirmed meeting is moved to a different venue, cancelled or postponed.

Questions on registration: Call +46 (0)46 286 3351

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