EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

9 April 2013
EMA/169648/2012
Human Medicines Development and Evaluation

Expert workshop on process validation for the manufacture of biotechnology-derived active substances

Final programme

9 April 2013
European Medicines Agency, London, United Kingdom

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

Introduction

This one-day workshop is organised by the European Medicines Agency (EMA).

In May 2011, the Biologics Working Party (BWP) of the Committee for Medicinal Products for Human Use (CHMP) issued a concept paper stipulating the need for a guideline on process validation for the manufacture of biotechnology-derived active substances. The request stems from the lack of detailed guidance on this topic and the need to provide practical recommendations on data requirements in the context of an initial marketing authorisation application (MAA) for a biotech product.

To assist the BWP in drafting this guideline, a one-day stakeholder workshop on biotech manufacturing process validation is being organised in collaboration with pharmaceutical-industry associations (EFPIA, EBE, EGA, EuropaBio). The aim of the workshop is to address key questions concerning specific evaluation/validation data that are required to confirm the reproducibility and robustness of the process steps, and ultimately guarantee a product of consistently high quality at the time of evaluation of the MAA.

It is expected that the output from the workshop will provide useful reference for the future Agency guideline on process validation for the manufacture of biotechnology-derived active substances.

Programme

Tuesday, 9 April 2013

8.30 Registration

Go to the second floor lobby to register and receive your badge. Then join delegates in room 2A.

9.00 Welcome and opening

Jean Hugues Trouvin

Chair EMA Biologics Working Party (BWP), Université Paris Descartes

Enda Moran

Chair EBE BioManufacturing WG, Pfizer

9.10 Initial lecture

General Concepts on Process Validation

Kowid HO

BWP, ANSM

9.30 Session 1(a): Traditional approach — Upstream process

Moderators: Brigitte Brake (BWP, BfARM), **Karin Sewerin** (Consultant for MedImmune)

Process parameters and quality attributes to be tested during:

- inoculation;
- expansion;
- harvest/multiple harvest;
- pooling;
- scalability.

Specific cases of:

- multi-facility production;
- scale-down models (relevance of different models/predictability/verification).

With specific focus on the data/studies performed for the validation of the processes and the data submitted in marketing authorisation applications.

9.30 General Aspects on Traditional Approach for the Upstream Process

Kowid HO

BWP, ANSM

9.40 Aspects of Process Validation of the Upstream Process

Vijay Chiruvolu

Amgen Inc.

10.00 Scale-Down Models for Cell Culture

Christian Hakemeyer

Roche

10.20 ***Discussion***

11.10 **Coffee break**

11:30 Session 1(b): Traditional approach — Downstream process

Moderators: Nanna A. Kruse (BWP, DKMA), **Ronald Imhoff** (Janssen Biologics)

Process parameters and quality attributes to be tested during:

- purification (columns, resins, membranes);
- pooling;
- holding-time/storage;
- reprocessing.

Specific cases of:

- multi-facility production;
- scale-down models (relevance of different models/predictability/verification).

11.30 ***General Aspects on Traditional Approach for the Downstream Process***
Kowid HO
BWP, ANSM

11.40 ***Aspects of Process Validation of the Downstream Process (part I)***
Marco Strohmeier
Roche

12.00 ***Aspects of Process Validation of the Downstream Process (part II)***
Norbert Hentschel
Boehringer-Ingelheim Pharma

12.20 ***Discussion***

13.00 **Lunch**

14:00 Session 2: Enhanced approach (QbD)

Moderators: Mats Welin (BWP, MPA), **Markus Goese** (Roche)

Process parameters and quality attributes to be tested for:

- continuous process verification;
- scale-down models.

14.00 ***General Aspects***
Kowid HO
BWP, ANSM

14.20 ***Continuous Process Verification***
Brendan Hughes
BMS

14.40 ***Scale-Down Models***
Frank Zettl
Roche

15.00	***Discussion***
15.30	**Coffee break**
16:00	**Final discussion and conclusions**
	Moderators: Jean Hugues Trouvin (Chair BWP, Université Paris Descartes), **Markus Goese** (Roche)
16.00	***Final discussion***
16.50	***Closing remarks*** **Kowid Ho** BWP, ANSM
17.00	**End of workshop**

List of speakers and moderators

Jean Hugues Trouvin	Chair BWP, Université Paris Descartes
Enda Moran	Chair EBE BioManufacturing WG, Pfizer
Piers Allin	EFPIA, EBE
Brigitte Brake	BWP, Bfarm
Vijay Chiruvolu	Amgen Inc.
Markus Goese	Roche
Christian Hakemeyer	Roche
Norbert Hentschel	Boehringer Ingelheim Pharma
Kowid Ho	BWP, ANSM
Brendan Hughes	BMS
Ronald Imhoff	Janssen Biologics
Nanna A. Kruse	BWP, DKMA
Karin Sewerin	Consultant for MedImmune
Marco Strohmeier	Roche
Mats Welin	BWP, MPA
Frank Zettl	Roche

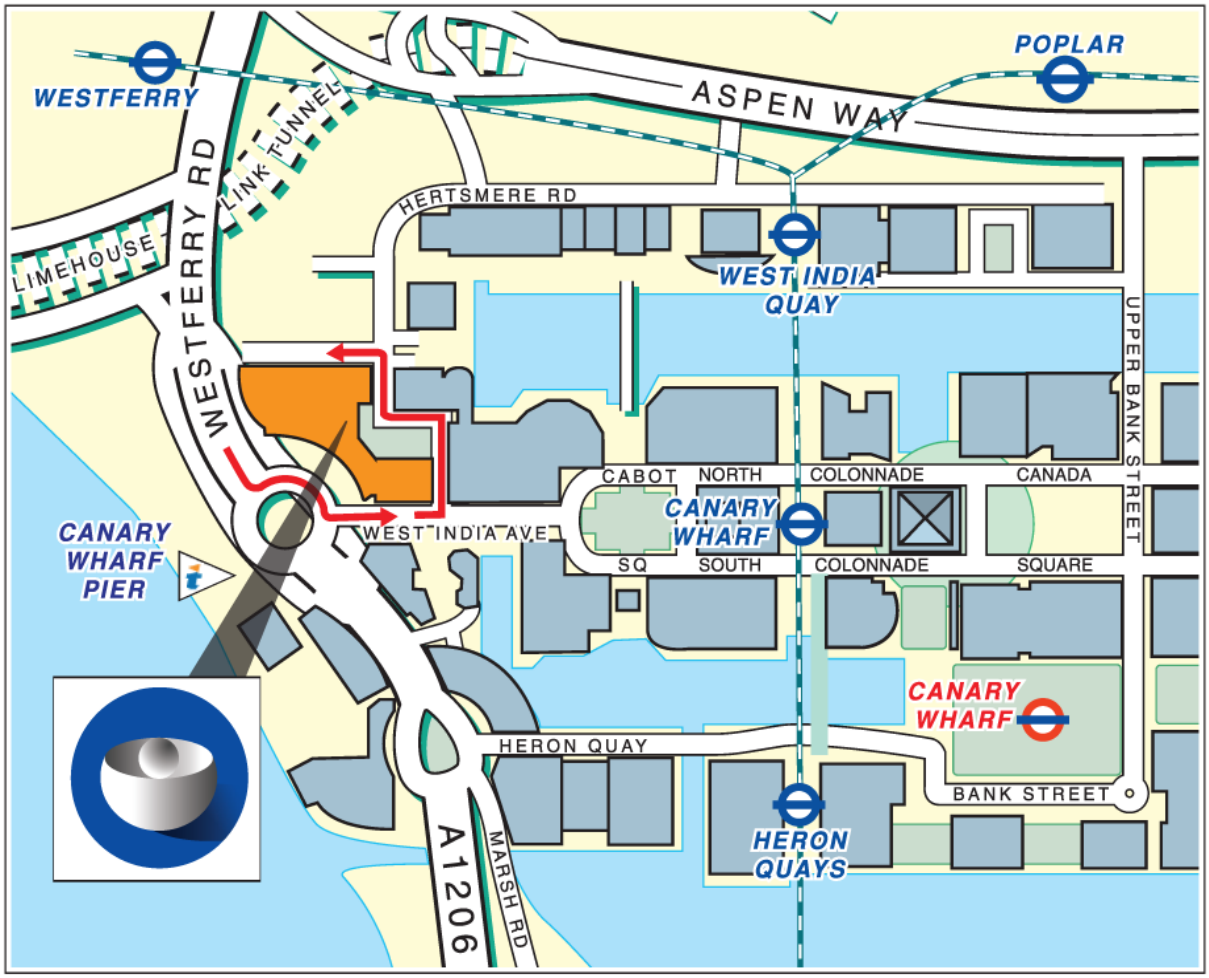
Practical information

Venue

The European Medicines Agency can be reached:

- **By Docklands Light Railway (DLR)**
  The Agency is a short walk from either Westferry station or Canary Wharf station on the DLR. Services run from Bank, Tower Gateway, Lewisham, Stratford, King George V and Beckton.
- **By Underground**
  The nearest stop for Westferry Circus is Canary Wharf station on the Jubilee Line.
- **By bus**
  Canary Wharf is serviced by local bus numbers D3, D7, D8, 135 and 277.
- **By boat**
  River services run between Embankment, London Bridge and Canary Wharf throughout the day.
- **From London City Airport**
  Take a taxi to Westferry Circus or alternatively catch the Docklands Light Railway, which goes to Westferry station.

Map



Entering the building

The Agency operates a stringent security policy. Upon arrival at ground-floor reception, you will be requested for identification and you will be allowed to make your way to meeting room 2A on the 2nd floor.

Physical disability

Let us know if you would like any specific help or information that would make your stay more comfortable. We will be very happy to help.

Registration

Registration will take place in the 2nd floor foyer where you will receive a badge together with a copy of the programme and list of participants. Tea and coffee will be available on your arrival in the 2nd floor foyer. We strongly advise you to arrive up to 30 minutes before the start of the workshop (i.e. 8:30), to allow you time for registration and settling down.

Meeting room

This workshop will benefit from a full house. You will be able to sit wherever you wish; note that the only reserved seats are for moderators, speakers and organisers of the workshop.

Presentations

We will not circulate printouts of speakers' presentations. However, you will be able to download them from the Agency's website approximately two weeks after the end of the workshop.

Catering

The Agency has a restaurant and a deli bar that offer a variety of food and drinks during the day. They both operate a cashless payment system. No cash or credit/debit cards are accepted.

You will be able to purchase a visitor card at the entrance of the canteen on 3rd floor at lunch time. In addition, visitor card terminals are available in the 1st floor reception area and 3rd floor restaurant. The terminals accept both GBP and EUR. The terminals issue a card with the balance of cash received, less a £3 deposit for the card (i.e. if £10 is put into the machine, you will receive a card with £7 that can be spent in the restaurant and deli bar; the £3 will be refunded when the card is returned).

At the end of your visit, simply reinsert the card in one of the visitor card terminals and the deposit plus any account balance will be refunded. Please note that the machine refunds in GBP coins only. For this reason, we encourage you not to load it with more than £20. If visiting the Agency frequently, visitors may wish to retain the card for future use.

Laptop computers

For those of you travelling from the continent and wishing to use your laptop, may we remind you to bring with you an appropriate UK power adapter. Access code to EMA Wifi will be provided at registration.

Media disclaimer

The Agency records a number of its meetings. This is part of the Agency's commitment to the principle of transparency. The Agency herewith informs attendees that this particular meeting will be recorded and the recording will be published on EMA website approximately two weeks after the workshop.

By attending this meeting you consent to any recording.

Conference venue and secretariat

European Medicines Agency
7 Westferry Circus, Canary Wharf
London E14 4HB, United Kingdom
Telephone +44 (0)20 7523 7083 / 7373
Facsimile +44 (0)20 7418 8668
E-mail alberto.ganan@ema.europa.eu **or** kamila.dudkova@ema.europa.eu
Website www.ema.europa.eu