EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

04 April 2014
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Stakeholders and Communication Division/SME Office

SME workshop: Focus on quality for medicines containing chemical entities

04 April 2014
European Medicines Agency, London, United Kingdom

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Background and objectives

Workshops for micro, small and medium-sized enterprises (SMEs) take place at the European Medicines Agency (EMA) annually, and have been organised by the SME Office since 2007.

This year we have initiated a workshop which will focus on quality aspects for chemical entities. Topics to be covered include building quality documentation early during development, scientific advice on quality aspects, considerations for veterinary medicines and innovation and emerging topics in pharmaceutical developments.

The workshop is open to companies that have been assigned SME status by the EMA and to representatives of stakeholder organisations. Other participants will be welcome space permitting.

Programme details

Friday, 04 April 2014

08.30 Registration

09:00 Welcome and introduction by Workshop Chair

Keith Pugh, Medicines and Healthcare Products Regulatory Agency (MHRA), United Kingdom — *10'*

09:10 Session 1: Building quality documentation early during development

Overview of applications for marketing authorisation – recent experience in assessment of quality — *25'*
Keith Pugh, Medicines and Healthcare Products Regulatory Agency (MHRA), United Kingdom

Quality aspects in investigational medicinal product developments — *25'*
Tone Agasoster, Norwegian Medicines Agency (NOMA), Norway

GMP issues for start-ups, quality in the supply chain and role of QP — *25'*
Patrick Costello, EMA

Questions and discussion — *20'*
Keith Pugh, Medicines and Healthcare Products Regulatory Agency (MHRA), United Kingdom

10:45 Coffee break

11:00 Session 1: Building quality documentation early during development (Continued)

Starting materials, active substances and active substance master files (ASMF) — *25'*
Ruben Pita, EMA

The European Pharmacopoeia and certificates of suitability (CEP) — *25'*
Andrew McMath, European Directorate for the Quality of Medicines (EDQM)

ICH Q3D 'Elemental Impurities' and M7 'Mutagenic impurities' – recent considerations — *25'*
Diana Van Riet, Medicines Evaluation Board (MEB), The Netherlands

Questions and discussion — *15'*
Florence Philippoz, Voisin Consulting SARL

12:30 Lunch break

13:30 Session 2: Scientific advice on quality and quality considerations for veterinary medicines

Highlights from recent scientific advice and protocol assistance on quality issues ***20'***

Blanka Hirschlerová, Czech Republic Medicines Agency (SUKL), Czech Republic

Considerations for veterinary scientific advice and marketing authorisations ***25'***

Mary O'Grady, Irish Medicines Board (IMB), Ireland

Questions and discussion ***15'***

Keith Pugh, Medicines and Healthcare Products Regulatory Agency (MHRA), United Kingdom

14:30 Coffee break

14:45 Session 3: Emerging topics in pharmaceutical developments

New active substance categorisation and orphan similarity ***15'***

Piotr Kozarewicz, EMA

Quality aspects of nano-based medicines ***15'***

Dolores Hernan, EMA

Paediatric formulations ***15'***

Diana Van Riet, Medicines Evaluation Board (MEB), The Netherlands

Questions and discussion ***15'***

Caroline Dick, Vectura Group plc

Additional Panellists

Thomas Girard, EMA

15:45 Regulatory update

Maintenance of information on authorised medicines by marketing-authorisation holders ('Art. 57') ***15'***

Ilaria Del Seppia, EMA

16:00 Closing remarks

Keith Pugh, Medicines and Healthcare Products Regulatory Agency (MHRA), United Kingdom

List of speakers and moderators

Tone Agasoster	Norwegian Medicines Agency (NOMA), Norway
Patrick Costello	Inspections and Human Medicines Pharmacovigilance Division, EMA
Caroline Dick	Vectura Group plc
Thomas Girard	Human Medicines Research and Development Support Division, EMA
Mary O'Grady	Irish Medicines Board (IMB), Ireland
Dolores Hernan	Human Medicines Evaluation Division, EMA
Blanka Hirschlerová	Czech Republic Medicines Agency (SUKL), Czech Republic
Piotr Kozarewicz	Human Medicines Evaluation Division, EMA
Andrew McMath	European Directorate for the Quality of Medicines (EDQM)
Ruben Pita	Human Medicines Evaluation Division, EMA
Florence Philippoz	Voisin Consulting SARL
Keith Pugh	Medicines and Healthcare Products Regulatory Agency (MHRA), United Kingdom
Diana Van Riet	Medicines Evaluation Board (MEB), The Netherlands
Ilaria Del Seppia	Procedure Management & Business Support Division, EMA

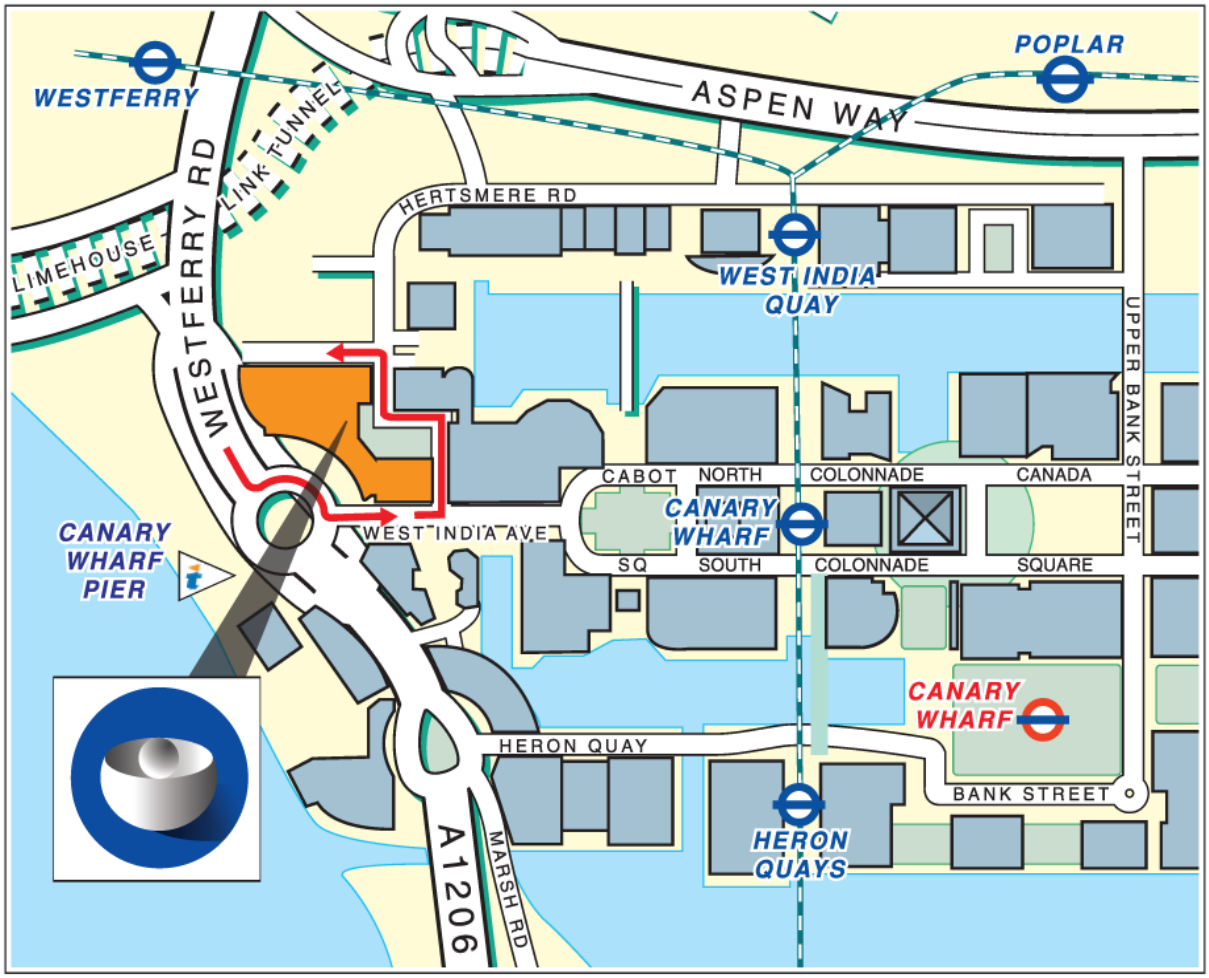
Practical information

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 given a security pass that will allow you to make your way to meeting room 2A on the 2nd floor. Tea and coffee will be available on your arrival in the 2nd floor foyer.

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

We strongly advise you to arrive up to 30 minutes before the start of the workshop, to allow you time for registration and settling down.

Meeting room

You will be able to sit wherever you wish; note that the only reserved seats are for the speakers, panellists 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.

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.

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Conference venue and secretariat

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