

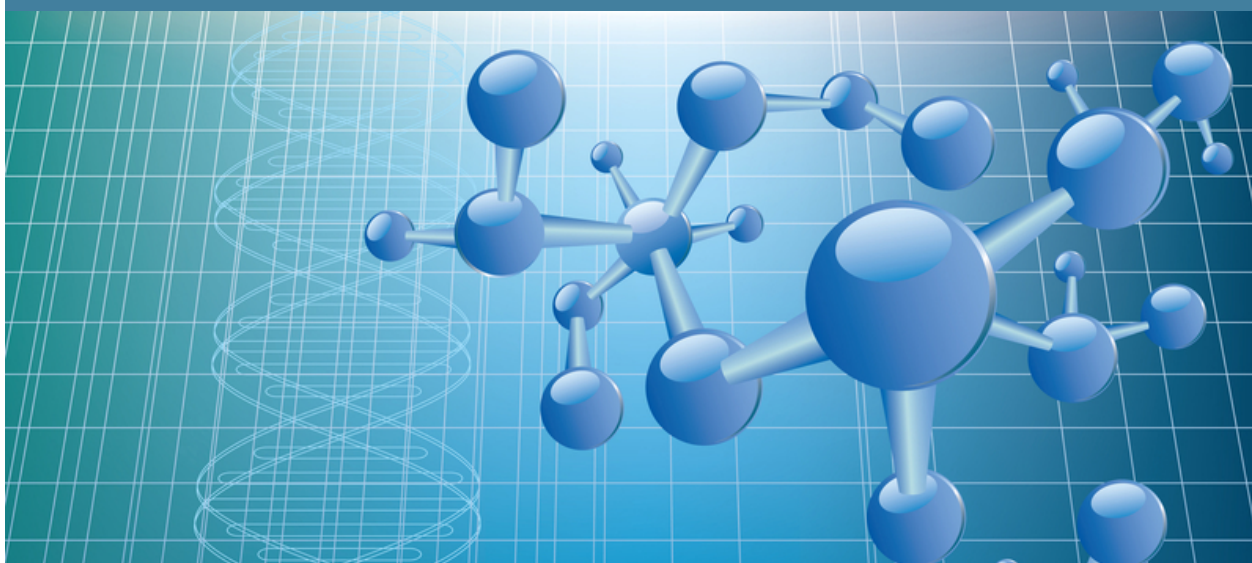


EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 April 2015
EMA/49639/2015
Corporate Stakeholders Department - SME Office

SME workshop: Focus on chemistry, manufacturing and controls (CMC) regulatory compliance for biopharmaceuticals and advanced therapies

16 April 2015
European Medicines Agency, London, United Kingdom



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 the workshop will focus on Chemistry, Manufacturing and Controls (CMC) Regulatory Compliance for Biopharmaceuticals and Advanced therapies. Topics to be covered include building quality documentation early during development, manufacturing perspectives, veterinary innovative products, CMC in IMPD dossiers and analytical perspectives.

The workshop is open to companies that have been assigned SME status by the EMA and to representatives of stakeholder organisations.

13:30	Session 3: Support to Innovation for veterinary products	
	<i>The new CVMP ad hoc expert group on veterinary novel therapies "ADVENT"</i>	30'
	Fia Westerholm , EMA	
14:00	Session 4: CMC in investigational medicinal product dossiers and analytical perspectives	
	<i>Preparing the CMC section of IMPD for biological/biotechnology derived substances</i>	25'
	Una Moore , HPRA & BWP, Ireland	
	<i>Raw (bio) materials and viral/TSE safety</i>	25'
	Johannes Blümel , PEI, Germany	
	<i>Potency assays and stability for advanced therapies</i>	25'
	Marcel Hoefnagel , MEB, Netherlands	
	<i>Questions and discussion moderated by an SME representative</i>	25'
	Thomas Saylor , Arecor Limited	
	Additional Panellists	
	Wilfried Dalemans , Tigenix	
15:40	Closing remarks by Workshop Chair	
	Sol Ruiz , AEMPS & Chair of BWP, Spain	

List of speakers and moderators

Pedro Andrade	Cell2B
Johannes Blümel	Paul-Ehrlich-Institute (PEI), Germany
Brigitte Brake	Federal Institute for Drugs and Medical Devices (BfArM), Germany
Wilfried Dalemans	Tigenix
Marcel Hoefnagel	Medicines Evaluation Board (MEB), Netherlands
Margarida Menezes Ferreira	National Authority of Medicines and Health Products, I.P. (INFARMED), Portugal
Una Moore	Health Products Regulatory Authority (HPRA), Ireland
Maria Pascual	Tigenix
Matthias Renner	Paul-Ehrlich-Institute (PEI), Germany
Sol Ruiz	Spanish Medicines Agency (AEMPS) & Chair of BWP, Spain
Thomas Saylor	Arecor Limited
Mats Welin	Medical Products Agency (MPA), Sweden
Fia Westerholm	EMA
Constantinos Ziogas	EMA

Practical information

Venue

The European Medicines Agency can be reached:

- **By Underground**

The nearest stop for Churchill Place is Canary Wharf station on the Jubilee Line. From East exit (NB. This is the closest exit to 30 Churchill Place): exit the station and turn left into Upper Bank Street, turn right at Canada Square and continue straight into Churchill Place.

- **By Docklands Light Railway (DLR)**

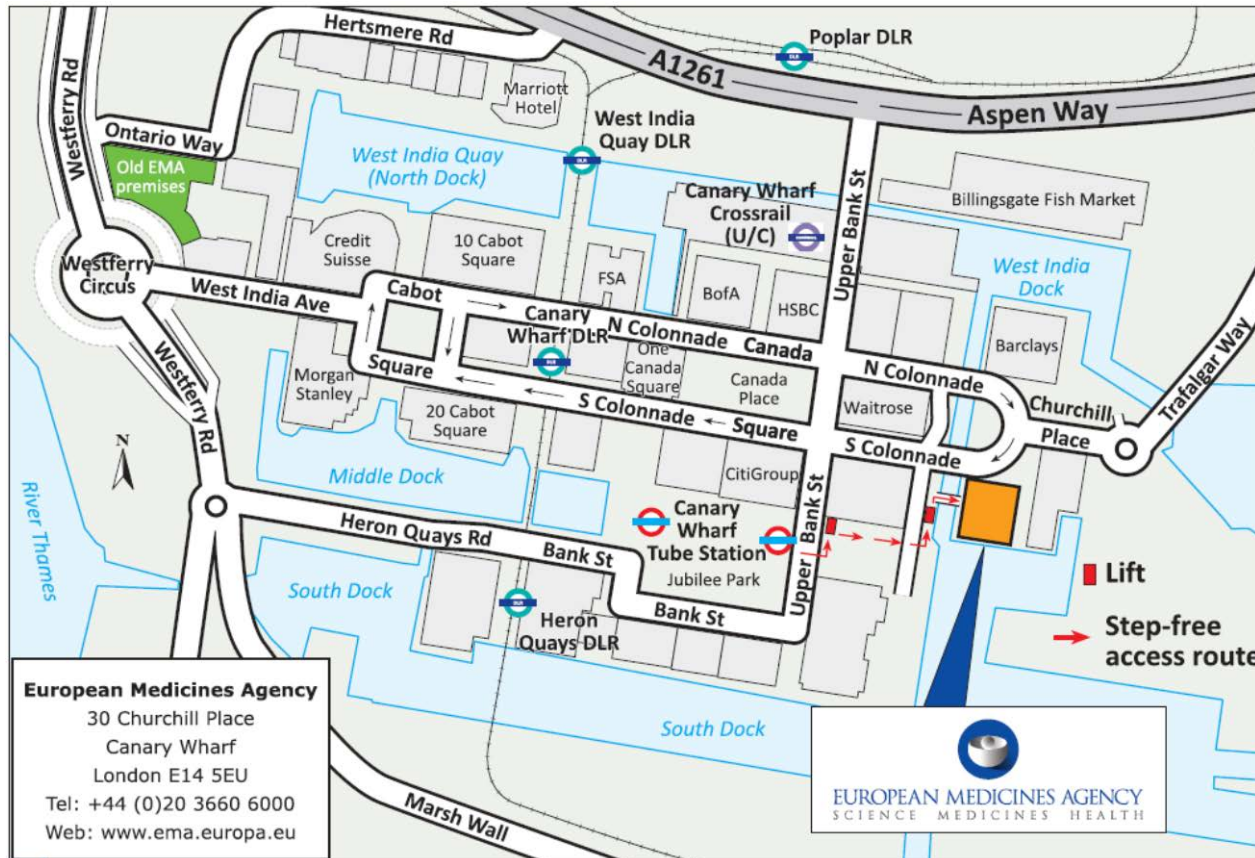
The Agency is a short walk from Canary Wharf station on the DLR. Services run from Bank, Tower Gateway, Lewisham, Stratford, King George V and Beckton. Exit into The South Colonnade, turn left towards Canada Square continuing straight into Churchill Place.

- **By car**

There are no parking facilities at 30 Churchill Place and it is recommended that you take public transport. However, four nearby public car parks are operated by Canary Wharf. Rates and further information can be found on the Canary Wharf website:

<http://www.canarywharf.com/aboutus/The-Estate/Travel--Roads--Parking/>

Map



Arrival at the Agency

On arriving for your meeting at 30 Churchill Place, please report to reception where you will be issued with an access pass. This pass will allow you to access our industry lounge, which you are welcome to utilise during your visit. The industry lounge is located through the sliding doors to the right of the reception desk past the security turnstiles. Your EMA contact point will meet you here.

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.

Wi-Fi access & Laptop computers

Wi-Fi is available throughout the EMA. Login details can be found on the back of your EMA access pass.

Media disclaimer

The Agency records or broadcasts a number of its meetings, including some virtual meetings. This is part of the Agency's commitment to the principle of transparency as enshrined in the Treaty on European Union. The Agency herewith informs attendees that this particular meeting will be recorded and broadcast. For more information about processing of personal data by EMA, please visit the website:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/home/general/general_content_000516.jsp&mid
or contact
dataprotection@ema.europa.eu

By attending this meeting you consent to any recording or broadcast.

Conference venue and secretariat

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