



European Medicines Agency

London, 8 February 2008
Doc. Ref. EMEA/331656/2007

2nd EMEA Workshop for Micro, Small and Medium-Sized Enterprises (SMEs)
"Focus on Quality"

DRAFT AGENDA

8 February 2008, 9.30-16.00

7, Westferry Circus, Canary Wharf, London E14 4HB
EMEA 2nd floor, Conference Room –2A

~ **Registration +Coffee** ~
9.00-9.30

Chairperson: Dr. John Purves

1.	INTRODUCTION	9:30-10:00 (30')
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1.1 *Introductory remarks*
Dr. John Purves, Head of Quality of Medicines Sector, EMEA

1.2 *Update from the SME Office*
Ms. Melanie Carr, Scientific Administrator, EMEA

2.	BUILDING QUALITY DOCUMENTATION	10:00-11:15 (75')
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Panellists/Presenters:

Prof. Jean-Hugues Trouvin, CHMP Biologics Working Party
Prof. Dieter Deforce, Scientific Advice Working Party
Dr. Cornelia Nopitsch-Mai, Joint CHMP-CVMP Quality Working Party
George Wade, Scientific Administrator, EMEA
Dr. Brendan Cuddy, Scientific Administrator, Inspections Sector, EMEA
Dr. Karen Quigley, Scientific Administrator, Veterinary Medicines, EMEA
Dr. Verena Stumpf, Medigene AG (SME representative)

2.1 *Scientific Advice on Quality Aspects for Biologicals – Highlights from recent Scientific advice and Protocol assistance on Quality issues (30')*
Prof. Jean-Hugues Trouvin

2.2 *Quality Documentation – Guidelines, Common Technical Document (15')*
George Wade

2.3 *GMP Compliance (15')*
Dr. Brendan Cuddy, Scientific Administrator, Inspections Sector, EMEA

2.4 *Questions and Discussion moderated by SME Representative (15')*

~ **Coffee Break** ~

11:15-11:35

3. MEETING REQUIREMENTS FOR EU MARKETING AUTHORISATION 11:35-13:00 (85')

- **Break-Out Session 1: Chemicals** (Room 2D)

Panellists/Presenters:

George Wade, Scientific Administrator, EMEA (Session Chairperson)
Dr. Cornelia Nopitsch-Mai, Joint CHMP-CVMP Quality Working Party
Dr. Ryan Tomlinson, MHRA
Ms. Ewa Wyszeccka-Kaszuba, Joint CHMP-CVMP Quality Working Party
Dr. José Belo, Joint CHMP-CVMP Quality Working Party
Teresa Potter, Scientific Administrator, Veterinary Medicines, EMEA
Dr. Marie-Christine Fortun, Orphan Europe (SME Representative)

3.1.1 *Overview of Applications for Marketing Authorisation – Recent experience in Quality Assessment (25')*

Dr. Cornelia Nopitsch-Mai

3.1.2 *Key considerations for a new chemical entity (30')*

Dr. Ryan Tomlinson

3.1.3 *Questions and Discussion moderated by SME Representative (30')*

- **Break-Out Session 2: Biologicals** (Room 2A)

Panellists/Presenters:

Dr. John Purves, Head of Quality of Medicines Sector, EMEA (Session Chairperson)
Prof. Jean-Hugues Trouvin, CHMP Biologics Working Party
Dr. Sol Ruiz, CHMP Biologics Working Party
Dr. Kowid Ho, CHMP Biologics Working Party
Dr. Ian Rees, Inspection and Standards Division, MHRA
Prof. Dieter Deforce, Scientific Advice Working Party
Dr. Adrian Thomas, CHMP Biologics Working Party
Dr. Brigitte Brake, CHMP Biologics Working Party
Dr. Wilfried Dalemans, Tigenix NV (SME Representative)

3.2.1 *Overview of Applications for Marketing Authorisation – Recent experience in Quality Assessment (20')*

Dr. Sol Ruiz

3.2.2 *Key considerations for a biological product (20')*

Dr. Kowid Ho

3.2.3 *Biological GMP Issues at Startup (15')*

Dr. Ian Rees

3.2.4 *Questions and Discussion moderated by SME Representative (30')*

~ **Lunch in EMEA's Self-Service Restaurant** ~
13.00-14.15

Panellists/Presenters:

Dr. Kowid Ho, CHMP Biologics Working Party
Dr. Evdokia Korakianiti, Scientific Administrator, EMEA
Mr. Nicolas Rossignol, DG Enterprise, European Commission
Dr. Constantinos Ziogas, Scientific Administrator, EMEA
Dr. Andreas Emmendorffer, euroderm GmbH (SME Representative)

4.1 *“Quality by Design”. Process Analytical Technology and Risk-based CMC development (30’)*

Dr. Kowid Ho
Dr. Evdokia Korakianiti

4.2 *Regulation of Advanced Therapies (25’)*

Mr. Nicolas Rossignol

4.3 *Innovation Task Force (20’)*

Dr. Constantinos Ziogas

4.4 *Questions and Discussion moderated by SME Representative (20’)*

~ Closing Remarks by Chairperson ~

15:50-16:00