



European Medicines Agency
Inspections

London, 9 November 2009
Doc Ref: CHMP/CVMP/QWP/696999/2009

PROGRAM

QUALITY ASSESSORS TRAINING

26.-27.10.2009

EMEA, 7 Westferry Circus, Canary Wharf, London E14 4HB

Monday 26.10.2009 – Assessment of Quality: Basics – Chair: Diana van Riet

Session	Speaker
10.00-10.20 Welcome and opening	Diana van Riet / NL
10.20-11.00 Introduction to quality assessment	Diana van Riet / NL
11.00-11.40 Legislative framework and scientific guidance in European assessment	Riccardo Luigetti / EMEA
11.40-12.00 <i>Coffee break</i>	
12.00-13.00 Good Manufacturing Practice & <i>discussion</i>	Cormac Dalton / IE
13.00-14.00 <i>Lunch</i>	
14.00-14.40 Writing an assessment report	Malcolm Dash / UK
14.40-15.40 Workshop on assessment reports	Malcolm Dash / UK
15.40-16.00 <i>Coffee break</i>	
16.00-17.00 Outcome of the workshop & <i>discussion</i>	Malcolm Dash / UK
17.00-17.10 Summary of day 1	Diana van Riet / NL

Tuesday 27.10.2009 – Assessment of Quality: Specific Topics - Chair: Cornelia Nopitsch-Mai

Session	Speaker
8.30-8.40 Opening of day 2	Cornelia Nopitsch-Mai / DE
8.40-9.20 Documentation on the active substance : ASMF and CEP procedure	Cornelia Nopitsch-Mai / DE

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK

Tel. (44-20) 74 18 84 00 Fax (44-20) 75 23 70 51

E-mail: mail@emea.europa.eu <http://www.emea.europa.eu>

© European Medicines Agency, 2009. Reproduction is authorised provided the source is acknowledged

9.20-10.00	Definition of starting materials	Christina Hoejelse / DK
10.00-11.00	Workshop on the definition of starting materials	Christina Hoejelse / DK
11.00-11.20	<i>Coffee break</i>	
11.20-12.00	Outcome of the workshop & <i>discussion</i>	Christina Hoejelse / DK
12.00-12.40	Evaluation of impurities	Hilda Köszegi-Szalai / HU
12.40-14.00	<i>Lunch</i>	
14.00-14.40	Proper use of the Ph.Eur.	Anne-Sophie Bouin / EDQM
14.40-15.20	New quality paradigm – PAT/Q8-9-10	Evdokia Korakianiti / EMEA
15.20-15.40	<i>Coffee break</i>	
15.40-16:00	Closure and final remarks	Cornelia Nopitsch-Mai / DE