

MODULE II Quality

Wednesday 20 – Friday 22 April 2011

Moderator: **Dr A.P. Sam, Merck Sharp & Dohme**

Wednesday 20 April

09.30 – 12.30 Pharmaceutical development – a general introduction
Dr A.P. Sam

14.00 – 17.00 Regulatory aspects of pharmaceutical development
Dr M. Zahn, 3R Pharma Consulting

Evening Case study
Dr M. Weda, Dutch National Institute for Public Health and the Environment

Thursday 21 April

09.00 – 12.30 The Investigational Medicinal Product dossier
Dr A. A. Mende, Bundesinstitut für Arzneimittel und Medizinprodukte

14.00 – 17.00 Key elements in the pharmaceutical dossier - interaction with the non-clinical and clinical dossier
To be announced

Evening Case study

Friday 22 April

09.00 – 12.30 European quality requirements for biotechnology products
Dr H.F. Schuring, Genzyme Europe BV

14.00 – 17.00 Biotechnology in a changing health care environment
Prof. dr H. Schellekens, Utrecht University/Dutch Medicines Evaluation Board