Day 3 – Friday 18 Nov

Plenary session (in Auditorium)

11:25 12:55 UTOPIA: THE SCIENCE OF A MODERN GUIDELINE

Interactive session (Each sub-session consists of a short introduction followed by an interactive discussion involving all conference delegates)

11:25 11:30 ***General Introduction – aim of the session***

11:30 11:50 ***The science of a modern guidance – focus on The common themes***
moderated panel session

11:50 12:20 ***The science of a modern guidance – focus on Ligand binding assays***
moderated panel session

12:20 12:50 ***The science of a modern guidance – focus on Chromatography based assays***
moderated panel session

12:50 12:55 ***Closing comments and next steps***

12:55 13:00 Plans for 2017 / Close Out

11:25 12:55 UTOPIA: THE SCIENCE OF A MODERN GUIDELINE

11:25 11:30 ***General Introduction – aim of the session***

11:30 12:55 ***The science of a modern guidance in 5 questions***

Five questions inspired by a recent EBF survey – September 2016 – in preparation for this session.

Do we feel that:

1. …a modern guideline should give more details on experimental execution or not?
2. …some of the current requirements for method validation should be refined or even removed from the guideline, and if so, which?
3. …some requirements for method validation should be added to the guideline and if so, which?
4. ...alternative validation approaches (e.g. tiered approach, scientific validation) should be included in a modern guideline?
5. …assay requirements for new technologies should be included in a modern guideline and if so, which? And why? Or why not?

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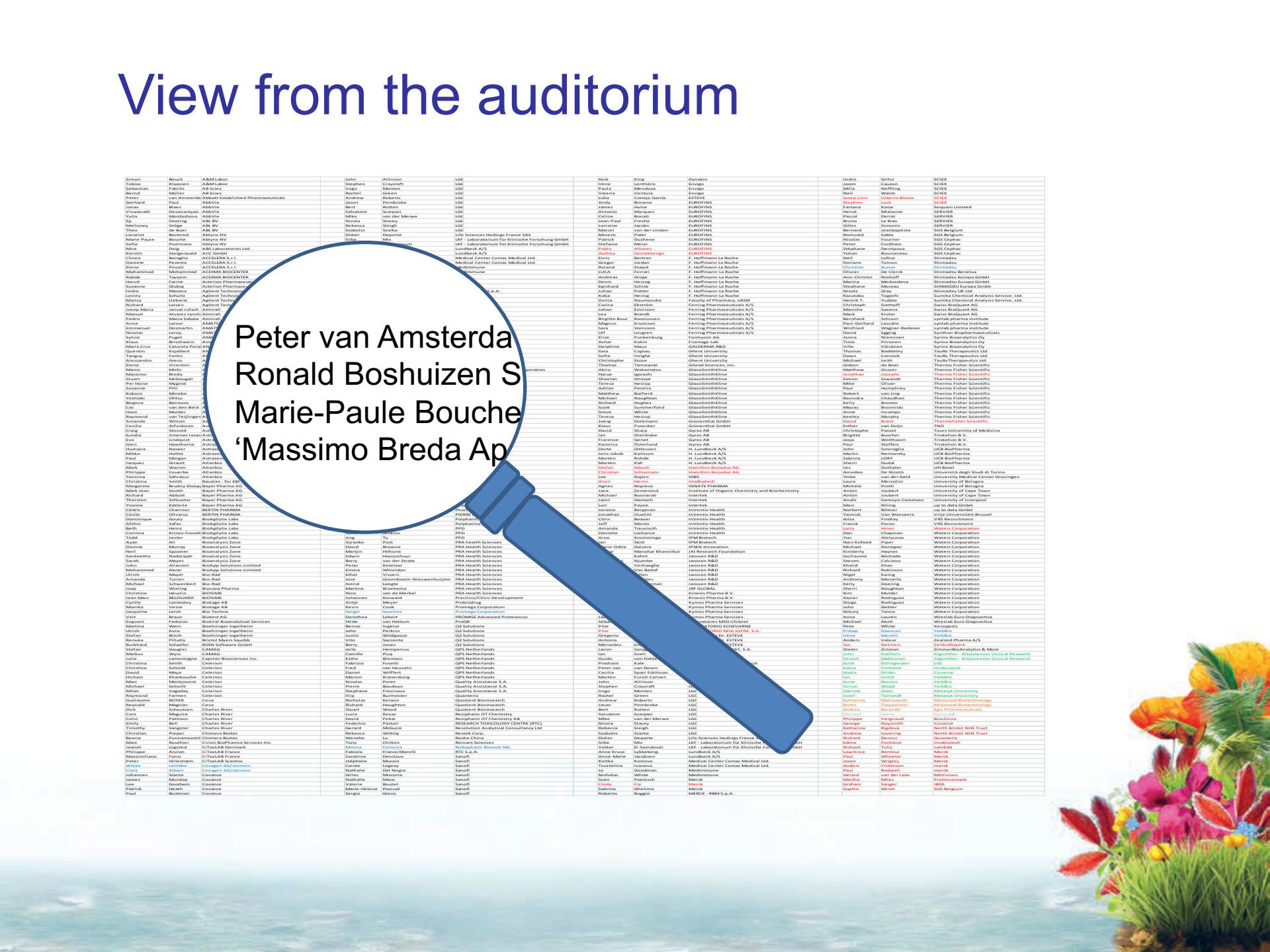
View from the panel

Panel:

John Smeraglia, UCB Biopharma
Timothy Sangster, CRL
Yoshiaki Ohtsu, for JBF
Michaela Golob, Nuvisan
Barry van der Strate, PRA HS
Amanda Wilson, AstraZeneca

View from the auditorium



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