

January 2013

Symposium - Raw materials for production of cell-based and gene therapy products

Location: EDQM Premises, 7 allée Kastner, Strasbourg, France

Duration: 1 day. Working language: English

DRAFT PROGRAMME

Wednesday, 3 April 2013

08:15-8:45 Registration

08:45-9:00 Welcome address

Session 1: EDQM, EMA and the RCG* Working party

09:00-9:20 Background to the Council of Europe, European Directorate for the Quality of Medicines & HealthCare (EDQM) and the European Pharmacopoeia Department

09:20-9:40 The European Medicines Agency's (EMA) views on raw materials for gene and cell therapy

09:40-10:00 Role and Proposals of the RCG Working Party

Session 2: User, manufacturer and academic viewpoints

10:00-10:25 Viewpoint from a User of raw materials (1)

10:25-10:50 Viewpoint from a User of raw materials (2)

10:50-11:20 *Coffee break*

11:20-11:45 Viewpoints from a Manufacturer of raw materials (1)

11:45-12:10 Viewpoint from a Manufacturer of raw materials (2)

12:10-12:30 An Academic Viewpoint

12:30-13:15 Panel Discussion with the Speakers

13:15-14:30 *Lunch break*

Session 3: Break-out sessions

14:30-16:00 Break-out Sessions

These break-out sessions are designed to gather input and offer the participants an opportunity to discuss in smaller groups and in greater detail quality issues pertinent to the manufacturing of raw materials, and their use in producing cell-based and gene therapy products. The results from a recent survey conducted by the EDQM will also be reviewed.

16:00-16:30 *Coffee break*

16:30-17:10 Feedback from Break-out sessions

17:10-17:40 General Discussion

17:40-18:00 Concluding remarks and next steps

18:00 End of meeting

18:00 Cocktail Reception

For registration or more information please visit the website: www.edqm.eu

* RCG: Raw materials for the production of cellular and gene transfer products