

## **EDQM SYMPOSIUM**

### **Standardisation & Control of Allergen Preparations - Establishment of Reference Preparations and ELISAs for the Major Allergens**

**Bet v 1 and Phl p 5 a**

**24 November 2011, Strasbourg, France**

**Duration: 1 day; Working language: English**

**Supported by the PEI Paul-Ehrlich-Institut, Langen, Germany**

### **DRAFT PROGRAMME**

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#### **OPENING SESSION**

**8:15-8:45**    Registration

**8:45-9:00**    Welcome Address and General Introduction

#### **SESSION 1: SETTING THE SCENE**

**9:00-9:20**    Use of allergens and their standardisation

**9:20-9:40**    Current control of allergens

**9:40-10:00**    Discussion

*10:00-10:30*    *Coffee break*

#### **SESSION 2: THE BSP090 PROJECT**

**10:30-10:50**    The European Union CREATE\* Project

**10:50-11:10**    **BSP090: Physico-chemical characterisation of candidate reference preparations**

**11:10-11:30**    **BSP090: Results from Phases 1-2**

**11:30-11:50**    **BSP090: Results from Phase 3**

**11:50-12:10**    **Impact of the new BRPs/ELISA on the control of allergen preparations**

**12:10-12:40**    Discussion

*12:40-14:15*    *Lunch break*

\*Development of Certified Reference Materials for Allergenic Products and Validation of Methods for their Quantification

### **SESSION 3: THE EUROPEAN PHARMACOPOEIA & REGULATORY ENVIRONMENT**

**14:15-14:35** Presentation of the revised general monograph and future plans

**14:35-14:55** The CHMP's Note for Guidance on Allergen Products

**14:55-15:30** Discussion

*15:30-16:00 Coffee break*

### **SESSION 4: GENERAL DISCUSSION**

**16:00-17:00** General Discussion

- *New candidate references and ELISAs*
- *Possibilities to speed up the process for establishment of methods and standards*
- *Alternative approaches to ELISA (MS)*
- *Need for methods for absorbed / modified preparations?*
- *Future of allergen control in Europe*

**17:00-17:10** Closing Remarks

*17:10 Close of the meeting*

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