

WEBINARS ON THE NEW EUROPEAN PHARMACOPOEIA APPROACH TO THE 'MANAGEMENT OF EXTRANEIOUS AGENTS IN IVMPs'

01 April 2020

Morning Session - Setting the scene (Webinar 1 for remote participation)

- Documents will be provided beforehand to help participants prepare
- The content of the webinars has been condensed to only focus on core items.
- Any question must be sent in writing, either before or during the webinars.

09:00-09:15	Setting the scene to the changes to the Ph. Eur. requirements for the management of extraneous agents in IVMPs Member of Ph. Eur. Expert Group 15V
09:15-09:30	<i>"Management of extraneous agents in IVMPs"</i> - the new General chapter 5.2.5, Member of Ph. Eur. Experts Group 15V
09:30-09:45	New approach for extraneous agents testing - Concrete examples Member of Ph. Eur. Expert Group 15V
09:45-10:00	New approach for extraneous agents testing - Concrete examples Member of Ph. Eur. Expert Group 15V
10:00-10:15	Answers to questions
10:15-10:30	The voice of industry Animal Health Europe
10:30-10:45	The voice of industry Focus on risk assessment
10:45-11:00	Answers to questions

Close of webinar 1



Afternoon Session - Regulatory landscape (Webinar 2 for remote participation)

- 14:00-14:15** **EMA Guidelines (including needs for revision or elaboration of new guidelines) and Q&A document as a tool for harmonised assessment**
Member of the EMA Immunological Working Party (IWP)
- 14:15-14:30** **The particular case of old master seeds used for the production of new vaccines: re-testing of well-established cell banks and master seeds? What can be used to justify no retesting?**
Member of Ph. Eur. Expert Group 15V
- 14:30-14:45** **Historical value of the previous requirements and detailed testing methods as mentioned in the Ph. Eur.: can the “old” detailed protocols now available in the Ph. Eur. archives still be used?**
Member of the EMA Immunological Working Party (IWP)
- 14:45-15:00** **Validation of new test techniques - expectation with regard to validation and documentation in the dossier**
Member of the EMA Immunological Working Party (IWP)
- 15:00-15:45** Answers to questions

Close of webinar 2