WEBINARS ON THE NEW EUROPEAN PHARMACOPOEIA APPROACH TO THE ‘MANAGEMENT OF EXTRANEOUS AGENTS IN IVMPS’

01 April 2020

Webinar 1 - Setting the Scene

(Time = hour:min:sec)

00:01:15-00:08:20 Opening Remarks & Short introduction to the webinar
Susanne Keitel, Director, EDQM, Council of Europe &
Catherine Lang, EDQM, Council of Europe

00:08:20-00:27:15 Setting the scene to the changes to the Ph. Eur. requirements for the management of extraneous agents in IVMPs
Anna Maria Brady, Member of Ph. Eur. Expert Group 15V

00:27:15-00:48:34 “Management of extraneous agents in IVMPs” - the new General chapter 5.2.5,
Céline Lorteau, Member of Ph. Eur. Experts Group 15V

00:48:48-01:03:26 New approach for extraneous agents testing - Concrete examples
Maria José Ferrer, Member of Ph. Eur. Expert Group 15V

01:03:40-01:24:38 New approach for extraneous agents testing - Concrete examples
Renata Kovacova, Member of Ph. Eur. Expert Group 15V

01:24:52-01:41:14 Answers to questions

01:41:14-01:55:48 The voice of industry
Frédéric Descamps, Animal Health Europe

01:56:18-02:05:33 The voice of industry
Mirta Weber Susanj, Focus on risk assessment

02:05:44-02:19:30 Answers to questions

Close of the webinar
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Webinar 2 - Regulatory landscape

(Time = hour:min:sec)

00:00:00-00:00:29  Short introduction to the webinar
EDQM, Council of Europe

00:00:29-00:18:42  EMA Guidelines (including needs for revision or elaboration of new
guidelines) and Q&A document as a tool for harmonised assessment
Esther Werner, Member of the EMA Immunological Working Party (IWP)

00:18:47-00:34:42  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? as mentioned in the Ph. Eur.: can the “old” detailed protocols now available in the Ph. Eur. archives still be used?
Ingun Lemke, Member of Ph. Eur. Expert Group 15V

00:34:52-00:42:30  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?
Esther Werner, Member of the EMA Immunological Working Party (IWP)

00:42:30-00:49:56  Validation of new test techniques - expectation with regard to
validation and documentation in the dossier
Caroline Guittré, Member of the EMA Immunological Working Party (IWP)

00:50:22-01:39:17  Answers to questions

Close of the webinar