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