



EDQM webinar

BINACLE Assay for Tetanus Neurotoxin: Outcomes of Project BSP136

12 November 2024, from 13:00 to 17:00 (CET, Paris)

Draft Programme

13:00 – 13:20 Opening of the Webinar

Introductory welcome from the Head of the Department for Biological Standardisation, OMCL Network and HealthCare, Laurent Mallet, EDQM

EDQM & the Biological Standardisation Programme (BSP), Catherine Milne, EDQM

13:20 – 14:50 Session I: The BINACLE and BSP136

The BINACLE assay, Heike Behrensdorf-Nicol, Paul-Ehrlich-Institut (PEI), Germany

BSP136 collaborative study – outcomes part 1, Marie-Emmanuelle Behr-Gross, EDQM

Challenges identified in BSP136 part 1, Heike Behrensdorf-Nicol, PEI, Germany

BSP136 collaborative study – outcomes part 2, Christina Göngrich, EDQM

Considerations for method validation and implementation, Heike Behrensdorf-Nicol, PEI, Germany

Q & A

BREAK

15:10– 16:45 Session II: Towards implementation of the BINACLE for QC testing of tetanus vaccines

The Ph. Eur. tetanus vaccine monographs, Gwenaël Ciréfice & Catherine Lebrun, EDQM

Q&A

Views from the vaccines industry, speakers to be confirmed

Q&A

16:45 – 17:00 Webinar highlights and closing of the meeting