



EDQM webinar - BINACLE Assay for Tetanus Neurotoxin: Outcomes of Project BSP136

**12 November 2024, from 13:00 to 17:10 (CET, Paris)
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 – 15:10 Session I: The BINACLE and BSP136; Moderator Laurent Mallet, EDQM

Entry Poll

The BINACLE assay for *in vitro* activity determination of tetanus neurotoxin, Heike Behrendorf-Nicol, Paul-Ehrlich-Institut (PEI), Germany

Review and harmonisation of toxicity testing requirements in Ph. Eur. Tetanus vaccine monographs: 3Rs achievements, Catherine Lebrun & Gwenaël Ciréface, EDQM

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

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

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

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

Q&A

BREAK

15:35– 16:50 Session II: Towards implementation of the BINACLE for QC testing of tetanus vaccines; Moderator Eriko Terao, EDQM

Towards the introduction of BINACLE in Ph. Eur. tetanus vaccine monographs, Gwenaël Ciréface & Catherine Lebrun, EDQM

Q&A

BINACLE assay for tetanus neurotoxin: optimisation perspectives for quality control use, Romain Pizzato, Sanofi

Q&A

BINACLE requirement for industrialization of the assay, Shahjahan Shaid, GSK

Q&A

Exit Poll

16:50 – 17:10 Webinar highlights and closing of the meeting, Catherine Milne, EDQM

Scientific Committee

Svein Rune Andersen (Norwegian Institute of Public Health, NO), Heike Behrendorf-Nicol (PEI, DE), Marie-Emmanuelle Behr-Gross (EDQM), Gwenaël Ciréface (EDQM), Øystein Evenson (Norwegian Life Science University, NO), Christina Göngrich (EDQM), Catherine Lebrun (EDQM), Laurent Mallet (EDQM), Catherine Milne (EDQM), Volker Öppling (PEI, DE), Eriko Terao (EDQM), Michael Wierer (EDQM)