Novel *in vitro* model as alternative to *in vivo* toxoid vaccines testing: Clostridium septicum vaccine as proof of concept

8-9 December 2020
EDQM Premises, Strasbourg, France

Draft Programme *(subject to change)*

Tuesday, 8 December 2020

12:30 - 13:30 *Registration*

Opening & Welcome addresses

Session 1: Activities of European stakeholders in the field of 3Rs

Activities of European stakeholders in the field of 3Rs

- **European Directorate for the Quality of Medicines & HealthCare, Council of Europe**
- **The European Partnership for Alternative Approaches to Animal testing (EPAA)**
- **The European Union Reference Laboratory for alternatives to animal testing (JRC - EURL ECVAM) of the European Commission Joint Research Centre**

Session 2: Clostridium septicum Vaccine Project (BSP130) - Study aims and results

Validation of cell-based methods as alternatives to the mouse tests currently used for in-process toxicity and antigenicity testing

Coffee break

Cell-based method optimisation and their principles (TNE+, TCP), Statistics and Results Overview

Session 3: Outcome of a Field Survey on Clostridium vaccines control

Feedback from BSP130 participants: experience and learnings

Enquiry on alternative methods implementation and their regulatory acceptance

17:15 First day closure

Wednesday, 9 December 2020 (starts at 09:00 a.m.)

Session 4: Regulatory process

European Pharmacopoeia (Ph. Eur.) monographs overview & revision proposal

National and international Regulatory bodies: plans for the future

Coffee break

Session 5: Potential application of the Approach to other Toxoid Vaccines

Experience in extending the approach of cell-based TCP and MLD assays to Clostridium perfringens vaccines

Perspectives for extending the approach to other toxoid vaccines

Lunch break

Sustainability of International Standards: Current situation, needs and responsibility for establishment

Opportunities for the future

Session 6: Round table and discussion

Interactive session based on discussion between Scientific Committee and speakers with audience

16:00 Close of the symposium