



THE EUROPEAN PHARMACOPOEIA & QUALITY OF MEDICINES

“THE CHALLENGES OF QUALITY REQUIREMENTS FOR FISH VACCINES”

**International Symposium organised by the EDQM, Council of Europe
10-11 May 2016**

Location: NMBU, Campus Adamstau, 0464 Oslo, Norway

Duration: 1.5 day. **Working language:** English

DRAFT PROGRAMME *(Subject to change)*

TUESDAY 10 MAY 2016

8:15-9:00 Registration

9:00-9:05 Opening Remarks & General Introduction to the Programme

9:05-9:25 General overview of Fish Vaccination

SESSION 1: General Overview on Current Legal Requirements

9:30-9:45 EDQM/European Pharmacopoeia (Ph. Eur.): Assuring the quality of medicines

9:45-10:00 How to use the Ph. Eur. and how to collaborate to the work of Ph. Eur. Group of Experts on “Veterinary Sera & Vaccines” (15V)

10:00-10:15 Special focus on Ph. Eur. Monographs for Fish Vaccines

10:15-10:30 General approaches 3Rs, alternative methods, consistency of production and humane end-points in the Ph. Eur.

10:30-11:00 *Coffee break*

11:00-11:20 EMA/IWP Guidelines on the Design of studies to evaluate the safety and efficacy of fish vaccines



11:20-11:40 Challenges while developing safe and efficacious fish vaccines

11:40-12:10 *Presentation to be confirmed*

12:10-12:45 *Presentation to be confirmed*

12:45-13:00 Discussion - Questions & Answers

13:00-14:00 *Lunch break*

SESSION 2a: BATCH POTENCY TEST

Experience with challenge, alternative methods, 3Rs, consistency of production and humane end-points

Manufacturer's point of view: *presentation of concrete examples of 3Rs/alternative method / humane endpoints currently in use or under development.*

14:00-16:45 Presentations - Questions & Answers

Close of day

WEDNESDAY 11 MAY 2016

SESSION 2b: BATCH POTENCY TEST

Experience with challenge, alternative methods, 3Rs, consistency of production and humane end-points

Authorities point of view: *presentation of regulatory expectations for the future, how to define welfare indicators to replace death as an endpoint, how to validate in vitro test for potency testing of fish vaccines, use of fish cells and tissue cultures, training needs.*

08:30-10:45 Presentations - Questions & Answers

SESSION 3: Round Table Discussion

10:45-11:45 Round Table Discussion

11:45-12:00 Final Conclusions & Closing remarks

Close of the symposium