



# EURL for fish and crustacean diseases training course: Validation of Diagnostic methods for fish and crustacean diseases

## 28<sup>th</sup> to 30<sup>th</sup> October 2026

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This three-day training course, organized by the European Union Reference Laboratory (EURL) for Fish and Crustacean Diseases, provides participants with a comprehensive introduction to the principles and practices of validating diagnostic methods for aquatic animal pathogens.

The course combines theoretical lectures, practical computer-based exercises, and participant-driven discussions. It follows the internationally recognised validation pathway developed by WOAHP (World Organisation for Animal Health), ensuring alignment with global standards for diagnostic testing in aquatic health.

Participants will gain insight into the importance of developing reliable and fit-for-purpose diagnostic assays, and the critical role validation plays in disease surveillance, outbreak response, and regulatory compliance.

The first day focuses on foundational concepts, including the importance of validation within the fit-for-purpose framework and the requirements for analytical validation. Special emphasis is placed on reference materials, controls, and internationally recognised standards necessary to support robust validation processes.

The second day addresses diagnostic validation, including key parameters such as diagnostic sensitivity, specificity, cut-off determination, and sample size calculations. These topics are reinforced through guided exercises and practical examples relevant to fish and crustacean diseases.

The third day explores broader laboratory requirements, including quality assurance systems, accreditation, and proficiency testing. The course also introduces emerging diagnostic technologies, such as multifluidic qPCR and environmental DNA/RNA approaches, and discusses validation challenges associated with these novel methods. Participants will present case studies from their own laboratories, fostering peer learning and collaborative discussion.

### **Learning objectives**

By the end of the course, participants will be able to:

- Recall key terminology and concepts related to analytical and diagnostic validation
- Identify international standards and guidelines for validation (e.g. WOAHP framework)
- Explain the purpose and importance of validating diagnostic methods in aquatic animal health
- Describe the differences between analytical validation and diagnostic validation
- Summarize the role of controls, reference materials, and standards in validation processes
- Use WOAHP validation guidelines to guide validation procedures in their own laboratories
- Calculate analytical sensitivity (LOD), diagnostic sensitivity and specificity
- Apply methods to determine appropriate cut-off values and sample sizes
- Compare validation approaches for different diagnostic methods (e.g. PCR, cell culture)
- Interpret validation data and identify sources of variability or uncertainty
- Design a validation plan or protocol tailored to their laboratory needs
- Present and discuss a validation-related case study based on their own work
- Describe the diagnostic procedures for listed fish and crustacean diseases in EU



# European Union Reference Laboratory for Fish and Crustacean Diseases

NATIONAL INSTITUTE OF AQUATIC RESOURCES, TECHNICAL UNIVERSITY OF DENMARK

## Target audience

This course is primarily intended for staff of National reference laboratories (NRLs) in Europe, furthermore professionals working in veterinary diagnostic laboratories research institutes, and related organizations involved in aquatic animal health are welcome

It is particularly relevant for individuals engaged in diagnostic testing, method development, and disease surveillance. The course is designed as an introductory-level training, welcoming participants with varied backgrounds and levels of experience.

## Teaching and learning approach

The course adopts an interactive and applied learning approach, combining:

- Lectures on theoretical concepts
- Practical exercises and calculations
- Case studies from fish and crustacean diseases
- Participant presentations and group discussions

Active participation is encouraged throughout to enhance knowledge exchange and practical understanding.

## Assessment

Participants will be invited to present a short case study or validation-related project based on their own laboratory work. This will form the basis for group discussion and feedback, facilitating practical application of the concepts covered during the course.

## Course materials

Participants will receive a reference reading list in advance to support preparation. Course slides and additional materials will be provided after completion of the training

## The course participants

Since course attendants can come from very different backgrounds, their starting point will therefore be mixed. This is a basic course where all students are encouraged to participate, irrespective of their degree of experience.

## Course supervisors

Argelia Cuenca (course responsible), Niccolò Vendramin, Britt Bang Jensen, Manuel Pérez Maldonado.



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Preliminary programme, subject to changes

Time slot	Day 1 – Wednesday 28	Day 2- Thursday 29	Day 3 Friday 30
9:00-10:15	<p><b>Introduction and presentations of participants</b></p> <p><b>The importance of accurate and reliable diagnostics &amp; Diagnostic assays and fit for purpose</b></p>	<p><b>Pooling</b></p> <p><b>Case studies crustacean</b></p> <p><b>Regulatory compliance and quality assurance</b></p>	<p><b>Predictive values of diagnostic data</b></p> <p><b>Maintenance of accreditation and Proficiency tests</b></p>
10:15-10:45	Coffee break	Coffee break	Coffee break
10:45-12:00	<p><b>The validation pathway WOH</b></p> <p><b>EURL Diagnostic manuals for listed fish and crustacean diseases</b></p>	<b>Diagnostic validation</b>	<p><b>Validation of novel technologies for aquatic animal diagnostics</b></p> <p><b>Multipathogen diagnostic</b></p> <p><b>Use of eNA for screening and surveillance</b></p>
12:00-13:00	Lunch	Lunch	Lunch
13:00-14:15	<p><b>Analytical validation</b></p> <p><b>Standard materials and controls</b></p> <p><b>Case studies</b></p>	<b>Diagnostic validation and examples</b>	<b>Practical exercises from students and discussion - part 1</b>
14:15-14:30	Coffee break	Coffee break	Coffee break
14:45-16:00	<p><b>Analytical validation</b></p> <p><b>Case studies - PCR</b></p> <p><b>Retrospective data</b></p> <p><b>Case studies -cell culture</b></p>	<b>Exercises diagnostic validation and sample size</b>	<p><b>Practical exercises from students and discussion - part 2</b></p> <p><b>Course evaluation and conclusions</b></p>