Workshop WP5 – *in vitro* model validation
Date: Wednesday 28 January 2026
Time: 13:00 – 17:00 (total = +/-4hours) *(preliminary)*
Location: Templars Hall – Royal Olympic Hotel – Athens Greece

Aim of workshop
Creation of awareness around the process of validation for regulatory purposes. Provide guidance in understanding the regulatory relevance and applicability of the *in vitro* model within CHIASMA. *We will build further on the information previously collected in the ToxTemp and the CHIASMA questionnaire.*

Draft agenda

Time	Content	Whom
13:00-13:45	Welkom	Wanda van der Stel (RIVM)
	OECD test guideline development	Eric Bleeker (RIVM)
	How to progress to regulatory acceptance, thyroid models as an example	*Ellen Hessel ?* (RIVM)
13:45-16:00	Breakout groups	
13:45	Breakout 1 : model 1	
14:15	Coffee	
14:30	Breakout 2 : model 2	
15:00	Coffee	
15:15	Breakout 3: model 3	
15:45-16:00	Coffee	
16:00-17:00	Plenary feedback & closure	*Tbd: Katharina Koch?* (IUF) Wanda van der Stel

OECD guideline development – Eric Bleeker
An brief overview of what it practically means to submit a model for an OECD guideline. What information is required before starting submission and what steps need to be taken and which are optional during submission? Who will be involved from the various stakeholders, what can you expect from them en what do they expect from you? What does "validation" mean in this context?
One of the major aspects of preparing your model for regulatory purposes is to formulate the regulatory question, it should answer. What should the regulatory question address? What are existing regulatory questions? How can we embed our models into a biologically relevant context (AOPs, clusters of models; IATA)?

How to progress to regulatory acceptance, thyroid models as an example – Ellen Hessel
Ellen will discuss the research they have done into thyroid models;
- What defines progression of a cell-based model from the research and development phase towards validation and regulatory acceptance? *[implementation curve and drivers+barriers research AFARA]*
- What do we need in order to retrieve information from a cell-based model to answer (parts of) a specific regulatory question? *[case study VHP4Safety, thyroid workflow, silicrystin regulatory question]*

Breakout groups
The teams of the model development will be divided into 3 smaller groups (3/4 models) to discuss the regulatory questions, applicability and status of their model. What needs to be done to get the models a/more steps further towards acceptance. We reserved 30min per model, with room for a little break in between.

Plenary feedback & closure
The 3 breakout groups will bring forward their main findings. Feedback can come from all participants and the session will be let by [tbd]. *Option: IUF. They have a broad experience in the process of validation and getting a model step-by-step further towards acceptance.*

Preparation before the workshop
Answer two questions:
1. Who will join in-person from the various model developing teams?
2. What are your questions concerning the regulatory aspects of model acceptance? We will try to incorporate them in the introduction or discuss them in the breakout groups.
Preparation of documentation
3. We want you to prepare yourself by bringing together some details of your model. We will provide at the end of the year templates for you to fill in. This will be based on the questionnaire we send out in the past. Please retrieve your latest version or start already preparing yourself by finishing the questionnaire this year.

Output
We also want to have a concrete output on paper to combine all results of this half a day Workshop I. Based on the results of the workshop, we will decide which form this will take.

Homework
After the Workshop I it is not over! Please keep everything you have learned in mind when developing your models further.
For Workshop II we would like to zoom in on 1 or 2 models that we have pre-validated within CHIASMA as examples. Give it a thought, this could be a good opportunity to promote your work.

Sneak peek for workshop II
Thank you all for providing a list of names for possible speakers concerning various aspects of model development and validation. For workshop I we decided to keep it interactive and focused on the models we have and the people in our consortium, really aiming to get these models a step further.
For workshop II, we want a broader audience to support a discussion concerning acceptance and validation of *in vitro* models. In there we want to include talks addressing topic like:
1) The existing/updated guidance for model acceptance (e.g. OECD Guidance Document 34),
2) The wishes and requirements from the end users.
3) What makes a model accepted by regulatory authorities?
4) What was the output of the pre-validation work within CHIASMA (clearly essential at that point in time)?
There will be room for parallel breakout groups discussing a few statements concerning (pre-)validation.