Validation Secrets: How Not to Fail

Validation of an in vitro method is often seen as a formal process focused on statistics, reproducibility, and interlaboratory studies. However, the true “secrets” of successful validation lie much earlier in the method development process. Validation does not fix a weak method. It confirms the performance of a method that is already scientifically sound, well defined, and fit for its intended purpose. One of the most common mistakes is starting validation too early, before the method has been sufficiently optimised and its variability properly understood. A successful method must have a clearly defined endpoint, standardised protocol, robust prediction model, and transparent acceptance criteria. Just as important is understanding the biological relevance of the assay and its limitations.

The lecture will highlight practical aspects that are often underestimated but essential for success: careful selection of reference substances, control of technical and biological variability, transferability between laboratories, and realistic expectations about what the method can and cannot predict. Special attention will be given to common pitfalls in validation studies, including poor protocol definition, overinterpretation of preliminary data, insufficient training, and lack of alignment between the method endpoint and the intended regulatory or scientific application. Validation should not be viewed as a box-ticking exercise, but as a structured scientific process that requires discipline, honesty, and strategic planning. By sharing practical examples and lessons learned from in vitro test development, this lecture will offer participants useful guidance on how to build strong validation strategies and avoid the mistakes that most often lead to failure.