

6th Euro Global Summit and Expo on **Vaccines & Vaccination**

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Immunoassays for unwanted and wanted immunogenicity including validation

Bioanalytical assays are a pivotal part of drug development, whether it is for determining and measuring the correlate of protection or the safety and efficacy of a drug product. This workshop will focus on ligand binding and cell based assays from scratch to fully validated assays as used for vaccines and biologicals. The first part will cover how to set up an assay, what parameters are important to test and control, such as blocking reagents, edge effect and many more. The second part will give an overview about the current bioanalytical guidelines on assay validation as issued by regulatory authorities and how we can implement them. Finally, we will look at the current discussion about qualification versus validation of bioanalytical assays. At the end of the workshop, the participants should have a broad overview about bioanalytical assay set up and validation and what the current requirements are.

Biography

Melody Sauerborn spent most of her undergrad years in well-known institutes such as the Centers for Disease Control and Prevention in Atlanta to widen her knowledge in virology and immunology. After obtaining her PhD, where she investigated the immunological aspects of antibody formation against aggregated protein therapeutics, she spent numerous years as a project leader, trainer and senior expert in immunogenicity and bioanalysis. Currently she is the head of non-clinical development at Mymetics, a viral vaccine company based in the Netherlands.

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