60 SECONDS WITH...

MELODY JANSSEN

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As a trained immunologist and virologist, Melody Janssen entered the fascinating world of biologics during her PhD. After obtaining her PhD, Dr. Janssen established herself in the areas of bioanalysis and immunogenicity testing by spending numerous years as a project leader, trainer and senior expert in CROs and biotech companies. She worked predominantly on developing and validating ligand-binding and cell-based assays for pharmacokinetics and toxicology, and immunogenicity studies for biologics, biosimilars and vaccines.

During her role as the head of non-clinical development at Mymetics, a viral vaccine company, she also extended and added to her expertise the production of biologics, vaccines and ATMPs and the aspects of potency assays and GMP.

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What are some of the current trends occurring in the biopharmaceutical industry with regards to bioassays and immunoassays?

One of the main trends currently is related to validation, and with immunoassays this is study parallelism. I see a huge difference in how people address parallelism, this is strange as it is clearly written in the guidelines. However, CMOs tend not to address parallelism during a well-defined PK study because they say we have a drug that we spike into the calibration and quality controls, so there is no need to assume that patient samples when treated with the same drug won't be parallel. CMOs will say that this means it doesn't make sense to address parallelism. So there is a clear difference between how regulatory bodies embed parallelism into the guidance documents, and how manufacturers perceive the parallelism quest and the need to embed it in validation.

How do you see the biopharmaceutical industry evolving with regards to bioassays and immunoassays?

One of the growing fields is ATMPs/cellular therapy products. A lot of the time these products are cell-based or stem cells and these pose a challenge to the industry with regards to bioassays and immunoassays because they are very difficult to handle and there is no clear understanding of how to define potency assays.

How can we handle that?
How can we evaluate the manufacturing?

There is a lot of variability with regards to defining biological activity or drug concentration in plasma, however industry will want to keep these assays as simple as possible in order to reduce variability in readouts, and at the same time keeping them true to what they are assessing.

What is most challenging when analysing bioassays and immunoassays?

There is a lot of struggle to have reliable and robust assays. This can be because of the intrinsic nature of the molecule in your assay or because you are using cells that introduce intrinsic variability as well.

How does your course Developing, Analysing and Validating Bioassays & Immunoassays help people to overcome these challenges?

Delegates on this course will learn how to set up and analyse an immunoassay, you will also be exposed to challenges that can occur during the assay lifecycle. So, when you do it on your own you'll be familiarised with best practices as well as common challenges.

What would be your top 3 tips for people working with bioassay and immunoassay data?

1. Understand the drug and its mode of action, what is it and what does it do? This can give you hints when things don't go right, it can indicate where the issues may be.
2. Work closely with other departments, if you are part of a big company I would urge you to share information and experiences with the assay between departments so that no one is confused with a given result.
3. Perhaps the most important tip – do not get frustrated!

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Developing, Analysing and Validating Bioassays and Immunoassays is a 5-week online academy starting 4 November

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