BISPECIFIC ANTIBODIES AND THEIR USE WITHIN THE FORMULATION FIELD

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Paresh joined Glenmark Pharmaceutical S.A. (La Chuax-de-Fonds, Switzerland) in June, 2017 in the Process Science Biologics group of Biologics R&D centre. In his role as Principal Scientist, he leading Formulation Development Team for early stage product development of Glenmark's portfolio molecules. He works with parenteral protein therapeutics and his current focus areas are developing formulations both as liquid or lyophilized in either as vial or PFS format for supply of toxicity and clinical studies. In addition, he is involved with UF/DF2 process development and optimization and stability management of (GMP and non-GMP batches) of DP and Bulk DS.

What are you working on at the moment? Is there anything particularly exciting for you in this field that you feel is a major development?

We at Glenmark are working on bispecific molecules which is what I see as a good opportunity. This sector is growing a lot, especially after getting the first bispecific product approved by the FDA in 2014. I think the interest is renewed in this class of antibodies. There are more than a hundred clinical trials on-going. I was watching a webinar a few days back, and it was really exciting thinking that people are betting big for these kinds of molecules.

What are the major challenges that you're facing with that in the moment with bispecifics?

The Bispecific antibody is somewhat opposite to a typical monoclonal antibody. Bispecifics are very potent, so we are talking about ultra-low concentrations (typically micrograms/mL to nanograms/mL). This is one of the main challenges not only for formulation/drug product manufacturing but also from a delivery perspective. When you have low concentration, you have a lot of chances of adoption losses at a variety of binding sites. The key thing is also the right analytical tools to really study the stability at those low concentrations.

Where do you see the field going over the next three to five years?

I wouldn't be surprised to find out that there is new technology coming into the picture for manufacturing of bispecifics. From a cell development to purification perspective, things are ever evolving with the introduction of single-use technologies and continuous manufacturing. I would see something coming out of the fill-finish especially for bispecifics, because these are an important class of molecules, and don't require a long period of time to convert into a drug product. The key thing is how you want to handle them, because they are in the same category as the hormones. They require a special kind of treatment or protections when the products are handled in a cCGMP facility. They're isolated, they have to be protected, and they have to be continuously monitored.

What are the core takeaways from this kind of conference?

The key thing is to see the data, because you put a problem statement, you go with a certain mindset and some indications, and then you prove that whether the strategy has worked or not, that's the key. So that data helps us if we are in some situations like that, how we can handle it, what are the guiding documents or the industry think-tank's views? Smaller companies work in a different way as compared to mid -sized pharma or mid-sized company would work differently to large pharma. It includes the mindset of how people are working on similar topics across the world.