PROGRESS AND DEVELOPMENT OF EARLY PHASE CLINICAL TRIALS

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Dr. Mysore Ramprasad is currently Director of Analytical & Formulation Development at Ambrx, and is responsible for all CMC related internal and external analytical method development, transfer, qualification, specifications, QC review of drug substance and drug product batch release data, and for overseeing all stability programs. He also manages Reference Standard generation, characterization and qualification, and leads formulation development and drug delivery of mAb, ADCs, and other protein therapeutic modalities including Fc fusion proteins and bispecifics, with site-selective conjugation using PEG and cytotoxic payloads. He has a Ph.D. in Molecular Biophysics from the Indian Institute of Science, Bangalore; was an Asst. Prof. at UCSD Medical School from 1995-1998, and has over 20 years' experience in Biologics Product Development from POC to Phase 3 clinical development. He also has a breadth of experience in CMC development of cytokines and growth factors, using multivesicular depot liposomes, and hyaluronidase-mediated drug dispersion technology. He led several Biosimilar Formulation Development projects at CMC Biologics, and has published widely including a book chapter on Analytical and Formulation Development Road Map for Protein Therapeutics, Elsevier 2017. He is the inventor of two novel lipoprotein receptors and has a US patent on Depot Hyaluronidase formulation for BPH treatment.

What is your focus for the next year? What big developments are you looking at going forward within your company?

Within the company, this would be early phase clinical trials, and advancing those into the next phase of development. Then we have a huge pipeline. It's a small company of around fifty people, but we get to do a lot with our site-selective conjugation platform technology. We can apply it very quickly with our expanded genetic code and precision engineered conjugation expertise to test feasibility, working very quickly from early stage pre-clinical to clinical development. That's the main focus; working with a lot of projects and enabling them from a CMC perspective, for clinical proof of concept studies

What are the biggest challenges within that?

Planning and managing all those projects and prioritising key deliverables. Then working with the resources we have – strategically thinking about using our internal resources and farming out some of detailed analytical characterization to CROs. We perform cell line and process development, provide in-process analytical support and conduct compatibility, comparability, forced degradation and clinical-use stability studies. So essentially much of the work is done internally, except GMP manufacturing and some biophysical characterization that we have to oversee as well.

What's your main interest at the moment in this area and what are the developments that you are excited for?

I've been in the industry for quite a while, I would like to see many of these programs advance from early stage into late stage clinical development. I'd really like to build a high-performing working team that is hopefully a centre of excellence in analytical and formulation development achieving many high quality milestones.

What is the main thing that you are hoping to get out of the conference today?

Part of it is networking; the visibility to attract other people who are interested in sharing their experiences in the same areas, and discuss solutions offered by some of the vendors to troubleshoot problems.

Which of the vendors are you most excited to talk to?

We work with several of them already. Wyatt, KBI, Lonza, Nanoimaging– many of your sponsors are people that we have worked with at some time or another. I think you're bringing the right kind of people here. Last year we also met quite a few people who we were able to initiate some business with later, so that was quite helpful.

What do you see for the future of the industry at the moment – where it stands – and the large molecule space?

It's a huge space with a lot of close competitors. We are also learning from each other and different companies, so that's a good thing when going to some of these different conferences—to apply the learnings and cut down the lead time for development. Still, there is a lot of versatility and uniqueness within the technologies –allowing intellectual property that we can develop for even virtual companies. I think that's really promising and encouraging.

What are you looking to achieve from conferences such as the one that you are at today?

This is a very focused group. I've attended a lot of IBC conferences in the past, focusing on formulation, analysis, and large molecules. This conference is mainly focused towards the San Diego and Southern California community, I believe. Several people within my group have attended this meeting in the last two years, so this could be a regular feature – especially for the scientists and research associates looking to attend local conferences and gain a breadth of knowledge from experienced speakers, and one-on-one interactions.