Cell and Gene Therapy Innovation Leaders Summit

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Speaker Interview

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What is your role at GlaxoSmithKline and what experience are you bringing with you to the summit?

I work in CMC Regulatory Affairs, which means I am responsible for the CMC (Chemistry, Manufacturing and Controls; also referred to as Quality) aspects of regulatory strategies and submissions for cell and gene therapy products. In my role at GSK and my previous role at Chiesi, I have gained significant EU experience on late-stage clinical assets and approved products, giving me good insight into the regulatory expectations for obtaining and maintaining a Marketing Authorisation.

Your presentation will be all about "Regulatory Insight on ATMP Development" – what can our delegates expect to learn from you?

CMC can be the rate-limiting step in ATMP development, and the most likely reason for a Marketing Authorisation Application (MAA) to not be successful. This is because, even if nonclinical and clinical data are compelling, market supply depends on a manufacturing process being robust, reproducible and economically-viable. My presentation will stress the importance of a solid CMC development strategy.

How has the cell and gene therapy industry developed over the past few years?

The industry has developed through the commitment of Big Pharma to cell and gene therapies. The expertise of the pharmaceutical industry is paramount to the commercialisation of these products, and companies such as Chiesi, Novartis and GSK have led the way.

What can we expect in terms of new innovation and the industry evolving?

I expect that the industry will evolve to become better at manufacturing in particular. Innovation will likely remain the domain of therapies based on, or targeting, the alteration of genetic function—including gene-modified cells, genome editing and viral vectors.

Does the regulation of ATMP development require further improvement and how can this be achieved?

I would say that the regulation of ATMP development works well, but the regulatory framework probably needs to be better understood by non-regulatory professionals. ATMPs are medicinal products, and their regulation is based on the framework applied to all other classes of medicinal products. As a regulatory professional, communicating this is part of my job and I am pleased to get to speak on the topic at this event. I would encourage conference organisers to include regulatory presentations on their agendas, and delegates to attend them!

What is important to know for developers of ATMPs in terms of quality, safety and efficacy aspects?

Quality, safety and efficacy are linked in that safety and efficacy can only be assured if the right quality attributes of the product are demonstrated. Demonstrating that a product has the 'right' quality attributes is the basis of CMC development. Although ATMP-specific guidance documents are thin on the ground, those that are available should be followed as part of the CMC development strategy. It is equally important to know which guidance documents written for biotechnological/biological products are applicable and to follow these too. Scientific Advice procedures should be engaged in to get regulatory agency endorsement of the quality, safety and efficacy aspects of development strategies.

In what areas does the cell and gene therapy industry need more funding?

Facilities and infrastructure for manufacturing to medicinal product quality at industrial scale, together with the necessary investment in staff training.

What are you looking to gain from your participation at the Cell & Gene Therapy Innovation Leaders Summit?

The cell and gene therapy industry is fast-moving. This event will be a great opportunity to keep up to date with the latest innovations that will shape the industry's future, as well learning how other organisations are tackling and resolving their particular challenges.