Q&A SESSION WITH UWE GUDAT

UWE GUDAT, Head of Safety, **Merck Serono**

Uwe Gudat received his medical degree from the University of Marburg, Germany. He is licensed in internal medicine and diabeteology as a sub-speciality, training under Michael Berger in Düsseldorf Germany. Uwe Gudat joined the pharmaceutical industry in 1995 with Eli Lilly and since then has held positions at Hesperion/Actelion, Novartis and Merck Serono. In this time he has led global clinical development teams, served as global medical brand director, led global clinical due diligence teams, and guided the oversight over clinical trial designs, first in man transitions and product safety assessments. Currently he is Head of Safety of the Merck Serono Biosimilars Unit.

You are talking about managing biosimilar safety at this year's Biosimilars & Biobetters Congress – what aspects will you be discussing?

I will be talking about how the product safety for a biosimilar is given by the structural congruence with the originator. The premise being that, if molecular structure determines clinical behaviour, then a high degree of structural resemblance translates into comparable clinical performance – that's the whole logic of a biosimilar. The clinical safety data serves to illustrate that point, namely that structural congruence translates into clinical congruence. Accordingly, it is justifiable to link to the originator safety data, because if the structure is essentially the same, performance is essentially the same and it is not necessary to rebuild the whole safety data set.

How do you think that the industry should be approaching the challenge of convincing clinicians that a new biosimilar is interchangeable with the originator?

Information is key – clinicians have to understand the logic behind the biosimilars pathway and appreciate that the analytical characterisation and the comparison against the originator with respect to structure gives a high degree of reassurance regarding the safety of the product. If we go with the premise that molecular structure determines clinical behaviour, when you have two compounds that are very close to one another in terms of structural features, one would have to assume that their clinical performance is also very close.

Is the pace of progress in the biosimilars field gaining momentum?

Like any life cycle, when people set off there was huge enthusiasm, a certain naïvety, and a focus on opportunity – it all initially seems easy when you are still a step away. As you get closer, you realise the importance of the details and you start facing very practical day to day issues. You learn how to overcome these, and it's that evolution that I think is significant.

When you go to conferences and you speak to people, you often find that they say they began biosimilars development somewhat blue-eyed, and they are now learning, maturing and making it actually happen. It's not as easy as people initially thought, but at the same time we are finding that these obstacles can be overcome.

Regulation is a topic many working in the biosimilars arena are very interested in – do you feel that regulations for development of biosimilars are particularly strict?

I don't think the regulations for biosimilars safety are any stricter than I would have expected. The logic of a biosimilar is that it is a copy – if it's a good copy, it will be almost indistinguishable from the original, which means it will do all the good things the original does, but it will also do all the bad things the original does – and we have to accept that. If the biosimilar appears distinctly safer than the originator, that would mean it would be questionable whether it is a biosimilar.