60 SECONDS WITH...

MARGIT HOLZER

BioProcess International Academy

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Margit is a specialist in process, product and analytical methods development for preclinical and clinical production phases as well as for commercial supply.After completing her doctorate in Vienna, Margit began working at Boehringer Ingelheim, eventually establishing and becoming the head of the new division of manufacturing sciences. She moved on to become the Quality Director and later on the Technology, R&D and Innovation Director for NOVASEP in France, before setting up her own consultancy. She now assists clients in the evaluation, optimization and development of processes, analytics and technologies including innovative ones for Up & Downstream processing and Formulation. She has 25 years' of experience in the industry and has worked on more than 50 different products.

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First, maybe you could tell us a little about your background and how you came to work in the biopharmaceutical industry...

I originally studied Biotechnology at BOKU (University of Natural Resources and Life Sciences) in Vienna which focused on different areas including food and environmental biotech, however I specialised very early on in biopharmaceutical development and engineering. During my master program I worked on clone improvement (selection and recombinant techniques), fermentation development and scale-up.

After this, I joined Boehringer Ingelheim in Vienna heading a downstream department. The company then supported my thesis specialising in downstream processing - development of a second-generation process for an interferon to respond to regulatory requirements. In parallel I took further responsibilities including project management and became Director of the secondary recovery and downstream processing departments. In 2000 I moved to Boehringer Ingelheim's cell culture site in Biberach (Germany) to create and head the manufacturing sciences division.

Following a very exciting time in this position I joined Novasep where I first headed the quality division, then I created the Biopharma business unit and worked as R&D and Technology Director before becoming the Scientific Director at Ulysse Consult.

How have you witnessed the industry change over your career, and how do you predict it to evolve going forward?

When I started my career, I worked mainly with molecules expressed in bacterial and yeast systems, these were less complex and included interferons, insulin and interleukins. However, as time went by I saw the introduction of more and more complex molecules and products such as conjugated proteins, mabs, viruses and cells.

The mode of action of these more recent biopharmaceuticals works differently. These products are often more targeted and efficient. Some gene and cell therapy products even work at the gene level and could cure defects by gene-transfer into human genome. These products also have different expression systems, which needed to be

developed to a stage that they are acceptable from the regulatory point but also in terms of economy.

Going forward, as our understanding of diseases, cell and molecular interaction increases, I imagine the industry will change to include medicines which are more personalised, directed to more complex diseases, or that compensate lacking or add new functionalities. Further digitalization will also help to measure, and control molecules involved, for instance, in metabolic diseases. For sure CMC has to change in light of this, with more complex systems, analytical and quality tests required.

Why do you believe Big Pharma are becoming increasingly interested in the biopharmaceutical industry?

If you look at the number of large molecules that have been approved, the ratio between small molecules and large molecules are changing in favour of large molecules. The industry clearly sees this change, and as research demonstrates the opportunity for increased efficiences in biopharm too, Big Pharma are taking more interest in order to maintain their competitiveness in the market place.

Do you believe that new industry entrants have sufficient knowledge and skills to work in this evolving industry?

I believe new industry entrants require a lot of knowledge such as understanding the products, the necessary controls, risks and the market.

It seems new entrants often lack knowledge relating to analytics, production processes, equipment, utilities and facilities. Often new entrants rely on more experienced people to pass on this knowledge. I have worked in companies with little training investment which resulted in people spending a lot of time and money to reach a certain level.

How does the Biopharmaceutical School help to address this?

Basic and continuous training is very important in this industry – this School provides the theoretical information which needs to be mastered for any professional in this industry.

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This programme is delivered by industry experts and gives an insight from people on the ‘shop floor’. When complemented with exercises, this can help participants progress and reach a level which is required for their daily work.

The Biopharmaceutical School is a 3-day course taking place in London 3-5 December 2019

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