60 SECONDS WITH...

THOMAS CHATTAWAY

On Tech Transfer for Biopharmaceutical Manufacturing

BioProcess International Academy

THOMAS CHATTAWAY

Thomas Chattaway is a Senior Life Sciences Consultant and has expertise in providing innovative solutions for patient needs and addressing manufacturing challenges. He has over 20 years' experience leading biotechnology-based product and process development projects and has worked in various countries serving customers in the pharmaceutical, biotech, medical device and health care industries.

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To start, what exactly is a Tech Transfer, and why is it important with regards to biopharmaceutical manufacturing?

In the narrow sense, Tech Transfer in the pharma industry occurs when production is transferred from one site to another and there is a GMP requirement to follow a protocol and generate a report. The main concern is to achieve identity, or comparability, of products between the sending and receiving sites. In a broader sense, we speak of tech transfer when going from laboratory or pilot to initial GMP production and when scaling up or changing facilities. Transfer of information is always critical: regarding product and process development, analytical methods, production recipes and practices.

Tech Transfer is important in any manufacturing industry, but particularly so for biopharmaceutical manufacturing for two reasons. First, because bioprocessing is complex and small differences can have a large impact; second, because the industry has always relied heavily on contract manufacturing, increasing the number and challenge of Technology Transfers.

What are some of the current trends you are seeing in the biopharmaceutical industry which are influencing the need for Tech Transfer?

- Some parts of the industry are reaching maturity and we are starting to see competition on the same products (biosimilars). This increases the incentive to outsource mature products for some companies looking to free their capacity for newer products or to find lower cost bases.
- Other parts of the industry on the contrary are at very early stages of manufacturing, e.g. the advanced therapy medicinal products (ATMPs) including cell and gene therapies. Here the capacity need is far greater than can be provided by the research and hospital labs these technologies grew out of. Companies are scrambling for capacity as projects get nearer to commercialisation. This creates a need for Technology Transfer to organisations which have the technical capacity. At the same time this technology itself is not mature.

What are the most challenging aspects of performing a Tech Transfer?

- The complexity of biopharmaceuticals – typically a process has a dozen unit operations to be coordinated and small processing differences can impact critical quality attributes. Additional to this is the intricacy of the analytical methods that have to be aligned, while maintaining their sensitivity. Many details need to be covered.
- Alignment between sites - there is often a lot of emphasis put on technological similarity between sending and receiving sites when planning a Tech Transfer, but what is even more challenging is alignment between sites in terms of communication, working culture and quality systems. Fostering a relationship where there is a shared willingness to solve problems is critical to successful Tech Transfer.
- Transference of analytical technology – this should be done as early as possible before it is needed, as the process can take longer than expected.

How does the new course Tech Transfer For Biopharmaceutical Manufacturing help to address these challenges?

This course will cover the main areas of Tech Transfer in biopharmaceutical manufacturing and address the challenges and risks to be wary of. You will gain a number of tools to use in your day to day role and we will use a rolling case study to bring examples to life.

Ample time will bee given for interactions and group exercises, allowing you to bring your own concerns, problems and experiences to the table. I hope this mix of structured inputs, case studies and interactions will provide a successful learning experience. Delegates are encouraged to bring examples of challenges they are facing so we can discuss solutions together.

What are your top three tips for people who are planning a Tech Transfer for biopharmaceutical manufacturing?

1. Transfer your analytical methods first.
2. Invest time in developing a productive working relationship between sending and receiving sites.
3. Design and use efficient data and knowledge sharing tools.

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Tech Transfer for Biopharmaceutical Manufacturing is a 2-day course taking place in London 30-31 October 2019.

Find out more >>

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