GENERIS

TOMORROW'S CONNECTION TODAY

Q&A With **Ryan Cox**

THE CHALLENGES AND OPPORTUNITIES IN BIOMANUFACTURING

AMERICAN BIOMANUFACTURING SUMMIT 2016

May 10th - 11th, 2016

How would you describe the current state/ landscape for the biomanufacturing industry in the US?

I believe that the biomanufacturing industry is currently in a state of major transition in the US. This is due to both generational and regulatory factors. As many people from the baby boomer generation are beginning to retire, the industry must find a way to transfer the skills and knowledge on to a younger workforce. From a regulatory perspective, the bar continues to be raised and new requirements such as serialization are causing companies to adapt more quickly than ever before.

Does (how does) this differ from international operations?

While the generational transition is more of a specific situation for US companies, the regulatory hurdles are similar and in some cases more difficult. It is particularly challenging to manage operations globally when dealing with vastly different regulatory review periods for new drug applications as well as making any significant changes to existing dossiers.

What do you believe are the biggest challenges biomanufacturers currently face?

The biggest challenge currently facing the biomanufacturing industry is the emergence of biosimilars. As these become more prevalent, there will be increasing pressure on biomanufacturers to compete in the marketplace.

How can these challenges be overcome?

Biomanufacturers must continue to focus on innovation in terms of making improvements to existing products in order to remain competitive. Technologies such as pegylation are already being explored as a way to significantly increase the serum half-life and stability of biopharmaceutical drugs.

In your opinion what is the biggest opportunity in biomanufacturing techniques/processes/improvements?

Techniques such as pegylation to extend half-life and protein engineering technology to reduce immunogenicity are areas where the biomanufacturing industry can continue to make improvements.

What do you foresee as the 'next big trend' to influence biomanufacturing?

Through technologies/techniques that I have described, I think we will see a trend towards what have been referred to as "biobetter" drugs that have a vastly improved pharmacological profile in comparison to existing products.

What major changes do you forecast the industry undergoing over the next 5-10 years?

With increasing pressure to reduce the cost of healthcare in the US, as well as the globalization of the industry and the regulatory hurdles that come with it, I believe that the industry will need to become much more flexible and "lean" over the next 5-10 years. I see this being done through by using more cost efficient manufacturing processes that incorporate more single-use technologies and PAT that can provide enhanced regulatory compliance as well.

Join Ryan Cox at the American Biomanufacuring Summit!

Participate in the in-depth discussions and build your road-map to achieve innovation, maximize manufacturing profitability, optimize plant floor operations and establish standardization across multiple manufacturing facilities.

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Biotherapies for Life™

Ryan Cox / Director, Bulk Manfacturing / CSL Behring

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Case Study: Examining the Technology Transfer Process of a Manufacturing Facility to the US from the EU

- Writing an effective technology transfer plan as an effective roadmap
- Critical steps and timelines, validation strategy and giling strategy
- Discussing the importance in-person communication and collaboration to strengthen teams
- Overcoming language, time zone and supply chain barriers
- Understanding the regulatory requirements for stability and comparability studies
- Reviewing engineering runs and performance to determine program success and lessons learned

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