

CELL & GENE THERAPY INSIGHTS

RAW AND STARTING MATERIALS:
TROUBLESHOOTING SUPPLY, MANAGEMENT
& OPTIMIZATION ISSUES

SPOTLIGHT

INTERVIEW with:

Jason C Lin, Director of Global Supply Chain,
FUJIFILM Irvine Scientific



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Meeting the evolving challenges of media supply to the cell and gene therapy space

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Q What are the major challenges in media production and supply to the cell therapy supply chain?

JCL: Generally the challenges are not directly supply related. In terms of the business aspect, it's more about getting the best value and service from the suppliers. We also want to ensure consistency of supply; sometimes that is related to

single sourcing, or potential shortages coming from the market.

The situation with the coronavirus in China is an example of a situation both directly and indirectly impacting supply. Some of the crude or raw material sources are coming from China, in particular the amino acids that go into the products that we produce. On the other hand, we are in position to prepare against this by having robust inventory, and having dual sources with multiple sites capable of producing material globally. It's definitely a headache, but we have a plan to address it on an ongoing basis.

Q How do you manage the disconnect that sometimes exists between media suppliers and the cell therapy industry?

JCL: Suppliers are eager to be part of the process from early on, and they hope to see business growth and be part of continuing collaborations by getting into the R&D phase of the business. But on the commercial side, we would not make a decision too early unless we're able to see the value we hope to achieve from it. For example, say that a supplier wants to be part of the formulation ingredient we produce, we would have to see a demonstrable track record, and ask ourselves if we are aligned in commercial value-adds. Ultimately we need to be seeing quality and consistency from suppliers before we can commit to a partnership.

What the supplier wants has to be balanced against what we need as a company in the long term, because we are in the business to ensure quality, and also the most effective and robust pricing of the products we produce.

Q What are FUJIFILM Irvine Scientific's procedures for the qualification of raw materials such as media?

JCL: The starting point is always to have the right documentation. This could include the Certificate of Analysis, the TSE/BSE statements, which concerns whether the ingredient is animal-derived or not, and any other relevant documentation on the materials side. On the supplier side this is anything about the manufacturing site itself, the production history, and what quality system the suppliers have in place.

In addition, we ask for samples of new raw materials; typically three separate manufacturing lots, to push through our quality system for testing and evaluation. Finally, a decision would be made on whether to qualify the material for use or not.



What is your approach to ensuring continuity of supply?

JCL: That's always a hot topic for supply chains in general. Whether we're dual sourced or not, the first approach to ensure continuity of supply is to have a robust supply agreement. We have terms and conditions to protect us as the customer, just in case the supplier decides to divest or close the business. This gives us the right to procure materials up to a certain point in time, typically 9 months or a year, until we have a chance to find an alternative source.

With a supply agreement in place, the next thing we would do for a single sourced material is look for alternatives and qualify the new supplier in the portfolio as early on as possible. This can be a challenge sometimes, because there may not be other suitable alternatives in the market for the same type of products – that's an issue we're always dealing with.

Lastly, building a relationship with the supplier and R&D teams is crucial. You have to have good relationships with the supplier, so that when you're in a time of need or there is a global shortage, you are considered an essential customer at the top of the list to have your needs fulfilled.

From an R&D perspective, you can look at the process early on and aim to avoid using a supplier or type of material that is going to put you in a single sourcing situation or a tough supplier situation. This becomes more difficult to address later on in the commercial production phase. It's easier to make these decisions early as they can have a big impact on your decisions or your business further down the road.

This is the process we like to follow if we can – it's not always possible, but our philosophy is always to employ good decision-making from the beginning.

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How is demand for media for cell therapy production evolving worldwide, and what are the keys for you in meeting the needs of this global sector?

JCL: The need for cell culture media globally is currently robust, and seeing very positive growth. In addition to this worldwide growth, from my time working in the Asia Pacific market I see the cell therapy industries booming there, too. All the existing industrial cell culture businesses such as Roche, Genentech, Amgen, and so on are continuing to have a high volume of media needs from various suppliers in the market.



What are the future media or critical raw material supply trends you foresee for the cell therapy space? How is FUJIFILM Irvine Scientific mobilizing to prepare for them?

JCL: We plan to focus on the ingredients that are driving the core volume to our business. Meaning that as we get requests for different formulations, whether it's a customer product or our own product, we really have to dig into all the sub-components and determine and rank the risk assessment level for each material, and make preparations for each. As mentioned above, some of these raw materials could be in sole sourcing situations, meaning nobody else in the world makes it. It's important that we manage to ensure supply.

We are confident about continually meeting these challenges from the supply chain perspective through robust management of the supplier, the supply, and also contractual understanding from both sides. And then lastly to have robust inventory, safety stock, and any other value-added activities we can create in the supply chain space. We feel optimistic about our success, both due to our proven track record and our continued efforts to be prepared for what the future brings.

BIO

Jason C Lin

With two decades of experience in global pharmaceutical/biotech material and product supply chain strategic settings, Jason Lin applies his expertise as the Director of Global Supply Chain with FUJIFILM Irvine Scientific. He oversees end-to-end raw materials planning, procurement, and materials management for media products across various business units, as well as drives Cost of Goods reduction actions such as manufacturing dispositions, raw materials/finished goods inventory control, and long-term materials pricing contractual agreements. As FUJIFILM Irvine Scientific expands globally, Jason will oversee the build-up of new manufacturing site supply chain functions, as well as continue to manage global network manufacturing optimization and production allocation for Japan, the USA, and the EU with the goal of meeting customer needs by region with the lowest manufacturing cost and best efficiency. Jason holds a Master of Science degree in Industrial Management and a Bachelor of Science degree in Industrial Engineering, both from Clemson University.

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