

## **How to Industrialize Strategic Sourcing of Raw Materials and Supplies? Interview with David Karakas, Sr. Director, Strategic Sourcing & Procurement, Bluebird Bio, BSMA Cell & Gene Conference, 8.5.2021**

Challenges faced by the nascent industry to qualify suppliers who understand the stringent requirements and forge a business relationship will be addressed. The just in time nature of the therapy imposes an unprecedented demand on suppliers. A robust and resilient supply chain requires manufacturers to strategically source raw materials and identify backup suppliers where possible, and where backup options do not exist, work with suppliers to de-risk their supply chain. Manufacturers are also working with CMOs for certain critical raw materials and processes that are capacity constrained which impact both pricing and availability to service market demands. Industry approach to audit suppliers will be discussed.



**David Karakas**  
Sr. Director, Strategic Sourcing &  
Procurement, **Bluebird Bio**



**Devendra Mishra**  
Executive Director and Co-Founder,  
**BSMA**

### **FIRESIDE CHAT**

**Devendra Mishra:** *You are an exceptional executive who has served three major biotech companies with the responsibility for strategic sourcing and procurement. How do you describe the formidable challenges of sourcing for the nascent Cell and Gene therapy that promises to revolutionize healthcare?*

**David Karakas:** As of late, while I think of supply chain resiliency, the formidable challenge has been to support the successful, commercial launches, not only from the known bill of materials but also capacity planning, quality release reagents, and even lab consumables, that nobody thought were important. And then you realize you run out of them and they become the most important.

**Devendra Mishra:** *With the plethora of products, API's and services that you have to procure globally, do they fall into certain categories for prioritization?*

**David Karakas:** It depends on how you want to characterize. Single use components could be a category of product whereas vector and plasma starting material could be a separate category. Critical reagent slash components could be another. We look at the Bill of Materials (BOM) and then develop high-level sourcing strategies and go down to the lowest levels.

**Devendra Mishra:** *To understand the landscape, when it comes to a bill of materials, one measure of how mature the organization is determined by how many MSAs and Quality Agreements are in place. What is the state of the union of the industry?*

**David Karakas:** Most organizations in the CAR-T Cell Therapy are spinning out technologies and/or platforms. For the platform, the processes are clearly defined which one is replicating. By using closed processes, you move to commercial operations with sound quality. Sometimes, we trip up on the MSA side across the board in case of self manufacturing, both clinical and commercial. There is a gap on MSAs for the material and even critical reagents, because it's not just the BOM item that is going to shut your facility down, it could be a mop head or a filter used in the process. Companies that depend on CMOS should not assume that the CMO has sufficient inventory. Going from five patients to 10 patients in a week is OK but it may be dangerous when you go to 500.

**Devendra Mishra:** *Earlier today, several of the supply chain executives talked about lengthening lead times because of the pandemic, the COVID-19. Is that something that keeps you awake at night?*

**David Karakas:** Yes, especially when lead times are 52 weeks out for some materials, which means they have no idea when they're going to get it or when we're going to get it. We have seen lead times extend beyond expectation while suppliers are working hard. I'm not a technical person and not allowed to walk into a lab because I'd probably burn it to the ground because of my ignorance. Timothy Moore of PACT Pharma spoke earlier today about single source suppliers. I've used single sources and it may not be an exception but we have made a decision to go with one and having that one listed in our SOP file. In case of sole sourcing, there is no place to go which makes the situation onerous for everyone in the supply chain. I think the only way to solve the issue is by those three groups – Quality, Sourcing and Supply Chain, to come together and figure out how to address it. The lead times are something that worries us when we are saving lives.

**Devendra Mishra:** *When a critical material comes to you and Quality Control discovers it be defective, what is the disruptive impact?*

**David Karakas:** There have been many times in my career, specific to cell and gene therapy, where we had to shut down, like stop making the drug product. And it has happened more than once in the pre-pandemic times in case of sole source. Organizations, who rely on CMOS, must fundamentally understand their network demand for raw materials. We shift inventory using special couriers. The cost of shipping is \$1,000 for two vials that cost \$500, which can drive Finance nuts.

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**Devendra Mishra: One of the issues facing the nascent industry of Cell and Gene Therapy is high cost of treatment. Does the cost of materials you procure contribute largely to this problem of the treatment costing very high? Will your efforts of strategic sourcing and procurement reduce the overall cost of the treatment?**

**David Karakas:** Everybody knows vector is not inexpensive! It really comes down to whether you own the IP. Do you own the process and technical know and the backbone of the vector itself? If you answer yes to those three things, then you can do a tech transfer. There is a cost to a tech transfer. I'm always fascinated about companies moving to in-house versus in-sourcing, vertically integrating and making their own vector and plasms, making drug product versus those that are relying on CMOS. Lately, I've been completely caught off guard because a few organizations are selling their assets, right to CMOS. The cost to operate some of these plants is extraordinarily high and you are de-risking your supply by divesting. I think in some instances, when used appropriately, sourcing can absolutely, potentially reduce the cost of those therapies. On the other hand, when you look at the cost of a drug to treat a patient over the lifetime, the total cost is much higher than a one-time treatment.

**Devendra Mishra: *What's your assessment of CROs and CMOS, having worked for two very large cell gene therapy companies?***

**David Karakas:** On the good side, they're highly collaborative people. On the decision side, not so good. In the traditional buyer-seller relationship, you need to have a much more careful consideration as a company who's going to work with an outside provider. It's okay not to know all the answers and to figure out how do we overcome the challenges. When folks keep information close to their chest and engage in finger pointing, the relationship is soured and makes things very difficult. And the CMO is the extension of your enterprise. If they fail, you fail

**Devendra Mishra: *David, you are a person who believes in establishing strategic relationships with suppliers. What message would you like to give to that large body of suppliers that we need for the for the revolution of cell and gene therapy that the drug manufacturers are engaged in?***

**David Karakas:** If I had one request, understand that we don't know. We're still trying to understand the process.

**Devendra Mishra: Thank you, may this only be the beginning of a dialogue.**

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