

Operations as a competitive advantage in biotechnology

An interview with Esteban Santos, executive vice president of operations at Amgen



Amgen, a biotechnology pioneer founded in 1980, aspires to unlock the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing, and delivering innovative human therapeutics. In this interview, McKinsey's Robert Lewis discusses the role pharmaceutical manufacturing will play in the future success of biopharma companies with Amgen's executive vice president of operations, Esteban Santos. Within Amgen, Santos is responsible for the operations organization, which encompasses manufacturing, process development, quality, engineering, and global supply chain.

McKinsey: *What are the main forces you see shaping today's biotech industry?*

Esteban Santos: Biotechnology has brought innovative medicines to addressing some of the most serious diseases facing society over the last three decades. And going forward we have an even greater opportunity to innovate, especially in genetics, the genome, and personalized medicine, which can significantly improve people's quality of life. Today, our industry is facing loss of exclusivity for our medicines as patent protection expires and competition increases. As a society, we need to reconcile the desire to manage short-term healthcare costs with the long-term benefits of better health outcomes. That's a challenge, and it will continue to shape our industry. We need to work with jurisdictions, governments, and payors to find a way to bring innovation that makes a difference to the people who need it.

McKinsey: *How do you respond to these trends in a way that differentiates you from the crowd?*

Esteban Santos: Amgen was founded on the belief that innovation brings value to society. We've done a good job in balancing the short-term cost pressures and the long-term need to innovate in order to

succeed. We innovate through our "biology first" approach to research and development and also through the technologies we use to manufacture our products. By innovating, we can reduce the cost of medicines as well as improve their safety, efficacy, quality, and reliability. We believe in our mission to serve patients and that is reflected in every aspect of our culture.

McKinsey: *How do you see operations evolving to meet challenges like these?*

Esteban Santos: We see operations as a competitive advantage for Amgen. To retain that advantage and advance our capabilities, we focus on reliability, efficiency, agility, and differentiation. Reliable supply—getting medicines to patients in an ever more complex world—has long been a strength for Amgen. That was a differentiator in the early days of biotech; today it's just the entry ticket.

The next element is to keep finding ways to be more efficient and productive. How do we eliminate work that doesn't add value and redeploy people and capital to fund the R&D machine and commercial expansion? Reliability and efficiency remain important, but they are no longer sufficient to ensure our success.

We also have to become more agile in how we deliver our products and services. That's nothing new for other industries, but it is for our industry and we need to get faster and nimbler. That's a challenge in a heavily regulated sector. We can't match the rapid product cycles you see in, say, electronics because we have to work with regulators in multiple jurisdictions around the world that sometimes have differing requirements.

And regulators tend to be on the conservative side, which is only appropriate given the impact of what we do on people's lives. If your app doesn't work you can just get another one, but if the medicine you take

to keep you alive doesn't work, that's a big deal. So we need to be thoughtful about balancing the desire to innovate with implications for the people we serve.

Finally, differentiation could be in better processes with higher titers, new manufacturing technologies, and improved products with better formulations and delivery devices.

McKinsey: *How do you make those strategic shifts in operations to remain competitive?*

Esteban Santos: First, we need innovation from our R&D labs, and then the ability to commercialize it. Operations has traditionally earned its seat at the table in a support role, not as the main event. But in an uncertain environment, the way we launch a new product can make a real difference. Operations is the team that turns innovation into something real in the hands of a healthcare practitioner and ultimately in the body of a patient. And it's up to us to supply reliably in a cost-efficient manner, but one that is faster to market and has differentiating product features.

As we head into markets crowded with products, it gets harder to predict the demand for established products facing loss of exclusivity, or new products facing competition from day one. So we can't be content to build to a forecast. The thing about forecasts is that they are by definition wrong—whether up, down, or sideways—but I don't know by how much. Agility is a countermeasure to uncertainty. It can improve speed to market and speed in the market when things change.

Agility can undermine the reliability that's fundamental to our business, but at Amgen we believe agility can enhance reliability. If it usually takes months to ramp up production and get a product to market, then as we become more agile by reducing our cycle times, we can be more reliable because we can react to an uncertain environment

with less risk to supply. We've been able to reduce the time to build and commission a new plant by two years. That allows us to wait longer before making a commitment, giving us time to have more certainty about the forecast before investing.

To get it right, operations needs to be plugged in to what's happening in the market, working hand in hand with the commercial team to get the right amount of medicines to patients. In addition to agility, we need to focus on differentiation in the areas of products, process, technology, and people.

And our process-development team plays a big role in building that ecosystem for patients, particularly where combination products are concerned. That's something we invested in and went from having one combination product to now having the capability to design and manufacture a suite of solutions for patients. We're continuing to invest in that capability.

That's the culture we're building: constantly innovating to make things better and faster. And the last element of differentiation is people. We have incredibly talented staff with expertise in manufacturing, quality, engineering, supply chain, and process development. Our job now is to see how we can move from having experts in individual areas to having leaders that integrate thinking across all of them.

These things aren't possible without the right people, so nurturing a culture of innovation focused on the mission to serve patients is important. Showing your team that you care about them and their development is key.

Whoever cracks the code for doing these things will have a competitive advantage.

McKinsey: *What kind of building blocks does it take?*

Esteban Santos: For one thing, we're looking at our supply chain end-to-end to help us react to

changes in demand much faster, without having to start all the way back in drug substance. We're isolating the long-cycle part of our business so that the short-cycle part can be closer to the patient, and then we're segmenting that part into steady products, new launches, and medicines facing patent or market pressures. We're going from a one-size-fits-all supply chain to one that's fine-tuned to each market's competitive landscape and needs.

We're also investing in our information systems to help us get a better view of what's happening and to react more quickly to signal changes. If it takes us a month to detect a change and another month to analyze it, we're two months too late. The challenge is to see what's going on and adjust our decision making in close to real time.

And we're reducing our cycle times as much as we can. I'm not talking about lopping an hour off changeovers, that's good continuous improvement, but I'm talking about the big picture. If I say "go" today, why does it take months to see the benefit? I want to turn months into weeks, and weeks into days.

McKinsey: *How is your view of manufacturing changing as you build new facilities?*

Esteban Santos: There's more to differentiation than products and processes. We have made a bold investment in advancing manufacturing technologies. Other companies have chosen not to; in a regulated environment, it's easier to stay with the known than move into the new. But our leadership believes in innovation and is willing to put money and resources behind it— and that's a key differentiator for us.

Take the disposable technologies we adopted to reduce our upfront capital investment on utilities, and our breakthrough in increasing the titers of our processes, which allowed us to create a smaller facility with the same output as a traditional one.

All this started several years ago when a group of process-development and R&D leaders produced a white paper about what the future of biologics manufacturing could be. Fast forward to today and our engineers and scientists have made it into a reality.

We worked closely with regulators around the world to make sure they understood what we were trying to do. We checked whether anything concerned them, and acted on their feedback without losing the essence of our concept. And we got approval in all major jurisdictions, which speaks for the regulators' enthusiasm for the technology. We already have the first product approvals and we're working on the second wave, so we're confident this is the right technology for the future.

McKinsey: *Earlier you mentioned cross-functional leadership; what part did that play in getting your new facilities off the ground?*

Esteban Santos: The idea of what's possible came from a technical team looking at the biology. How could we make cells more productive and get higher yields from our processes? Big ideas—but our leadership was behind us. Then our manufacturing, quality, engineering, and supplier-relationship teams made sure we could harness emerging technologies on the factory floor.

Back in 2013, we didn't have a single Amgen staff member in Singapore. Today, we have a new factory with approval to supply commercial products. From idea to reality, I think we set an industry record for speed. All that involved a very broad set of contributions from many people.

McKinsey: *How do you think regulation could change in the future to keep the industry safe while relaxing some constraints?*

Esteban Santos: We've learned that by engaging regulators early on, we can maintain continuity

in our interactions. They tell us what they think and we make an honest effort to understand them and translate their feedback into practical applications. Maybe you need sweat equity to make the investment, and then constant contact to bring the regulators along with you as you evolve technologies. When concerns arise, you need further conversations to establish how fundamental they are; sometimes they can be mitigated by different but suitable means.

I don't think there's a simple answer. It's a lot of work. But if you don't do it, either you're not innovating and fall behind, or you risk your innovation being left on the shelf.

McKinsey: *Company leaders today have to work under high uncertainty across multiple functions while also pushing the boundaries of innovation—which is asking a lot of people who grew up in a very different environment 20 or 30 years ago. How do you manage this at Amgen?*

Esteban Santos: I'm feeling optimistic about what I've seen so far, and confident because I've got my team behind me. I'm also optimistic because of

what we've demonstrated we can do. We expanded from being primarily in the United States and Europe to being a global company in about 100 countries. We've built capabilities in combination products that we didn't have five years ago. We've brought forward innovative technologies like our next-generation plant in Singapore. I talk to leaders within and beyond ops about what we're doing well and where the opportunities lie, and their feedback helps develop my thinking. So does my experience in other industries. I didn't grow up in pharma; for the first part of my career I saw similar things happening elsewhere, which helps me understand some of the possibilities.

Amgen has an incredible culture that helps people get it intellectually, and then get it done. We're not a command-and-control organization; to make things happen, we have to win people's hearts and minds. ■

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