

Enabling Emerging Biotechs with Supply With Care

Speakers:



Richard Segiel

Vice President of Business
Development North America,
Almac Clinical Services



Paul O'Connor

Global Vice President of Quality,
Almac Clinical Services

Emerging biotech companies were responsible for 65% of the molecules in the research and development pipeline, compared to less than 50% in 2016. Despite their explosive growth, the sector faces challenges ranging from cost pressures and supply chain disruptions to regulatory changes and geopolitical instability.

In a recent Almac Clinical Services-sponsored Biopharma Dive webcast, “Enabling Emerging Biotechs with Supply With Care,” Paul O'Connor, Global Vice President of Quality and Richard Segiel, Vice President of Business Development North America, highlighted the role that strategic partnerships and technological advancements can play in overcoming the obstacles faced by emerging biotech companies.

“The most successful organizations are the ones that are developing a framework to address a circumstance or a situation or a scenario that arises that is unanticipated.”

-Richard Segiel

Understanding the Obstacles

Emerging biotech enterprises are focusing on accelerating innovation. At the same time, there is a forced lag as regulatory authorities work to address new manufacturing technologies and therapies.

According to Segiel, all biotech companies from small virtual organizations to multinational companies focused on a particular therapeutic class or emerging technologies face challenges on the path to commercialization. Their top challenges include:

- A disparate global manufacturing supply chain
- Inefficiencies associated with managing multiple partners
- Regulatory instability

Emerging biotech companies face additional challenges of being lean organizations with narrow but deep expertise and limited resources.

A dedicated and reliable partner understands geographical expectations, standards acceptance in different regions and the process of moving therapies across borders. Partners can offer regulatory support, including customs expertise, to mitigate risks and ensure timely product delivery and market success.

“What's not regulated one day can easily become tightly regulated quite quickly in a targeted territory. Things can change at pace.”

-Paul O'Connor

Power of Partnerships

Although challenges are to be expected, emerging biotech enterprises might need help to predict or plan for unexpected obstacles. Segiel believes that strategic partners offer several benefits:

Sharing a different perspective: Strategic partners with vast experience can offer a different, often more comprehensive, view of a situation and experiences that can be valuable for developing solutions. From a practical perspective, partners might have more experience getting therapies to patients and be prepared to support managed access programs, named patient programs or other initiatives to help bring medicines to small patient populations in unique territories to drive commercial success.

Engaging stakeholders: Private equity funding can expose emerging biotech companies to a tremendous network of individuals, organizations, academic institutions and consortiums that can collaborate to solve problems. Engaging key opinion leaders early in the process can result in stakeholders supporting the adoption of therapies post-commercialization.

Assessing risk: The right strategic partners can take a long-term view of an issue, evaluate multiple elements and assess risk and possible outcomes, providing invaluable insights for accelerating innovation.

Embracing Innovation

Innovation is essential on the journey to becoming a more complex and robust biotech enterprise. O'Connor points to improvements in temperature monitoring and location management of medicine along the supply chain as one example of how technology reduces barriers and improves access to medicines and therapies.

"As we've improved the technologies, we've added location monitoring and temperature monitoring," he says. "We can...make sure that

the journey works, make sure that we stay compliant, make sure that the patient gets what they need and when they need it."

O'Connor says the overarching goal that all biopharma companies are trying to achieve is getting the right product to the right patient at the right time. A strategic partner is more than a vendor; the right strategic partner is a fixer who can address unexpected challenges and "supply with care."

[Watch the full webcast](#)

