

CASE STUDY: NAVIGATING AND MAKING BETTER TECHNOLOGY DECISIONS

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CHALLENGE

This case study centres around the central challenge of:

How to evaluate and strike the right balance between new technology ROI and its impact on P&L

Avril discusses her approach to this challenge and describes in detail three key decisions she and her team are currently navigating, plus some of the things they've learned so far.

ABOUT

Avril has been with Adverum Biotechnologies for the past year but has over 20 years' experience in the field. Avril has covered the breadth of the industry with experience at a CMO, a big biotech, a top supplier and now a gene therapy start-up. The common thread is that her roles have always been at the intersection of process development and manufacturing and focused on how to industrialise our bioprocesses to get products out to patients.

In this case study, Avril shares her experiences of striking the right balance between new technology ROI and its impact on P&L.

DECISION 1 - SINGLE-USE TECHNOLOGIES

Considerations:

1. Off-the-shelf vs customisation
2. Balancing design and application (closed processing)

The challenge with single-use as a start-up is that adoption cases are very established, especially in a start-up environment and for gene therapy, there's a lot of adoption for single-use. However, with Covid-19, the competitiveness of the market and the subsequent supply chain challenges, there is new complexity and diversity, so how do you select the right single use?

At the beginning of my career, a lot of off-the-shelf equipment was used and just taken at face value. There was never a question of whether it met our needs, but the levels of compliance and understanding around single-use materials have significantly improved. I have worked on the customisation of single-use technology in the past for certain applications where you have very specific, almost novel requirements in terms of tech. At the time, we were working closely with our vendors, so it was possible to easily align the technology and the applications. Now there is a lot more alignment in terms of the range of single-use options and the various needs of the industry.

DECISION 1 - CONTINUED

As part of my role, I oversee the pilot plant where we don't need to meet all the compliance of GMP so there are different options open to us and can different single-use designs can be used vs the GMP environment. Although, we have some concerns about contamination and closure and are limited in some areas.

If you are adopting single-use products off-the-shelf and taking your future needs for granted, it may result in a headache. I advocate up-front risk assessments to understand your applications' requirements and to ensure you've outlined the alignment you're getting from your single-use design.

Cost considerations were also a challenge. It's critical to establish a clear problem statement and assess whether your single-use design meets that problem statement. It's common to be overly conservative, which results in making longer-term decisions around your operating costs that may not be sustainable or efficient. When designing single-use systems, we have CAD drawings that align perfectly but single-use systems can get very complicated in reality. They can be large and unwieldy, taking several operators to build or install, so just understanding the 3D reality of what you're designing or employing is a key consideration. I always endeavour to take the 3D design and use pilot operations as a design lab, making sure you have alignment in practice and not just in theory.

DECISION 2 - GOING DIGITAL

Considerations:

1. Data management
2. Automation
3. Talent pool as a competitive edge

One of the biggest challenges I've seen is that a tremendous amount of data is generated and, at least in the first half of my career, we only looked at a tiny percentage of that data to gather meaningful justification for decisions, let alone potential insight into future decisions.

The good news is that there are so many more options for the guided implementation of solutions. I would say pick one and start! A lot of organisations spend a lot of time evaluating different options and it's wasted time when we're thinking about the speed of our industry and our current reality. Pick one – whether it's analytics, digitalisation of your records, keeping batch records and SOPs – and start with it. You'll learn a tremendous amount by doing and those learnings can be incorporated into your next steps. 'Be willing to try something' is my biggest piece of advice.

DECISION 2 - CONTINUED

In terms of talent, it's important to remember that other partners and companies in the industry are moving forward, and that's what I meant by potentially losing out on a competitive advantage. If you don't have some systems in place to onboard and quickly upscale talent, you're going to be spending a lot of time on that in the future.

At my current company, we're evaluating new technologies at the moment. We're using some old school tools like Excel as well as evaluating new ones. Of course, JMP® is a longstanding tool in the industry for running statistics and there are more advanced options available.

Another important piece of data is material attributes and history, not just of your single-use but all raw materials and components. I've seen a lot of investigations and projects that look at this retrospectively and it's a tremendous amount of effort to put together those data sets and start looking for meaningful information in them. There are projects and examples available where that's being automatically done and the data are telling us information as opposed to us going to look for answers in our data.

DECISION 3 - PARTNERSHIPS

Considerations:

1. Team approaches
2. Transactional vs strategic
3. Partners to support core competencies

A philosophy that's carried me through my career is that a high-performing team can do wonders. My aim is always to understand the collective strengths of a team and leverage them to get even more intelligence than the sum of its parts. With that in mind, I'm at a small company where we can neither afford nor have the time to recruit all the expertise we need. So we have to evaluate what we have in-house and where we feel strongly that we need to maintain a core competency, then what the gaps are and whom we can collaborate with to put together a team that will meet the objectives ahead of us.

As an organisation, we are more forward-looking about the attributes of a partner that will best work with our team. I would advise all my colleagues to think about what they might need in the future and where they might get it. Luckily, there's a huge ecosystem around us so it's all about networking.

This case study was presented at Evaluating Biopharma's recent virtual networking event 'Bioprocessing Strategies for Operational Efficiency', which included three in depth case studies and two interactive networking sessions.

Details of future events can be found [here](#).

You can watch Avril's case study in full and on demand [here](#)



Case Study #1
Navigating and Making Better
Technology Decisions

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