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## Q&A: Expert Insights

"Digital transformation is more about the journey than the destination: it's an opportunity to change the organization's mindset from working heads-down to being eyes-up and focused on the data." – Dale Curtis, CEO, Astrix

### Strategies for Leading a Successful Digital Transformation in the Laboratory



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### Strategies for Leading a Successful Digital Transformation in the Laboratory

Digital transformation has become the top priority for scientific laboratories and quality manufacturing sites across the globe. The path to achieving a successful digital transformation initiative is often unclear with the many considerations and challenges to the best possible approach to address the specific needs of your organization.

Astrix CEO, Dale Curtis, along with some of the top minds in the informatics space have gathered to lend their expertise to address the most compelling questions surrounding digital transformation from leading companies across the industry.

#### **Foreword from Dale Curtis:**

I'm super excited to be able to bring together this panel of experts that all have varying degrees of expertise across multiple industries to address the questions from each of you while trying to take on this journey. That's really what this digital transformation area is, it's a journey that each of us will take in our in our respective industries. Our discussion will focus on how this is absolutely achievable and the impact that some of these types of initiatives can have and that we're seeing in laboratories every day.

### Q: What does it mean to digitally transform your laboratory?

Dale: This is a question that I am asked by many customers, in all different capacities. Digital transformation in the context of a laboratory, it does mean different things to different people depending on the maturity level of the organization and what systems that you've already invested in.

Let's step back and think foundationally. It's a couple of things; number one - it's a journey all right and it's a journey that is not something that has to be a transformative end-all, be-all, 'boil the ocean' approach. It can be taken in bite-sized chunks, such as a single workflow, where the endto-end digitalization of that workflow is defined, tackled, achieved and then built upon as a foundational element within the organization. From there it takes the form of a technology stack. Whether it's an investment that has been made over many years and purpose built for the technology or therapeutic area that you have been working in for the past 20 years or multiple systems, technologies and people that have evolved over many years that make it very challenging for us to do what digital transformation is set out to achieve.

The goal of digital transformation is to do things faster, cleaner, better and enable us to make informed decisions using information that we have our at our fingertips, but we have yet to really be able to extract that in a rapid amount of time. The other piece of this from my perspective is also about people and processes. If we try to digitally transform a piece of technology, it's also impacting the way that our scientists work in the laboratory every day and that's a daunting challenge in some respects. So, I think we need to keep in mind that when we look towards technology as the answer, we also have to ensure that our people and processes are being managed properly and that we're aligning expectations that this is a journey we're going to go through together.

We're not going to flip a switch and all of a sudden have access to everything that we that we ever dreamed of in the perfect digitalized business world. It's really about working through this together and taking this in bite-sized chunks such that we can deliver it to the organization in a commercially reasonable time frame along with value, which comes in the form of efficiency, productivity and predictive decisions.



Dave: Digital transformation is all about the people side of things and actually much less about the technology aspect. Regardless of what the vendors might say, you can't just go and buy a magic solution and then 'boom', you deploy this system and you'll be digitally transformed. It doesn't work that way, so at its core, being transformative in the digital ways is actually truthfully using the data in in productive ways. In this case we're talking about supporting R&D, so that might mean all of the stages from decision making, through documenting, filings, and all aspects of the processes that R&D gets involved with. It actually means moving those into digital modes and that that is a huge cultural challenge.

As scientists, we love Excel, email, hallway conversations, and all those traditional exchanges of information. I think it's important to realize that digital transformation doesn't preclude or replace those, it's meant to actually augment those types of things. It's not about turning all forms of communication and all forms of flow of information into a digital form, but to direct it in a productive way and identifying those parts of the organization that are being impacted by inefficient communication, particularly around data. This is especially important from an interdepartmental perspective or across geographies.

Productivity gains will be achieved by moving from a system-oriented approach to a dataoriented approach. It's not about your LIMS or ELN systems and which vendors those are from, but rather how those are used to move R&D data, and that's really what the transformation is about.





Q: What do you believe are the best practices on converting legacy data warehouses to better benefit from new technologies and data platforms like Databricks, Dataiku, and others in order to enable more real-time business intelligence reports and AI/ML?

**Eliot:** For less of an architecture consideration, but just what's the baseline for doing this, I think to use any of those technologies that you just described that are available to the industry, many of them have been used in the pharmaceutical and other industries before, but the one common thing is having a good solid foundation such as having harmonized processes and good, harmonized data.

If you don't have your data house in order for example, or you're not using those technologies to achieve getting your data house in order, it's very difficult to gain the main benefits from them, so I think seeing all these exciting technologies that are available to us, it's important not to just try and use them, it's about understanding what your current situation is.

It's about having a common language across the organization and just getting those foundational aspects right, which may not involve technology at all in the first instance as Dave pointed out. It's about getting the people aligned, and getting the data clean, ready and available to use so that you can get the most out of it through these exciting new possibilities. So, I think that's where I would start, from a foundational point of view rather than specifically an architecture point of view. Larry: One of the key important things before you get on this journey, and I like the word journey, because it is a long multi-year journey, is to make sure you have a roadmap. In the data world you need a data roadmap because in today's world the data is all over the place. I don't care how well you think you've done; it's dispersed over the entire organization. So, build a roadmap to know how you're going to pull that data together, how you're going to integrate and rationalize it, and really, how you're going to use it, even before you start thinking about all these applications and all the other technologies. Rationalizing your data strategies and governance is critical before you even talk about Databricks or any other technology.



# Q: When it comes to digital transformation, where does Quality 4.0 come into play and what are people seeing in the marketplace related to this?

Srikanth: Interesting question, so the adoption to Quality 4.0 has been growing significantly over the last couple of years. We are often asked if Quality 4.0 is replacing traditional Quality, and the answer is no. Quality 4.0 is intended to build upon traditional Quality and it's usually a natural extension of all the advanced technologies that are being derived by Industry 4.0 to enhance the traditional best practices in the quality management area, so while it certainly includes digitalization of quality management, more importantly it's the impact of that digitalization on quality people, processes, and technology and how that technology can improve your culture, collaboration, competency and subsequently, your leadership.

The transition to Quality 4.0 is not going to be as easy as people intend to or think, and the reason is that Quality 4.0 talks heavily about big data.

Leveraging big data analytics, AI/ML cognitive technologies, and the transition to all of those is pretty challenging. There is going to obviously be the usual suspects around those challenges, which as you know Quality is very disparate. They're stored in siloed systems and there has been a lot of talk surrounding that recently in the marketplace, but what people are forgetting is some of the nontechnology related issues that companies are facing right now in that the role Quality plays in the overall digital strategy is not clearly defined. The reason is that most organizations fail to see that Quality has a clear and compelling role in delivering corporate digital strategy for them. That's mainly due to the fact that Quality historically has been seen as a department or even like 'Quality Police' to ensure compliance.

So, when Quality organizations are trying to determine if they really want or need their objectives and initiatives to be aligned with ensuring compliance or if they need to be more of a performance driven organization, that is going to be the key to making sure that the Quality organization they are putting in place is more performance driven.

Support from the top executive management is imperative as well because Quality needs to be a priority agenda on their leadership strategy. Once you have the vision and the strategy aligned, then you can start by implementing some use case pilots. The total cost of Quality is usually high because of your CAPAs and deviations, and the time it takes to review and approve documents or SOPs. So, start small with your AI/ML and see where you can get some quick wins with some targeted pilots, but beware that you don't end up in 'pilot purgatory' by taking on a pilot that you cannot repeat or cannot scale. Ensure that you're aligning all of your pilots by going back to the strategy or the roadmap that the organization is dictating so you're not going and building this random act of digital projects out there.

The final point that I would like to make goes back to what has been discussed about the people aspect. Historically, Quality never hired people coming from a data scientist background or statisticians, but given that the focus of big data, analytics, and cognitive technologies that 4.0 is bringing, the whole talent acquisition and development strategy that needs to go around building your Quality organization has to drastically change. You need to start bringing in different kinds of skill sets into your organization so you can actually get into the right path going towards Quality 4.0.

Eliot: Quality by design by its nature takes on a more statistical element, so you need those skills to design the experiments in the first place. A statistical design of experiment is not necessarily natural to people who were trained in sciences 20 or 30 years ago. Having a large design space, requiring lots of smaller changed experiments through design of experiment is directly aligned with automation and fits well with creating and managing more data, which ultimately ties back to the broader scope of digital transformation.



### Q: What considerations should be made for implementing an on-premises vs SaaS solutions?

Larry: The big trend today is to push everything at the public cloud and use SaaS applications. There's a lot of advantages for that from a cybersecurity point of view, a cost point of view, and an aggregation point of view, but it's not for everybody. Every organization has to make their decision relative to how much data they want onprem and protected by their on-prem versus how much they want to push up into the cloud, and I think in part your data roadmap and data strategy has to address where the data is going to reside, what is the best place for it to reside, and whether you're going to take advantage of the cloud valueadded or you're going to stick with which tends to be more legacy, but it is very appropriate for a lot of organizations.

Dave: There's a tendency to look at the cloud as some magic answer to typically financial challenges. I get into this discussion guite a bit and recommend to everybody that you really have to take a total cost approach. Installation, provisioning systems is a trivial part of the actual cost to an organization of any particular system. The main cost consideration is the ongoing support. There are pluses and minuses to varying levels of "cloud-based systems" depending on the way the provider is actually doing that, how efficient and effective they are and if they're truly doing multi-tenant and coordinated releases then you have to be aware that that may impact your change management processes quite severely, and that's costly. Having to revalidate systems with the current CSV approaches is very expensive and so there's a lot to be put on the table there.

The other piece, since we're talking about data and digital transformation here, that I don't think necessarily gets enough thought put into this kind of decision making is, what is the relationship between this system's data and other data? Also, integration across clouds and integration across on-prem cloud has a whole set of challenges unique in and of itself.

Typically, vendors that are providing strong managed service SLA's and multi-tenant have constraints on how data flows in and out of their systems. They won't let you do anything that you possibly might do because they're at the end of the day they are responsible for that operating that system if it goes down because your direct connection to their database did something then they're at fault in the way these contracts are typically structured. So sometimes it's a little bit 'hands-off' with respect to some of the underlying data and the integration patterns are very important to look at this before understanding whether or not that cloud approach is truly as financially and operationally attractive as it looks and you're not just kicking the cost into a different part of the program.

# Q: How do you address a customer who's concerned digital transformation will leave them open to hackers?

Eliot: It's like any other technology, it depends on the due diligence of the vendor and their security policies. We often see with these extensive cybersecurity assessments of vendors these days and it's necessary to make sure you have the confidence in a vendor and their way of managing your data, so I think that's absolutely appropriate, but again, a lot of the technologies that Dave mentioned earlier are established. Right there you know somebody using these as the basis of their technology. Amazon Web Services, you know these guys have done it, been there, done it hundreds of times, thousands of times for other organizations and a lot of the more modern technology vendors are just piggybacking on that. They're not reinventing security models. They're using things that are very established, otherwise for them, for everybody, it's a missed opportunity to just try and add your own security policy to something that has already been well established.



Dave: I would add to that, I see a lot of false equivalencies in this in this kind of analysis. To be quite blunt, if you think in-house you can do better at operating a data center than Amazon does, you're in the wrong place. Azure and Google Cloud would apply the same way. This is what they do, and anybody trying to make the argument that onprem is somehow or other more hacker-resistant does not understand how much effort it actually takes to maintain a security profile in an actively used environment. It's not that their faultless, I mean those systems have vulnerabilities, but if you actually look behind some of the more dramatic cases of problems in those systems you'll find a lot of that is actually misconfiguration and misuse of the systems honestly, and they do things wrong. Technology is more fundamentally vulnerable and that is the grand trade off here. There is no magic impenetrable way to do it other than to never let go of the data, which means not to digitize.

From a hacking point of view, you know you're probably more hackable than Amazon, that's for sure, and I think the digital transformation roadmap journey should have a thread of cybersecurity as you start replacing infrastructure and moving to the cloud. You have to think about cybersecurity in a holistic way. You can't think about it in each little application or data store because the hackers know how to thread through the multiple applications and layers of your technical architecture. I would encourage one to effect this theory as part of your planning process and use the assessment vulnerability testing and capabilities that are out in the marketplace. Constantly keep testing your environment because in a journey, things are changing all the time and every time something changes you become more vulnerable.

I would lastly echo the fact that the clouds are more secure than any on-prem or anything that you build. It's just by nature, they're building it for many users and they have significantly more dollars to spend on cyber resilience. As a result, when you start moving to these new digital transformation clouds, you will pick up a layer of cybersecurity resilience that you didn't have before. Q: So, this is probably a good last question for the group to ponder and hear some wisdom on. How do you measure the success of a digital transformation program or project at your company?

Srikanth: I'm sure everybody will have a different perspective on this. The way I see it, I don't think it's easy to measure the success of a digital transformation. By nature, digital transformation is a never-ending journey because it's more of a continuous transformation. There is no finite endpoint to it, so how do you measure the success of a program that does not have an end? It's like you're claiming a victory when the war is still ongoing.

But what you can do is have small victories along the way. For example, take stock of your digital maturity program that you have today and if the roadmap that that you have is moving your digital maturity curve in the right direction. The processes and the technologies you're using, are they maturing over the time or even that implementation, are you moving from a point solution to an on-prem or are you moving into a cloud? If your processes today are manual, are they becoming more intelligent and automated? Those are all the stocks that you can actually take along with the digital maturity curve. You can actually have tangible KPIs and metrics to measure those, more from an operational standpoint.

In terms of the Quality function, if I look at the maturity model from an operational standpoint, what are my operational efficiency gains and all my metrics measured as part of that? If I take my CAPAs for example, which again are my biggest pain points, are they going down or are my deviations going down? Are my review and approval times decreasing? That translates directly to my cost and it actually brings my total cost of Quality down, so that can be easily measured.

Larry: Each organization has to prioritize why they are doing this and what it means to their business. Some are doing it to remain competitive, others because of efficiencies. If they're not an efficiency organization, they may want to change the workforce and mix it up or have remote workers, so there's a dozen different reasons and objectives for digital transformation. Once you figure out the 'why', then those measurement metrics become an ongoing evolutionary measure of success.

Eliot: While each organization will have a different set of KPIs, some of the classic ROI type measurements would be around efficiency and quality, but when it comes to digital transformation I mean the clue's kind of in the name. You're doing things that are perhaps fundamentally not possible today or are really hard, so how do you measure the difference between the before and after cases? It's pretty tough to do that if it's truly transformative.

Dave: Right, that's the key to me. A lot of our programs and our methodologies around ROI analysis before and after are all based upon incremental improvement. If you're truly running a transformative program, and that is your goal, then you need to have high level reasons for why you're doing it what you are trying to achieve, like breaking through into new markets. Those things are going to be by nature very difficult to quantify.

So, one of the things that I try to do is while you're moving through the roadmap, each step in the road, you should be able to put together four or five bullets about what do we get from this step, what do we get from the next step and so forth. Somebody has to keep the bigger picture in mind that all those things are adding up to the path but measure success by doing it one a step at a time. Trying to invent KPIs and put together some fancy dashboard for a three to five year journey is just in my mind not a very productive use of time. Make sure the steps that you're taking are actually quantified, measurable, you're checking them off and that they're in alignment with where you're trying to get in the end in the end.

Larry: What you are really doing here is modernizing your business, you're not digitizing your business. So, as you are modernizing your business, use technology and all these things we just talked about to help move the business forward because if you don't, you're going to be in the dark ages. It's like the first time you adopted IT to start with, if you didn't do it you're out of business, so this is just an evolutionary process of moving the business forward. Therefore, you're going to start measuring things at the high level not at the technology level.

**Eliot:** Your measurement really is how what you're doing is taking you forward a step in that journey, in that plan. It's a foundation for moving forward, so again, it's a bit more of a qualitative measurement, but is it taking you towards your wider corporate goals?

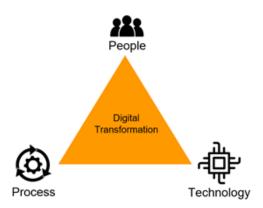
Srikanth: One last thing worth mentioning is that digital transformation is a three to five year program. The other challenge that comes into play is that the digital landscape changes so fast, you need to have a process in place to make sure that you're continuously monitoring the pulse of the digital landscape so you can go back and redo or make adjustments to your strategy if there's new smart innovation technologies coming out. How much of an effort is it going to be for you to kind of make that change? Is that going to be a significant effort? You just need to make sure that your strategy is open enough to accommodate some of those disruptions that are going to happen while you go through this journey.

#### **Closing remarks from Dale Curtis:**

First and foremost, I want to thank the panelists that attended this and helped, it's just an incredible discussion. Just to summarize, digital transformation touches on three fundamental principles: People, Process and Technology. Not any one of those is the answer, they all have to work in unison and evolve to digitally transform a laboratory, an ecosystem, or an organization.

We've run many of these types of programs and have noticed, as a vendor-independent organization like Astrix, it's not a specific technology or a platform. It's varying degrees of technology advancement that's happening. We don't really dote on any single platform. People with the right domain experience that understand the things you are doing any why you are doing them are critical. It's important to have a really good understanding of the objectives and the 'why' behind doing a digital transformation within your organization and clearly defining those outcomes and that roadmap will help guide this journey over the next three to five years. Also processes, trying to make this more efficient and effective for the organization.

This is a really an exciting type of program for companies small or large. We work with companies that are small biotech companies up to the largest pharmaceutical companies in the world, and when you get a type of a digital transformation initiative like this underway, it really does energize an organization. It gets a lot of people behind it and almost acts as a catalyst to change in itself. People really just are excited to see what the outcome of something like this could be and get behind it. So, I think all three of these elements are critical to making sure that digital transformation is achievable.



#### **About Astrix**

For over 25 years, Astrix has been a market-leader in dedicated digital transformation & staffing services for science-based businesses. Through our proven laboratory informatics, digital quality & compliance, and scientific staffing services we deliver the highly specialized people, processes, and technology to fundamentally transform how science-based businesses operate. Astrix was founded by scientists to solve the unique challenges which science-based businesses face in the laboratory and beyond. We're dedicated to helping our clients speed & improve scientific outcomes to help people everywhere.