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ASTRIX DIGITAL TRANSFORMATION PODCAST SERIES

# Accelerating Digital Transformation in Science-based Businesses

Program #1: October 2021



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## Play the Podcast

Astrix Digital Transformation Podcast Productions tackles today's most compelling issues shaping digital transformation in scientific businesses. In this series, interviews with thought leaders from across the industry deliver expert insights for accelerating your digital transformation strategy.

Below is a transcript of this informative program!

### **About this Program**

In this program, Dale Curtis, CEO of Astrix and Dave Levy, Global Product Director of Scitara Corporation join forces to discuss the optimum strategy to accelerate digital transformation within the scientific laboratory.

### **Special Thanks to our Partner**



Kevin: So, I want to thank everybody for joining us today and welcome to the Astrix Digital Transformation podcast series, where we're bringing interviews from thought leaders and experts throughout the industry on developing a successful digital-first strategy for transforming your business. I'm Kevin Miller, your host for today's podcast, and thank you very much for listening.

We're very pleased to have some of the great minds in the scientific community joining us today. We have two leaders in innovation that are charting the course for digital journeys throughout the entire global scientific community. It is my pleasure to introduce Dale Curtis, the CEO of Astrix, which is a market leader in dedicated digital transformation and staffing services to fundamentally transform how sides based businesses operate.

Also joining us on today's podcast is Dave Levy, global product director for Scitara Corporation, which is a global provider of cloud based software solutions for science based industries, powering digital transformation by enabling them with modern lab data connectivity infrastructure and tools to accelerate science.

So, I'd like to have our guests tell you a little bit about themselves and maybe their background in their own words. Dave, how about if you go first?

**Dave:** Sure, thanks so much, Kevin and Dale, it's great to see you again. So, Dave Levy, here. My responsibility is product management at Scitara Corporation. I've had the opportunity and the pleasure to work at a lot of great companies over the course of my thirty plus year career in the space, including Waters Corporation, NuGenesis Technologies and I also spent time at Cambridge Soft and PerkinElmer, before joining Scitara. So, it's been a great time and I really appreciate this opportunity to focus on a challenge that I think we've all been working to address one way or another through all of our careers in different forms.



**Dale:** Thanks, Dave. Great to talk with you again, a pleasure. Dale Curtis, Astrix Technology, CEO, super excited to be part of this podcast series. Digital Transformation is at the heart of the scientific community these days, and Astrix is in business of helping create a better world through science. We deliver innovative solutions to world class people, processes and technology, and we're in business to fundamentally improve the outcomes of scientific endeavors and the quality of lives everywhere. We're really excited to be part of this. I've been in this industry for more than twenty years. I've got a similar background as Dave mentioned, in working with the likes of the Molecular Simulations, Accelrys and Symyx Technologies, so some of the leaders in the technologies that are being used out there in the marketplace today to help digital transformation.



**Kevin:** That's great, and thank you very much for that introduction from both of you. So, let's dig into it. Our discussion today is going to center predominantly around digital transformation, and this is certainly one of the most talked about topics not only in the scientific community but across a variety of industries, as we all know. Companies, such as big pharma, are investing significantly in digital transformation programs, but most, they frankly have a long way to go before realizing the full potential of what is there. So, I'd like to pose a question to our experts. What is driving this "digital-first" initiative, and how can a science based organization leverage the strategy to help transform their business? Dale, maybe if you want to kind to kick us off and I'll let you guys take it from there.

**Dale:** Excellent, Kevin, thank you, and this is a topic at hand in almost all conversations that I have with every executive in the scientific community these days. It's really important, you know, the rapid requirements for bringing drugs to market and materials to the production line is something that's just a challenge for everyone. And it really starts with the data, right?

Data is the fuel that powers these types of predictive models, and in order to do digital transformation, we need to be able to create models that have a better chance of accurately predicting future outcomes. We've got to have access to that data across the organization, not just in a specific silo, and that data needs to represent the outcome that we desire. These are things such as supervised learning, which is represented in a lot of these artificial intelligence tools.

It's a difficult task to manage analog processes that are still in existence, both inside and outside of the lab. Moving to an old digital process and underlying data, making it available to other systems in tools such as AI and ML scoring engines, it's at the heart of this digital transformation initiative and the belief is that with enough data of the right type we can develop and use predictive models that lead to success. And it's not a 'boil the ocean' type of transformation. We can start small. We can do this at an individual workflow level, not at an entire organization level. And there's a continuation of doing more with less. The theory that being able to use data more effectively, it's going to change time and cost functions of R&D and that's what we're in the business to do - try to get better access and more value out of the information that we have at our fingertips.



There are large amounts of process inefficiencies in R&D, i.e., communication, coordination across groups and conflicting access to shared resources. These are the things that are a big challenge today.

Dave, you guys have a great technology stack and maybe you could talk a little bit about how we're helping each other and helping customers to connect this information.

**Dave:** I'd be happy to, thanks. I think you, you hit on some really good topics there, Dale. And you know a lot of these kinds of digital transformation movements, and other sort of crossroads that we see technically, very often there's a tipping point if you will. And I think that there's been a mounting frustration within science based organizations over the years around the challenges and the difficulties of interfacing instrumentation and applications together, and it's very fractionated. It's not complete. It's not holistic, and then I think quite honestly, the Covid-19 pandemic brought it to light and accelerated it, and really drove a need to be able to more efficiently move data back and forth between all these systems and in a remote way.

So, I think that from what we're looking at, data transformation demands the ability for data exchange, multi-directional data exchange, and that's very difficult to do today. There's individual technologies and companies that are out there that support it, and I know Astrix has been in the middle of this as well, based on customer needs to build out these individual integration platforms, but it's hard to maintain them all, and the matrix effect is huge. So, you wind up in a situation where if you try to deal with every single conceivable possible integration that a scientist or a laboratory might need, you're trying to manage this huge, ball of spaghetti and it's almost impossible.

**Dale:** Absolutely, then you've got all the vendors that just don't want to get along with each other as well.



**Dave:** Exactly, and so the challenge becomes, and this is really where we're stepping right into the middle of this, is it possible, and we absolutely believe it is! We're doing it now to create an infrastructure that all of these different instruments applications can plug into that facilitates this multi-directional data exchange. And if you do that, if you can separate that infrastructure, the exchange layer, if you will, from the individual applications and instruments that need to use it, then you wind up with a much more efficient mechanism to exchange that data and move it around.

**Kevin:** Great! Those are obviously some super insightful answers, and we appreciate that. The one thing too that I think a lot of people try to get their heads around is when a company goes through something like this, what do they look like once they've come out the other side of digital transformation, and what notable differences can both their employees and hopefully the consumers of their products alike expect to benefit from after an effort like this? I'd love to get your thoughts on that. So again, what does the company look like once they've finished this whole transformation?



**Dave:** I think there's some very practical, on the ground things, and metric oriented things that you can look at. First and foremost, there's still an awful lot of manual 'walk down the hall with a thumb drive' or manual key punch kind of efforts going on. The reason that there's a tremendous amount of that goes back to the conversation that we just had around the complexity and challenges of handling all of the different types of digital data exchanges that need to be made. So, one of the first things that I would say companies will enjoy coming out the other end of this, from a laboratory perspective, understanding that digital transformation is a pretty big animal and can encompass a lot of things, but you should see a lot less manual key punch activity.

Many things can be automated, they just aren't, and the triggers that initiate these types of automated actions can be configured, they can be managed, so, less manual activity and the ability to address things more remotely so you don't have to physically be in the lab to do things that you might not otherwise before a digital transformation program has kind of taken effect. You would have to physically be in a certain spot to do something, that goes away. And then I think accessibility. A lot of the FAIR principles come into play as well. If you're efficiently moving data around and you have real data mobility, then you should be able to get access to that data in a secure way from a lot of different places, and this then accelerates the pace of science.

The final outcome that we're obviously looking for is accelerated science. Even though we moved at light speed for the COVID-19 vaccines, for example, to those of us out here in the real world, it felt like forever. So, you'd love to see things moving out at just a faster pace, but still be able to maintain that high degree of data integrity, of assurance that we're doing things the right way, that people don't get nervous that we're cutting corners, and I think there's plenty of opportunity for that. There's plenty of runway for us to work with there.

**Dale:** I agree. It's been a rapid acceleration of expectations that have been set to bring therapies to market, at a lightning speed and it poses challenges on organizations. Things like direct connectivity. I like the universal connectivity piece. This is critical here. The direct connectivity in a lab has the promise of providing access to complete and consistent, and original data, free of transcription and transmission of errors, etc, and make it available. It's needed almost on demand. And direct access to things like lab data - it's laborious and prone to error like you were saying, Dave, in terms of making sure that we have that data integrity piece as we're moving at this lightning speed.

Since that data is the foundational component of interpretation, defining experimental results, and improving access and quality, it's highly impactful to a lot of processes. It's really important that this is taken care of, and there's a lot of technologies out there, and vendors' claims to have platforms and things like that in the industry and I think it's about three things. The technology is certainly an aspect of it, but it's also about people. It's about having the right people, the right roles and understanding, and change management component, because we're also asking people to do things differently, right?

And then there's obviously, the technology as I mentioned, and then the processes. If I go back to an example, something that we've done in the past with a major pharmaceutical company we've worked with on a number of different digital transformation pieces, we try to break it down into bite-sized chunks so that things can be delivered in a commercially reasonable time frame. For example, looking at developing a cross-functional data model and ontology, capturing all the results of a workflow end-to-end electronically and capturing relevant sample metadata electronically, and then establishing integrated data sharing platforms. These are the sort of the foundational elements of a good digital transformation strategy.

By following these types of things, we found that you can get to a reasonable state of digitally transformed workflows in months, not years. Establishing things like what we call minimal, viable packages, or bite-sized chunks of information. So, setting a simple and consistent vocabulary for scientific work, that could be an outcome, minimal, but impactful viable set of new workflows that can be implemented quickly, non-intrusively, but focus on the data elements that are absolutely required by the use cases that you define.

Assess which elements affect the quality of the data, and in processes on FAIR principles that Dave talked about earlier, and defining governance on the elements.

Lastly, best-of-breed informatics tools. These should be aligned with your strategy, meeting the minimal requirements of that package that you're trying to define, and make it ready so you can implement it now, because people want to see and feel that change and I've seen it first-hand. If you can deliver something that's tangible in a short period of time, so many people get behind it. It excites an organization, and then all of a sudden you've got this flow of change management happening behind the scenes without even having a formal change management infrastructure place.







**Dave:** That's a great comment, Dale, and it really does come back to the data. Once you take that first step, and do those tangible, practical things that you can do and see the benefits, it does naturally, really naturally flow. I know we've all heard before, that we're like drowning in data, right? It's not that we don't have enough data, we almost have too much data, but I think that a big part of that really is the quality of the data, that the data that we have access to tends to have all kinds of issues. I know we're going to talk in a little bit about artificial intelligence and machine learning, and that's a great topic, but you know, leading up to that, I think, the ability through an effective digital transformation strategy in the laboratory, and then universal connectivity that we bring to the party, as well as the configurable, what we call orchestrations or workflows, can add an element of quality improvement to the data itself, and that should and will improve our

ability to leverage that data. This has to hold true over the course of years. When you think about digital transformation and some of the things that labs have to deal with such as changing instruments, swapping out old instruments, bringing in a new instrument, workflow changes, different procedures that come into play, how do they manage that? The infrastructure, that connectivity infrastructure and the workflow infrastructure has to be able to adapt to that. You have to be able to very quickly on-board new technologies.

To your comment about best-of-breed, very appropriate because new ideas are coming out all the time, new innovations happen every day. If you really want to take advantage of the acceleration and speed that life science organizations want, right, they want to be able to on-board that stuff as quickly as possible now. I'll just share one other quick thought about this and then we can kind of take it to the next level. In a quality organization there's this natural kind of to quote Doctor Dolittle, "Pushmi-Pullyu" sort of thing where they're almost reluctant to innovate in some cases, because of the impact it's going to have on validation, and that's something that we have to figure out a way to overcome. This communications infrastructure that we've been talking about today helps to do that to at least some extent.

Kevin: Well, let's move our focus over Quality Management and Quality 4.0 since you brought that up, Dave. What do you feel are the trends that are leading organizations towards a digital transformation of the quality function?

Dave: Well, I think very much like you know I mentioned before there's been a kind of a growing frustration with the way that things have been, and a growing dissatisfaction with just sticking with your current program and sticking with your current instruments until they completely die and literally turn to dust on the bench simply because they're validated and everything is great. The Quality Management, Quality 4.0 principle embodies and embraces a change of approach, and really looking at the same problem, but looking at it in a completely different way.



We took that same kind of conceptual approach when we started Scitara. We went back to first principles and instead of looking at instrument integration the way that it's always been, and trying to refine it, make it better, we basically said, "wait a minute, let's just wipe the slate clean and start over and come up with a new and a different model." That's the kind of thinking that is now being assimilated and discussed in a lot of these Pharma and Quality 4.0 initiatives, which is, why does it have to take so long to validate something? What is it that we're really trying to get at here? And we're taking the same approach.

Our goal at Scitara is to provide that underlying infrastructure that removes the barriers from quality organizations to adopting new technologies. They can bring the technologies in. They can connect them up quickly. They can physically get the data interactions going back and forth with all the other components in the laboratory, and from both a technical and, to a large extent a validation standpoint, we can support the digital data integrity for data in flight.

As these instruments and informatics systems exchange information, because we're capturing that transactional activity back and forth, we can very quickly adopt and bring in new technologies, allow companies to respond to that innovation, allow them to respond to changes in workflows that simply improve the way that things work and give companies that easily accessible access to the entire digital chain of custody as the data is moving around the laboratory. That's the role that we would play in that.

**Kevin:** What are your thoughts on that, Dale?

**Dale:** Dave, that was a great response. So, the digital quality compliance is near to my heart. In fact, we've invested in that area quite heavily over the last year, because it is absolutely critical now for the success of all these types of transformation projects. I look at it in sort of four categories. There's an innovation component, then you've got to ingrain it, integrate it, and then you invest. If you look at the innovation component, to talk to some of the things that you said, ensuring the solutions that we are or were providing the customers are addressing the digital and automation needs of our clients, right, leveraging the digital technologies, partner with our

clients to create a quality automation framework from the use cases, the pilots, for projects and program transformations and leveraging data to establish data integrity, prevent disruption and loss.

I've got a client that came to us and said, "I lost nine million dollars of a lot of a material and I can't tell exactly why that lot failed." I know that the stability was poor, but why weren't there any indicators? Why wasn't there information to help me gauge, or even predict that something like that was happening, and these are all integrated. And I'm seeing a huge amount of investment being made of trying to connect lab type systems with the quality type systems, and ingrain and shifting from a transactional relationship to being more of a of an integrated, over-arching program inside the company that governs all things that we do. I think the whole digital quality compliance component, validation, all these things, they have to be integrated with the processes and the people that that run these types of programs is really important, so I couldn't agree more.



**Kevin:** Great! Well, you know we've got around ten minutes left of time and I would like to ask you both to provide thoughts on artificial intelligence. At that time, it's a little bit unfair, but I'd like to do that, right? So, I mean we see AI and ML cloud services and how they fundamentally change the way medicines are manufactured, delivered, and ultimately are going to be part of the future of health care. What do organizations need to consider as part of their digital transformation approach to best prepare for incorporating these advanced analytics into their overall strategy? Thoughts on that, guys?



**Dale:** Well, I'll do a quick sort of perspective, and from the services standpoint, I think things like data annotation, extending metadata, will be an iterative process as R&D progresses, more is learned and needs to be captured in relation to past data, for example, and this requires a data architecture and an engineering approach that's based on changing models of the data, and I think this is a change management component, a different way of thinking. But when I think of architecture, I don't want people to think about the architecture of a given system, right, or a LIMS or an ELN system, these systems that house data, but rather how the data flows, how things are architected at a much higher level, such that you are putting information in the right system so you're not stuffing data that never otherwise belonged in a particular system, like a LIMS system. And I've seen this time and time again, and it extrapolates the problem to an infinite degree of complexity. You're just not able to solve it very easily, and I think if people could back up, think about things from a two to three year horizon, making certain that the decisions that they are making, the information that's getting put into these systems is purpose built for that type of data.



The connectivity things make sense, they map up to your business processes, they map up to your workflows and map up to the desired outcomes, like I mentioned before. A lot of these problems need to be solved in order to feed information, the whole, and I hate to use this play on words that has been used forever in this industry, 'garbage in, garbage out,' but it's the truth. If you don't have a good understanding of the quality of information you put into these AI/ML systems, they're just not going to run and give you the results you expect.

Dave: Yeah, I think you're absolutely right, and this really goes back to again, some very basic practicalities. When you think about digital data in today's world it's like oxygen to the body. If good quality digital data flowing to the right place at the right time makes things happen, and we're talking about speed and improving our ability to develop things faster, well, machine learning and artificial intelligence are going to form a key to that.

Imagine if you know your body was delivering seventy five percent of the oxygen to your heart that it really needs or to any other organ, that's not a good thing, and that's kind of the way that that the situation is today around AI and ML. We see this from a practical

perspective, and I think once we get over this, it opens up a whole lot of interesting doors for the future. But a lot of the AI and ML initiatives are hampered by the fact that there's so much data curation and data cleaning that needs to be done, people spend more time and the quality of the data is just not good. A lot of the data is handled manually still with people flipping switches and copying things in. And so, what we see is the laboratory is kind of like a living thing, and we see our ability, and we think we have an opportunity to provide the infrastructure that's like the circulatory system to move the data to the right place.

To us, a data lake is just like a LIMS, ELN, or an instrument. It's another endpoint, and there's an opportunity there for us to provide data, high quality data to that data lake that will not only improve the speed with which data gets there, but also potentially improve the quality of the data when it arrives, or at least flag people that there's a piece of data that just came in that needs curation, or it's missing a particular thing. So, I do think there's huge opportunity here around the AI and ML piece, and we're very excited about working together with you guys in and helping that along.

**Kevin:** That was well done. I didn't think you could address those heady topics in that brief period of time. So, we have a few minutes left and I'd like to give both of you the opportunity to tell us maybe in a moment or so, where your organization fits in this, and how you're helping these companies transition?

So, Dale, why don't you tell us briefly what Astrix is doing to help companies and shepherd them through this digital transformation, then we will ask Dave to do same and I think we can wrap.

**Dale:** Excellent. I'd be happy to. And this is a super exciting topic for us, and partnering with companies like Scitara is exceptional for us. We're an independent or vendor agnostic services company. We are about providing the right resources the right people, processes and technology to bring to these types of problems. We start by providing an upfront, thorough business analysis process, really ensuring that your 'As-Is' and 'To-Be' business processes are mapped properly. This is the foundational element of a successful digital transformation component and that leads to this enterprise architecture component that I mentioned earlier, which is also very critical in certifying that your project begins with the right design right and then we have a comprehensive viewpoint on the overall lab, quality management and selection services.

This methodology ensures that once these business processes are mapped and we have candidate architectures in place, that we're making sure that the vendors that we're looking at to plug into these holes that you have in terms of technology are the right vendors, and it's not always a single vendor. More oftentimes it's multiple vendors, but it's ensuring that the vendors are providing a capability that maps to those requirements. It's really critical, and so we pride ourselves in hundreds of man years of experience over the last twenty five years of being in business to be able to provide that expertise. We have more than 250 trained lab informatics experts in the organization that can provide these kinds of capabilities, and see the through its full cycle, and even helping run that technology for you in a managed service environment. So, that's really what Astrix is about. It's connecting people, processes, and technology to ensure that you're getting the absolute most value out of the huge investments that are made in these technologies.

**Kevin:** Ok Dave, wrap us up.

**Dave:** Will do. We are also vendor, application, and instrument agnostic. Our role aligns very nicely with the role of Astrix in that we are really the infrastructure that facilitates



digital data exchange. We do not see ourselves as an application. Our goal is not to create yet another application that scientists need to work with. Our goal is to fundamentally facilitate the movement of digital data between instruments applications and other laboratory resources. So, in the ideal world, data just shows up in the right place at the right time in the right format, and it allows scientists to really accelerate and move their processes forward. We work together very closely with service partners, like Astrix, and other vendor partners that we've been working with to create that seamless infrastructure that allows customers and laboratories to really achieve that digital transformation goal.

Kevin: Great that's awesome, Dale and Dave. I don't think we could have asked for two better folks to come on and lend their thoughts about digital transformation in the laboratory to kick off what we hope to be an exciting podcast series moving forward. We're going to go ahead and wrap up and thank Dave Levy and Dale Curtis for joining us today. And we want to thank all of you for listening into the Astrix podcast.

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