Pangaea transcript

Tom: [00:00:00] Welcome to the industry insights by SAP podcast series. I'm delighted to host this podcast and share key trends and innovations for each of the 25 industries we serve. At SAP. We like to say that we speak the language of our customers. And this language is industry. We've been supporting all industries for more than 50 years now.

And it's exciting to launch this podcast and discuss with industry experts, that business value that they get from our solutions.

Hi, everyone. Welcome to the industry insights podcast by SAP. My name is Tom Raftery. And with me on the podcast today, we'll have my special guest. Chris, Chris, welcome to the podcast. Would you like to introduce yourself?

Chris: Absolutely. Tom. So hi everybody. My name is Chris chambers. I'm a partner with endeavor consulting group and Pangea solutions, which is, uh, the company that makes the product that we're going to be talking [00:01:00] about today.

The digital thread for life sciences and, uh, looking forward to speaking.

Tom: Okay, super thanks. Christie digital thread for life sciences. We we've mentioned once or twice on this podcast, digital treads, but maybe people haven't heard that episode and life sciences is something we haven't touched on so far in this series of the podcast.

So could you maybe explain what a digital thread for life sciences?

Chris: Definitely. Yeah. So I think the term digital thread has existed for a while and been applied in in many ways. Um, I know in the aerospace and defense, it has been, um, that along with digital twin have been spoken about with respect to, um, product lifecycle management or PLM.

Um, but for life sciences in particular, that's a little bit unique and different from, let's say, discrete industries, uh, where you have things like computerated design and CAD drawings that can represent a physical product. And life sciences, you're dealing with much more abstract drug development, um, [00:02:00] processes with respect to PLM.

And this has been a space that has, for several reasons, that'll get into, have been evolving for a while, but because of the abstract nature of it, um, it doesn't, it hasn't had as much of a clear footprint in terms of how digitization and software can enable, um, process improvements that we're hoping that DTLs will.

So,

Tom: yeah, that, that, that brings me to the question. What problem is it trying to solve? What w why, why did you come up with this? What problem did you see out there and, and w what, what's it doing? What's it fixing?

Chris: Yeah. So, um, great question. I think when we, when we look at our implementations and endeavor and Pangea do a lot of, um, enterprise solution implementations for life science companies over the years, we understood start to understand common themes.

Uh, and problems specifically. Um, a lot of our work is in the GMP or good manufacturing practice space, uh, which starts to evolve to the process [00:03:00] development and drug development that, that feeds into the GMP manufacturing. As we talk to our clients, we noticed a significant shifts, um, in the way that drugs are being developed based on the, the paradigm shift of bio.

And what we call large molecule drug development versus small molecule. And, uh, if you, if you look at the industry, historically, the drug development process for pharmaceuticals and, and this obviously has gotten a lot of tension and in recent years, for, for obvious reasons, there's traditionally been a very long lead time associated with bringing a drug to market.

And it's an expensive, uh, very complex process. And, um, that involves several clinical trial stages. And a lot of documentation documentation that has historically been very paper-based and very functionally siloed. And could afford to be because historically using what we call small molecule drugs, relatively simple, uh, we call this a solid [00:04:00] oral dose things that you swallow a pill that you swallow.

And obviously that's a medicine that the world takes a wide demographic medicine. If it took you seven years to bring that drug to market, if that was fine, because for the next 30 years, you would have that. There's obviously generics and things like that, but, um, a very lucrative business that has not needed, um, to necessarily change.

And in recent years with the mapping of the human genome and the ability to do gene editing and that gene editing was the basis for several of the vaccines for COVID, uh, using MRI RNA vaccines, which is won't get too technical in here, but that's changes the way that we drive. You know, historically vaccines for instance, have been taking kind of a weaker version of the virus and developing an immunity to it.

But with our ability to actually drive the protein creation through RNA, we actually can mimic the virus without. Giving you the virus when, and, and create [00:05:00] resulting immunity toward that virus. And that has been a function of gene editing and gene editing. Um, it has been a highly disruptive change to the drug development process and the way we think about medicines.

And then frankly, it's what has excited me most about DTLs because. Um, you're now talking about what we call personalized medicine or medicine that is tailored towards a specific genetic makeup, not something that the world takes necessarily, but. Somebody with a specific predisposition to certain diseases or certain, you know, uh, gene makeup or age or race.

There there's many different drivers for this. And that is exciting, but it also has resulted in a lot of complexity because it's large model. Drugs. These are drugs that don't have a very simple, you know, a, uh, components of carbon and six of hydrogen. These are, you know, 1300 amino acids that are mimicking human cells and often are actually using human cells, highly [00:06:00] complex drug development.

That is also, uh, for smaller demographics and require a much quicker lead time to market. And that's a long-winded. Um, for why we need to change the drug development process, we can no longer afford very long lead times. And unfortunately, um, the, the industry needs to be disrupted in a way that no longer relies on paper processes has a digital framework.

Um, and I mentioned this earlier, the FDA, and what's called the ICH, the international, uh, code of harmonization. I have said this, we no longer can have long narrative, a drug applications. We need structured digital data. Well, DTLs enables that. Within the SAP framework. And that is a very logical choice from our perspective, because it is the basis for many other enterprise solutions that would also contain the data needed.

There, um, things like manufacturing, execution systems and QMS systems, all of those systems typically are [00:07:00] already integrating to an enterprise framework like SAP. But now if you can supplement that, and this is where

we've asked our customers. Um, you know, how are you managing this today? Do you have an ability to do that?

And they've said, you know, we really need a digital solution for that. DTLs is our answer to that question. And

Tom: just to, to clarify what advantage does shifting from a paper-based solution to a digital solution give, is it just speed to, to, to market or are there other advantages?

Chris: Yeah, that's, uh, that's also a great question.

And obviously, and I think it's gotten, you know, sometimes digitization and industry four dot oh, are used a little bit as buzzwords and a cliche. Um, but obviously having something in a digital format, um, Allows me to quickly structure data, but more importantly, for things like changes and impact analysis, which are key tenants of, of the, of, of the drug organization or the regulatory [00:08:00] authorities, uh, drivers for, for what is needed in the future.

I can quickly understand that changing this critical process parameters is going to have an impact on this, what we call critical quality attributes, which is how we can, uh, determine the safety and efficacy of a product. Whereas I used to have a hundred binders before, uh, spread across functional areas.

Now I can quickly run a report. To see not only the impact, but also the risk associated with that impact in a very quick way. Um, that not only improves the quality of, um, my process. In other words, I won't miss something in those hundred binders. Um, but also the speed. And, and in DTLs specifically, we have a bit of a time machine element with, with literally a time slider where I can go back in time.

And see and compare differences with, uh, changes that have happened. And they often do happen by the way as we scale up. And as we use different bio-reactors in our, in our process, um, they have an impact on what I initially did in a very small lab. And I understand, [00:09:00] oh, when I changed this, um, I'm going to have an impact on these relevant parameters.

So when you look at the analytics, as well as the governance associated with making those changes, there's very clear advantages to digitizing the process.

Tom: Okay. And do the, are the regulatory bodies on board with this or when you're submitting stuff to them, do you have to print out reams of paper and courier it over to them?

Chris: Yeah, uh, I think the regulatory authorities are very much. Driving this. So the FDA has driven something called Katha, which is, um, their initiative, which is in process right now. They have a vision that's continuing through 2025, uh, knowledge aged, um, assessment. Uh, and it's basically trying to change something that used to be those printing of reams of paper into its structured digital format that actually can be transferred electronically.

Um, again, That has been a vision. It's been an exciting vision, but it's been a vision [00:10:00] with no substance behind it. Um, and it's getting better, you know, when they start defining, okay, here's how the XML will be structured and things like that. We're getting closer to a place where things can be transmitted electronically.

The international. Code of harmonization, which is not only it's, it's the regulatory authorities for north America, Europe and Asia have very specific what they call guidelines. They're called ICH guidelines around quality. And those have spoken pretty specifically about a methodology and structure for how this should be managed in a way that can be, is very conducive to digital or digitization of tech transfer and submissions, but have, um, again, No one has a vision for how to do that.

It's, it's, it's exciting. And I guess this is the natural evolution of a vision like this. You, you, you put the vision out there and then figure out technically how you're going to manage it. Then I think the challenge that we've seen specifically with our pharma companies is there have been [00:11:00] attempts to do this.

And th there's been two kind of inherent flaws. The first is that the, the process for managing and has not been intuitive enough, um, in an ideal way, when you're, when you're defining a drug development process, you would do this with pictures. You'd be able to create, uh, you know, process flows and relationships and things like that by dragging and dropping and creating, um, you know, Vizio like pictures, the tools that have existed have not been like that.

They've been much more text-based and, you know, defining a process and that it has this input. And then that output is more difficult to convey. If it's not a picture is problem. Number one. Problem number two, and we believe detailed

us addresses both of these problems, by the way, is the attempts that have happened with more nimble solutions.

And I call, I call these cloud-based solutions in which you can draw. Those pictures have been very disconnected from the very data that they would need to rely on within the enterprise framework. In other words, [00:12:00] Uh, companies have created a, a cloud-based solution. That's just kind of sitting there on a URL.

That's not connected to the various systems that would make a digital thread like limbs or laboratory instrument management system, or MES system manufacturing execution system, or QMS system, or your ERP system, which has your master recipes. All of that information, um, being inside an enterprise framework is very conducive to.

Your drug development, PLM solution inside that same framework, because that's how you enact these elements. And I haven't talked too much about thread Weaver, which is our tool to actually make these connections. But, um, our, our view is it needs to be much more than an API, um, a way at which is a traditionally way that we integrate systems.

It needs to have a framework, configurable framework and really a cookbook around the way we would. Um, one to solve the various use cases involved with the digital thread. So two pieces they're not [00:13:00] being intuitive enough and being a standalone. Um, our, what we've, you know, hopefully solved with DTLs. And the last piece I'll mention there is with the standalone solutions.

It's very difficult from a, what we call a computer systems, validation perspective, um, or CSV when you have cloud-based public solutions. Um, The, the, the testing and the rigor involved. If for anyone buddy, who's worked in regulatory industries, uh, and, and implemented software solutions knows there's a lot of overhead with respect to validation.

Um, It really, uh, the, the digital signature piece, as well as, uh, approvals for testing, uh, when you have a standalone cloud solution, um, that is now connecting to GMP systems, you're gonna need to do regression testing every time there's a new release. So putting that inside the same framework, and specifically with SAP, having the ability to host in the private cloud so we can control our upgrades, uh, is very conducive to a solution like DTLs or [00:14:00] PLM for lifetime.

Okay.

Tom: Just at a very high level. And can you walk me through what's the traditional process from, uh, coming up with an idea for a drug through to drug delivery, and then how DTLs comes in and short circuits.

Chris: Yeah, th that's great. So, you know, you have kind of the, the initial drug development process, and you think about this, you know, this is a design of experiments process where you're isolating variables, you're evaluating compounds, um, your understanding and in maybe a lab notebook, but there's a tool called electronic lab notebooks, which again is something that the thread can connect to.

Um, and as you start to develop something that seems by. You then can start to, uh, define what we call a general recipe that becomes a psych recipe, which can be a, you know, an R and D development site initially. But, [00:15:00] um, you know, as you then scale that up and prove that what you did in the lab is now viable on a little bit larger scale.

You can drive that into what we call preclinical. Um, so in the clinical trial world, there's preclinical there's phase one, phase two and phase three. Again, some of this. Um, has gotten a lot of publicity recently just with the COVID vaccines and things, but, um, you know, there's a lot of detail inside that there's material specifications.

There's the process parameters, there's the facilities and the equipment associated with it. Um, the process itself, um, the way that we test the, the viability and. Um, the, again, the ICH group has created a methodology called quality by design or QBD that allows us to define the relationships between process parameters and critical quality attributes.

And I'll keep, I mentioned this a couple of times, but, um, in this QBD methodology, um, that there was [00:16:00] not really a clear software for, uh, We basically are saying that if you meet the ranges of the following critical quality attributes. So in other words, if, if you're in between this number, um, for whatever you're measuring the potency or whatever, the piece of the drug is, then you can guarantee the safety and efficacy of the product, which are the key two tenants of drug development.

So that's what we call a quality, quality target product profile. If you are within the correct range you have done. You've you've actually correctly manufactured the drug and that's the way we measure it. But in order to be within that range, you have to have the following critical process parameters as you're making the drug in this very complex molecule within the following ranges.

So if you think about this, and this is a little bit hard to convey Tom verbally, but if you think about this in three dimensions, um, an X and a Y axis, which represent two different colors. Process parameters [00:17:00] and then the Z axis representing a critical quality attributes. And really think about that in three dimensions, you have this weird blob in the middle of shape, and that shape represents the low and high limits of the two critical process parameters and the low and high.

Target limits for the critical quality attributes. And we call that a design space and one of the nice things about DTLs and, and I'll, I'll continue going through the process is later when you're actually doing your R and D test runs, we have an electronic batch record solution that allows us essentially to feed in our recipes from DTLs and.

Based on the actual batch runs that we do. Did I go, did I fit within that blob? Did I fit within the low and high range? Or am I outside? And how did that affect my critical quality attributes? Because a lot of this through this process, I just mentioned is evolving. We're learning about the process, particularly with scale up.

Is it still meeting the requirements and not in this range when I scale up to bigger [00:18:00] equipment, but essentially, um, the most important piece of this process and drug development, uh, after we get to a viable site, recipe or process is what we call tech trends. And that tech transfer for pharma just represents me transferring the technology, the process, the details, the equipment facilities, all the things that I just mentioned from one site to another site.

And that could be scaling up work and just be transferring to another location from a development perspective, uh, in the scale-up world. Sometimes it involves transferring information to a contract manufacturing organization or a CMO, which is outside. You know, we, we need an ability to do that in a relatively simple way, including managing and communicating changes.

So as you're going through preclinical phase one, phase two, phase three, and then filing and eventually getting to commercially manufacturing, the product. That entire [00:19:00] process, which can take years. And obviously the goal is to shorten that process needs to be connected, um, through a thread, through a digital thread and which I can tie back those activities.

And I'm not looking in binders from five years ago with different folks working on information. Then we're working on it five years ago. Where did we put that

into information? Uh, how, how can I be sure that if I change this, that doesn't impact anything, uh, having that digital time machine and that digital link is how.

We can greatly improve the quality and efficiency of the process and really prevent a lot of risk associated with it, which is always a big piece when you get into things that, especially in today's market that carry over years. Um, and, and, you know, I, I, as much as we need to be diligent, documenting, narrative-based, uh, detailed.

That are in paper documents are much more risky, um, to, to missing things then having something that, which you digitally search based on [00:20:00] risks. So I think the, the speed to the market, the speed to filing, I think those are all the goals of, of the ICH and FDA, uh, groups. But I think also, um, being able to manage, um, risk and also even the governance of the data itself as I go through that digital thread being candid.

It is very critical and I think where there's huge value to DTLs. Okay. Super

Tom: R I mean, that's all very good in theory, Chris, but can you speak to any actual outcomes you've had

Chris: from. Yeah, it's been very exciting. Uh, I think we have been working and, and I think like a lot of software products, this is always best when you take it from a theoretical, a lot of the concepts I've been describing so far and bring it into actual use cases and through, uh, one of our key clients, AstraZeneca, um, we we've been doing, we've been working with several clients, but.

Uh, I think with AstraZeneca specifically, um, they were very far ahead of the curve in terms of, [00:21:00] um, the vision here of what they would have expected out of a software. And they actually had looked at other software. Uh, solutions as well, um, prior to looking at DTLs, but, um, we had some great benefits in a biologics, um, use case.

And when I say biologics, this gets back to what I call large molecule before very complex drugs, uh, which, which AstraZeneca site that we work with had, we basically took their process and. Uh, you know, took what was essentially 800 pages of paper information and consolidated that down to a digital format to create what we call a digital product profile, which now, you know, represented these, this huge binder.

And, and I will say that. You know, was done in a proof of concept way that is now being applied in production across the board for them. But it was really just to kind of prove this concept out for them and, you know, Tundras and hundreds of, of equipment, detailed process parameters, thousands of [00:22:00] calculations.

And I haven't talked too much about this, but in addition to. The complexity of the molecule itself has just, if you just think what goes behind that relationships between, uh, objects and calculations and, uh, it's a huge strength. We have something called the calculation engine, uh, which is almost like a calculator, but you could reference any function inside anywhere and DTLs with an alias, uh, things that, you know, again, Having a notebook somewhere and then translate it.

They instantly get updated and governed. And we really drove that process based on a lot of the challenges and learnings from, from AstraZeneca, uh, as well as our other clients, to be honest. But AstraZeneca was the one where. Put it to the digital system and really put it to the test over a series of six months, lot of wonderful learnings at agile stand-ups every day, but, uh, resulted in a, in a better product that they're now so excited about with, uh, that they're gonna go live this year and speak a little bit about it, but, um, [00:23:00] That just disproving that, that tech transfer concept can work and we can digitize this process was very exciting to see in a real format, because again, you can go very far, um, doing the theory associated with this, but when you're actually taking those buyer reactors and upstream and downstream processes and, uh, creating the process flows, the pictures that I mentioned earlier in inside DTLs and then driving the details behind those pictures.

And I've mentioned this a couple of times, but re you really. Are dragging and dropping, um, process flow steps to, to mimic the process and lines between them and then, um, updating the data associated with them and then viewing that data. Um, and, and again, you know, we are gradually doing this. We have the ability to.

I have this in a digital format, move it to places digitally, but also very quickly create what they currently use as documents, um, be a print functions using Adobe forms and SAP. So if they do need, [00:24:00] for instance, to communicate to a COO, who's not necessarily connected. Although that's another exciting area I can talk about, um, then they can quickly create a PDF and send it based on any time period, any.

And the other piece I will mention that was huge to AstraZeneca is what we call flavor management, which is that I have either jurisdictional differences in the process or other aspects. Um, you know, this process parameters needed for regulatory submission. This process parameters needed for MES and.

DTLs is built upon a very, uh, configuration like framework. It's, it's super important when developing software like this to not have it be a rigid or hard-coded, but it has to have enough of a framework and an intuitive framework that you do have some guardrails, but also if there's information that you need to gather or it's specific to your organization, It should be configurable.

I need to, you know, have these attributes tied to it. I need the vendor for this specific material [00:25:00] and some of it's information attached and, um, eh, you know, our developers at DTLs having developed a lot of similar SAP solutions. Uh, knew how important it is to make this something that's scalable. And it's not just the vision of even a company like AstraZeneca in 2022, but would support their vision in 2026 without any code changes or software changes.

So for those familiar with SAP, there's a lot of extensibility tools. Um, you know, I think it was the oldest one, which is classification, which is the ability in SAP to essentially extend the attributes of many of the, of the objects with something that, uh, Yeah, I'd say if he didn't conceive of initially, but you can create any characteristic you want.

And I think that concept is in DTLs, um, with metadata and flavor management. Uh, and I will mention the flavor management piece feeds right into what's called segmentation, which is an exciting new piece in general, in SAP. It came from the fashion industry, but it's the ability to actually. Segment or [00:26:00] create master recipes and transactional data for a specific flavor.

So when you think about segmentation, it's basically flavor management. I have four or five for us, the Australia version of this process. I have these steps that are applicable and for the Brazil version, I have these other steps. And for China, I have both and all those different flavors, um, we can manage and the other, um, core tenant of DTLs, which was very leveraged from our work in SAP.

Is things like configurable process parameter types, where I can say that I will have these fields based on this process parameter type. And then if I use another process parameter type, I'll have these fields and all this is completely

configurable, uh, across the board for all the objects, for relationships, for equipment, from materials.

So a very solid framework using SAP workflow engine, but also very extensible and configurable.

Tom: Okay. Super.

Chris: Yeah. So I think right now, um, you know, as we've started to socialize [00:27:00] this, and I think Tom, this is one of the more important aspects. I often think it gets neglected by people like myself, um, that are talking about new, exciting technologies is how do I make that?

Paradigm shift. If it's a seismic shift, it's almost an oil tanker level shift in an industry that has never really had the drive and the drive has been around dollars and need. And now that exists, but in order to, to drive that enabling technology, Our experiences, you need a cookbook, you need a very clear change management path.

How do I break down those functional silos? You have folks that in some cases, you know, at the R and D and science and the scientist level that are not that keen on not having their paper processes and, and you know, they're not that keen on having to work with supply chain on something that they're not convinced is.

You know, ready for prime time yet. And how do I get a cross-functional across the board process with [00:28:00] a risk averse crowd that is very stuck in a paradigm. Um, and I think this is the most important aspect of it. So I think just as important to us as the tool itself, I don't think change management is a budget buzzword.

I think we need. Um, and we're developing even through AstraZeneca, a recipe and a cookbook for how I would make this change. And I will say it's not, you know, necessarily a big bang for organizations. It's something where you have to actually kind of prove the concept and start digitizing, but also start to change the processes in some cases, that means some parallel processing, um, you know, you know, Some paper and some digitization, but I think we have seen tons of excitement from various functional areas.

Um, there's a lot of different functional groups that would be impacted by this, um, as mentioned a few, but, you know, supply chains and other manufacturing quality, all the organizations which would have oversight with through different

lenses on this. [00:29:00] As we have talked to our clients, we have several of them, several of the large pharma clients interested in this and are doing proof of concepts this year.

Um, probably the most important piece would be making sure they have that cookbook, making sure that we can start enabling. And we don't necessarily want this to be something that involves a lot of, uh, long implementation life cycles. Um, embedded in the tool itself has a lot of, uh, intuition, a lot of guidance supplemented by best practices in our methodology and cookbook.

But I think, um, driving that in a way that we can start to put a dent in this, um, we're seeing, we're really turning the corner of this product on the SAP store. I think we're seeing organizations. Um, more willing and, and frankly recognizing the fundamental problems with the current processes in a way that is making them excited about the ability to do this.

And of course they were, they may have been excited before, but they didn't necessarily have a viable software product that would support that [00:30:00] vision. So our. You know, through this podcast and many other mechanisms, we really want to get the word out there that there's a tool to do this now. Um, and it very nicely builds upon many of the other SAP digital tools, um, that would connect to this.

So the way we manage our spec management system, which is in the product compliance tool, uh, regulatory submissions, um, spec management, Contains SAP offers the IDMP, which is the way we define medicinal products and the way that regulatory authorities expected a global label management enterprise product development, um, which is some very exciting.

Uh, exciting new territory that SAP is now driving, leveraging things like the Reba network to actually connect to CMOs and do specification collaboration with our CMOs. So we can do redlining of bill of material items and the things that would be involved with a tech transfer process. But then. We are building that in concert with, with all [00:31:00] those other tools.

And we, we very much, you know, work with our SAP colleagues to make sure that we're connecting, uh, for our clients. So we're in the midst of a lot of, um, I would call architectural, um, and functional roadmaps with several of our clients that involve DTLs and many of those other components, um, to, you know, to hopefully as quickly as possible, create a digital framework to support these processes.

And again, very exciting.

Tom: Super super. We are coming to the end of the podcast. Now, Chris, is there any question I haven't asked you that you wish I had, or any aspect of this, we've not touched on that you think it's important for people to think about?

Chris: No, I, I think, um, I think we've covered most of it. Um, we can talk a little bit about, you know, where, where folks can see DTLs or learn more about it.

But I think for the most part, um, this is a good primer and obviously. I think the information that I'll give you can help drive some, some more answers, hopefully for [00:32:00] folks that are more interested.

Tom: So, okay, great. That brings me nicely into my last question. Chris, if people want to know more about yourself or DTLs or any of the things we discussed in the podcast today, where would you have me direct them?

Chris: Yeah. And, and, uh, you know, we mentioned it's hard to, to describe a link here, but hopefully this is fairly simple. Um, if you go to dtls.ca. Um, that is the website PA is a good start. And then through that connection, um, yeah, there'll be a lot of ability to, to reach out and connect. That will be kind of the introduction, but then, uh, for things like a demo or, or maybe more detailed discussion, that's a great way to, um, to understand more about.

Fantastic.

Tom: Fantastic. Well, we'll put a link to dtls.ca in the show notes as well, just in case, just to be sure to be sure, but that has been really interesting, Greg. Thanks so much for coming on the

Chris: podcast today. I really appreciate that. Thanks so much. Thank you for

Tom: listening to the industry insights by SAP podcast.

If you want to explore our industry portfolio [00:33:00] to find the solutions you need to run your business better, faster, and simpler. Please visit us at sap.com/industries.