accenture

REDEFINING REGULATORY THROUGH INTELLIGENT AUTOMATION WEBINAR

VIDEO TRANSCRIPT

NICOLA BEALL: Good afternoon, everybody. Just to let you that our session will be starting in approximately one minute's time. Thank you.

00:00:50
Hello, everybody. Just for those who are currently joining us, we are going to be starting our session in approximately 30 seconds time, just to let everybody get on the call and get comfortable.

00:01:35
Kim, we'll just give it a couple more moments and then we will start. I just want to do a quick sound check with you if that's okay. Can you hear me alright?
KIM BROWNRIGG: I can.
NICOLA BEALL: Lovely. And you're coming through perfectly clear, thank you.
KIM BROWNRIGG: Thanks, Nicky.

00:02:05
NICOLA BEALL: Excellent. Let's get cracking. So welcome everybody. Thank you for joining us today for our webinar session. We are really delighted that you're able to join us.

So a couple of housekeeping points before we start. This session is being recorded and it will be available after the event on Accenture.com. We do encourage you to ask questions throughout the session using the Q&A module that you will see on the left, at the bottom hand side of your screen. Please as we go through this session, enter any questions that you may have and we'll be able to answer those at the end of the session.

The 3rd piece of advice is to rethink your go to market strategy. As I said before these types of products are not sold through distributors to retailers in a traditional way they have to have an ongoing relationship with the customer that often means either a direct go to market motion or at least a direct relationship with the user of that product that requires fundamental changes across the whole sales cycle typically there requires changing your sales force the way the sales force is compensated and recognized for its quota and requires also changes to thinking through your go to market and what new players you need in your ecosystem.

Typically, these products become platforms and the platforms are supported by 3rd party developers and other software companies who influence the sale of your product and the experience over time. So when you go to market you need to have an ecosystem relationship strategy as well. The fourth piece of advice is to really understand the changes required to your operations and your infrastructure across the whole lifecycle.

Many people dramatically underestimate this change but the reality is most product companies have built up operations and IT systems for decades that were based on a transactional SKU based product they are not supporting a recurring revenue model. Take some simple examples; how do you actually price and provision an as-a-service service offering?

00:04:12
But as Nicky said, I'm Kim Brownrigg. I am the Regulatory, the main lead, European Regulator, the main leader at Accenture. I've been here

7 years, but I also had a career in industry before joining Accenture. So I've lived through some of the challenges from companies experience day-to-day. I also worked with the companies that are trying to prove those, so I'm here today to talk specifically around some of the evolution of data management within regulatory and also, the potential for Applied Intelligence and Automation.

00:04:48
And I am – I hope most of you or all of you on the call have already read through the white paper that was a precursor for this and I hope it was an interesting read. And if you have any other comments on that as well as Q&A's, as Nicky said, just post them in the chat.

00:05:03
So let's get going. So on the agenda today in the webinar, there's three main sections. And the first as I sort of alluded to is around the increase in data generally within regulatory and how we need to deal with it. We then look at our section around how can we improve how we manage that data and what do we need to focus on to really draw the best from the data that we have? And the last section is really on the potential that's envisioned with using the data better and using Applied Intelligence and Automation to also leverage and use that data to optimize processes.

00:05:50
So that's what we're talking through today. And so, if I go straight into the first section. So to just kind of set the context a little bit and I think this is true for everything industry, but I feel that regulatory is particularly stuck in the dark ages in places, not everywhere, but in places. So as we're looking at how regulatory has evolved. And it has evolved back in sort of 2000, we didn't even have it easy today. So we come a long way and along bringing easy today and obviously, now with some of the strategy data and IDMP. But generally, your life outside of regulatory has changed a lot more than your life within regulatory and we do communicate so often through text and chat and voice. And things are changing around us, things are changing are even more with current times. So we just need to bring some of that thinking and some of that innovation back into regulatory.

00:06:55
So I've got obviously the data tsunami and what we're talking around here is that regulatory information, again, going back 10 years or so, it was generally viewed as what goes in your dossier, what is registered with the Health Authority is your regulatory information. But that thinking is evolving. It's now more than just what's submitted in your dossier. And I think as people are starting to look into IDMP a bit more, they're realizing some of the data that's needed to submit out of there isn't all seen in your dossier. So it's bigger and more complex now.

00:07:35
And it's really the data about the products and about touching the research as well as led up to the product and the registration and the agency correspondence, but it's now viewed and structured and unstructured sources. And the challenge we, as an industry, is kind of asking ourselves on a daily basis and what I see with lots of clients is now how do we manage keeping up with that data volume and the data kind of perception whilst also considering user experiences and the agency expectations? And just to elaborate on that a little bit more, but the data volume will bring a lot more complex products to market, a lot of the biotech knowledge goals that your dossiers have got exceptionally large and they were large before.

00:08:19
So there's a lot of information that's being developed on your product. Your potential also looking at a lot more markets and as I alluded to with IDMP, you have a lot more data to control. So the data world is growing, but also, these are experiences are growing. You want to have more access, accessible information at your fingertips as you come to work as you do outside work with Uber and with Netflix getting up all your preferred content and the rest of that.

00:08:50
So that's the world we see outside regulatory isn't the same and we need to have more interconnectivity and synchronization and we need to really be focusing on value-add activities. And some of the changes around that data management and potentially moving to platforms and other things. It doesn't always simplify the process. So let's try and look at automation and the potential with data management to really get back to the true kind of drivers for a lot of us getting into regulatory in the first place.

00:09:20
And then just some of the agency expectations

perspective, they are asking for more increased data transparency with audits now. It's not just enough to assume that the right information has got to the right market or got to the right patients. You really have to confirm that whole value chain of the data and more and more. And you need to ask yourselves, as companies, how confident am I in everything that's getting through? And we need to ensure that.

00:09:47
We also need to now manage structured and unstructured data. Let's all hope that this is just a transition phase why we moved to more structured data, but in the interim, you've got the same data potentially going through a structured and an unstructured message to Health Authority. So we've got that temporarily duplication of information that we need to manage.

00:10:08
And then we've also got the regulatory landscape around this that's maturing with Middle East countries taking up easy today and they want to evolve their thinking and they also want to – sometimes do things their own way a little bit and it's not always consistent. So a lot is growing around us and there's a lot more questions being asked, a lot more data to be had to be presented.

00:10:30
So you put all that together, the world of regulators in the middle and we kind of stuck there and we really need to be the ones that are coming up with the answers to help drive some of this forward and to be more agile with agency expectations and to be able to be more agile with the volumes of data coming through. And sometimes, that takes a couple of minutes to take a post point on where everything is within the industry, within your company to really get the right data management frameworks in place.

00:11:02
And just on that, I'm just going to switch to Nicky just to have a quick poll question.
NICOLA BEALL: Lovely. Thank you, Kim. So we want to invite everybody to join us in a poll, as Kim just said. So it's a select a relevant answer. How confident are you in the quality of your regulatory data in your company? So select which one is relevant for you, hit the submit button and we can see the results taking place. Oh, that's really interesting. Kim, would you expect this type of answer straight away, 100% on high confident with only a few bits of data?

00:11:50
KIM BROWNRIGG: We'll give everybody to add to this, but it's – yeah, that's an interesting result for me. I think it's what most people expect in high confidence in all your data is probably an overestimation, but at the same time, everybody's going to have definitely confidence in certain sections. So just to say, this is really confidential, so we're not going to report back on individuals. It's just to get an understanding of the kind of broad learning of the attendees and just to make sure we're all aligning on the same challenges we're facing with regulatory and that is difficult to have a confidence in your data across your whole company.

00:12:33
NICOLA BEALL: Yeah, and to add to that as well, give everybody a couple more minutes to submit their answers, but it was really interesting the comparison that you made a moment ago on your previous slide about the amount of data that we handle in our personal lives every day, to the amount that we handle on a work level. And I just think it's when you think about it, it's incredible the amount of data that we're dealing with every day. It's fascinating.
So thanks everybody for taking part in that and, Kim, back over to you.

00:13:14
KIM BROWNRIGG: Thank you, Nicky. That was a practice run because there's one more poll question to come. So hopefully, that's a warm-up for the next one.
But let's get back to the topic at heart, so why do we feel that companies are struggling to manage their data and as we showed on the slide before, based on the feedback on that poll, a lot of people only have confidence in some of their data that is accurate quality check. So our research showed the same. Only one-third, say 33%, of executives that we researched and approached had high confidence in their data. In fact, have been validated extensively and 25% say there's a lot they need to do ensure data quality and then the remaining 40% was somewhere in the middle.

00:14:09
So I think it's broadly understood and it's a challenge. But to kind of understand the reasons for the poor data management and if we look at, I've got six on the screen, so underutilized system functionality. We hear from some clients

that invest in certain tools and then they're a bit scared to using some of that functionality because they're not too sure how well it will be received or they don't want to have all the constraints some of those functionalities may provide. But that is sometimes needed and we need to find a way to deal with the complexity of all different countries and try to simplify as much as possible. So if we can use some of the system functionality to enable that, then that's something we should consider.

00:15:58
Deficient data migration. This could be on going from one RIM system to the next or potentially also from acquisition of data. If that data isn't pulled into your systems in the right way at the right time, then going forward it's always going to be a challenge.

00:15:15
Ineffective quality control. This is probably my biggest issue, but also, potentially one of the easiest ones to solve. I know that needs resource, but if nobody thinks somebody's looking at the data they put in the systems, then they kind of take their foot off the pedal a little bit with some of that quality and kind of their cultural challenge around that. So if you have somebody looking at their system and checking it, and whenever that quality control is manual or automated, to some extent, then your quality of input does improve.

00:15:48
And I had one company where we were actually using some of the information in their dossier to kind of build a current view. And actually, 25% of submissions we reviewed within their RIM system, had something that needed populating or something that wasn't quite right with the entry. And some of those were very minor, just with not the right dossier attached to that submission entry, but then some of them significant around actually their own product information being touched. So that was a good statistic to show because we actually – we use the information and I would encourage all to have some deep level of quality control.

00:16:28
And disconnected systems. This isn't just disconnected systems within regulatory, but also try to make sure information is flowing from other systems used or other stakeholders. You know, be that your change control system for CMC and some of that information on the products or the descriptions of the changes, why not be able to just push that straight into your RIM system when you're building any change submission entry or whatever. So try and get those all aligned, get all your ducks lined up, you don't want to keep having to do duplicated entry all over the place.

00:17:05
The last two are a bit more around the people aspects. So poor user training, it's not just poor user training, it's just making sure it's accessible at the right time, making sure it's repeated, making sure it's broken down into the right chunks. It's not just saying we do this huge training exercise once often and then it goes away. It needs to be the right kind of trip fast training. And also, you're having the system intuitively working. We don't all have bibles on how to use iPhones and yet, we all work it out. So it's just a blend of user training and system experience and user interface.

00:17:45
And then the last one around ineffective resource assignment. What I'm really trying to get to here is if sometimes when you do move to a new platform play or you have a RIM system, there needs to be complex to account with some of the complexity that is inherent in regulatory, but if you're then having somebody who is doing a lot of strategic activities or really trying to take guidelines and build up strategies and then they need to switch to do a lot of data entry, that's not necessarily efficient use of their time to kind of change their mindset from something strategic to something data entry. So making sure you're assigning resources or breaking up kind of operational order and tasks, so that you can kind of get the most out of the people that are doing the activities. And whether that's offshore and whether that's a hub-based approach to do some of the more data entry activities, just aligning those to the needs of the business.

00:18:43
So that's really kind of my two slides and just in the context on data as a challenge, the reasons we see in industry from a lot of interactions I've had with probably nearly all the top 20 companies one way or another as the data automation. And what I'm proposing next and what was the pivotal part for our white paper is to try and confirm data veracity, as it's called, and increase your confidence. You need to change the way you collect, curate, interpret and apply data.

00:19:18
And we are doing that sort of for this kind of reason. Knowledge, just a little bit, but people in regulatory first generally choose professions to help patients. And they don't get into the data entry and then a lot of the roles have become data entry focused. So let's try and do things better. Let's get back to our roots. The data entry is important, but let's just find a better way of managing it all.

00:19:44
So these are the sort of the four key steps discussed in the white paper. And the first two, I'd say are just setting the foundation and the basics. And then the three and four are then actually using your data to your own advantage. And so, one on collecting data. So I think a lot of the companies on the line or a lot of the class we're working with, they are or they have moved to cloud-based solutions, which enable everybody globally to access the information either in a single repository from the platform play or you have set of modules that are aligned and linked together and they are accessible.

00:20:30
And we're trying to move definitely to a single source of truth and you'll have the same information all over the place. And I think everybody, I don't think there are any exceptions here, but everybody kind of would agree that we need to move away from local variance of information, be it that in local files or Excel spreadsheets. And we need to make sure all of you in the same information correctly and succinctly. And we need to do that by integrating everything across the value chain.

00:21:00
So I think that's a very basic principle, but that's one we need to get ready first. And then once you work at how you can collect all the information in the right systems, it's also then curating that information, learning and doing the most from that information. So we then need to – and I wanted to go hand-in-hand, but we need to make sure we're setting up the right data standardization. We need to make sure we are mitigating free text subjectivity wherever possible. Some nuances are out, but let's try and get everything standardized. Let's make sure we're making all the control of our categories from the referential in store. Let's make sure we're trying to have some master data management in controlled terms. And if possible, having a common pool of data that pushes one to the other and that you can run modeling on and enrichment on is the ideal, but it's a journey sometimes to get there.

00:21:55
And data government. Data governance, the whole quality pieces, the whole policies, the whole excavation, compliance, tracking, everything around data governance really cannot be underestimated. And for all of you just to have a good thing to make sure your data governance models are up to scratch.

00:22:15
And then we get to the juicy stuff on the bottom. Three being, we've got all the data, it's all accessible, what can we do with it. Best draw some insights from that data. Let's make sure we're driving business decisions. You know, be that forecasting, be that staff performance levels potentially, be that how we can optimize operations. You get a lot from that data that there is. So let's try and actually do something from it and drive value from it.

00:22:44
And then we can also start to learn from the data and recommend activities. So I've got a couple of examples. We'll go into that in more detail, but if you think you get agency questions all the time, but you've got a big repository of questions that you've responded to over the last 10, 15 years. So let's search, you know, use some good analytics or searching functionality to try and recommend some answers to those questions or at least bring up responses that are similar. And that technology is very accessible nowadays. So let's start using the data that we've got to our advantage.

00:23:22
And then if we go on apply. This is even juicier because this is where we can use the intelligence or the information we've got from the analysis of the data, but then we use an automation there on top of it. So we don't just pull up results that might appear in Google, but Google automatically takes you to the page of the top of the recommendation. You kind of taken those results and then you're just pushing that into the system to operationalize those.

00:23:56
And also, pushing the right data in the right places as well, making sure you can show the right data to QPs or you can show the right data to certain marketing teams, making sure it's all

accessible and where it's needed and when it's needed.

00:24:12
And what does that look like in a very high, simplified, data architecture? So if there's IT gurus on the line, this is meant to be a sort of a simplified view. I'm sure some of you have seen this before, but just laying across the top four sort of framework pieces and viewing that in an illustrative sort of system landscape.

00:24:37
And why is this important? And why do we find this a lot on the automation side or I will focus on the automation side in the rest of this webinar and the reason is sometimes in the business case around the data management is hard to define. You need to really collect some of the data on the discrepancies or have to have done a real big compliance project to show where those issues in your data to get the supported money to remediate those. But if you start viewing the aspects in the far right, the applications, and you start thinking how intelligent automation can really drive business focused outcomes and business focused efficiency gatherings, cost, time, money and others, which we'll talk about later.

00:25:26
If you focus on the output and the value it's driving, it really does help some of that value case and the business decision. But also, if you focus on how you're using the data, it also changes some of the data strategy or the data stewardship around how you set up some of the data management and I'm working with a couple of companies that are going through RIM platform implementations and trying to understand when is the right time to have conversations around automation. And you need to get to some of the foundations on that platform data module and how you want to use it and how you make it relevant for your company. But then you need to start thinking, well, there's a couple of different options on how I can put my data in that system.

00:26:09
You need to think how you're going to get it out. What value you're going to drive from that? And that's where some of this automation vision really becomes key in the messaging and the story. And the other thing just to say here is a combination now really of automation that drives a lot of business case around data management programs, but also compliance programs like IDMP. IDMP might not been overly well received when it came out and when everyone so frantically trying to get some work done before the BMA went and moved and gave us some breathing space, but it did catalyze the direction around looking at making data information as data.

00:25:50
And now that it's coming back to the forefront, there's a lot more justification around becoming regulated compliant for IDMP. If you couple that with some of the automation pieces, then you really do have a good value proposition for improving your whole data and management data concept.

00:27:12
Good. Now I know some of you will need to put on your glasses and this is definitely a place where you might want to enlarge your screen, but this isn't meant to read all this in detail. What I want to try and move to now is if we are focusing on the automation aspects to drive some of that transformation, then what sort of automation use cases do you want to consider?

00:27:33
And if you look around the top here, high level capabilities in regulatory and then just some example use cases of automation possibilities. And the technologies around those use cases, but also where Accenture is on the kind of deployment and how far we've progressed on those concepts.

00:28:00
So I would encourage you as a company, a lot of these ideas came out from design sprints that we've done with various clients. So normally, how you look at this is you look across your capability continuum and then you, as a company, needs to understand where your particular pain points, how's the operational structure, where's the real business value across them, across those different capabilities. And a lot of that comes down to maybe the resource costs for different activities and the throughput. So for companies that have a high life cycle maintenance and I know some companies have submissions or some of their effort is definitely on life cycle maintenance, then that really needs to be your focus area to drive some of the initial return on investment and business value.

00:28:55
But also, between those areas, what else – in a throughput compliance challenges, just general cultural aspects on how the company's evolved that you need to maybe focus on because you can miss big opportunities there. So you look through some of those different capabilities and then once you've got sort of the capability that you think you should discuss a bit more, you can do some sort of design sprinting or design thinking and workshops to come up with some of those ideas. And you can, obviously, leverage when just to bring some of those ideas to you as well, but you should definitely also try and consider some internally and reward and recognize people that do part with those concepts and really try and embed innovation throughout the organization.

00:29:41
Okay, so this is just some of the ideas, but what I'm now going to do is just go through three in a little bit more detail, just to give you a flavor of the art of the possible that you can envision.

00:29:54
NICOLA BEALL: And, Kim, just before you do that, sorry, just before you do that, I can see that we've had some really good questions come in, but can I just remind everybody that if you do have any questions, submit them via the Q&A module on the left-hand side of your screen and we'll be happy to cover those at the end of this session. Sorry to jump in there, Kim, but thank you so much.

00:30:15
KIM BROWNRIGG: Yeah, and sorry, we'd love to just go through these as we go through but, obviously, you want to get through the content. That's why we're keeping them to the end. But please do keep them coming and if we don't get to all the questions, we will follow-up on those and get you some answers or responses.

00:30:31
I think questions is a good thing. People asking and engaging. So great feedback. Thank you, Nicky.

And then just to go through a couple of these ideas. So one around regulatory requirements and content. And so, this is focusing on the today, it depends on company by company, but generally, GRA, somebody in an essential function is either reviewing a database or approaching affiliates or be your representatives to understand the requirements for particular information of a particular country.

00:31:10
And then based on that sort of activity, which they normally do on a case-by-case basis. So every time you get a submission, there's a level of checking that's done. Based on that, you would then build a country specific content plan. You prepare the content. You then might actually have another check where the regulator affiliate would look at that content to see if it's acceptable. And then you might have rework loops or if the affiliates think it's acceptable and it's gets to the Health Authorities, they may think that they need something else as well. So another further work loop.

00:31:46
As I said, they often repeat it for each submission. They can lead to long lead times with this sort of free work, especially if some activities done on the strategy six months potentially or longer before you actually get the dossier out and some of those requirements have changed.

00:32:03
And then if you move towards a potential tomorrow, you can actually leverage the content plans that you've already produced or the dossiers you've already submitted to your benefit. So if you started to make a new submission and you have the submission properties for that new submission matched after applying your certain rules to your repository of past submissions, you can actually or you or a robot or whatever you want to call it, can find the best matched submission and it can actually recommend the content you need or the documents, should I say the requirements you need, based on that past submission.

00:32:49
And if you submitted five documents last time for a change of manufacturer or whatever, it can recommend the same five documents, which should be specific to the country. Obviously, you can put rules around the time that submission needs to be the last six months for it to be accurate. You can also try and understand if that submission had any follow-up questions or documents submitted as a result of agency questions and you can try and incorporate those as well. But effectively, if you manage submissions six months ago and it's accepted and no questions were asked and the conditions

and the similarities of that new submission is almost identical, then why not just submit the same thing? And especially where you're using maybe a lot of team members or you've got a very big team or potentially outsourcing with a big team, you're not always going to have the same people writing the same dossiers. So they might not even be aware that the last submission was made within a recent timeframe.

00:33:44
So, yeah, you can leverage those past submissions, you can recommend the output, you can automate some of the content creation and then if it isn't quite right and I guess the affiliate and something might have changed, there might be a very recent update coming from the Health Authority, then that feedback rate is incorporated into the next submission. So the affiliate only has to say that once and then next time, they know that they should make it in the right dossier.

00:34:09
It's something simple, kind of around that analytics picture that should really drive your approvals in a quicker timeframe, get you more consistency of output and you should get more right first time submissions and actually, the amount of questions you get from agencies should potentially decrease because you're kind of leveraging those past activities.

00:34:31
So that's just one example and just going to cover a couple more just to give you some other insights. Labeling is a challenge for nearly every company we speak to and I feel for labeling, part of the challenge of labeling, there is this sort of one gold standard technology or tool, and there's not let's say one gold standard process. A lot of companies do labeling slightly differently. How they put the shift of responsibility or the share of responsibility between global teams and local teams and how there's a few nuances with labeling that need to be accommodated.

00:35:09
So we often see companies trying to understand how to do end-to-end labeling better. And one example is around if you don't view your company called Data Sheet as a single document, but you break it down into components, you could potentially leverage those components to understand if you change something in your company called Data Sheet. Where those components changed elsewhere in local labels? How do they map back to that company called Data Sheet? How do you actually have a workflow around it that controls any deviations and the translations of certain activities and kind of component information that go to your affiliates.

00:35:56
And I know I've just jumped straight into tomorrow, not covered today's much, but generally, the company called Data Sheet roll out to local affiliates is quite a challenge and it's very difficult for labeling heads to understand how the local labels do map to their company called Data Sheet. It's something we see all the time. So we've got kind of a concept that's been developed around trying to do that mapping and leverage within the machine translation to build that view.

00:36:29
Obviously, you can then push that information into your artwork as well. So there's a bigger then just the labeling. You can make sure that's consistent across your artwork or potentially even consistent across other labeling terms where they're shared either agency websites, be the marketing databases. Let's make sure we're having the same information track consistently across the value chain.

00:36:54
And then the last one is around Health Authority correspondence processing. This is my little favorite, but if you just think how we do things today with half of our correspondence. It's a simple piece of the puzzle, of the regulatory capability puzzle and process, but we get communication from Health Authorities which might go to central teams if it's a centralized product or something more centrally managed or it'll go to like affiliates. You have to understand what the information is about. They then have to translate it potentially, save it, put locally and/or central database. Let's hope it's just central database. But they need to understand what to do with that later and then they need to perform some actions often within the system.

00:37:46
So if you break that down to its components, it's quite simple and it's quite similar to like invoice processing that the financial industry has been doing for years and years and years and how they leverage automation. And what you could and position to and what we've actually looking

to design and build this out current at the moment is around getting your correspondence as letters or emails sent to more of a central hub. So it doesn't go direct to the affiliates necessarily, it might go to a regional hub or a central kind of service desk, which then would get that information into, I'll say, a service queue, whatever you want to consider that as. If it's scanned, then it needs to use OCR, leverage some of the intelligence to extract the information from the scan. And then if it's an email, it's obviously already structured.

00:38:39
But you can leverage technology to do the translation of that document and then categorize that document. So with artificial intelligence, if you build certain rules, it knows your natural language processing, what that document is, what use case it matches to that you taught it to look for. And then based on the use case, it's matched to, it also knows to extract certain information. So if it's a use case for a filing decision, it knows to extract the information on the registration number or the country or the product or the submission title, as well as the approval status, with the approval kind of decision and the approval date. And then once it extracts that information, then it's ported and it's all structured data, you can then find information or match that information to a submission entry within your RIM system, registration system and you can actually put that information through.

00:39:43
So you can actually automatically update using RPA or process automation or other types of process execution, push that information so it updates your submission entry live. And it can do all of that in a very quick timeframe if you've got the right kind of staff force augmenting and supporting that. So if you can get that within definitely less than a day or ideally within a few hours depending on obviously the throughput.

00:40:13
And for the ones that don't fit into that pre-matched use case, that Service Desk, they can say, well, this isn't a letter that we're expecting or it's something a bit unusual and either turn it direct to the affiliates or do any other activities as necessary with that letter. And also, with both the Service Desk, the triaging piece or the process execution with pushing the information into RIM, you can also push the letter in as well and save the right meta data to the letter that you've extracted from the document as well.

00:40:48
So, certainly that's another kind of example. So all of these are a little bit creative and change some of the view that you might have with your regulatory processes today. But you just kind of need to just get your creative hats on, you know, your out of the box thinking and just go through some of these examples leveraging how we see technology used elsewhere and how you get some ideas from that.

00:41:15
Okay, so I just wanted to kind of wrap-up that little section. The last section is a bit on the benefits we see with automation. But Nicky's going to do a poll question number two, which allows you to respond to as well please.

00:41:30
NICOLA BEALL: I am. Thank you, Kim. And I've had a couple of responses back from the last poll that we conducted. Several people pinging me saying, no, I gave a different answer. So let's keep our fingers crossed and see how we get on with this poll. Exactly the same format please. Click your relevant answer to the question of what progress is your company making with intelligent automation in regulatory? So you've got five answers here that you can select. And just I want to remind everybody, when you are making your choices, as Kim said, don't worry, nobody else is going to see this. Nobody else is going to be privy to the information that you're sharing. It's just to find out where we are and how the industry's seeing intelligent automation and how it's being received.

00:42:32
And just to that point, Kim, the three slides that you gave a moment ago, the three slides of examples were wonderfully detailed. And I appreciate, like you said, Kim, people are going to need their glasses for some of the slides. But seeing that the session is being recorded, I know that you'll be more than happy to sit down and speak to people on a one-to-one basis about those examples in more detail if somebody listens to this is the recording of the session and then thinks, okay, I want to learn more about this. So don't be shy. If you do want to speak to Kim about any of those examples or if you want to discuss any ideas or suggestions that you've got, please feel free to contact Kim or myself and, yeah, we'd be really interested to hear your thoughts and views and ideas.

00:43:35
KIM BROWNRIGG: This looks better. I think we were the king, we're flicking to the slides, the result slide last time, so that's probably our fault.

00:43:45
NICOLA BEALL: I think so. And what are you thinking, Kim? Is the type of response you would have got or is it this –

00:43:55
KIM BROWNRIGG: Yes, I think what this shows is - well, two things. If you look at the top three percentages, so what's that? Let's say almost 75 if my math is all right. That's saying about 75% are starting to do something with Intelligent Automation. And the funny thing is if I'd asked you that three years ago, that would have been probably 15%. So it's really come along in the last sort of two or three years and companies definitely started to move and that's great. And I think there's a lot of lesson learned from different clients and different companies as to how that's gone, different approaches, whether they've done that through a regulatory bottom up or whether they've done that sort of across R&D perspectives as well. So, yeah, it's a lot of good distribution, I think, is the answer there.

00:44:54
Okay, so we've only got 15 minutes left, so I'm just going to go to the next slide and just make sure we leave a few minutes for addressing some of these questions at the end. So what's the potential for some of these activities? And I've kind of picked this up as a bit of a typical journey to, I've put Intelligent Enterprise, but in this case also, intelligent regulatory function.

00:45:22
As I said early on the collect, curate, interpret and apply, there's different steps to go to and even if you start looking at automation solutions, you've going to have to get your data in the right quality and consistency in order to be able to leverage that to do automation and data does drive the benefits from automation. So you may need to go through a sort of step-wise approach, depending on where your company maturity is currently.

00:45:58
But those potential benefits, I think 50% is actually not an over exaggeration as you kind of go through all the improvements and the step-wise approaches underneath it. And it's just showing the potential where we are highly manual within regulatory currently, even with some of the companies that may have started moving into the automation kind of arenas. There's a lot more we can still do.

00:46:27
So that's just where I wanted to kind of set the context for that slide which, again, is in the white paper for people that want to look in a bit more detail. And then it's not just the kind of the efficiency saving, although that's also very important. But you can get more of a disrupted benefits above and beyond the cost quality of productivity improvements.

00:46:50
So if you think a little bit sort of downstream on this, once you've got all the information in the right format, it's so easy to send it places and do things with it. So you can send it in different channels, in different internal/external stakeholders and this is where kind of IDMP also kind of converges with some of those data management approaches and automation because you've got that data more accessible and then you can push it out to where it's needed more easily.

00:47:22
You also see a lot of innovation and there's two innovation on this. There's both the middle two, but it's on the center. One is around the product advances and the acceleration and the continuous improvement. So as you start to be able to focusing on life cycle maintenance for now, again, actually start to be able to push those changes through more quicker and more cheaply to Health Authorities and they're getting improved quicker as well, that doesn't mean you're going to get less of those changes come through the system. The company's going to catch on and by the way, you can manage more of these now, we can put through a lot of more product advances. And if you get a lot more innovation through for your products as you can do more than you agile. So that's the one piece.

00:48:13
And similarly, if you go down to the bottom, it's one around agility to also respond to regulation and guidance that don't – a lot of the kind of barriers for change is around if the Health Authority wants to roll something out, obviously, it's got it's whole consultation period and transition periods, but their structured in such a way with such timelines because, companies really need to learn to adapt to those changes

and if we can become a little bit more agile as a result of better data management and help with automation, then you can get hopefully a little bit more innovation coming through from agencies as well.

00:48:57
And then just a couple more on this slide. A little bit of less reliance of in country local experts. We want to make sure in country local experts are providing current expert advice where it's needed. You don't want them to keep fishing out the same advice just because we haven't got the right capabilities to store and leverage that advice they promoted previously. So let's take away a little bit of the reliance in country and like let's put some new things in it that will help to centralize.

00:49:26
And then just a little bit more on waste. If you think about how we can manage certain dashboards and have more visibility of trends, especially around labeling and how long it's coming through and if there's at our manufacturing site, if you were about to put a bit stock order through that's just going to be sitting on our shelf for a long time in a warehouse, if you know that there's something about to be approved, then understanding how you can leverage that from your supplier product perspective, making sure you're actually getting the new information on the products sooner because you've got visibility of when it's coming.

00:50:06
And also, looking at staff satisfaction on another time here, but if you have the – and we've got kind of a wide variety of resources on the staff levels on the call, but if you were working for a company that has the best processes, you don't have to do a lot of this data entry. They're at the peak of the industry, you're going to get the best people, you're going to be able to track them and that in itself brings greater and bigger benefits to a company.

00:50:37
And as with everything, just on the right-hand side here, the percentage with the 50%, once you have started automating tasks, you're going to have to adapt to your operating model. You're going to have to look at, well, this one person now only does half of a role for this. So how do you repurpose them? And I really feel that there's going to be potentially more blended role as we progress with taking a bit more product oversight advancing labeling CMC and other activities will be so siloed. I think they're going to converge a bit more because the activities, they do a very similar and I think if you take out some of the transactional roles in both of those types of activities, then you can just have somebody that's strategically focused in driving the right outputs for regulatory – sorry, for CMC combined potentially. But it's definitely going to look different. So we need to be prepared for that change.

00:51:37
I've just got a couple more slides here and then we'll get to some questions. But I just want to kind of leverage some of the best practices we've seen from doing the supply intelligence and intelligent automation implementations. And I will say we've done loads in the regulatory space, so we've made it across the R&D space and some of the regulatory space, but also, more broadly in other industries. They're the same learnings that Accenture can apply to this space as well.

00:52:08
So some of the defining or driving principles or guiding principles for looking at refining, redesigning regulatory with intelligent automation, I think these three key principles are pivotal. One is around making sure everything you're doing is business outcome oriented. Don't just automate the process for the sake of automating the process. It's at the right process in the first place. You know, make sure you're driving value through that. And you quite often do need to overhaul or rethink some of those processes to really drive the best out of the automation and the optimization that it will bring.

00:52:49
You need to kind of consider how you interact from technology solutions. There's a lot of open source solutions, broad ecosystems nowadays, which are actually really quite accessible and you can leverage a lot of those technologies to kind of integrate them to have like a better architectural pitch and to really kind of make the most of the data and drive those outputs. So don't just be restrictive with some of the technology thinking.

00:53:19
And then, the third sort of pillar behind this is around the human centered approach. Really, let's try and make sure what we're doing is making the user experience better. We're trying

to augment the workforce generally. There are a couple of activities that not necessarily need to done by humans, so you can potentially automate a couple of activities fully, but on the whole, we're trying to augment them. We're trying to make the user experience better. We're trying to streamline and add value with the people we have in our workforce and make sure we focus on that.

00:53:57
But they are kind of the three guiding defining principles, but it doesn't always go by that either. There are some things that you will need to invite. So around making sure you have holistic oversight of all your initiatives. There's a lot of overlapping objectives that can be quite chaotic, especially if you're doing this bottom up and trying to get it without the right senior endorsement or sponsorship. And I would urge sort of companies to look at this at least cross R&D to really drive a lot of the best efficiencies and synergies across some of the technology perspectives.

00:54:39
One thing we do see and I think actually in particularly in regulatory, I think it is changing, but if IT does one thing, business does the other and ultimately, you need to put work together for the output. IT now isn't just around maintaining a couple of systems or hundreds of systems in some cases. It's more about driving, enabling technology to let people do their job better and it needs to have a lot more synergy between those two.

00:55:04
The HR management or change control is on a similar theme. HR Management around making sure you're having the right messaging around how the people will be repurposed. This isn't, as I said, this isn't just about lowering headcount, it's about doing more and better things with the headcount you've got, so you need to have the right messaging.

00:55:22
And then around the kind of the control, change control aspect as well as implementing these, what's the journey for the user, how does it actually improve, do they have to get used to a certain technology before we start actually leveraging around some of the automation? That kind of thinking.

00:55:38
And then finally, around their responsible automation. What are the ethical and legal implications and who is actually responsible for some of those decisions and outcomes? And some of that especially when our GXP validates environment, we have to consider thoroughly and make sure it's all documented and traceable obviously.

00:56:01
So I think that's me. So I know we've only got five minutes. I just want to finish on this last quote, which is in the white paper. But it's certainly 1911, but it so resonates still today and we only advance with the – by the number of important operations we could form without thinking about them. And that's really what we're trying to do.

00:56:25
Alright, Nicky, I've got four minutes for questions and I'm sorry, I took a bit of time, but let's try and get to as many as we can and then we'll take the others offline.

00:56:33
NICOLA BEALL: Perfect. And no need to apologize, Kim. We've had some really great feedback and questions come through in the chat module. So as Kim did say, anything that we don't get through at the moment, we will come back to you offline and make sure that every question is answered. So are you ready?

00:56:51
KIM BROWNRIGG: Sorry, just before you do that, Nicky, in case some people are leaving. At the end of this, there's a very, very short survey where you can also provide some feedback on what you might want to hear more of. And so, if you can, just complete that. It'll literally take a couple of minutes, if that, and then we can provide you the additional support that way as well. Go on, Nicky.

00:57:08
NICOLA BEALL: Brilliant. Great point. So first question, is the recommendation to folks on a few RPA ideas to start with or something that uses AI as well?

00:57:23
KIM BROWNRIGG: Yeah, and this is kind of – I'm looking around on the intention automation continuum. And my recommendation is RPA has a place in certain very transactional activities

and you can get some really quick wins. However, RPA sometimes does that just replacing the process for the sake of it. And what I would say, if you're going to use RPA, we need to really make sure it's driving business value. And the best recommendation I would say is to make sure you're considering more complex opportunities in parallel potentially to some simpler ones. Let's make sure you've got an angle of how you can really transform a process and really make some disruptive difference and benefit. And if RPA plays a part of that, great, but don't just think let's see some RPAs and test the water. You definitely need to have more of an ambitious creative vision as well.

00:58:21
NICOLA BEALL: Excellent. Okay, so this question and this comes from as well, looks to be on the similar theme, but how do you go about selecting ideas to prioritize for intelligent automation?

00:58:36
KIM BROWNRIGG: Yeah, and I think – I touched on this a little bit, but you really need to make sure the ideas that you select are relevant to your company. So that the best way you can do this is probably setting up some sort of innovation program or council that has some criteria for assessing different types of ideas. As I said, from a business value side, some things you need to consider around cost to current resources or some of the return on investment, transactional throughput to make sure, again, you're going to have enough value from the system. But you also need to think about how stable that process and system is or subject to change maybe from a regulation. So you don't want to go and build something that could potentially change in six months' time. So there's a few different criteria we normally work with and happy to kind of follow-up with some people offline if they want to learn more about that as well.

00:59:30
NICOLA BEALL: Brilliant. Okay, I am conscious of the time, so just a couple more if we may. At what level do you look to manage data, regulatory across our R&D, enterprise-wide?

00:59:46
KIM BROWNRIGG: Yeah, and I've seen all three done. I think it depends on the size of your company and how they're structured. My kind of recommendation is you really need to do some of this architectural setup at R&D level or visualize it in R&D level, regulatory might be a first use case or example that's building that. You need to visualize it at R&D level. However, you do need to also set some guiding principles or framework at an enterprise level. So that there are some synergies with other data management initiatives that are ongoing. You don't want every single functional component to do it differently.

01:00:29
So just to summarize. Look at the enterprise governing rules around data management, but don't get too caught with making sure everything is streamlined or harmonized and then really focus on driving value from an R&D, because there's data value chain with how information flows through from clinical, safety and regulatory anyway. So that would be my focus.

01:00:51
NICOLA BEALL: Perfect. Now one last question if that's okay. And I'm so sorry to all of those others who have submitted questions, but as we said, we will come back to you. So last one, Kim. Have you've got a point of view on how receptive Health Authorities are towards automation? That's really interesting actually, have you collaborated at all with Health Authorities?

01:01:13
KIM BROWNRIGG: Yeah, we've had a variety of discussions at a few different levels. We've even brought some kind of regulators into some of our science thinking workshops as well. So generally, there's a desire to move into AI, both within an agency perspective and there's some agencies that are looking to do certain things there, but also, to make sure we can kind of encourage pharma to do the same. However, there is still kind of the validation restriction. So we need to make sure how we're structuring this, the rules based approach, the percentage approaches. Everything is governed correctly and documented and validated in order to kind of have that view and how we can really leverage automation to help with some of those GXP type activities.

01:02:03
NICOLA BEALL: Brilliant, brilliant, excellent. Okay, so I am going to close the call there. We've run over just a few couple of minutes, so we really appreciate everybody hanging on the line with us. Kim, superb presentation today, packed with so much information. Thank you so

much. And I know that you've put a lot of time and effort and you've got so much experience with this topic and we'll be more than happy to follow-up with individuals if they want to explore any of this on a deeper level. So thank you for that.

01:02:39
We will be sending out the recording. The slides will be available. So once again, thank you very much everybody for joining us, really, really appreciate it. And we look forward to you joining us on our next session. Thank you very much. Take care.

Copyright © 2020 Accenture
All rights reserved.

Accenture, its logo, and
High Performance Delivered are
trademarks of Accenture.