OpenAI - Associate Director, Regulatory Affairs at Canary Medical Inc.

Interview conducted on August 10, 2023

Topics

Regulatory Research, Medical Devices, Pharmaceutical Industry, Search Tools, Challenges, FDA Guidance, Predicate Devices

Summary

The Tegus Client spoke with an Associate Director of Regulatory Affairs at Canary Medical Inc. who confirmed that manual research is time-consuming and involves searching through regulatory sites, government agencies, and enforcement actions. The Associate Director expressed interest in AI-powered tools that can automate research but emphasized the importance of accuracy and validation. The Tegus Client suggested a tool that consolidates information from government websites and provides summaries would be valuable, and the Associate Director agreed. They also discussed the importance of accessing regulations and 510(k) summaries for identifying suitable predicate devices. The Associate Director explains that the decision to pay for a tool depends on the company's size and budget, and they discuss the search process for product codes and regulations. They also discuss the tools used for synthesizing information and the potential benefits of AI-powered tools in streamlining research.

Expert Details

Associate Director of Regulatory Affairs at Canary Medical Inc. The expert can speak to the regulatory search industry.

Associate Director of Regulatory Affairs at Canary Medical Inc., a medical data company seeking to improve healthcare outcomes through the continuous, passive collection and analysis of data derived primarily from “smart” implantable medical devices that are proposed to report on function, diagnostic information, patient activity, complications and treatment failure for up to ten years – all without significant patient or physician involvement.

Senior Project Manager of Regulatory Affairs at MicroVention-Terumo, a rapidly growing medical device company that has pioneered the development of catheter-based, minimally invasive, neuroendovascular technologies that provide therapeutic advantages for neurovascular disorders, leaving October 2021. The expert managed a team with a focus on the US, EU, and Canada territories. The expert managed several product-development projects and can speak to the entire project process of bringing a new product to market. The expert used Rimsys as their regulatory management solution. Prior, the expert was using in-house solutions that required a lot of manual input.

Former Regulatory Affairs Manager at Edwards Lifesciences, leaving July 2020. The expert was a part of a team in regulatory affairs helping with the product development lifecycle. The expert can speak to the regulatory process and the medical device industry in general.

Q: How often do you search for regulations or enforcement actions in your industry?
A: Frequently. My role requires me to search for regulations for every new medical device in development at our company, change or modification existing medical devices, or plan to commercialize into new markets.

Q: How much time per month do you spend searching and interpreting regulations in your industry?
A: Every day.

Q: Which tools do you use currently to perform searches related to regulations or enforcement actions?
A: FDA website (e.g. search for 510(k) predicates, PMAs, De Novo, Product Codes, Regulation Numbers, FDA guidance, enforcement actions) and newsletters, Medtech/industry announcements on new standards, regulations, and guidance, industry forums (e.g. RAPs)

Q: What are some limitations of the tools you use to do your job (could be non-regulatory)?
A: These tools are very manual (require manual research).

Tegus Client
Hello. Thank you so much for taking the time to speak with me today. So the purpose of this call is to get critical feedback on a product from a company that we're researching. I've heard from a number of reg affairs folks that searching through enforcement actions, whether they're from government website, agency websites or they're from periodicals, things like that. When it comes to reg affairs or reg intelligence, in certain use cases, it can be challenging. Does any of that resonate with you?

Associate Director, Regulatory Affairs at Canary Medical Inc.
It does. And I would even say just in general, I don't know what certain use case is. And when I say in general because it's very, very manual based when we do our regulatory research for new product development. As you kind of mentioned, we have to go into these regulatory sites, government agencies, pull up guidance documents, standards, regulations, look into enforcement actions. All of that work is very, very manual.

Tegus Client
Got it. And how often you run into something like this? It seems like it's pretty frequent from the questions you've answered.

Associate Director, Regulatory Affairs at Canary Medical Inc.
Very frequent. Like I said, new product development, we have to run through, like when we do our regulatory planning and strategy, we have to do all of that assessment, evaluation and we do this manual research.

Tegus Client
Got it. And then I mean in what ways is it difficult?

Associate Director, Regulatory Affairs at Canary Medical Inc.
It's just time consuming and also like, let's say, I am a new company, trying to get a new product out, and this is the cost and, part of the research is kind of identify if this product is a Class one, two or three product from a risk classification. And we would have to go into that website and look at regulations or product codes to see where this device falls in.

And part of that is also looking for what we call predicate devices, like devices that are basically the same type of device so that you can refer to that device. And what FDA's website has, for example, is they have predicate devices and you have like sort of 510(k) summaries. I'm not sure how familiar you are with the 510(k), but basically what that is.

Tegus Client
I'm quite familiar.

Associate Director, Regulatory Affairs at Canary Medical Inc.
Good. So part of it is looking at some of the 510(k) summaries that are publicly available and not a lot of the 510(k) is consistent and structured and format and you have to really click into the summaries, read into it, see if that information's applicable to the product that you're working on and things like that. And so that can take quite some time to read through a number of different predicates and regulation numbers to see

where your product, that you're developing, fits.

Tegus Client
Got it. And then what tools do you use already to do this? You mentioned you're going to government websites or you might look into a reg intelligence tool. I mean are you able to share some of the tools that you currently use?

Associate Director, Regulatory Affairs at Canary Medical Inc.
Yes. So, high level basically, it is those government websites. You go in there, you look at regulations, standards, requirements. Often on authorities like regulatory discussion on informal, not very formal like discussion boards to kind of see what's out there, what people are talking about. FDA has newsletters that you have to subscribe to for free but they'll send daily or weekly updates to see if there's any new regulations or requirements or guidances that we should be aware of?

So not only just the U.S. side, all the other countries, markets also have like sort of similar types of databases to look through. So those are kind of like the general tools. Like there's no single application or program that you can use to do the research. However, I have been hearing about sort of these new types of tools, AI powered tools where these programs and software can do some of the research for you, you know what I mean? I haven't taken advantage. I think it's still quite new to the industry, but I can see how that could help a lot with research.

Tegus Client
Got it. It could be helpful. Why haven't you tried any of those?

Associate Director, Regulatory Affairs at Canary Medical Inc.
I played around a few with just like trials, but we haven't licensed anything on it. I think it's still too new. Just the whole AI chatbot stuff, there's certain inaccuracies to it. I mean, to be honest, I actually have used ChatGPT and Bard, Google and the one by Bing, yes, that is the ChatGPT. And I viewed some of that initial research, but I've also noticed a lot of inaccuracies in that. So while it saves me a little bit of time as kind of like a start to looking into certain things, regulatory questions, I still have to do my own research to make sure the information that is provided by these programs are accurate.

Tegus Client
It sounds like what you really need is like a better search tool.

Associate Director, Regulatory Affairs at Canary Medical Inc.
Yes. A validated search tool, validated, more accurate search tool.

Tegus Client
Yes. I mean, at the end of the day, you or your colleagues are making the decision. Maybe it's less important if the tool is validating it. Because at the end of the day, no matter how good a system is, I just don't see a scenario where most folks like yourself, and maybe you're unique. But most folks like yourself are still going to what they call trust but verify.

Associate Director, Regulatory Affairs at Canary Medical Inc.
Exactly. And that's part of our job just making sure what we gather is actually accurate and is linked to the right source of information.

Tegus Client
Got it. And you said you specialize in the med devices.

Associate Director, Regulatory Affairs at Canary Medical Inc.
The pharma world, yes.

Tegus Client
I mean, have you worked in pharma? Or are you just primarily focused on devices?

Associate Director, Regulatory Affairs at Canary Medical Inc.
I actually started my career in pharma, but very briefly, just for like a year or so. But I can tell you that sure the regulation and the pathway are different, but the method of collecting information is still the same, it's still the same tools.

Tegus Client
Got it. Now if you could wave a magic wand, what are some capabilities that you would want kind of out of the box and a tool that could search all these things for you really quickly?

Associate Director, Regulatory Affairs at Canary Medical Inc.
Yes. I mean I think we kind of touched on it, a software tool that can do a lot of the research for us like something that can collect all of the 510(k). Assuming this is all accurate information, it's been validated and everything. If it can collect all of that and for example, provide the most applicable predicate for the device that we're working on. Or if I want to look up all the regulations, like what are all the applicable regulations for this new device? What are all the applicable FDA guidance and standards that we should be looking at all in one place.

Tegus Client
Interesting. I'm just kind of surprised that there's nothing in the industry. You've been in it, it sounds like for quite some time, and you haven't run into something that you like. Would you be open to trying a tool like this, if it existed?

Associate Director, Regulatory Affairs at Canary Medical Inc.
I would.

Tegus Client
What would it take for you to trust it?

Associate Director, Regulatory Affairs at Canary Medical Inc.
That's a good question. I mean I would have to understand sort of like how do they validate this tool as far as like the accuracy of information that it's pulling from? Like where is it pulling the information from? I would have to do at least a number of test runs to see if it sort of matches, if the information that they're pulling from is correct and if it just aligns with the regulation requirements and things like that, as if I would have done it manually.

Tegus Client
Got it. So it sounds like what you want something is to interpret this information for you, but it doesn't quite sound like if something just pulled all the information in one place, that wouldn't be as valuable. It sounds like you want them to interpret it for you.

Associate Director, Regulatory Affairs at Canary Medical Inc.
I don't think I would want it to interpret it for me because I want it to summarize all of the information better. But I don't think we're at a point where some of these tools can interpret it for us because regulatory in general is a very gray space. It's not like black and white, you know what I mean? Like at the end of the day, it still requires us experts to sort of make the decision, especially if we're in sort of a gray area from a regulation perspective. I want the tool to collect the right information from the right places and be able to summarize succinctly that information.

Tegus Client
Got it. So even if it was as simple as going through all these government websites consolidating that maybe

through a search or a bookmark like experience where you can put all of it in one place and then tell a story about here's the reg. And then here is the kind of application of it or here's the summary of it. That is something that you would at least want to see in action. And if something like that you would at least do a trial of bit?

Associate Director, Regulatory Affairs at Canary Medical Inc.
Yes. I mean me personally I don't know if the company allows it, whatever. But for me personally, I think that's a really useful tool. And I'd be happy to try it, sample it out.

Tegus Client
Got it. So the key data sources would be all regs related to med devices, I'm assuming CFR and those details. All the 510(k)s, you mentioned predicates, explain a bit more about predicates that you find useful about?

Associate Director, Regulatory Affairs at Canary Medical Inc.
Yes. So part of the planning and strategy and if we consider a device as a Class II device, we would have to identify a predicate to submit in that, I think, submission. So part of our research is looking into all the possible predicates and then identifying what is the best predicate to use and sometimes it's multiple predicates. And how we define what the best predicate is, is based on a few things.

It's based on what that indication for use is or intended uses. It's based on the technical logical characteristics. It's based on the specifications, testing that's been done. And what you'll see in a lot of these 510(k) summaries, when we're doing research that's publicly available, some companies have like these nice tables that list out all the different tariff categories of their device versus another predicate device. Sometimes these 510(k) summaries don't have it. So it's just a little frustrating, but it's just not available.

But if they had a tool that's stable to kind of search through all of these 510(k) summaries and then provide a nice table of all the predicates, of all of the different characteristics for comparison in a nice and succinct fashion, I think that would be really helpful.

Tegus Client
Got it. Even something that you could convince your company to pay for it?

Associate Director, Regulatory Affairs at Canary Medical Inc.
Maybe. So I work for a startup, it might be more difficult to convince a company like that. It depends on how big the company is and like if a company is only doing one or two products, it's not going to make a lot of sense to many – use of this tool. But if you're at a bigger company and there's just a bunch of different new products in development and things like that with all different types of products, it probably would make a lot more sense for that sort of situation, scenario for a company to get a license for that.

Tegus Client
Well, the thing that's unclear to me is it sounds like this is something that could be useful to you. Now you work for a start-up, which is totally reasonable. Is it the fact that you have to pay for it is the issue? Or is it like the amount that you have to pay?

Associate Director, Regulatory Affairs at Canary Medical Inc.
Yes. I mean it depends on how expensive the business. Like if it's just a few thousand a year, yes, I mean it just depends on our company's budget.

Tegus Client
Of course, how expensive it is, how useful, but it sounds like it'd be useful, but then the next question is, okay, what is the price that you actually have to pay.

Associate Director, Regulatory Affairs at Canary Medical Inc.
Exactly.

Tegus Client
Got it. So it sounds like small startups may have some friction to it, but if it's really kind of blowing you out of the water, then that's interesting.

Associate Director, Regulatory Affairs at Canary Medical Inc.
Right.

Tegus Client
Got it. And when you're doing searches, so like I know I'm pretty familiar with the 510(k). Do you know specifically the device you're looking for? Do you know the names? I know you mentioned the regulation numbers. Just kind of talk me through what your search experience is looking like? Because I know there's like so many ways you can go into the search and the databases exist. I just want to hear kind of a little bit more context.

Associate Director, Regulatory Affairs at Canary Medical Inc.
I mean I think the first thing is when we have product development, we're trying to classify our device, like what type of device is it? Is it for wound healing? Is it like some sort of software, for diagnostics and things like that. Like that's something that we have to identify internally and also what is the actually intended use. And then based on that information, we start to look into what's the product codes that are associated with this type of device? It may be that there's no product code for it.

Tegus Client
Where do you get the product codes from?

Associate Director, Regulatory Affairs at Canary Medical Inc.
From the FDA website. The FDA website actually does have a nice search for product codes, but you have to kind of know the right keywords to use. It depends on what the function of this device is. So you have some key words on the function of the device. And that's how you find your product codes and those product codes kind of link you to the regulation numbers and like certain previous 510(k)s and predicates.

But it could be that there's no protocols available and that will also drive the regulatory pathway and it could be that there's no predicate available then this could be a de Novo submission, for example. So that's how that search starts identifying the product code and then that will lead into identifying the regulations, the predicates, 510(k) summaries. And then you start your more in-depth research and you start leaning into the intended use of these predicates and the technical, logical characteristics and things like that.

Tegus Client
Makes sense. So you got your product codes, you got all your documents in one place. Now once you've identified your documents, how do you then extract information and combine it and then synthesize it into a decision?

Associate Director, Regulatory Affairs at Canary Medical Inc.
Yes. So now you're comparing like the potential predicates that you want to use. The indication and independent use is probably the biggest thing. Some predicates might have similar language. Others might be slightly different. So you're kind of just configuring to see which one you intend to use in indications aligned with the most. But the technological characteristics are also really important, too, because one device might approach the intended use differently.

So for example, like wound healing. There's a lot of different technologies for that. There's like oxygen and there's negative pressure. The intended use if you read through them are actually very similar. And the wound types that they treat are very similar, but they go about from an operational perspective and technological perspective, very differently so that you have to compare your product to those technological characteristics.

So there's a lot of different considerations when you're looking at that and you're trying to see where your device fits in the best amongst the predicates. And it could be that you have multiple predicates too, like your device might fit better with one intended use or indications per use, but some of the technological characteristics are from another predicate, for example. So that's kind of like the evaluation. But this device is 90% from a technological perspective, very similar to what you have mentioned from the company you're researching.

Tegus Client
Right now, what do you use? It sounds like is it SharePoint and Microsoft Word? When you're synthesizing this information?

Associate Director, Regulatory Affairs at Canary Medical Inc.
Yes, like Word or Excel sheets or just look at any usual office tool. It is just basically putting my thoughts on to some sort of document and then synthesizing a clear story based on that.

Tegus Client
Interesting. Do you have any other information you think we might find useful for this call?

Associate Director, Regulatory Affairs at Canary Medical Inc.
Yes. The research part is difficult, and this is the part that takes most of the time, it's collecting information. I was kind of joking with some of my colleagues. And like I said, I'm aware that there's groups that are working on certain AI powered tools to put things together for us and you're like oh, it's going to take our jobs away. But at the end of the day, like I think this is super useful, but it's not going to take our jobs away because like I said, being able to understand and navigate the regulation because like I said, there's a lot of gray areas.

At the end of the day, it's the expert's job to sort of make that decision. But having a tool that synthesizes and collects like a lot of the research and present it in a very simplified way would help us from a time's perspective, eliminate a lot of the manual work and going to these websites and linking all the regulations together, that would definitely help us, in my opinion.

Tegus Client
Got it. Well, thank you so much, this was incredibly helpful. Have a good one.