MEDTECH

US Regulatory Submission "Best Practices"

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Interview by Darwin Shurig
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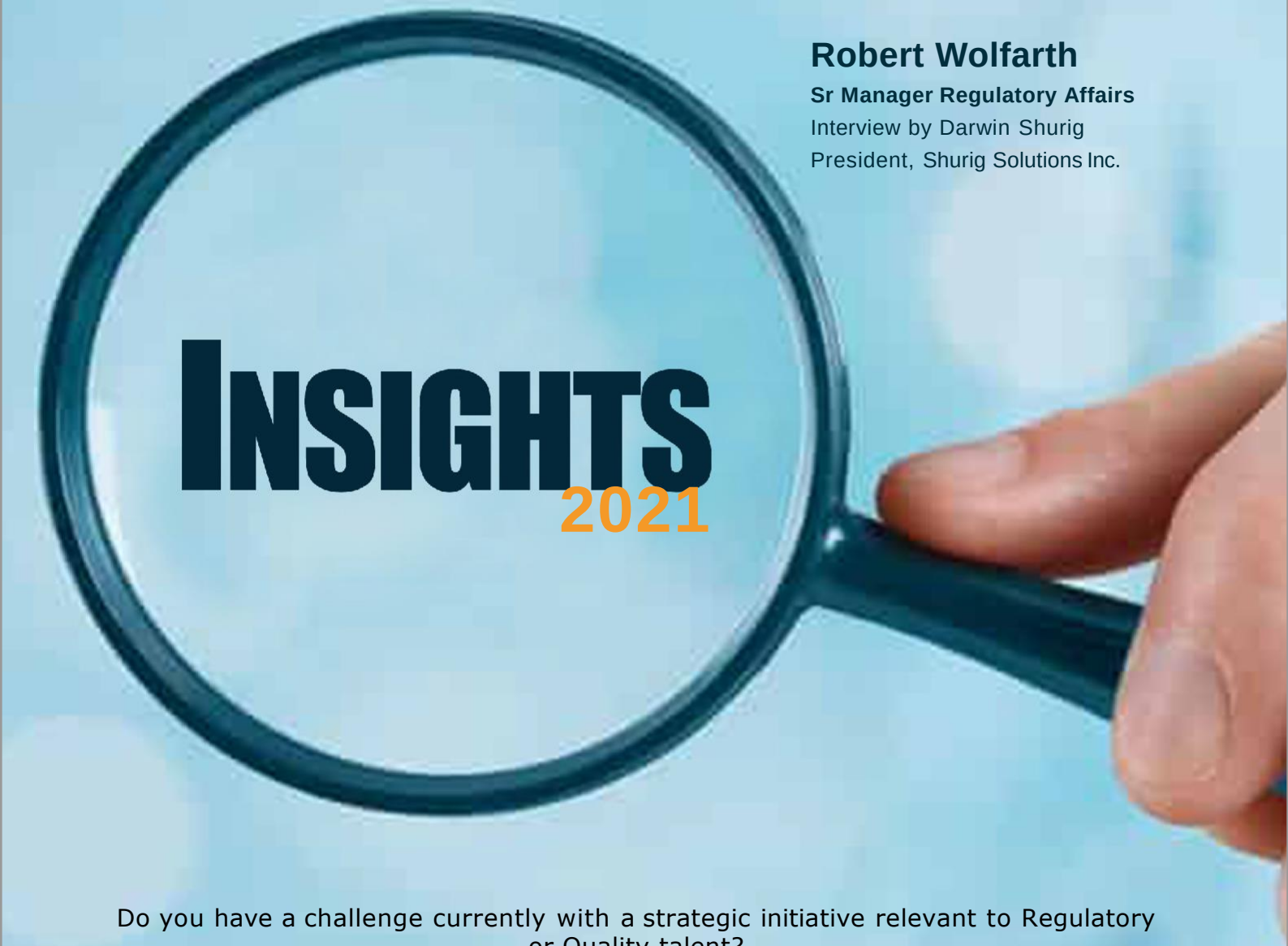

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DARWIN SHURIG

PRESIDENT - SHURIG SOLUTIONS INC.

Darwin understands the key qualities that companies look for in candidates to grow market share, while enhancing their positive culture and team environment. He has a clinical background of over 20 years, including 15 years of sales experience within: medical device, diagnostics, medical distribution, and sleep therapy; 8 years in sales management success; 3 years in operations; and extensive experience in negotiations and business development.

SSI has been growing for over 5 years with a focus on RA, Quality and Engineering within the Medical Device and Pharma industries. With over $2.5 Million in revenue and a 91% offer acceptance rate, SSI is helping companies find unique talent that makes a difference, brings value and decreases the risk of a mis-hire.

Robert Wolfarth

SENIOR MANAGER REGULATORY AFFAIRS

Robert holds a double bachelor of arts in International Economics and Russian Language from the University of Texas at Austin. After six years of foreign policy/defense/intelligence work for the US Congress in Washington, Robert moved into the medical device industry where he has worked for 28 years, mostly in cardiology and orthopedics. In Salt Lake City, he was Director of Regulatory Affairs and Quality Assurance for eight years for Amedica Corporation and Regulatory Affairs Principal Project Manager for Edwards Lifesciences before joining Merit Medical in 2015 as Senior Manager, Regulatory Affairs. He held an adjunct faculty position at Utah Valley University where he taught graduate-level regulatory affairs and developed curricula, and has received his Certified Quality Auditor certificate. He is involved in many trade organizations and also has held a private regulatory consulting firm. Robert was the founding Chairman of the Utah Chapter of the Regulatory Affairs Professional Society (RAPS).

As a congenital heart defect patient, Robert wishes to dedicate his life to helping others gain access to the good medicine and resources that saved his life. To pursue this beyond his employment, he supports many charitable activities as a Scottish Rite Freemason and a Shriner in his community. He is a past Grand Master of Freemasons in Utah (2017). He has published many articles internationally and delivers speeches on issues of ethics and philosophy, served as editor of several journals, organized and/or presented at many conferences, and has traveled to over 30 countries. He is fond of good music, ethnic foods, laughter, walks in the forest, good deeds, dinner with friends, and fine port. Robert adopted a boy and a girl in China.

Link to Full Webinar

MedTech: Medical Device Classes

Robert: In 1976, the FDA implemented a system of regulations which delineates all medical devices into one of three classes. These device classes are based on their risk to the patient. The first class dubbed Class 1, captures the low-risk devices, so examples of these would be a bandage or a tongue depressor. Class 2 devices are not surprisingly the medium risk devices, for example a blood pressure monitor or perhaps a surgically invasive device but one that's only invasive for a short period of time. So, there could be in the Class 2 some risk to the patient, but it's not going to be catastrophic risk.

Video Link

Darwin: I always think about that in terms of the EKG machine or something that affects the patient but is not invasive. (Continued on video)

Class II/510(k)

Robert: Let's talk about the medium risk category, which is unique in its approach. No other country in the world has designed a system the way the FDA did to address these mid-range devices. Class 2 devices are brought to market by claiming and proving to the FDA that your device is 'substantially equivalent' to another device, or what they call a predicate device, which is already on the market and has the same indications for use as yours, so you're putting them side by side and saying ours is substantially equivalent to theirs. The process for convincing the FDA that your device is substantially equivalent is through preparing and submitting a large set of documents collectively called a Pre-market Notification, but it's far more commonly known by its reference to the section and the regulations that addresses this process called 510(k).

Video Link

Darwin: In terms of 510(k) submissions, I read that anywhere from 45-48% of them are denied oftentimes because of something being wrong in the submission in one of the sections that was left out.

Robert: Yes, in fact there's a screening process where the FDA will kick it back to you if it doesn't even have all the basic elements they expect to see. (Continued on video)

Classes

Emergency Authorization Access

Robert: Emergency Access devices are allowed for medical countermeasures to national emergencies; that's what they're designed for and COVID 19 is one of those, but it's only used when there are no alternatives. So, under the emergency access program FDA commits to an accelerated timeline of review of your submission. I have a little bit of experience with these, and frankly it really wasn't that accelerated. We did have their attention more, so there's more back and forth interaction with FDA, but in terms of overall time at least in our case it wasn't that much.

Video Link

Darwin: In terms of emergency authorization for some of these different products that are going on, it doesn't mean final approval yet. You're getting that authorization to use it, but there's still additional data that needs to be collected and reviewed before that final authorization is completed. So, I'm real curious to see how that plays out because there's been quite a few products that have gotten that during the pandemic.

Robert: That can be the case. They can give you the go-ahead to market it but only under these circumstances or only to a limited population. It's kind of a gray area before you get the final approval, you can get the final clearance to market it, but it doesn't always happen that straightforward.

510(k)Submission Types: Standard, Special & Abbreviated

Robert: There are three types of 510(k). The first is the traditional 510(k). This is the original type. The basic format of this hasn't changed much over the years although the data that's necessary to support one has become a lot more rigorous over time. This traditional type is used for all new devices or devices that are already on the market and have substantial changes. You compare your device to a predicate device that's on the market and try to show that yours is substantially equivalent to theirs when used for the same purpose. The FDA tries to have a decision back within 90 days on the traditional, they are not bound by any law to do that. That's a goal. They want to, it makes them look good to their bosses and so forth, but it's not a hard and fast rule. (Continued in Video)

Video Link

FDA request for additional information

Robert: So, when they do accept your 510(k), consider it likely that you will be asked for additional information sometime during the review. No matter how complete you think your submission is, you may have written a brilliant 510(k), they are likely to come back and have some kind of question. This request for additional information sometimes comes as an informal email or a phone call, sometimes it comes as a lengthier AI letter (additional information letter). If you get one of those letters, that will typically stop the clock of the review cycle so, if they're in a 90-day review cycle you might hear silence for 80 days and then you get an AI letter. (Continued in video)

Video Link

Darwin: How much time do you have before you have to get your responses back to them? (Continued in Video)

Strategies for working with FDA on submissions – part 1

Robert: Let's jump into some strategies for the 510(k) process. What are some tips and tricks for success? How do you maximize your chances for successful clearance to market your device? Here's a little nuance notice: I said 'clearance' and that words are important to FDA. 510(k)s are cleared, they're not approved. If somebody in your marketing department wants to say this is 510(k) approved, be careful. FDA can get bent out of shape about that. PMA devices are approved, 510ks are cleared. A subtlety but important to FDA. (Continued on Video)

Darwin: I think that's a great example, a huge aspect of Regulatory Affairs as a profession is that emotional maturity, how you de-escalate risk and how you lead stakeholders. Obviously, you don't have to be an expert at every single section. You're having people that support you in those different sections, but you've got to understand all the data that goes in there and to your point being able to defend.

Video Link

Robert: Exactly, there's a perception, I think it's kind of a standing joke among regulatory professionals that other departments picture us as simply taking data from all other departments, pull them together, and mail it off. Why do we pay these people to do this? (Continued in Video)

Strategies for working with the FDA on submissions – part 2

Robert: If you are listing numbers, present them in tabular format. It's easier to understand numbers in a table than it is strung out in a paragraph. FDA loves tables, before and after tables, side-by-side comparison tables, all kinds of tables. It's cleaner and gives it better structure. Jpegs of your devices, isometric drawing, its packaging, maybe a drawing of it being used, maybe side by side drawings of your device and the predicate device, visuals are very helpful to the reader. (Continued in Video)

Video Link

Darwin: In FBI negotiations they always have more than one person because you're more likely to miss something if you just have one person. We have those checks and balances here for sure.

(Continued in Video)

Pointers on Communications with the FDA- Part 1

Darwin: What's been your experience in terms of percentage of interactions with email versus on the phone having a conversation?

Robert: I would say most everything starts out by email. That's been my experience. I like having something in writing. It's not just to document, and that's important. You do want to document what FDA is looking for, but it helps if you need to forward that email over to the engineer who designed this. It's great to be able to capture the exact wording of what FDA said and just forward it over to them and they can look at it, rather than you remembering what was said in a phone call and something getting lost in translation. (Continued in Video)

Video Link

Strategies

Pointers on Communications – Part 2

Robert: FDA still has rules for when and how to reach out to them. There's a guidance document that helps with communication with FDA. But they are openly encouraging more early interaction with them so that you don't get to the end of the regulatory submission, only to find out that they don't like your whole approach to that topic. (Continued in Video)

Video Link

Darwin: I always say, every time you interact with somebody either gain credibility or you lose it.

Robert: If you ask for too much time, they will let you know, so ask for the time you think you need and see what they say. Before you hang up the phone, be sure that you're very clear on what they want. You don't want to think you know and then have to go back and contact them again. (Continued in Video)

Pointers on Communications – Part 3

Robert: Don't offer to send them more information than they asked for. That could lead you to unnecessary questions and delays.

Darwin: That ties into the de-escalating piece in terms of how you answer questions the right way, and if you don't answer it the right way or you don't sound confident on what you're talking about it's going to lead to more questions. So, in terms of offering something that they didn't ask for, it goes along the same lines of de-escalation versus an additional light on something you didn't need to.

Video Link

Robert: Another point: don't try to give them a lengthy explanation on the phone, if you are on the phone with them, try to keep answers relatively simple. Most answers they're going to want in writing, and certainly if it's something complicated, they're going to want it in writing.

(Continued in Video)

FDA Q-Sub Meeting

Robert: The Q Sub Program grew out of the Pre-IDE Program so, when you're putting together an IDE to support a clinical trial, the FDA realized that this is a very useful program to have a Pre-IDE discussion. They broadened it into the Q Sub Program and through this program you can arrange to have a discussion with FDA before you send in your 510(k). (Continued in Video)

Video Link

Communications

510(k) vs PMA

Robert: The PMA process could hardly be more different. Rather than trying to prove that you're substantially equivalent to a predicate device, you're starting from scratch with your own device. You don't care that it's equivalent to another device. In fact, you can claim that it's superior to another device if you want, as long as you can prove it in a PMA. You can't do that through a 510(k). They will not clear superiority claims. If you put superiority claims in your 510(k), the FDA is not going to clear it. They're looking for equivalence, with a PMA it's whatever the data shows. If your data shows that you're equivalent, they'll ultimately approve the PMA and allow you to claim its equivalent.

Video Link

Darwin: That's why it costs so much more because you've got to gather that data, do the trials.

Robert: Exactly. If your data does show that it's superior or non-inferior (those are two different things), then submit that data. If it's solid, if FDA agrees they'll approve that, and you can put that in your marketing literature. That's not an option with a 510(k). PMAs are as you expect far more complicated. The FDA user fee is about $12,000 for 510(k), $365 000 just the user fee, for a PMA. That's a drop in the bucket. You can expect to spend $20 to $25 million dollars total, because not only do you have to do extensive bench testing, possible animal testing, but you're very likely to need a full comparative human clinical trial to support your PMA. (Continued in Video)

Pandemic Perspective:

Darwin: Give us some things that you've seen in terms of working remotely, managing teams remotely and how the pandemics affected you?

Robert: I'm in mid-level management. I've actually been in management probably 18 years and before the pandemic really surfaced, I had a couple of direct reports that were remote from my location. So, I had a little bit of experience with that but of course my company, like probably most companies, as soon as the pandemic hit, we all went home. (Continued on Video)

Video Link

Darwin: Last number I saw was that 54% of the United States is working from home.

Robert: That's very impressive. It was a grand experiment for my company.

(Continued in Video)

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