How to Enhance your Medical Device Approval Process: Interview with Sheila Heyer, President of Heyer Regulatory Solutions

In this interview with Sheila Hemeon-Heyer, President of Heyer Regulatory Solutions, we learn where medical device companies are missing the mark when it comes to the FDA approval process. So, who is Sheila Hemeon-Heyer? Prior to starting at Heyer Regulatory Solutions, Sheila's most recent position was the VP of Global Regulatory Affairs for Boston Scientific. This is what we are going to learn in this interview with Sheila:

- The three most important steps you can take right now to get your medical device approved faster.
- Quality submissions and solid relationships. The importance of honing these two concepts in order to enhance your medical device regulatory approval process.
- What characteristics do great medical device regulatory professionals all have in common?
- How can the FDA and industry work together to improve the regulatory process for medical devices?

Scott Nelson: Hello, everyone. It's Scott Nelson, and welcome to Medsider, home of the free personal medical device MBA, and on today's call, we have Sheila Hemeon-Heyer, or Sheila Heyer, who is the President of Heyer Regulatory Solutions. Before she started Heyer Regulatory Solutions, she was most previously the Vice-President of Global Regulatory Affairs with Boston Scientific. So, without further ado, welcome to the call, Sheila. Appreciate your coming on.

Sheila Heyer: Thanks so much for having me on.

Scott Nelson: So, let's start with a little bit of background about what you're currently doing now with your company Heyer Regulatory Solutions.

Sheila Heyer: Oh, sure. Thanks. Well, I started this company just about a year ago and my goal is to bring my experience in regulatory affairs to companies out there that really are in need of some good regulatory strategy, solid help with submissions, with the pre-market and post-market compliance side of things, and really I just love working with a wide variety of clients and helping them to solve their regulatory problems.

Scott Nelson: Very good. That's a nice overview. Now, you work specifically with medical device companies.

Sheila Heyer: That's correct.

Scott Nelson: Okay, and is there a certain type of company demographic in regards to size or where they're at in terms of the regulatory process?

Sheila Heyer: No, not really. As I said, I love the variety. I love working with companies at all stages, so the startups that are really exciting, they're getting their product going, they're really starting to weed their way through the regulatory morass. It can sometimes seem like a maze that you're in and just don't know how to get out of, and so it's really exciting to help those companies to position their product into the best possible light to really understand the regulatory requirements and help them through that process to successfully putting sometimes their first product on the market. That's really exciting.

Then you have larger, more established companies that sometimes just are in a period when they have their own regulatory and compliance staff but for some reason, they need to bring in some outside help, either because they have so much to do they need some extra hand or they need a fresh eye on their product to help them with a new strategy, or in actually many cases nowadays, they have encountered some problems primarily with FDA on the compliance side of things and need some folks to come in and help them solve their problems.

So, I really work with a wide variety of companies and a wide variety of technologies. I think my background is general enough that I can take pretty much any type of device and help a company figure out what's the best pathway to market.

Scott Nelson: Okay, and are you biased towards a particular specialty within the device space, whether it's cardiovascular or orthopedic, etc., or do you kind of work with all different realms?

Sheila Heyer: Again, no. I don't limit myself to a particular specialty. My background, I've been in this business for over 25 years now and spent 15 years of that as a consultant with Medical Device Consultants, Inc., and again, there I got a wide variety of experience. At Boston Scientific, the last six years, of course, Boston Scientific is primarily a cardiovascular company, but they also have a large neuromodulation group, they have an endo-surgery group, so even there, again, a wide variety of experience, I don't really feel like I want to limit myself to any particular specialty. Too many exciting new technologies out there.

Scott Nelson: Okay. Yeah, very good. That actually provides a nice little segue into your background. I don't want to spend too much time kind of digging into the smaller details, but the bottom line is you spent in essence so much of your whole career within the medical device kind of regulatory niche, and can you just kind of go back a little bit and provide an overview into your background leading back to like kind of your undergrad and then kind of the steps along the way?

Sheila Heyer: Sure, no problem. So, my undergraduate degree was in biomedical engineering and then I also got a master's degree in biomechanics, and when I'd finished my master's degree I found myself in Washington, DC, and was really fortunate to find out that the FDA had an open hiring window. The government from time to time will give FDA the ability to hire a certain number of folks, and I just hit at the right time and was hired to work in the Office of Device Evaluation as a scientific reviewer.

So, that was my first entry into the world of FDA and really started from scratch. I really didn't know what FDA did with respect to medical devices, so it was a great education I was in working

with orthopedic and restorative devices, and also surgical lasers, so learned all about the FDA regulations. I had actually done some clinical study work prior to joining FDA, so I was able to review clinical studies, IDEs, 510(k)s, PMAs, so it was a great education and I loved working for the FDA.

My situation changed, and we ended up leaving the DC area, and that's when I started working for MDCI and worked as a consultant for many years. Then along the way, I decided I wanted to go back to school. Didn't have enough to do. So, I went to law school. I really looked at what would be the best pathway for me, and I loved combining my engineering and science background with the law because that's essentially what I was doing anyway, you're interpreting law and regulation and applying those laws and regulations to the science.

So, the law degree just seemed to fit perfectly, and it did. It helped me a lot. It helped me in terms of my analytical thinking skills, my writing skills, being able to look at two sides of the situation, and being able to anticipate questions and holes in your arguments, and that's a lot of what we do in regulatory. The science background is very important to a good regulatory professional because you have to understand the technology, but also being able to present the product to an audience.

I'm talking about the reviewers, who may have some understanding of course of the technology because you'd be presenting it to the reviewer within a particular medical specialty, medical area, but they may not know anything about your device, so you have to be able to clearly present that information. You have to be able to make sure that you're complying with the regulations and the expectations of the reviewers. You have to anticipate what type of questions the reviewer might ask, what type of risks there may be within your submission. So, I bring the law degree, and that experience really helps me to best be able to formulate that submission and comply with the regulations.

Scott Nelson: Sure.

Sheila Heyer: So, anyway, I did that along the way and then was very fortunate to be able to join Boston Scientific, which is a great medical device company. I got a lot more experience in terms of global submissions. I was able to head up a wonderful group of regulatory affairs professionals, and not only in the US, again, but all over the world. So, that was a phenomenal experience for me.

Scott Nelson: Very good. Thanks for providing that background. So, in summary, right after your undergrad you spent some time with the FDA as a reviewer, spent about 15 years roughly with Medical Device Consultants, Inc., got your law degree along the way. I like how you put it, time wasn't an issue along the way, so you decided to go ahead and get your law degree, that's great…

Sheila Heyer: Well, I continued to work. I did that part-time.

Scott Nelson: Yeah. Right.

Sheila Heyer: I continued to work in the regulatory field.

Scott Nelson: Right. Then most previously, prior to starting Heyer Regulatory Solutions, which is your own company, you were with Boston Scientific for about five years as the Vice-President for Global Regulatory Affairs. So, needless to say, you're well-versed in the medical device regulatory arena.

Sheila Heyer: Yeah, it's a great field to be in. It's constantly presenting challenges.

Scott Nelson: Yeah, no doubt. So, when you were explaining the benefits that your law degree has within your career, your regulatory colleagues that you've worked with over the years, some of the better ones that you've worked with, do they have a law degree as well? What stands out to you in terms of like characteristics and background that when you look at some of your colleagues that you've worked with along the way, in terms of making someone really good within the regulatory space?

Sheila Heyer: You know, there certainly are some regulatory professionals that have law degrees, not many. I haven't really met too many others, and probably because it's not a career that you have to have a law degree to practice in as compared to, for example, patent law, which I find to be very similar in terms of what a patent lawyer does. They represent a client to a government agency, they write patent applications, and ironically, you do have to have a law degree to practice in that space. You don't in the food and drug law space. Now, there are a lot of law firms that have food and drug lawyers who do a lot of what I do, but anyway, you don't have to have a law degree to be a regulatory professional, so there probably aren't that many.

You asked a great question about what makes a good regulatory professional, and I used to say when I was at Boston Scientific and if we were hired into a position, particularly an entry-level position, what I would look for first and foremost would be a science background. I do think it's important for a regulatory professional to have a science or engineering background so that they can talk with the folks they're working with, the R&D folks, the manufacturing folks.

Scott Nelson: Yeah.

Sheila Heyer: But beyond that, good writing and analytical skills are key. You have to be able to communicate clearly, in written word first and foremost, but then also verbally as well because a lot of what you do is interacting with the regulators on the phone, in meetings. So, that's what I would look for. Then, you know, I could teach someone the regulations. I didn't always need to have someone to come in already knowing the regulations. That you can teach someone. But good analytical, good writing skills, good verbal communication skills are really key.

Scott Nelson: Okay, and so that provides a nice little segue into really the regulatory environment. There's so much buzz and I'm sure you would agree, and we talked a little bit about this in our pre-interview. There's so much buzz going on about the 510(k) submission process, the medical device user fees, etc., etc. It's almost endless the number of headlines that I read on

a daily basis that pertain to the regulatory environment. So, I'm going to ask you to make maybe a general comment about that, and then maybe we'll get into some specifics.

Sheila Heyer: Sure. Well, 510(k) has certainly been in the news and we can talk quite a bit about that. I think what's happening there, of course, is that as we advance in every new technology coming out all over the place, and it's a wonderful technology for patients, we're trying to figure out how these fit into the current regulatory paradigm in the US. We have these two pathways, we have 510(k) and we have PMA, and traditionally 510(k) has been thought to be the quicker pathway because it essentially was designed for "me too" devices.

But a lot of these "me too" devices now have new materials, new methods of operations, so forth and so on, so even though they may fit within a 510(k) classification, the new technology may raise very new questions, and so FDA has been asking for more and more data under a 510(k). So, many times a 510(k) now looks very much like a Class III PMA, and companies have struggled with that but it's understandable. The FDA, their charge is to protect patient health, to protect the public health, and they struggle. They are scientists. The folks at FDA are bright folks. They take their job very seriously, and again, they don't always understand a device, and so the companies need to work together very closely with FDA to understand why FDA is asking for more data and to really work with FDA to get their products to market.

So now, getting back to the buzz about 510(k), getting a lot of criticism about the process, it's taking a lot longer, and so FDA has proposed several changes they'd like to make to improve the process. Many of those were acceptable to the industry. Better training, for example, better guidance, clarification of different terms. So, I think that if the industry works together with the FDA, we can come out with a better process.

Now, interestingly, the Institute of Medicine did do their evaluation of the 510(k) process and their recommendation was basically to scrap the 510(k) and start over, come up with a new paradigm for lower-risk products. That was not received well by the FDA or by industry. The feeling was I think that that was just too drastic at this time when FDA is strapped for resources when they spent so much time trying to fix the process. I don't think the recommendation to start over was received very well. So, we're not sure how this is all going to come out. The IOM issued their report over the summer and FDA is still digesting it, still working to propose what they want to do on the 510(k).

Scott Nelson: Sure.

Sheila Heyer: I think on that issue we do need to stay tuned, and as I said, I think if industry and FDA are willing to work together, we can come up with a really good process.

Scott Nelson: Right. So, in essence, you've got on the FDA side, as you mentioned before, they're obviously acting in the best interest of the patient, which is completely understandable, and I think the industry would agree in that a lot of their messaging is, ultimately, we want to develop new technologies for the patients. So, you have two different sides, but the problem on the industry side is the submissions are getting longer. It's taking longer to get approval. Certain

devices have been approved in the EU and they've had a CE Mark for years and years before they're even approved in the US. A lot of companies are beginning to seek approval OUS and even go IPO OUS, and it all stems back from a regulatory standpoint. So, other than enhanced communication or working together, are there certain things that really stand out to you that would be really valuable for the FDA to maybe do, and then also industry to do in order to come and try to make this work?

Sheila Heyer: Yeah, sure. So, I mean, what you described, certainly we've seen a lot of that lately, and it's a result of the pendulum, as I like to say, the pendulum swinging way over to one side where FDA is now and has been for a while in much more of an enforcement mode and also hiring a lot of new reviewers. They were criticized quite a bit for presumably or allegedly letting some products on the market that may not have been as safe and effective as they could've been. There are all kinds of reasons, but it is certainly true that the FDA reviewers are asking for more data, more questions, and it's very frustrating to industry.

So, how can we address that? I don't want to sound Pollyannaish, but it is true that companies need to make sure that they foster or develop a relationship with their reviewers. Respect the reviewers, respect their position, and make sure that the submissions are as complete and clear as possible. I've had some really good experiences recently with submissions. We have a PMA that I can't go into detail on but it was novel breakthrough technology and FDA was very excited about it, and the company was able to work with the FDA to get this PMA approved within, I think it was nine months from the date of the last module, and it was an innovative technology that FDA was actually quite proud of. They want to see themselves, and they do see themselves as a science-based organization, and they want to help companies get innovative products to market.

So, this is a very good experience I had. I know a lot of companies have not had as good experiences in some cases and may feel like they are being asked over and over again to answer the same questions. I haven't really been involved in any of those situations, so I don't know what the root cause was. Personally, in my experience, I have found that if you keep the lines of communication open, work with the reviewers, go in and meet with them as much as possible, bring your product in, do a show, and tell. Sometimes reviewers can get stuck on something, and then if you're able to really explain to them how it works, it's like I just turned the lights on. It's like, "Oh, that's what you're talking about."

Remember, these reviewers haven't been involved in the development process of this product. They don't know the product inside and out. On the other side, it is certainly true. Some of the frustration arises, especially on the 510(k) side where companies feel that the reviewers are asking more and more questions really so they can understand the technology and that I'm not necessarily, in the eyes of the company, needed for a conclusion of substantial equivalence. So, they're kind of applying the PMA level of safety and effectiveness to a 510(k) situation.

Scott Nelson: Okay.

Sheila Heyer: That does happen, and that can be very frustrating for a company.

Scott Nelson: Yeah. So, in listening to you describe the situation, I guess I'll start with one question that kind of leads to my second question, but it almost sounds like, and I've kind of long thought this in being involved in the device space on the industry side. There are certain companies that seem to get devices approved with relative ease, and one is that true? Do certain companies have better relationships with the FDA than others? Then, two, does that relationship really matter? Does it make a big difference in how the people and the professionals that are submitting or formulating the request for approval, do their relationships, and the way they submit, does it matter? Does it make a big difference?

Sheila Heyer: I think it does make a big difference, but I think the relationship relates back to the quality of the submission and the quality of the testing that's been done. FDA says all the time that one of the reasons they're revamping the 510(k) process and the difficulties they have is that they do receive a number of submissions that are of very poor quality, and I have to believe that that's true because when I was at the FDA I saw a number of very poor submissions. They may have met all of the requirements, but very poorly written, missing appendices. You make a reference to somewhere in the document and you go look for it and it's not there; submissions where you open it and you start reading and you're like, "What are they talking about?"

Scott Nelson: Yeah.

Sheila Heyer: I have to admit, in my career, when I've received documents from companies, sometimes I have the same reaction, and I have to spend a lot of time working with the company to write the submission or write the test reports in a way that's going to be clearly understood by the reader. You need to write to your audience.

Scott Nelson: Yeah. Just to stop you real quick, that goes back to what we mentioned earlier in terms of what makes a really good or a really great regulatory professional, is the writing and verbal communication.

Sheila Heyer: Correct.

Scott Nelson: I guess that's a great point. I just wanted to mention that real quick. But go on, I'm sorry for interrupting.

Sheila Heyer: The quality control, I can't say enough, the quality control on submissions is very important, and to be honest I don't see a lot of it in companies. A lot of companies for very good reasons are pushed to get the submissions in quickly, which obviously time to market is very important and I understand that, and sometimes they'll cut corners. Sometimes they'll decide to put in a submission, a 510(k), without a particular test report, for example, because they haven't finished that yet and they have some deadline they need to get the submission in by.

Well, that's fine, but the company needs to understand that that is going to probably mean a delay on the other end because that is going to mean that the reviewer is going to ask for that anyway, and these reviewers are very smart. They've seen submissions from all different companies, and they know what they're looking for. So, they're going to probably ask for that

test report that you omitted anyway or if the submission is not well written, not clear, you're going to get a lot of questions, and that's just going to add time on the other end. So, my approach has always been to make sure that the submission that goes in is as complete and clearly written as possible at the outset. You can't have a perfect submission obviously. If you did you'd probably never submit.

So, there are some times when you have to submit maybe before you'd like to, but then you need to highlight okay, what are the risks of submitting early, and make sure everybody understands. But I don't see a lot of companies, I don't see formal quality control procedures in place for their submissions. There should be a formal procedure. There should be a review by someone not involved, who didn't write the submission. It can be internal. It could be external. There should be a review in place. There should be a procedure that governs that review, that governs what they're looking for when they review that submission, and there should be a formal approval that says, yes, the submission is ready to go. It's complete, it's clearly written, it meets the regulations, there's nothing missing, so forth and so on.

Scott Nelson: Yeah. So, maybe in essence spending a little bit more time and effort upfront is most likely going to lead toward a more efficient approval process.

Sheila Heyer: That's always been my belief, and that belief has borne out in actuality.

Scott Nelson: Sure. So, that's interesting because, in essence, you're in kind of a unique position you're often coming in as a third party to small or large medical device companies in order to help them with a certain submission process or regulatory process, I guess it's the same, and so you can see okay, what's been submitted on behalf of the company, and then what does the FDA look like and what are they coming back from, and you're obviously playing a consulting role. So, are you saying that submissions a lot of times, that the reason the FDA is asking for more information, more questioning, is not necessarily a change on their behalf, it's more so the quality of the submission is just poor or is missing a lot?

Sheila Heyer: Well, I definitely do see that. Even when the submission is a good one though, there are often still a lot of questions. Again, it's hard, a company can't always anticipate what everything a reviewer is going to ask, and so even with a good submission, you're likely to get questions. I think it's very rare that you ever get a submission through the FDA without at least one round of questions. You want to try to minimize those as much as possible, and you'd like to try to handle those questions interactively with the reviewer. That's where the relationship comes in.

FDA does have this policy and procedure in place for interactive review. The first round of questions really should be through a phone call, email, much more interactive, and if you can keep the questions on that level so that they're pretty quick, straightforward, you can answer quickly, that's going to save yourself a lot of time. It should only be if you have a situation where there's a large deficit in the submission or some testing that the FDA wants you to do that you didn't do that you have a submission actually be put on hold with a formal request for additional information letter. I guess, to answer the question, it can be for a variety of reasons, but you'd

like to get a submission through without any questions but it's probably not going to happen right now given where FDA is.

A lot of these questions; remember that FDA hired a lot of new reviewers too, and a lot of very high-level folks, many of whom come out of academia. That's the other thing to remember, that there's a vast minority of reviewers that actually have ever spent any time in the industry. So, most of the reviewers are coming at things more from an academic, theoretical point of view. You find that the folks who have been in the industry, generally it's much easier to deal with them because they understand the process a lot more. But that's another thing for companies to keep in mind when they get these questions. Sometimes you get questions, just as I said, FDA sometimes gets submissions and can't understand them.

A lot of times companies will get questions from reviewers and they can't understand the question and they're like, "Now, where did this come from," or "what are they trying to ask?" That may be because the reviewer again is not really familiar with the device or even the development process that the company went through. So, if that's the case, again this is where communication and relationships come into play. Pick up the phone, call the reviewer, say, "I got your questions, thank you very much, but let's go through them so I can make sure that I understand what you're asking." Then don't go away from that phone call until you're really sure what the reviewer's asking and how you're going to answer that question.

Of course, there will be times when you really feel that the question is not appropriate or the request is not appropriate, like reviewers asking the company to do some additional testing which the company feels is not necessary. So, there is an escalation process at that point. Again, respectfully, transparently, but you can go above the reviewer to the Branch Chief. Go up the chain of command. If that doesn't work, there is the Ombudsman in the Office of Device Evaluation. There are steps companies can take.

Scott Nelson: Okay. This is a nice way to reach a conclusion here. Looking at the next few years as the regulatory process is only going to become more and more important, and because the overwhelming majority of the people listening to this call are on the industry side. Are there one or two things that really stand out that if you were talking to the Vice President of Regulatory Affairs at Medtronic or St. Jude or even a smaller startup company, what's the one or two things that really stand out to say, you need to do this and this in order to really make for a better submission and approval process with the FDA?

Sheila Heyer: Well, a lot of it I think I've already discussed, so a lot of this will be repetitive…

Scott Nelson: Right.

Sheila Heyer: …but planning is key. Make sure that from the outset you have a good plan in place to make sure that the product is going to be developed and tested to meet the regulatory requirements. First of all, developed and tested to make sure that the device is shown to be safe and effective, but also to meet the regulatory requirements. When I counsel clients' companies, I want to make sure they're not doing the development work just to meet the regulatory

requirements. Companies come to me and say, “What test do I need to do to get this through the FDA?” And I say, “That's not the way you should be thinking. You should be thinking, “What test do I need to do to demonstrate all of the performance specifications for the device?” Out of that will fall the tests that the FDA needs to see.

Scott Nelson: Okay.

Sheila Heyer: Okay, so don’t design and test your device just for the FDA. You have to do good science, good device development, and testing. But along with that also, of course, you have to be familiar with what the FDA is going to expect for that particular type of device, regulations, guidance documents. There are a number of guidance documents out there. Look at what your competitors have had to do to the extent that you can get that information. Open a dialogue with the FDA as early as possible, especially if it’s a novel technology or there's something different about the device that you’re developing.

Have an early meeting, but also make sure that when you go into a meeting with the FDA, you provided them with enough information ahead of time so that you can have a good dialogue. The waste of time to go into a meeting and a lot of companies will send the FDA a PowerPoint presentation the night before the meeting, and then expect to have a good dialogue. Well, if the FDA hasn’t had time to understand your product and specific issues, it’s going to be a waste of a meeting. They’ll just sit there with blank looks on their faces. So, make sure you do your planning, your pre-work, have meetings early, and as often as FDA has time for, and again, keep the lines of communication open throughout the process.

Scott Nelson: Okay. Now, that’s great stuff. In conclusion, to sum up, this whole interview, Sheila, you’ve had a ton of success, experienced a lot of success along the way throughout your 20-plus-year career in the regulatory space specific to the medical device arena. Are there a few things that stand out that you’ve really done well in order to experience all this success?

Sheila Heyer: Oh.

Scott Nelson: I’m going to put you on the spot a little bit. I guess the easier way to ask that question is…

Sheila Heyer: Yeah. Again, I just stay so excited about this field because it’s a great field to be in. There are just amazing technologies out there. What companies are doing continues to amaze me and I just love being a part of an industry that exists to help patients’ interest, to further patient care. So, it’s a great industry to be in. Anyone out there that is thinking about going into regulatory affairs, again it’s been a great career and I love combining the science and technology with the legal and regulatory and analytical side of things, so it’s a great career and it’s a great industry.

Scott Nelson: Sure.

Sheila Heyer: I've seen it go through lots of changes. We're in this period of FDA enforcement and more data and more data, and this may continue, but also I've already seen a little bit of the pendulum swinging back the other way. We've gone through these cycles before, so companies should just keep on doing what they do best.

Scott Nelson: Very good. For those listening that want to reach out to you with questions or maybe even bring you on as kind of a third-party team to their particular situation, where is the best place to reach out to you? Is it via LinkedIn? If so, for those listening I'll make sure to add that link in the post online. Is that the best way to reach out to you?

Sheila Heyer: Sure. LinkedIn is good. My email to my company is Sheila, s-h-e-i-l-a@heyer-regulatory.com.

Scott Nelson: Okay, Sheila, s-h-e-i-l-a@ heyer-regulatory, that's h-e-y-e-r-regulatory.com.

Sheila Heyer: That's correct.

Scott Nelson: Great. So, I'll make sure to link that up in the post, but those are the best places to reach out to Sheila. So, Sheila, I'll have you stay on the call here but thanks a ton for doing this interview. I thought it was great. I have a decent overview of the regulatory process, but this was like you provided some great insights. We could probably do a whole other interview just on some of the questions that I asked you specific to certain things the medical device companies can do to improve the process. Anyway, thanks a ton, Sheila. I really appreciate it.

Sheila Heyer: Thanks, it was fun.

Scott Nelson: Alright, and thanks everyone for listening. Until the next edition of Medsider, take care.