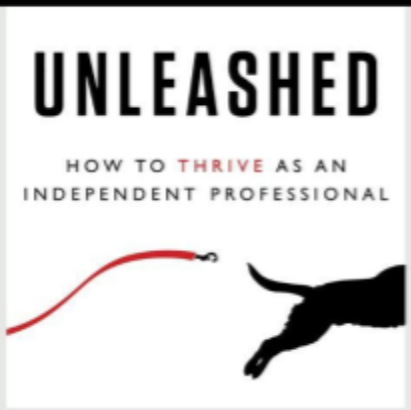

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KATRIN SIEBENBUERGER HACKI ON LIFE SCIENCES CONSULTING

EPISODE 169

Will: Hello, Katrin. Welcome to the show.

Katrin: Hey, Will, how are you doing?

Will: I'm doing great. Katrin, when we met in Zurich and were chatting about your practice, I was fascinated and delighted that you agreed to come on the show to talk to me about it in more depth. Maybe before we dive in, just give us a quick overview of your practice today, and the types of work that you do.

Katrin: Yeah, absolutely. Love to be on the show, thanks for having me. We have a small practice in the Lake Geneva area in Switzerland that works with exciting up and coming life science companies, mostly in the medical device and digital health area, but also some biotech, to help these companies commercialize and get revenue faster. That's what really our purpose is, is to help startups, medium sized companies, organizations, also sometimes multi-nationals, improve their commercialization strategy and improve their go-to-market strategy, and improve their approach to the market ... understand areas and drivers of adoption of their technology and what their potential is, and how they can best capture this potential.

Will: Now, I'm going to reveal my naivety or ignorance here a little bit. Tell me what commercialization strategy sort of means in practice.

Katrin: Good question. In medical devices, especially in medical technology life sciences, there's actually a relatively standard framework that one can use to understand how adoption of medical technology between the actual practical use in the hospital or in a doctor's office, or with health care professionals, how that happens. There's a number of so-called adoption drivers and market development drivers, and there's a number of barriers, basically, that exist that are timed, and that have a specific order to them, that a company that's

aspiring to launch a product business market in this area can understand, and can try to address and overcome in a succinct way.

Katrin: That's kind of the theoretical part of it. The practical part of commercialization strategy, it covers basically everything once the product is developed. The product is approved on the market, the regulatory approval is there. And it covers everything in the clinical data and the clinical proof of concept and the clinical support for the technology is there. And everything from there is covered by what we call commercial strategy. Which means ... Who's my target audience, who's my target user, what's my reimbursement strategy, how do I get paid? What's the benefit for the patients, the physicians, the hospitals, the health care professionals using my device or my product? Which are the geographic markets I want to go in first? What's my opportunity size?

Katrin: How do I access the patients or beneficiaries of the technology ... where are they today? How do they flow through the health care system? How do they relate, where are all the patients compared to where all my users, or my physicians are, my surgeons, or my doctors are? And what type of approach [inaudible 00:03:34] to the market, a direct approach or a distribution approach, or an online sales approach in extreme cases. And what should be my pricing strategy, what's my competitive position, what's my value proposition, how do I monetize the value proposition? That's all that we cover under commercial strategy.

Will: That's a really helpful overview for me. So, that would be one piece of your work. Commercialization strategy also talked about go-to-market strategy. How is go-to-market strategy different than, or does it overlap with commercialization strategy?

Katrin: That's a good question. It overlaps, of course. Because once you understand how you want to go to market, which includes things like unit economics, and understanding what type of distribution or access, market access distribution, you want to get, and you should choose. Once you understand that, you should be able to execute on that. So therefore, they overlap. One is the understanding of economic factors and the market factors. And then the other one is the actual execution and hiring of people, and co-operation with partners, and building of structures, organizational structures and marketing and sales structure.

Will: So, the go-to-market, that's the ... kind of the execution of all those factors?

Katrin: Yes. And the go-to-market is also really understanding ... There's some very helpful ways to think about go-to-market. One of the most common

conversations we have with mostly start-ups, we also work with large multi-nationals which understand this better, but the start-ups understand this a little bit less well. One of the most common conversations we have is, "Oh, we have this great product. Everybody should use it. It solves an enormous unmet need. We are in the process of developing it. A prototype, we're developing. You know, we're in the process of getting it approved for market access, for market authorization. And then we will find somebody that sells it for us." Mostly it's either a distribution partner, or an established medical device or pharma company.

Katrin: That's actually interesting, because first, that's not as easy as it sounds in real life. And second, there might or might not be economic rationale, to be able to do that. So, if you have a product that gets used potentially in a large quantity, but it's not a very expensive product, it might not actually make sense for a single product to have, to build a sales force, or even put it into a distribution organization. Just because there's not enough unit economics, not enough margin per product sold, or per unit sold, that gets generated, to pay for the expenses of this channel.

Katrin: On the other extreme, if you have a product that's very, very rarely used but very, very expensive, and therefore a very high-margin product, you can potentially ... but also probably, complicated to sell, you can have somebody to detail this to the target group, and explain it. And spend a long sales cycle to try to sell one or two units. It's just understanding these dynamics, and the market, and understanding that, towards the customer segments and which segments to target. And how concentrated or diluted the segment is. All of this is covered in the go-to-market strategy.

Will: That's fantastic. This is a very helpful overview for me. Could you ... Maybe we could talk through a case study? We could certainly sanitize it. But pick some sample medical device, and walk us through the different stages that you would go through with the client ... of sizing the market, and looking at what patients, what doctors, and the other aspects that you just went over.

Katrin: Yeah, absolutely. I just had a conversation with a small team in Zurich yesterday. Which highlights perfectly this problem. This is a team of smart scientists that work out of the technical university in Zurich. And they've developed a method to harvest, they're called split-skin grafts, from a patient. These are used for covering smallish, so 4 x 4, or up to 12 x 12 area, of skin that's damaged or wounds that don't heal. And grafting, i.e., taking it from somewhere in the body where there's healthy skin, and putting it on the wound or the area that needs to be covered, and protect it from infection, et cetera.

Katrin: It's the gold standard of treatment. It's the best medical treatment, one of the best medical treatments for these types of conditions, often. And right now, this is done with a scalpel. Often there's some product, they're called dermatomes, that are very expensive, and need to be used by a licensed physician. Can't be used by a technician or a nurse, to harvest these skin grafts. And these are really a great way to harvest them in a standard thickness, and in a standard size, in an easy to apply manner. And they've developed it in [inaudible 00:08:45] coming out of an engineering, basically, approach, that could work or that would work.

Katrin: And that's great. Now their question is, if we target chronic wounds and chronic ulcer patients, or we target, for example, large melanoma [inaudible 00:09:05], these are two immediate applications that come to mind for small skin grafts. And we target, let's say, the top five countries in Europe, which is Germany, France, Italy, Spain, U.K., Switzerland, maybe Austria and Nordics, Benelux ... Who does the skin grafting? What patient groups, sub-groups, are we targeting, and what stage of wound-care do physicians or health care professionals think about grafting? Where are these patients today? Which doctor or physician specialty treats them?

Katrin: What are they using today? How receptive would they be to an alternative method to do the skin-grafting? How big is the small split-skin graft market? How many grafting procedures are done in country ... Germany, for example, per year? And therefore, how big is the market opportunity, and what are unmet needs in physician specialty centers? Dermatologists that have a surgical specialty, or in wound-care centers that do skin grafting, or in a surgical ... let's say a plastic surgeon specialties.

Katrin: All of these questions, they have not really gotten much of any data on. Or any structured approach to think about these questions. But these are absolutely critical questions for them to understand. First, is it even worthwhile to commercialize this product? And second, so for us to spend maybe a couple of years unpaid as officers in the company, and as the team and the company, and second to attract any funding from serious investors, they'll need to answer most, if not all, of these questions.

Will: How would you go about answering maybe the question around, just how many of these procedures are done, and who the doctors are? I imagine for certain types of diseases, there's ... You know, so many people have diabetes, or so many people have lung cancer. But to get something where there may be doing these kind of skin grafts for lots of different diseases, how would you even get started on that, of quantifying that?

Katrin: Yeah, that's the perfect question. That's exactly the challenge here. If we were talking about, even diabetes is not as easy as some, but we talk about, for example, cardiovascular disease, it's much easier to figure some of the data out. There's more public registries, and databases. So there's a couple ways. The challenge here, on this particular disease area also, is that we have a mix of inpatient and outpatient procedures. Right? So, X% of all the skin grafting is done in dermatologist offices or plastic surgeon offices, private offices, or in outpatient centers ... and X% is done in hospital.

Katrin: One of the challenges is always, there's often in countries, even in Europe, is an okayed set of hospitals, so inpatient procedure data, but there's almost nothing available publicly, that's on outpatient procedures. So that's the first thing to also note. The other thing is, this isn't ... Like you say, this is first, not a single indication or a single disease. It's a multitude of indications. And second, within an indication, such as like chronic ulcers, or non-healing wounds, or even let's say, Class 2 or 3 peripheral artery disease with claudication and pressure and ... ulcers, sorry.

Katrin: There's a disease progression, at which, maybe they'll be treated conservatively with dressings and medication and cleaning out the wounds, for example ... for a while, for a few cycles. And then somebody, when that doesn't work, somebody would say, "Now we need to think about other options," as for example, grafting, skin grafting. So, not only is there not one indication, there's also just not a single disease state at which probably 10 out of 10 physicians will say, "This is when we will start the skin grafting process." When you ask 10 health care professionals that deal with these patients, you'll probably get 10 different answers of what the physician criteria are.

Katrin: So that's the challenge here, and we work ... That's the challenge in many, many cases we have. We work with published articles to find out, for one hospital, if there's a study that's published, how that was done. On the type of patients they included and excluded, and how many there were. We get these, this is corroborated. We get ranges of, in general, the distribution of these patients. There's so many Class 2s, so many Class 3s, so many Class 4, whatever class scale we use. Probably around, we'll get a range, and we'll make assumption for this country. We might then make assumptions and extrapolate that for other countries that we think are similar. Although in skin dermatology, that's not very easy to do because the processes and the systems work quite differently.

Katrin: We get, of course, public registries and databases and coding that ... You know, ICB code databases. And in some countries, that's quite well-published. In others, only the top diseases are covered and published. And then,

dermatology often, or derma, skin grafting, isn't on them. We do interviews with people that we have in our network of physicians. How they treat their patients. We do them in a cost-effective manner, because this isn't a company that's able to afford like a large-scale primary market research study. So we get just some corroboration off the initial assumptions and data we make. And usually, what we deliver to these kind of, let's say, start-up clients that we have, we deliver to them a model that's probably a good approximation of the reality.

Katrin: And we will say, "Look, if you really wanted to validate all of these numbers, we'd have to do a larger scale market research. We have our data that we have from various reports, and various projects we've done, from various discussions we've had. And we're pretty sure about this data, but all the other stuff you might have to validate. And that will cost this amount of money that you might or might not want to invest or have. And therefore, either use these assumptions, and then, every time you go and see a potential customer, or you see a potential corporation partner, just ask as many questions on this as you can, and validate it over time, and make sure. You're probably not order of magnitudes wrong ... for this country or that country, or this indication or that indication."

Katrin: This is how we work. So there's a lot of primary research, clinical publications, study research, research on data that's publicly available in hospital, and sometimes a clinic or outpatient clinic treatments. There's a bit of primary interviews with health care providers that have patients, see patients. And then there's a whole lot of assumptions, and kind of just knowledge about how our health care system works, and mapping it out, and then making assumptions about the patient flow and the way they are treated.

Will: How do you go about setting up and sourcing those primary interviews with health care providers?

Katrin: I have a couple more junior people working with me, and like I said, we're a small team of five people. I have a pretty good network in the European physician landscape, so I have actually, many close, relatively close, personal friends that are physicians, that of course I can call for ... if it's in their specialty. In addition, in general the associations for that particular physician specialty, for example, of dermatology ... although that's not necessarily dermatology surgeons, which you need for transplant. But maybe plastic surgeons, for example, the plastic surgeon association.

Katrin: They do have member lists and often it is possible to ... either they'll publish them on their website, or it's possible to check with them to get some names potentially. Of course, there's also just searching for names. Usually we look

at publication rates, and we try to find, so to speak, friendly ... or physicians that we think, either we meet them at conferences directly, and go to the conferences, and actually speak to them after talks, et cetera. Or we cold call and reach out to them and say, "Hey, this is what we're doing. This is for this and this topic, and we would be interested in speaking with you. Would you be available to spare a half hour on a phone call?" Or something like that.

Katrin: Again, I'd like to do that rather through contacts. So if I know one physician in one country, usually they can give me a couple more names. And I can go from there to there to there. But if I have to, I'll just call as often as I need to do, to speak to somebody.

Will: What's changing about this kind of work that you do? This kind of commercialization strategy, go-to-market strategy? Are there new tools that are coming out, new source information, Artificial Intelligence? What sorts of things are changing in your space?

Katrin: Three things are changing. The first thing changing is demand for a data-driven approach. In our industry, which is mostly medical devices, life science, digital health ... not really pharma. Pharma's very different from that. In our area, it was still until a few years ago, it's quite common to say, "Hey, we've done it this way. We know what we're doing. We know these people, and we know these doctors, et cetera. We know what works and what doesn't work." That's not really flying often anymore, because it's more [inaudible 00:19:12] and data-driven and analytical. We see a lot more demand for analytical approaches to understanding.

Katrin: So, sizing the market, understanding the opportunity, mapping patient journey and patient flow. To understanding and ... to customer segmentation, patient segmentation. All of this is now much more requested to be done on a much more quantitative level than it used to be. The second thing that's changing is the ... like you said, the availability and through digitalization, the availability and the relationship between datas. Especially in Europe, where this is a big problem. Because every country and every sub-region publishes their data in a different format. And they're not easily matchable or linkable. That's starting to get a lot better.

Katrin: So now we also have companies [inaudible 00:20:05] service providers of just getting, scraping all the data from all the countries that are interesting, wherever we can get it. Even sometimes going to court to get this data, because they are public records, in principle. And then putting them into huge relational databases, and mapping and linking this data. So there's a lot more of that available. Makes it very confusing for some of our larger clients,

because if they have a lot of vendors knocking on their door, it's telling them that they have all the data that they need.

Katrin: And when you start looking into it, though, you realize everybody has more or less the same data. But not necessarily the data that these companies are interested in. And the third thing that has changed, is that we have a huge amount of digital health start-ups that are coming with machine-learning AI approaches. There's a lot of buzzwords flying, but I do think, especially in image data, image guidance specialties, that we'll see a lot of innovation in making data as the servers a business model in health care. And then, that will ... I don't know how this will affect us.

Katrin: But it'll affect our customers. Where they'll be able to maybe get insights, basically, much easier than today. So, our customers, but also providers of hospitals and clinics, as well as hub insurers, as well as governments and everybody. How that will affect us, I can only think it's positive. Because the more the data-driven approach to understanding your opportunity, and targeting the right opportunities with the right tools and techniques ... The more that's done in the industry, the better for everyone, I think.

Will: What, if anything, about the medical device industry, do you think would be surprising to just the average layperson like me?

Katrin: You got me there. I think the most surprising about this industry, for a layperson, is how sales-driven it is. And that sounds terrible, but basically, medical devices that have a huge effect on people's life. Anybody that gets touched by, as a patient or as a caregiver for a patient, that gets touched by medical devices ... Medical technology is able to do mind-boggling things. Right? Repairing ... like surgeon skill, surgeon equipment, implants, diagnostic devices. Mind-boggling advances on science and on human welfare and human well-being on healing. It's just insane.

Katrin: So I'm a huge fan of the industry, but I also know how much it depends who you see, which physician you see, and which company that physician kind of works with, when you as a patient go see your doctor. Because it's not black and white, because every patient is different, because every technology has pros and cons ... There is not the one thing that will do everything that you want this device or this treatment to do. Because there's differences, because there's certain preference.

Katrin: There is physician preference, there is physician knowledge. It is not necessarily the best treatment you're going to get. It is the best treatment that your physician thinks, for various reasons ... and they can be financially motivated. They can be clinically motivated. There can be many, many reasons

why somebody is ... why your physician or your health care provider suggests a certain treatment. And the most surprising thing for me is how few of us that are working within this industry, we trust the medical process. We won't go to the doctor unless we absolutely have to.

Katrin: If I had to do an operation today, I will check around for like 10, 20 different surgeons. I'll go see them and test them, and I will ask their staff, et cetera. Because I know how variable the outcomes are, based on surgeon skill, based on treatment, based on pre-prior ... on prior medical history, on [inaudible 00:24:23]. And also on what a physician and the health care system, a country's health care system, thinks is an acceptable outcome.

Katrin: There's health care systems that think an acceptable outcome is that you're more or less pain-free, and that's it. And there are health care systems that think an acceptable outcome is only if you're of course, pain-free, but also you have basically [inaudible 00:24:45] full functionality of the organ or the joint or the body part, that gets affected. That's a huge difference amongst countries, and amongst even hospitals or physicians. It's mind-boggling, in a way, also, to me.

Will: Have you seen cases where there would be some medical device, and maybe it's a new idea, or maybe it's just something that has been around for a long time ... But because there's just not enough margin there to sell it, maybe it's sort of, at this point, kind of a generic. Like, nobody could patent it, and therefore, there's no sales force pushing it. That it's not really used as often as it ought to be. And maybe there's some higher, more profitable device that's being used instead. Because you can afford to pay a sales force to sell that product instead.

Katrin: I don't know if I have a specific example of something that is not promoted, because it's old, or maybe not profitable ... and another one that gets promoted but basically does the same thing, but differently, or more expensively, or more better or whatever. I don't know that I have that as an example. I'm not sure that it's actually even that black and white. What you do see is, in the same vein though, is how cool technology and surgeon preference basically, in the surgical specialties, for example ... supplant more tried-and-tested, and being around for a long time, and how that happens.

Katrin: For example, robotic surgery versus [inaudible 00:26:35] so, laparoscopic surgery versus open surgeries. But there's a clear benefit often, depending of course, on the health care professional. So it depends, case by case, but often there is definitely a benefit of doing a minimally invasive surgery versus an open, very, relatively invasive surgery, that can be done either

laparoscopically with laparoscopic equipment, or it can be done robotically, with a surgical robot.

Katrin: And what we see is that the hospital has an absolute interest, once they spend a lot of money on the robot. And they work together with the companies that sell the robot, and sell it for higher utilization, the hospital, the surgeons, et cetera, this is also very cool technology, has a couple really cool features ... do have a tendency to do robotic surgery for everything when even sometimes the laparoscopic approach could be equally good if not better. I think that's quite a typical example that's also publicized in the news, if you go search for robotic surgery. I think that some of the critique, especially in Europe, that you'll hear about robotic surgery, that it's overused in some cases, just because it's a cool, hot new technology.

Will: Wanted to switch gears a little bit. We were talking a little bit about podcasts, and you were telling me that you're a big fan of podcasts. Tell me about some of your favorites, and maybe when you listen to them. I'm always interested to hear what other people are listening to, and what shows I should be investigating.

Katrin: Listening to [inaudible 00:28:19]. I am a huge fan of podcasts. I also have quite a ... not a very long, but I have a good commute every day. So I spend about an hour and some in my car. I spend another half hour walking to get to the office, and I have a couple, 10 minutes here and there, during the day, that I like to relax on listening to podcasts.

Katrin: So I'm a big fan of NPR shows. There's some very classical ones like Fresh Air and a couple med tech specific interviews. I'm also ... some of the shows that are produced by a new, well, it's not that new ... a podcast company. They're called Gimlet Media. Specifically, they have a show that's called The Pitch, which pitches start-up, where, in a roomful of investors there's ... every week in their season, there's a start-up that comes in and pitches to these investors.

Katrin: And then the investors ask questions, and kind of make decisions if they would invest or not. In a podcast form, probably similar to maybe something like a Shark Tank or something like a show. I like it. I think the quality of the investors is great. The mix of the [inaudible 00:29:42], and I, as a person involved day-to-day with start-ups, and with financing and funding, I really enjoy that show.

Katrin: [inaudible 00:29:49]. I'm a big fan of true crime podcasts, so there's, a lot are very famous now, out there. Like Serial, of course, and The Undisclosed Team, and there's ... from Canada, [inaudible 00:30:09] that I like. I also like a podcast called Masters of Scale, which talks about how tech companies and

fast-growing companies scale. And I'm also a big fan of the NPR show, a show that's called Planet Money, and The Indicator, which is two economic NPR shows.

Katrin: There's a wide variety of podcasts and I have to make sure I'm in touch with all of them, so that I don't run out of things to listen to.

Will: That sounds ... would certainly fill up your listening schedule. Katrin, how do you sort of maintain your visibility in the industry, so that new start-ups in the med tech space are aware of you? Do you go to conferences, or are you publishing white papers? Or is it mainly individual one-on-one relationships? How do stay visible in your space?

Katrin: That's a constant challenge for me, personally. Because I'm also very involved in delivery, and in working with my team to produce very good quality for our customers. And that takes up a big part of my time. So I don't have, never enough time for this type of work [inaudible 00:31:36] to be able to reach out and to do all the things I would like to do on that front. In general, we'll follow, as you just mentioned also, a couple of common strategies. I have a good network in this industry, so there's a lot of word of mouth.

Katrin: I just get people reaching out to me because they've been recommended to reach out to me by somebody that they already work with. In Europe, Switzerland and Germany have, especially there's an immensive good infrastructure of coaching and support for start-ups, that ... ranging from incubators to government-funded and regional-funded economic development schemes that include often facilitating the setting up of a company and also the coaching. And little sums of money as grants, [inaudible 00:32:31] funding and grants that is provided to companies, and quite easily accessible. Too easy, as some people say. I have a very good network. I work with some of them. I'm a coach on some of these, and if I see ...

Katrin: You know, I see a lot of the [inaudible 00:32:47] industry and the start-ups that are passing through that would fall into my area of interest. In addition, we are present at a lot of conferences. And I go, I am a judge sometimes in a jury panel. Or I just attend, or I have ... there's a small table set up to present ourselves. I should do a lot more on social media and on writing white papers and then publishing, and on being more visible. Absolutely true. I just don't, at the moment, have the time.

Katrin: But it's definitely on my list. And lastly, the industry is not that big, and it's ... There is a lot of events and coaching events. Events where start-ups present themselves. Even if I don't go, I download, or get the list of companies that are there. I look up what they do. If they are in the right stage, if they are funded

enough to even work with external suppliers or providers. And then I make, have a running list of many, many, many start-ups that I just reach out to cold if I don't have a contact in them.

Will: Fantastic. Katrin, for folks that wanted to find out more about your work, maybe get in touch, do you want to give a website? Or what's the best way for people to find out about you?

Katrin: Yes. So, my email address is ... so, they can always reach me through email. My email address is ks@phare7, and that's written P-H-A-R-E, the number 7 dot com. www.phare7.com is our website. We will be taking names, but we'll redirect the website from there. We'll have a more updated presence. And in addition, on LinkedIn, I'm very, very easy to find.

Will: And we will include those links in the show notes. Katrin, this has been a-

Katrin: Thank you.

Will: ... fantastic discussion. I learned a ton about commercialization strategy. It was fascinating. Thank you so much for coming on the show.

Katrin: Thank you so much, Will. It's been an immense pleasure.