MEDSIDER

VOLUME IV

MEDSIDER MENTORS

LEARN FROM THE FOUNDERS AND CEOs OF ABLATIVE SOLUTIONS, CRESILON, PIXIUM VISION, TYMPA HEALTH, VESTECK, AND MORE

SCOTT NELSON

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INTRODUCTION

In the ever-evolving world of health technology and medical devices, staying ahead means learning from those who've been in the trenches. As the founder of Medsider, I've been privileged to have conversations with some of the industry's most accomplished entrepreneurs, giving me a unique vantage point on what it takes to innovate and succeed.

That's why I'm excited to bring you the latest compilation of the most inspiring interviews: Medsider Mentors: IV. Whether you're just starting out, have a few industry battle scars, or are simply intrigued by the fusion of technology and healthcare, this is your go-to guide.

For those of you who've already enjoyed the previous volumes of Medsider Mentors, this next installment is going to add fresh perspectives. And if you're new here, you can jump right in, but you might also want to catch up on our previous editions to get the full 360.

Here's a taste of what's to come:

Will Martin on Quality and Innovation

Will Martin, CEO of IRRAS, catapulted his company to the forefront of intracranial bleeding treatment. Leveraging over two decades of experience, Will reveals why a nuanced understanding of user needs, internal networking, and rigorous quality management have been key to his success. This conversation is an invaluable guide to innovation whether you're in the medical device space or looking to break new ground in a different healthcare arena.

Joe Landolina on a Fast-Track to Regulatory Approval

Joe Landolina, CEO of Cresilon, took an unconventional path when he created Vetigel — a product that rapidly halts severe bleeding. Drawing from his early interest in chemical lab research and his foray into entrepreneurship at just 17, Joe shares tips on charting non-traditional paths in medtech using strategic planning, navigating the often daunting FDA processes, and finding the sweet spot between creativity and compliance.

INTRODUCTION

David Kuraguntla on Killing Risk Early

"High risk, high reward" is how the saying goes, but David Kuraguntla has another angle: mitigate that risk early and watch your venture thrive. David is the co-founder of Alio, a startup at the forefront of kidney health solutions. He talks about how to "kill risk" effectively, shares his strategies for securing $60 million in funding without traditional venture capital, and discusses the transformative power of alignment in business partnerships.

Timothy Blair's Three Pillars of Success

Timothy Blair, CEO of ICHOR, has a Swiss army knife-career in sales, marketing, and strategy, in both multinational corporations and startups. In this interview, Tim shares what it takes to successfully bring a medical device to market and provides tips on the three cornerstones of success: a formidable team, the right funding, and a robust regulatory strategy.

Rob Ball on Sidelining Pitfalls

Rob Ball, CEO of Shoulder Innovations, shares what it takes to avoid the common pitfalls of the orthopedic industry — one of the most innovative spaces in medtech — through managing capital wisely, designing efficient clinical trials that meet distinct requirements from different stakeholders, and more.

Joseph Rafferty on the Power of Inhouse R&D

Through years of hands-on experience, Joe Rafferty, CEO of Vesteck, has cracked the code. In this conversation, Joe dives deep into why having an in-house R&D team gives you unparalleled control and agility, why tenacity and the right mentors can make all the difference, and shares his battle-tested strategies for market analysis and team building.

INTRODUCTION

Mara McFadden's Iterative Path to Winning

From leading roles at healthcare giants to co-founding Endolumik, Mara McFadden champions a unique business philosophy: iterations as a path to successful innovation. Combining her engineering background and business expertise, she has cultivated a unique perspective on smart prototyping, maintaining a strong customer focus, and curating the right investors.

Brett Wingeier on Regulatory Best Practices

Dr. Brett Wingeier, a multidisciplinary expert in medicine, biology, and engineering, brings a dynamic approach to the game. He takes us behind the scenes of his quest to develop neurostimulation devices that promise to change lives. Brett shares insights on navigating the regulatory & clinical landscape and balancing consumer expectations with medical efficacy. While his lessons are critical in a field as complex as neuromodulation, they are applicable to any medtech venture.

Lloyd Diamond on Smooth Sailing in Global Markets

Lloyd Diamond, the CEO of Pixium Vision, has navigated the labyrinthine worlds of both the European and American medtech markets. That's exactly why he brings a seasoned perspective on what it takes to succeed in this challenging arena. His current venture, Pixium Vision, is on the verge of altering the landscape of ophthalmology by developing a retinal implant system that treats advanced dry age-related macular degeneration. In our conversation, Lloyd shares invaluable advice on everything from team building to regulatory and fundraising best practices.

Kate Rumrill on Trials that Lead to Triumphs

Shifting gears from an aspiring neurosurgeon to a medtech entrepreneur, Kate Rumrill, CEO of Ablative Solutions, epitomizes the art of seizing opportunities. She has amassed over 30 years of diverse experience in the sector. Driven by her parents' struggle with hypertension, for her, Ablative Solutions isn't just business; it's deeply personal. She shares hard-earned practical wisdom on designing clinical trials and shaping effective reimbursement strategies.

INTRODUCTION

Shriram Raghunathan on Solving the Right Problems

Shriram Raghunathan traded circuit boards for a mission to alleviate neurological discomfort when he founded Noctrix Health. The experience gave him a fine glimpse into the high-stakes world of medical device startups. Shri shares nuggets of wisdom on earning FDA Breakthrough Designation, his philosophy on team dynamics, and how solving the right problems can not only help patients but also catalyze fundraising and operational efficiency.

David Narrow on Optimizing Startup Life Cycles

David Narrow is a name you'll see under both Forbes' 30 Under 30 and Baltimore Business Journal's 40 Under 40 lists. He's pioneering automated ultrasound technology at the helm of Sonavex. David provides a multi-dimensional guide covering the lifecycle of a medtech startup, from ideation to commercialization — including crucial strategies for building a product that not only gets FDA approval but is also primed for market success.

Allison London Brown on Understanding Your Gaps

It takes a special kind of savvy to ace roles in Fortune 50 companies like Johnson & Johnson and GE Healthcare. Now leading Luminelle, Allison is using that experience to streamline hysteroscopy by cutting through the red tape with innovative solutions. In this interview, we talk about the importance of not just leaning into strengths but also acknowledging weaknesses. Allison also touches upon her modern and traditional methods for securing capital.

Krishan Ramdoo on the Power of Show & Tell

Dr. Krishan Ramdoo is not just an ENT physician; he's a pioneer in ear and hearing health technology. Serving as the CEO of Tympa Health, he has developed the world's first all-in-one ear and hearing health assessment system. Krish shares how he tackled an overlooked area in ENT care by bringing innovation to the humble otoscope. See what he has to say about the careful dance between listening to external feedback and following one's vision by making believers out of skeptics through tangible demonstrations — a strategy that has played a significant role in Tympa's fundraising efforts.

INTRODUCTION

Sean Morris on the Power of Empirical Evidence

Having worked his way up from a medical device salesman to now CEO of Amplifi Vascular, a startup aiming to revolutionize dialysis patient care, Sean offers a comprehensive look at the industry. He talks candidly about the highs and lows of startup life, the importance of gathering clinical data to build credibility, the vital role of mentorship, the need for simplicity in strategy, and how establishing an early dialogue with investors and acquirers can significantly shape your business' trajectory.

It's no surprise that I eagerly anticipate every single one of these discussions, as I can learn from and apply practical gems of wisdom when leading my team at FastWave Medical. Therefore, I hope this volume proves to be as beneficial for you as it has been for me.

Thank you for being a dedicated reader, and as always, feel free to share your suggestions on who you'd like to see featured in the next edition of Medsider Mentors.

Best wishes,

Scott Nelson

Founder of Medsider

Co-Founder and CEO of FastWave Medical

Interview with CEO of IRRAS
Will Martin

Will Martin

Preview

Will Martin, CEO of IRRAS, delves into how his team's holistic approach to innovation has revolutionized his company's intracranial bleeding treatment. He also shares his insights on understanding user needs and cultivating strong internal relationships while maintaining robust quality management systems.

About Will

Will Martin is an accomplished executive with over two decades of hands-on experience in the medtech arena, including roles at Boston Scientific, Access Closure, Hotspur Technologies, and Athromed. Will's expertise in sales and marketing leadership propelled him to become the CEO of IRRAS, where his team is revolutionizing the treatment of intracranial bleeding. His contributions to startups and established strategics have solidified his reputation as a proven leader in the medical device space

Key Learnings

- Go the extra mile in meeting users' needs by considering every facet of their experience.
- Establishing solid, genuine relationships with customers and influential thought leaders is one of the best things you can do for your company.
- Keep your eye on the ball when it comes to quality management, which will ensure your company is ready for a successful M&A event

Tried-and-True Recipes for Success: Interview with IRRAS CEO Will Martin

Catering to Every User: The Ultimate Success Formula

The product or technology you're developing has to cater to users' needs across the board. This covers not just the clinical and economic aspects but also the user experience. Will says, "You have to absolutely make sure that what you're building meets and exceeds the needs of your customers in every possible way."

To understand the market needs from all possible angles, the best thing you can do is to keep the communication flowing. Involving diverse stakeholders, including physicians and naysayers, allows companies to pinpoint potential stumbling blocks early and strategize accordingly.

For instance, their flagship technology, IRRAflow, was initially designed with neurosurgeons in mind. However, the company soon realized this wasn't enough for widespread adoption. Instead, Will took a holistic approach to the product, taking into account both its primary and secondary users.

This helped them identify that nurses weren't comfortable with the product's learning curve. IRRAS was able to fine-tune its training and software, making it more user-friendly for nursing staff, and just like Will anticipated, this update brought a wider range of users into the fold

How Smart Internal Networking Yields Commercial Success

In an early-stage startup, internal customers are among the most important actors. From his own experience, Will explains how recognizing the significance of these relationships and subsequently cultivating trust within the organization paves the way to growth and new opportunities.

Business functions such as marketing, clinical affairs, and scientific communications must closely collaborate in their efforts, including the distribution of vital information. With better coordination amongst these core teams, you can give yourself a better shot at a successful product launch through a cohesive approach.

According to Will, another party you should build strong connections with is the industry thought leaders, i.e., people with wisdom and power to influence others. Founded in Europe, IRRAS needed to establish a presence in the US market from scratch. Will shares how they spent around 18 months building a foundation of thought leaders to support their product launch.

In his words: "If you are working with the right physician thought leaders, not only through your product development but also understanding the three to five accounts and three to five territories that you want to invest in first, it makes everything you want to scale from that point forward a million times easier."

Tried-and-True Recipes for Success: Interview with IRRAS CEO Will Martin

Why Quality Assurance is Crucial to an M&A Event

When it comes to mergers and acquisitions, quality management systems can make the difference between failure and success.

Audit readiness and solid quality systems are some of the most important things a startup can put forward. In Will's words: "The ease of integration, how closely an early-stage company watches and invests in quality within the organization, and the ability of the quality management system to be easily incorporated into a company's quality management system... Those things are oftentimes overlooked but are oftentimes the most challenging parts of diligence."

Quality management also impacts company valuation, which is vital for startups looking to attract potential acquirers. According to Will, failing to empathize with the BD team responsible for evaluating your company can lead to significant gaps in your operations and hefty remediation costs.

Quality systems may sound like a basic, foundational concept, but paying extra attention makes a real difference. In Will’s words: "Don't underappreciate those basic foundational things. They'll come back to bite you hard."

Will's perspective serves as a good reminder for startup leaders to prioritize quality management systems to successfully navigate the M&A process.

An Unorthodox Path to Medical Device Success

Interview with CEO of Cresilon
Joe Landolina

Joe Landolina

Preview

Joe Landolina, CEO of Cresilon, reveals the development process behind Vetigel, a groundbreaking product that stops severe bleeding with remarkable speed. Joe expounds on the unorthodox paths he took to build the company and the importance of a well-rounded team that's able to balance creative and conservative strategies

About Joe

Joe Landolina was introduced to chemical lab research at a young age, which kindled a lifelong interest in discovering responsive, nature-derived materials. Embarking on his journey as an entrepreneur and innovator at only 17, Joe invented the technology behind Vetigel, a major breakthrough in the field of trauma care. As the co-founder and CEO of Cresilon, Joe continues to push medtech frontiers with his unwavering commitment to innovation

Key Learnings

- Having a solid strategy is key when exploring unorthodox approaches in the medtech industry. You need to reassess the market needs and your next steps continuously, stay vigilant to seize opportunities, and be flexible to pivot when necessary.
- The FDA regulatory process isn't always straightforward, and can sometimes seem like a black box. For that reason, make sure you nail the fundamentals before getting too creative and surround yourself with an experienced regulatory team to de-risk every step along your journey.
- Be cognizant of communicating your company's narrative in a clear, succinct fashion. To do that, decide what your ultimate mission will be and simplify the complex jargon to help your audience understand your product and the value it brings. This approach attracts not only customers, but also potential investors and partners

An Unorthodox Path to Medical Device Success: Interview with Cresilon CEO Joe Landolina

Building the Ship as You Sail

Joe's journey to founding Cresilon was far from a cakewalk, and their inflection point as a company came about in an interesting way. Namely, a friend of Joe's, who was working at the Wildlife Conservation Society, told him they were struggling to treat the injured animals in the wake of Hurricane Sandy in 2012 due to limited access to hemostatics. Recognizing the pressing need and potential opportunity, Joe seized the moment, establishing the company's initial focus on animal health.

This approach came with several advantages. Joe recalls, "We realized really quickly that animal health was unique because the regulatory barrier to entry is lower and there are no specific veterinary device regulations, so we took the human device equivalent." This strategic direction proved to be instrumental in generating revenue long before their human-use applications were developed.

Another decision Joe made was to go down the path of verticalization. He explains that although it's a common practice to outsource early-stage design and manufacturing to contract firms, it's not always the best option.

Cresilon intended to develop highly specialized formulations, such as stem cell tissue engineering and scaffolding. These solutions demanded equally specialized manufacturing processes with a steep learning curve. In Cresilon's case, outsourcing their production wasn't viable as it wouldn't have given them the wiggle room needed for early-stage development.

Therefore, instead of partnering with a contract manufacturer, Joe found it more practical for Cresilon to assume full responsibility, steering toward verticalization.

This wasn't an easy decision and it required substantial capital, which can be detrimental, especially during the early days of a startup. Although Joe doesn't advise other entrepreneurs to tread the same path — unless there's an absolute necessity — he concedes that Cresilon is now in a far better position than if they had taken a traditional approach. He recalls, "I think the engineer in me enjoys having control over not only the R&D and the manufacturing, but also the clinical communication because as you get feedback, you can use that to modify all of the pieces of the business."

Today, Cresilon has submitted for 510(k) clearance, and the team is excited to treat their first human patients. The company has also partnered up with Walter Reed National Military Medical Center for the treatment of Penetrating Ballistic-Like Brain Injuries (PBBIs), a critical medical issue military personnel often face.

An Unorthodox Path to Medical Device Success: Interview with Cresilon CEO Joe Landolina

The Importance of Strategy and Teamwork in Balancing Regulatory Risks

To successfully chart a path through the complexities of the regulatory waters, Joe leans heavily on strategic planning, risk distribution, and a balanced team. He candidly acknowledges the inherent uncertainties when engaging with FDA, especially with innovative technology.

Cresilon's product is regulated as a medical device due to its polymer composition, a material that's extensively used in the medtech industry.

However, Cresilon's journey with FDA hasn't always been smooth. He says that most regulatory delays happen due to miscommunication when working with third parties, including Contract Research Organizations (CROs), consultants, and lawyers.

In his words, "The key thing we've learned and done an okay job at is realizing that the biggest X factor that comes into any FDA submission is not necessarily the FDA. It's not the company or the technology. It's where you have to bring in third parties."

He emphasizes the importance of understanding this up front, having backup plans, and distributing risk across multiple areas to avoid major delays, favoring a "fundamental-driven strategy rather than a growth-driven strategy."

Joe's approach to navigating this landscape is employing a balanced team, both within the company and with external consultants. His magic formula is pairing maverick consultants, who are experienced and comfortable with pushing boundaries, with more conservative consultants who know the regulatory rules by heart.

This combination often leads to creative yet workable solutions, straddling the line between risk and compliance. Joe applies a similar strategy when selecting CROs, preferring larger, more robust organizations for safety testing but engaging smaller, innovative groups when exploring alternative approaches. He adds, "It may not be the most capital-efficient approach, but if it ends up with the best result and the safest, most efficacious product, then in my opinion, it's worth it.

It’s Critical That You Communicate a Clear Message

The life science industry can be highly complex. It's paramount that you distill your mission into something that the general public can easily understand. In other words, make sure you avoid complicated jargon or explanations that require people to jump through mental hoops to internalize.

For example, Cresilon has managed to encapsulate its product in a bite-sized, 22-second GIF GIF that effectively communicates what they do. This doesn't just help with brand awareness, it also aids in raising capital, finding customers, and attracting potential partners. In Joe’s case, it landed Cresilon a huge partnership with Walter Reed.

The collaboration came about in a serendipitous manner. A researcher at Walter Reed saw Joe's interview on late-night TV, found Cresilon's work interesting, and reached out to him the next day. The duo then explored a new application for Cresilon's technology beyond its core competency of hemostasis. Now, Cresilon is developing a product to treat Penetrating Ballistic-Like Brain Injuries (PBBIs), such as gunshot wounds or shrapnel injuries to the brain.

While still in its preliminary stages, this new application could represent a paradigm shift in the treatment of PBBIs and may become one of Cresilon's next commercial indications.

Aligning Mutual Interests to Build Long-Term Partnerships

Interview with CEO of Alio
David Kuraguntla

David Kuraguntla

Preview

In this inspiring conversation, Alio co-founder and CEO David Kuraguntla shares his journey from aspiring surgeon to revolutionizing kidney health. Dave discusses common entrepreneurial challenges, such as killing risks early on, being diligent around clinical accuracy, and collaborating with the FDA

About David

Dave holds a degree from the West Virginia School of Osteopathic Medicine. While pursuing a surgical residency, he co-founded Alio, developers of transformative solutions for kidney health, including a remote patient monitoring platform that provides non-invasive, highly accurate, and multi-metric patient data

Key Learnings

- It's important to kill risk ruthlessly, especially in the early stages, by aligning the interests of key stakeholders, being responsive to customer needs, and remaining open to pivots, if necessary.
- To effectively manage the fundraising process, you first need to demonstrate your company's commitment to long-term, sustainable growth.
- It's critical to foster the right partnerships with individuals and organizations whose vision aligns with yours. This will benefit all parties involved, especially the patients your company aims to serve

Nipping Technical Risk in the Bud

The CEO's role as the primary risk manager is to identify and mitigate potential pitfalls before they snowball into problems. Mitigating risk early on is advice that is often echoed amongst medtech leaders as they often emphasize the importance of using early-stage capital to address high-risk items.

Dave also advises early-stage CEOs to “be ruthless about killing risk." The concept of “killing risk” is multifaceted and encompasses various aspects of business operations, from stakeholder alignment to quick and decisive decision-making.

One of Dave's key strategies in forging a strong company culture and setting the ground for sustainable growth lies in aligning the interests of the '4Ps': patient, physician, product, and provider.

He notes, "I'm sure we're not original in aligning the 4Ps, if you will. With that being said, I think we’ve fully embraced that concept." When you provide value to every key stakeholder and encourage team solidarity, you set the tone for success and prevent any party from feeling undervalued.

Next on Dave’s risk management checklist is reacting proactively to customer needs, especially considering the user experience is the most important factor for your product to gain traction. In Dave’s case, Alio initially focused on the vascular access component of monitoring, only to receive customer feedback that they were only partially addressing the reasons patients land in the hospital. This feedback was crucial in helping the company to broaden its scope.

When it became apparent that their original direction of developing an implantable device was not viable, the company, as Dave says, "made a transition from an implantable to a wearable in about two months." The capacity to make quick decisions wouldn’t be possible without a cohesive team. And the pivot was a further demonstration of the value Alio was looking to showcase to customers, partners, and investors.

In short, by responding quickly to customer needs and being ready to pivot when needed, you can significantly reduce the risks for your startup, secure the necessary financial support, and ensure your long-term vision is aligned with current market needs.

Mastering Fundraising and Capital Management

When it comes to fundraising, Dave again emphasizes the importance of alignment: "I think getting alignment quickly is important. It leads to either fast yeses or fast noes. I think the worst is anything that's a slow no or even a slow yes."

Dave's view of fundraising is not just about securing the necessary capital; it's about creating synergy between the startup's vision and the investor's passion. He raises two important questions when looking for the right investors: “Do they want to go on this journey and are they as passionate about this arena as you are?” This alignment can make the difference between an interesting opportunity and a grueling process that drains energy and resources.

Investors expect startups to tackle low-hanging fruit, but the ability to quickly mitigate significant risk is a differentiating factor. In Dave’s case, this relentless pursuit of risk mitigation has allowed Alio to raise an impressive $60 million without traditional VC dollars.

But being a CEO also means you have to face rejection quite often. Dave encourages startup leaders not to take these responses personally: "Don't be offended by it. Don't take it personally. Once again, it's people trying to make decisions in a very short amount of time." Not giving up on the deal and keeping potential investors updated, even those who initially decline, can yield fruitful relationships down the line.

This approach has helped Dave attract financial partners who resonate with Alio’s long-term vision and are willing to stay the course. He believes that "the best way to build a company is to build a business," and this strikes a chord with investors who understand that building a sustainable business is more valuable than short-term gains. This strategic approach has also allowed Alio to circle back to investors who initially said no, but later reconsidered their decision thanks to the company’s demonstrated commitment to building a long-term, viable business.

Aligning Mutual Interests to Build Long-Term Partnerships: Interview with Alio CEO Dave Kuraguntla

Finding Alignment Through Strategic Partnerships

Dave acknowledges that making direct contracts with medical service organizations and integrated delivery networks is crucial. In his case, establishing a partnership with Carium, a virtual care delivery company, was a turning point.

Carium provided a unique and compatible perspective that aligned with Dave's mission. He explains: "They've done the work, they've spent the time, and they made it really easy because I think it has to be frictionless and sticky all the same time."

The value of such partnerships, however, goes beyond channeling opportunities. As Dave puts it, "A great partner like Carium has already reduced the friction for clinicians to interact with data." In essence, the partnership with Carium helped Alio establish a solid foundation for future growth.

From Dave's point of view, partnerships rooted in alignment lead to more fruitful discussions and are more satisfying than transactional relationships.

At the end of the day, shared values and perspectives can forge the foundation for successful, long-term alliances that benefit all parties involved, particularly the patients they aim to serve.

What it Takes to Bring a Medical Device to Market

Interview with CEO of ICHOR
Timothy Blair

Timothy Blair

Preview

In this interview, Tim Blair divulges his journey from medtech enthusiast to influential innovator. He dissects critical startup challenges, from surrounding yourself with talented specialists to keeping communication flowing with regulatory entities and navigating the tricky landscape of venture capital

About Tim

With a rich, 30+ year career in the medtech industry, Tim has held diverse roles spanning sales, marketing, and strategy development, both in multinationals and startups. In 2009, Tim brought his strategic vision to NAMSA, shaping it into one of the world's first Medical Research Organizations (MROs). Currently, as CEO and co-founder, Tim is leading ICHOR on its quest to transform thrombectomy in the peripheral vascular system

Key Learnings

- Building a strong team from the very start and focusing intensely on user needs are crucial for successful, capital-efficient product development.
- One of the main roles of a CEO is to secure funding. This means you need to ensure your product is not only innovative but fundable, and the only way to do that is to perform adequate upfront due diligence and market research.
- Prioritize regulatory strategy from the very beginning and keep the communication flowing with the FDA. A well-detailed plan dictates timelines and sets an overall operational strategy, forming the backbone of a startup's runway.

What it Takes to Bring a Medical Device to Market: Interview with Tim Blair, CEO of ICHOR

Anchoring Success: The Team, Partners, and User Centricity

"Team is everything. Investors love tech, they love cool things, but what they really love is the team," says Tim. Based on his experience, building a thriving early-stage venture requires three major pillars, with the core leadership group being paramount. He advises arming yourself with people who have proven experience, as this can help you minimize risks and streamline the path toward growth.

Tim also draws attention to the importance of building a diverse ecosystem that includes multiple stakeholders. Alongside engineers, the inclusion of marketing professionals and regulatory strategists in the product development process is crucial for devising a well-thought-out reimbursement strategy.

Tim's second pillar is forming meaningful partnerships that'll benefit all parties in the long run. For example, for a startup, there are potential risks associated with youthful engineering firms, as they may not provide the necessary long-term stability, especially in the field of medtech. Tim advises taking the time to choose the right partners to avoid disruptive shifts in the future.

Lastly, Tim highlights the importance of adopting a user-centric framework when developing new technology. He believes it's crucial to understand the perspectives of everyone involved, from techs to physicians and nurses, as they will be the ones using the device and determining its success.

Break Fundraising Down Into Its Building Blocks

In a world where capital is essential to drive growth, the ability to attract and secure funding is one of the most crucial roles of a company leader — without it, even the most promising ideas may never reach their potential. As a CEO, you need to continuously work on securing more funding as you scale and evolve your business. Tim says: "The primary task of a CEO is fundraising. Regardless of the variety of roles you have to play, the need for raising funds is constant. It's a continuous process that requires substantial time and effort to secure commitments."

A prudent approach to securing capital is moving forward on your device development with confidence and a clear vision. Tim stresses the importance of making sure you have a market opportunity that will impress investors before you start spending your initial funds on prototypes and testing.

Break Fundraising Down Into Its Building Blocks

On top of the quantity, the quality of the funding matters, too. Early-stage capital raises often come from high-net-worth individuals, key opinion leaders, and people from the industry. These investors not only understand the medtech space but can also provide invaluable insights and guidance as the company continues to evolve.

To keep the quality of your investor base high, Tim suggests maintaining a minimum investment amount when approaching high-net-worth individuals. This way, you can avoid the administrative burden of managing many small investors while attracting more sophisticated parties who can provide a greater amount of capital. And as a bonus, having intelligent investors on your cap table also raises the likelihood of them understanding the inherent risks and rewards associated with your startup.

Work on Your Regulatory Strategy From the Start

As an early-stage startup in the medical sector, your focus might heavily lean on the engineering aspect of the product you're building. However, Tim advises placing equal emphasis on your regulatory and clinical strategies from the start of your entrepreneurial journey.

To do that, Tim recommends engaging early with FDA through pre-submission meetings to outline your company's plans, such as bench testing or device validation. This will allow you to gather valuable feedback and receive a guiding document with the required tests. Moreover, it will significantly enhance your budget, time, and risk management.

However, Tim underscores that this is just one facet of the broader effort required to bring a product to the market. His overarching advice for early-stage startups is a well-mapped, go-to-market strategy, driven primarily by regulatory planning. Organize your product development, timelines, and budget allocation around the go-to-market strategy to avoid unwanted surprises

Bridging the Gap Between Clinical Trials and Commercial Success

Interview with CEO of Shoulder Innovations
Rob Ball

Rob Ball

Preview

Rob Ball shares his unique journey from the automotive industry to the realm of orthopedics, emphasizing the importance of balancing technical problem-solving with commercial realities. He delves into the complexities of designing efficient clinical trials that align with both regulatory requirements and commercial viability. Moreover, he underscores the value of prudent capital management, specifically for early-stage companies, which sets them up for success in subsequent fundraising rounds

About Rob

Rob Ball, a graduate of Kettering University with a deep-rooted passion for engineering, has dedicated over two decades of his professional life to medical device technologies. He currently serves as the CEO of Shoulder Innovations, a leading orthopedic device company recognized for developing one of the most robust and stable glenoid platforms in the industry. Rob has over 30 issued or pending patents and has been instrumental in the growth of several organizations, most notably Tornier, where he drove the company's revenue from $40 million to an impressive $300 million within a handful of years.

Key Learnings

- Engineers naturally excel at spotting technical problems and finding solutions for them. However, entrepreneurs should always try to balance their technical focus with the commercial aspects when developing a new product.
- Clinical trials are crucial, so set them up in a way that answers pertinent questions from clinicians while aligning with the key regulatory requirements.
- Capital efficiency is critical during a startup's early stages. If done the right way, you can both attract further investors and ensure early-stage financial partners a good return on their investments.

Balancing Technical Solutions With Commercial Realities

As a startup entrepreneur, one might often find themselves caught up in the details of a technical problem that their venture is poised to solve. And while their solution might be sound from an engineering perspective, its commercial viability can often be underestimated or entirely overlooked. Rob's experience serves as an important reminder of this common pitfall.

Rob candidly admits that there have been times when he's been too engrossed in the technical details of his professional journey: "It's very easy to get tied up in how we, as engineers, are trained to articulate a problem we're solving. But I think we can get a little too caught up sometimes in the technical aspect of the problem when trying to come up with a solution."

Rob points out that regardless of how great your product's technology is, if the commercial aspects aren't given the proper attention, it could spell the end for your business. He advises clearly articulating the idea behind your solution, matching it with the business model, and ensuring the product fits the industry norms.

But the success of an early-stage venture often lies in its deep operational engagement, which is not only about mere advisory or financial support, but also involves actual participation in the startup's day-to-day operations.

Rob emphasizes: "We literally have people packing boxes for Genesis companies." This hands-on involvement affords startup employees a practical understanding of the business's inner workings, ultimately driving capital efficiency. This direct involvement in every aspect of the business is what differentiates Genesis portfolio companies from others.

Setting Up Clinical Trials to Address Clinicians' Needs, Regulatory Requirements, and Market Demands

An efficient clinical trial set-up is crucial for early-stage startups. Rob underscores the importance of answering specific questions that clinicians may have and balancing this with regulatory requirements.

Rob highlights a common oversight in the realm of orthopedics: when designing a product, there's a gap of up to five years before the outcomes present themselves. The resulting challenge is not only about gathering data, but ensuring the collected data focuses on the right questions clinicians are most interested in.

Setting Up Clinical Trials to Address Clinicians' Needs, Regulatory Requirements, and Market Demands

Still, addressing these problems is just one facet of trial designs. Startups also need to align their clinical studies to both meet regulatory standards and hold up to commercial scrutiny. Rob notes that this isn't always the forte of clinical and regulatory partners, who might often design trials around objectives that aren't commercially relevant. As he points out: "Frequently, clinical data is designed around indications that are not necessary. You end up collecting more data and spending more time as compared to doing the minimum of what's necessary to be commercially successful."

Rob's experience serves as a reminder for startups to be careful when designing a study with too many voices at the table. Instead, identify key opinions that matter and tailor the study design to address the right questions. This approach enhances efficiency and positions the company on a path to commercial success.

The Value of Prudent Capital Management

For a startup, securing initial funding is a win to be celebrated, but it's also just the first step of many. How you manage this capital actually determines your future success. This is especially pertinent when planning for subsequent funding rounds. Rob recalls: "We would have never gotten our Series D done had we not been so efficient in the earliest stages of our company, because the cap table just wouldn't have supported the type of financing that we did."

While capital efficiency is not the sole determinant of success, it is an essential factor that startups should take into account as they approach their fundraising process. It's not about bootstrapping or achieving positive cash flow at the onset but about making judicious decisions about spending. Rob advises: "Don't start with five executives around the table."

The issue of mismanaged capital becomes even more pronounced in later funding rounds. Rob warns: "If your cap table is too dysfunctional, for lack of a better description, it's going to be extremely tough." In other words, a poorly managed cap table can lead to unappealing valuations that deter new investors and disappoint early-stage partners.

Moreover, startups should be wary of overinflated valuations that cannot be substantiated by their progress or product. Such ungrounded valuations, as Rob points out: "introduces an existential risk that's hard to combat."

The Value of Prudent Capital Management

This highlights the importance of mindful capital management from the earliest stages of a medtech startup. Rob's experience serves as a cautionary tale for founders and CEOs, and he urges them to strike a balance between spending on essential activities and maintaining an appealing valuation for future fundraising rounds.

In this regard, Rob is quite excited about Shoulder Innovations' potential over the next 12 months. After ensuring sufficient resources, the startup is now in a position to build a commercial organization, backed by strong operations, finance, and R&D teams, to create a standalone orthopedic company with a phenomenal future.

How Recruiting Top Players Sets the Stage for Medtech Success

Interview with CEO of Vesteck
Joseph Rafferty

Joseph Rafferty

Preview

In this conversation, Joe Rafferty shares his remarkable journey in the medtech space, from his broad range of experiences within the cardiovascular arena to his current role leading Vesteck. Joe offers valuable insights on building a high-functioning in-house team and raising capital, and gives tips for successful commercial launches.

About Joseph

Joe Rafferty is a seasoned executive with a wealth of experience designing, building, and commercializing medical devices. He brings a comprehensive understanding of the challenges and opportunities in the field with his deep interventional medtech background. Joe is currently serving as the CEO of Vesteck, an early-stage device company developing solutions for aortic aneurysms.

Key Learnings

- Recruit the right people and find ways to keep them on board. Compared to working with contractors, developing in-house capabilities for critical functions like R&D gives you greater control and saves you from unanticipated delays.
- Proficiency in interpersonal communication is indispensable. Don't hesitate to seek guidance, as mentors can be especially helpful during the early stages of your startup. Also, make sure you understand what investors are looking for in order to increase your chances of raising capital.
- For a successful commercial launch, single out top performers within your team, conduct a thorough market analysis, and implement effective positioning strategies. Hiring exceptional talent and executing a well-defined plan will set your company up for revenue growth

Enhancing In-House Capabilities

For a startup, the transition from alpha to beta builds and subsequent iterations are pivotal, especially during the early stages. Drawing from his wealth of experience in product development, Joe underscores the crucial role of assembling a skilled in-house team for efficient prototyping and R&D: "When you've got rockstar engineers, you don't need to wait for a contract manufacturer or contract R&D person to fit you back into the queue and try to develop the ideas that you brought to them."

By harnessing the expertise of exceptional engineers within your company, you can sidestep the pitfalls and delays that often occur with external partners. Joe astutely highlights the potential downsides of placing undue reliance on contract manufacturers, whose engagement wavers like a “sinusoidal wave,” to use his words. Once you step away, they need to allocate their hours to the next client or the following project, resulting in a discontinuous workflow.

In Joe’s case, working alongside engineers who can iterate quickly and act on physician feedback, Vesteck was able to move through early development efficiently while ensuring clinical input was incorporated in a meaningful way.

Fundraising Strategies for Success

Fundraising is a challenging journey. It requires determination, resilience, and a strategic approach. Having traversed the landscape himself, Joe shares valuable insights on overcoming challenges and securing the initial investments that are the lifeblood of a startup.

At the crux of his wisdom lies the importance of perseverance and unyielding tenacity. According to Joe, these virtues distinguish the triumphant trailblazers from the rest: "If it was easy, anybody could do it. That's why you're here. So get on with it," he says. It takes determination and willingness to put one foot in front of the other, even when faced with obstacles.

Joe ardently advocates for seeking guidance and counsel from seasoned mentors who have scars from pursuing similar paths. He admits he didn’t make it all come true all by himself: "There are some wonderful mentors that have been very kind to me from a business standpoint, teaching me the do's and don'ts in the early stages." And this was pivotal in his success in product development and market penetration.

Fundraising Strategies for Success

On another note, most investors want to know that a leader is coachable and open enough to ask questions, showcasing humility and willingness to learn and improve. The same idea echoed in a recent conversation with Carol Burns, CEO of Cagent Vascular, where we talked about how CEOs need to be comfortable not knowing everything.

Moreover, a good comprehension of the language around raising capital cannot be overstated. Using the right phrases and terminology is essential for effective communication with investors. Understanding the expectations and conventions of fundraising discussions enhances the chances of securing the necessary investments.

Pillars of a Winning Commercial Launch

Launching a device requires meticulous planning, astute market analysis, and deft positioning strategies. Drawing from his rich experience, Joe shares his time-tested strategies for steering startups toward successful commercialization.

His first advice is to identify and nurture the cream of the crop within the organization — those with unparalleled skills and a proven track record. Building a robust team, fostering their growth, and retaining exceptional talent serve as the bedrock for successful commercialization, and it takes an eye for talent. Joe states, "If you don't know what you're looking for and how to find it, you're done, and an organization will be done quicker than you think." Investing time and effort in selecting the right team members is crucial.

Market analysis and positioning strategies loom large in Joe's approach to commercialization. By delving deep into the intricacies of the target market, comprehending the competitive landscape, and attuning to customer needs, startups can carve out a unique niche that sets them apart. This thorough understanding empowers founders to make informed decisions regarding pricing, marketing, and branding, ensuring maximum impact upon launch.

Joe also cautions against the assumption that regulatory clearance alone means your device is ready. What paves the way for sustained growth and long-term success is a comprehensive approach encompassing both regulatory compliance and a well-crafted go-to-market strategy.

Failing Forward in Medtech

Interview with CEO of Endolumik
Mara McFadden

Mara McFadden

Preview

Mara McFadden, a seasoned medtech professional turned entrepreneur, shares her valuable experiences, from her early days at Johnson & Johnson to co-founding Endolumik. We talk about her philosophy of embracing imperfections and learning from your failures, why customer engagement and team culture are integral to business growth, and how the art of smart fundraising can lead to a thriving venture.

About Mara

Mara, co-founder and CEO of Endolumik, graduated as a mechanical engineer from the University of California, Berkeley. She further developed her business acumen during her MBA at Carnegie Mellon University and in various leadership positions with renowned healthcare companies such as Johnson & Johnson and Philips Healthcare. Mara co-founded Endolumik, developers of an innovative fluorescence-guided esophagogastric calibration system.

Key Learnings

- Fail fast, fail often, and fail inexpensively. Don't obsess about perfection during the prototyping phase. Your first iterations are bound to have flaws, but there are also valuable lessons in each phase of testing.
- The success of your startup greatly depends on what kind of culture you cultivate. Build a supportive, enthusiastic, and passionate environment with a customer-oriented approach to everything you do.
- You need to understand the numbers from the perspective of your investors when it comes to fundraising. Focus on capital partners who are comfortable and have experience in your industry. You'll save time and energy by making sure your investors align with your company's vision

Failing Forward in Medtech: Interview with Mara McFadden, CEO of Endolumik

Learning From Imperfections and Documenting Everything

In the vibrant world of startups, no two journeys are the same, but the challenges we face can be surprisingly similar. In our interview, Mara encourages an essential mindset shift – embracing imperfections and capitalizing on failure.

As she recalled the early alpha and beta prototypes at Endolumik, she admitted: "We wanted to make sure that every dollar we spent was tied to a meaningful milestone." But getting there isn't always picture-perfect, as their early prototypes were far from flawless. Yet each one served as a steppingstone to the next phase of the company's development.

"Prototypes aren't supposed to be perfect," she notes. "Don't let the fear of failure hold you back. The goal is to fail fast, fail inexpensively, and learn from each and every iteration."

This ethos is an empowering concept and is critical when trying to overcome the fear of failure that often holds entrepreneurs back. As a CEO, you're bound to face failures. The best way to handle them is to shift your perspective from dreading them to welcoming them as cost-effective teachers and recognizing their role in your learning process.

Another crucial aspect of the growth process is documenting everything. "Gathering and documenting the heck out of your requirements so you have a really clear definition of what good looks like really helps everything down the road go much smoother," Mara explains.

Relying on Customer Feedback and the Importance of Team Culture

Drawing from her formative experience at 4Moms, Mara recognizes the mistake of assuming you know your target market like the back of your hand. It's a trap that could lead any founding team off the beaten path. "It can get so tempting to think that you know everything that you stop checking in with your end users and your customers," Mara warns. Being overconfident and veering away from market data was a hard lesson for her at 4Moms. Staying close to your customer base and listening to their voices is a fundamental tenet of product development and start-up growth.

In addition to her customer-centric approach, building an inclusive and enthusiastic team culture is a must in Mara's leadership approach. Reflecting on her spirited young group at 4Moms, Mara sheds light on the power of a vibrant, collaborative environment in driving growth.

Failing Forward in Medtech: Interview with Mara McFadden, CEO of Endolumik

Relying on Customer Feedback and the Importance of Team Culture

You need to foster a supportive and energetic company culture that empowers employees and encourages people to truly go above and beyond their normal job function. “It was a really fun environment where people were volunteering their time and effort, and it really felt like we were building something special," Mara recounts, hinting at a balanced cocktail of energetic hiring and enthusiastic onboarding.

In essence, the formula for start-up success, as gleaned from Mara's experience, isn't a tangled knot. It's about staying engaged with your customers and allowing their voices to shape your path forward while simultaneously nurturing a dynamic culture within your team.

Making Smart Choices in Fundraising

When you’re looking for financial fuel for your venture, it’s easy to get swept up in the roller coaster ride of emotions. But during this process, do your best to take a prudent and strategic approach.

Mara has learned the hard way that fundraising isn’t just about securing capital, it’s about securing the right capital. "You've got to do the math. You've got to know your multiples. You have to understand that you can't raise too much, or your startup won’t be attractive for anyone else down the road," she notes. Overcapitalization might seem alluring but could ultimately dilute the value proposition for future stakeholders.

More importantly, she advises a targeted pitch that focuses on investors with proven interest and expertise in your field. "You really do have to do your homework and find people who are comfortable investing in your space," Mara counsels. This advice isn’t just about efficiency; it’s also about building meaningful relationships with investors who can provide more than just capital.

The right investor brings industry insight, strategic guidance, and a deeper understanding of the specific challenges in your sector. Mara cautions against a broad, undiscerning pitching strategy: "You'll often hear advice to just shotgun and pitch, pitch, pitch. Your time is your resource to waste." Investing time in prescreening potential investment partners to ensure a good fit is always a good idea. To do so, you also need to understand your deal size and your place in the broader ecosystem.

Failing Forward in Medtech: Interview with Mara McFadden, CEO of Endolumik

Making Smart Choices in Fundraising

By keeping the fundraising round targeted, startups can attract investors who offer strategic perspectives along with initial capital. She reiterates: "It's honestly a waste of time (if you approach the wrong investors) because you have to do so much education about the landscape and the risk profile and the timelines." In short, in fundraising, as in many aspects of business, quality trumps quantity

Shaping the Future of Mental Health

Interview with Co-Founder of Magnus Medical
Brett Wingeier

Brett Wingeier

Preview

Dr. Brett Wingeier, co-founder and CTO of Magnus Medical discusses his journey of developing innovative neurostimulation devices to treat various conditions, including epilepsy and depression. He shares valuable insights into understanding the system you're working with, balancing consumer and provider perspectives, and ensuring cost-effectiveness for successful reimbursement

About Brett

Dr. Brett Wingeier is a prominent figure in neuromodulation, leveraging his expertise in medicine, biology, and engineering to advance the arena within medtech. He was part of the pioneering team at NeuroPace and co-founded Halo Neuroscience. Brett is also the co-founder and current CTO of Magnus Medical, whose FDA-cleared SAINT™ Neuromodulation System aims to revolutionize mental health care

Key Learnings

- You need to understand the system you're working with and aim for a significant effect size in your clinical trials.
- When developing new technologies, try to balance consumer and provider perspectives to ensure a smoother path toward regulatory approval.
- Your product has to make financial sense to raise capital and ensure reimbursement. Once you prove the business model, you'll enjoy greater opportunities in follow-up financing rounds

Shaping the Future of Mental Health: Interview with Magnus Medical Co-Founder Brett Wingeier

Maximizing Effect Size With Systemic Understanding

Brett's experiences have taught him that deep knowledge of the system you're part of allows you to anticipate challenges, develop better-informed strategies, and accelerate innovation in a cost-effective manner. In his case, this includes understanding medical needs, regulations, clinical trial processes, reimbursement strategies, and the healthcare industry in general.

When you've got a handle on these core areas, you're better equipped to navigate roadblocks, design impactful clinical trials, build solid reimbursement plans, and ensure your groundbreaking tech doesn't simply end up as a fancy paperweight.

Brett places significant emphasis on the value of effect size, a term used to quantify how the effect of a treatment stands out from other sources of variation. The larger the effect size, the bigger the impact your device makes on patient care and outcomes. When you can prove your device makes a notable difference, people will start to care more about it. As he says, a large effect size provides a "real tailwind" to every aspect of business development. "If you don't have a bulletproof effect size with a wow factor, it's going to be an uphill battle," Brett reiterates. For him, this is a lesson learned the hard way in consumer markets, where the wow factor has to be immediate, not spread over weeks of careful tracking.

Reflecting on his tenure at Halo, Brett admits that he would have expedited the focus on medical applications sooner as healthcare providers are more accepting of varied patient responses; there's less expectation that a device will work instantly for every customer. "In a medical device, if you have an effect size that is clinically meaningful and statistically significant, you can build a market around it," he elaborates.

Although it might seem frustrating to slow down and take time to generate solid data in the lab, a deep understanding of the system you're trying to affect – which is tough to achieve in working with the brain – is indispensable if you're trying to design a good treatment. When there are gaps in your understanding, you can't rely on guesses and assumptions. Instead, a clear understanding of the device's functionality, along with coherent data, is crucial for regulatory bodies and the company moving forward

Shaping the Future of Mental Health: Interview with Magnus Medical Co-Founder Brett Wingeier

Balancing Consumer and Medical Perspectives

Regardless of the type of product you're building, risk analysis and understanding the product's benefits are at the core of your business. And the most essential component is the data — you have to understand what your device does and be able to show it.

Both consumer and medical devices follow the same fundamental principle of weighing risk against benefit. The difference lies in the trade-off: consumer devices necessitate a lower risk profile, and their benefit might be perceived differently compared to medical devices.

A significant lesson for Brett was understanding the balance between the consumer and provider sides of developing a new product, especially in neurotechnology. In Brett's case, while Halo was an attempt at a consumer play, the company developed their brain stimulation devices with grounding in the world of medical-device engineering and with an eye toward medical applications, in comparison to pure consumer devices like Fitbit and Whoop. After recalling his experiences at both NeuroPace and HALO, Brett now thinks prioritizing medical applications would have been more rewarding. Although it takes a long time to prove the medical relevance of a device, this challenge eventually leads to more impactful devices and, in turn, the chance to carve out unique moats in the market.

Even though they form the foundation for eventual commercial success, a comprehensive data generation strategy and an impactful effect size alone aren't enough. In medtech, you need to demonstrate to regulators that your device is safe and effective, which is why collaboration with regulatory bodies is a key part of the game.

As an entrepreneur, it's important to remind yourself that regulatory bodies aren't the enemy; on the contrary, they are there to support your efforts. Brett notes that the life sciences industry and the FDA are ultimately aligned in their goals: providing beneficial treatments to the public. To realize that, it's important to continue to build relationships with these regulatory bodies to make sure they understand what you're attempting to do with your device and can most effectively engage.

Shaping the Future of Mental Health: Interview with Magnus Medical Co-Founder Brett Wingeier

Twin Pillars of Reimbursement: Data and Cost-Effectiveness

For any innovative medical or health technology startup, the road to success goes beyond technical challenges and regulatory compliance. It extends into the domain of reimbursement. Brett's experience in various healthcare companies has shown him the importance of strategic data collection and an early focus on cost-effectiveness.

He emphasizes: "Data is the foundation. Data is the fuel for reimbursement". By data, he means robust health outcomes, utilization statistics, and cost metrics. All these form the bedrock on which a compelling case can be made for reimbursement.

Brett elaborates: "One of the most important things to do is, to the extent you can from the start, build in the ability to collect not just healthcare outcomes data, but the utilization data, cost data, and other things from the system that help build your overall case." Brett's experience across different companies has instilled in him the importance of integrated data collection from the very inception of product development.

Another core principle Brett highlights is cost-effectiveness. The healthcare reimbursement ecosystem is not just about proving efficacious outcomes but about ensuring that these are achieved cost-effectively. The pivotal part of Brett's approach is that innovative solutions must also make financial sense for the health system. In his words: "Thinking about that from the start, how are we not just helping patients, but also ticking the boxes that make financial sense for the system? It's a key early part that everybody should be thinking about."

Interview with CEO of Pixium Vision
Lloyd Diamond

Lloyd Diamond

Preview

Lloyd Diamond maps out his journey from consulting in Europe to leading Pixium Vision, a medtech game-changer. He shares practical lessons on building a lean and adaptable team, navigating the intricacies of regulatory processes, and succeeding at strategic fundraising. His insights, drawn from hands-on experience, provide actionable advice for startups making their way in the challenging medtech landscape.

About Lloyd

Lloyd Diamond, CEO of Pixium Vision, has a rich history of guiding medtech and biotech companies, with a career that spans decades, continents, and sectors. Lloyd's tenure in both European and American markets, as well as his experiences with large strategic and promising startups, have equipped him with a unique entrepreneurial viewpoint. His current company, Pixium, is developing a groundbreaking retinal implant system that brings hope to patients suffering from advanced dry age-related macular degeneration.

Key Learnings From Lloyd's Experiences

- In the unpredictable world of startups, an agile and lean team that can wear multiple hats is a priceless asset. Tapping into academic ecosystems is one way for cost-effective R&D and talent discovery.
- To survive the stressful process of earning regulatory approval, acknowledge its complexity, anticipate delays, and consider the reimbursement landscape early on.
- Fundraising is more than just securing capital; it’s about cultivating relationships with investors that align with your vision. Treat capital raising as a unique opportunity rather than a tedious necessity.

Defying Boundaries in Medtech: Interview with Pixium Vision CEO Lloyd Diamond

Strive for a Lean, Multitasking Team

The first cornerstone of Lloyd's advice is to keep things lean. In his words: "Everybody says to do more with less, as cliché as it sounds. When you're an early-stage startup, you have to remain lean." On one level, this refers to learning how to manage your resources wisely and operate on a tight budget, but it also applies to pursuing agility within your team. As Lloyd puts it, you need people who can "wear several hats."

In a startup, employees often need to take on multiple roles simultaneously. The ability to handle diverse responsibilities — be it understanding and communicating complex scientific concepts or simply cleaning up the kitchen after a meeting — becomes a priceless asset. According to Lloyd, however, such qualities are becoming increasingly hard to find, particularly amongst the newer generations who are wired for instant gratification and specialization.

Lloyd's tip for building a proficient, multidisciplinary, and humble team is to stay close to the universities. He notes: "[The university] is an extra resource you can leverage. It has people that are always looking to do research. So, put PhDs to work and use the university setting to really hone and scientifically prove what the tech you're trying to bring forward can do."

In summary, universities can be priceless opportunities for startups whose goal is to iterate cost-effectively. By doing so, you also help educate and train the next generation of professionals and then benefit from that pool of talent.

Lloyd's Five-Point Strategic Approach to Earning Regulatory Approval

Regulatory approvals are often one of the most daunting challenges for medtech companies. Fortunately, Lloyd is a resourceful executive when it comes to regulation. He advocates a five-point strategic approach when trying to achieve regulatory clearance.

First of all, Lloyd bluntly states that "it always takes longer than you expect," so anticipate delays. Even with his three-decade-long career in the field, he acknowledges that regulatory processes invariably run over schedule due to many factors outside of your control. As a CEO, your task is to incorporate a buffer time in your timelines to mitigate the impact of any unforeseen delays.

Defying Boundaries in Medtech: Interview with Pixium Vision CEO Lloyd Diamond

Lloyd's Five-Point Strategic Approach to Earning Regulatory Approval

Lloyd acknowledges that the regulatory environment is rapidly changing. His second piece of advice is more of a reality check: "Regulations are getting tougher, not easier." Devices that used to take 18 months and a couple of million dollars now require 10 to 12 years and about 150 million dollars, depending on what you're developing. This means companies need to be proactive and stay updated on current regulatory shifts and allocate their resources accordingly.

Another crucial point Lloyd makes is that regulatory compliance "always costs more than you anticipate." For that reason, you need to surround yourself with investors who truly believe in your mission. Lloyd suggests finding "one or two investors early on...friends, family, angels... who really believe in your mission and whom you can count on when things get tough."

It's not just about the financial backing; their collective wisdom and experience can prove invaluable in navigating the many obstacles that early-stage companies often encounter. Even though securing initial investment doesn't guarantee an easy ride, it equips startups with the resilience and agility they need to survive in the medtech space.

Another step of Lloyd's strategic approach is understanding the long-term consequences. This involves weighing different regulatory routes with their results in mind. While some processes might be faster and easier, they may not offer the best long-term result you're looking for.

Finally, Lloyd stresses the need to consider reimbursement requirements from the beginning. He notes that while most companies understand how important this is, it often falls by the wayside when balancing timelines, budgets, and data requirements. A disciplined approach, despite the high costs and extended timelines, ensures that your clinical trials will support payment at the end of the day.

Defying Boundaries in Medtech: Interview with Pixium Vision CEO Lloyd Diamond

Fundraising in Style: How to Identify Vision-Aligned Investors and Pitch Gracefully

Lloyd's decades-long experience in raising capital has given him a unique perspective. He condensed it into three key principles in our discussion.

First and foremost, being selective about your potential investors is of critical importance. The initial funding is the lifeblood of your company, but unfit investors who don't align with your company vision can undermine your progress in the long run. Lloyd suggests cultivating relationships with investors who can offer capital, valuable connections, and the potential for continuous support in subsequent funding rounds.

Next, Lloyd cautions against appearing desperate when seeking capital. While recognizing that the quest for funding can be stressful, he advises viewing your interaction with potential investors as an opportunity rather than a dire necessity. He says: "Remember, you're offering them a great and unique opportunity to make money because your technology is top and stellar."

The third principle in Lloyd's arsenal is strategic foresight, i.e., considering not only the immediate funding round but also future capital raises, too. He argues: "When you're pitching the A round, you need to think about the C round," stressing the need for viewing fundraising as an iterative process, where each round sets the stage for the next, moving the company forward on its growth trajectory.

Adding to his primary guidance, Lloyd brings up a real-life example that underscores the vital importance of maintaining a financial buffer. When the COVID-19 pandemic hit, he observed several management teams scrambling for resources, despite knowing their cash reserves would be depleted in a matter of months. He pondered why any leadership team would let themselves reach a critical point where they are left with a single month's worth of cash. He uses this example to admonish founders to plan ahead and always maintain a reserve to avoid precarious financial positions.

Seizing Unexpected Medtech Opportunities

Interview with CEO of Ablative Solutions
Kate Rumrill

Kate Rumrill

Preview

Kate Rumrill's journey from being an aspiring neurosurgeon to leading a medtech startup underscores the power of seizing unexpected opportunities. In this interview, Kate, CEO of Ablative Solutions, dives into her three-decade-long career and provides valuable lessons on the importance of thorough research, strategic clinical trial design, and effective reimbursement strategies.

About Kate

Kate Rumrill, CEO of Ablative Solutions, is an accomplished leader with over three decades of comprehensive experience within the medical device and pharmaceutical industries. She brings a unique blend of expertise to the table, spanning roles from clinical affairs to executive management, with pivotal stints at prominent companies such as Eli Lilly and Covidien.

Key Learnings From Kate's Experience

- Sustained success in medtech requires three ingredients: thorough research, a deep conviction in your technology, and a complete understanding of its potential impact on patients' lives.
- When designing clinical trials, you must take into account the required capital, regulatory compliance, and end-user experience. This involves engaging with the right stakeholders, investors, regulators, and practitioners early on to pre-empt potential issues and future-proof the trial design.
- A comprehensive understanding of your technology's unique landscape is crucial to devising a successful reimbursement strategy. Your plan must be comprehensive and articulate, as investors are interested not just in the technology but in how it will get paid for.

Seizing Unexpected Medtech Opportunities: Interview with Ablative Solutions CEO Kate Rumrill

Leaning Into and Leveraging Personal Drive

The medtech terrain is often risky, challenging, and fraught with uncertainty. Yet, for seasoned industry leaders like Kate, these are the very elements that catalyze innovation and opportunity.

Having held influential roles at Covidien, NeoSync, and, currently, Ablative Solutions, Kate's career journey offers essential insights into leveraging strategic pivots to ascend the professional ladder.

Some of the most important things for professional success, according to Kate, are having a comprehensive understanding of your product along with a deep belief in the technology you're working on. More than merely understanding a company's position, Kate underscores the need for personal conviction in the technology's potential to impact patients' lives. In her case, both of her parents struggle with hypertension and aren't fond of taking their medications. This personal background reinforced her drive to explore medical devices for this particular problem.

When stepping into unknown territories, Kate posits that understanding the medical need and having a vested interest in your target illness is crucial. She explains: "What is the unmet medical need and what are you trying to do there? I always try to think about that."

Despite facing skepticism, Kate's conviction in the potential of renal denervation led her to join Ablative Solutions. Her belief was anchored in expert opinions, a nuanced understanding of hypertension, and meticulous scientific evaluation.

The critical lesson learned was understanding the real-world implications and having realistic expectations of a technology developed for treating a complex medical condition like hypertension. She says: "Hypertension is a lifelong illness, and it's very complex because it's not just what's going on with your sympathetic nervous system. It's diet, it's exercise, it's lifestyle. All of those sorts of things factor in."

Overall, Kate's experiences underline the value of extensive research, personal connection, realistic expectations, and a firm belief in the technology you're developing.

Seizing Unexpected Medtech Opportunities: Interview with Ablative Solutions CEO Kate Rumrill

Devising a Strategic Clinical Trial Design

The medtech realm is a highly competitive space. And one thing to keep in mind is that the best technology doesn't always win. A great product blueprint is only as good as its reach and utilization. It's also critical to ensure your product aligns with the available reimbursement mechanisms.

The lesson here is straightforward: you need to factor in all the different aspects of your product when designing clinical trials. Fundraising, regulatory expectations, and end-user experience should not be afterthoughts but guiding forces from the inception of the business plan. A failure to do so, or postponing these aspects to later stages, can potentially derail your venture before it even takes off.

To successfully navigate all of these key arenas, Kate advises consulting with the right people early on. In her words: "You need to be looking ahead, and you need to be looking around the corner when designing your clinical trial because after it's implemented, it's too late to make significant changes."

The *right* people she's referring to are investors, regulatory stakeholders, and practitioners. When you involve experts from diverse aspects of the product's life cycle, proactively addressing the potential questions that may arise in the future, you can ensure your clinical strategy is built on a robust foundation.

Do Your Reimbursement Homework or Suffer the Consequences

When stepping into the world of medtech startups, predicting the unpredictable is a core tenet of success. As Kate bluntly states: "You need to constantly be challenging yourself and thinking about the what ifs." The industry is dynamic, and unexpected hurdles are more of a certainty than a possibility.

What distinguishes successful medical device entrepreneurs, according to Kate, is their capacity to adapt in the face of these unforeseen circumstances. Based on her experiences, preparing for the unexpected comes down to one thing – thorough homework.

Kate explains that reimbursement strategy is not a one-size-fits-all concept. "It's hard to give general advice because reimbursement is so different depending on the technology," she shared. That is why understanding the unique landscape of your technology is crucial, and it's a question investors will certainly ask.

Seizing Unexpected Medtech Opportunities: Interview with Ablative Solutions CEO Kate Rumrill

Do Your Reimbursement Homework or Suffer the Consequences

"You have to have a strategy, know what the landscape is, and know what your plan is at least at the 30,000-foot view because you're going to get asked about it," she advised. No investor wants to see a deer-in-headlights look when they ask, "Who's going to pay for this technology that you're developing?" Having at least an overarching strategy can be the difference between walking away with or without a check.

From her days at NeoSync, where she cut her teeth in fundraising and perfected her pitch, to her current role at Ablative Solutions, Kate understands that investors are looking for more than just a compelling product — they want to see a roadmap to success that includes a thoughtful reimbursement strategy.

From Circuit Boards to Brainwaves

Interview with CEO of Noctrix Health
Shriram Raghunathan

Shriram Raghunathan

Preview

Shriram Raghunathan, founder of Noctrix Health, shares how a mindset of exploration has driven his venture into the development of novel medical solutions within the challenging terrain of neurology. He offers valuable insights on the critical importance of focusing on unmet needs, building a high-performance team, and navigating regulatory and capital-raising challenges.

About Shri

Shriram Raghunathan is a neuroengineering pioneer and founder of Noctrix Health. Shri has been leading his team in the development of innovative solutions to improve the lives of patients with neurological disorders like restless leg syndrome, aiming to level the playing field between medical devices and pharmaceuticals in patient care.

Key Learnings From Shri's Experience

- In the medical device industry, need-to-have products come with much lower friction than want-to-have products. Focusing on the unmet patient needs rather than trying to create a new market for your solution will yield much better commercial results.
- Surround yourself with talented, insightful people who are not afraid to challenge your assumptions. This type of high-performing team can help you navigate risks and offer fresh ideas to drive your venture forward.
- It is crucial to validate the scale of the problem and demonstrate your device's capacity to solve it. This not only manifests the true value of your solution, but also paves the way for its receptions, which is key to attracting the right investors.

From Circuit Boards to Brainwaves: Interview with Noctrix Health CEO Shriram Raghunathan

The Importance of Solving a Real Problem

Shri's foundational precept is coming up with a product that solves a legitimate problem people frequently deal with. He points out: "The one thing that you absolutely cannot change is your unmet need. That's remained our North Star." All other elements of the startup, such as team, product, or technology, can change, but the problem you aim to solve should remain consistent.

In the medical device space, most products are necessities rather than luxuries. Shri reiterates: "We have to remember that we're in a market where things are needs, not wants. Making sure you focus and spend as much time as possible understanding that unmet need allows the rest of the operation to go smoothly."

When you focus on solving a real problem, you inherently pave your path to success in other aspects of the business-like fundraising, regulatory, and commercial. As Shri states: "A strong unmet need with a big market rarely needs a ton of publicity or hype."

Aligning the unmet need with the relevant stakeholders is another crucial aspect that Shri emphasizes. When this happens, smoother operations are often a by-product. For example, if you can align your clinical trial outcomes with both reimbursement and regulatory requirements, that results in a lot of synergies.

Shri also acknowledges that the early development stages may take longer as you need to find measurable ways to assess that your product is addressing the need you've pinpointed, but "it pays dividends on the back end" as your clinical trial outcomes match stakeholders' needs.

As Shri emphasizes, any skilled engineering team can generate possible solutions, but the real challenge is ensuring that these solutions are targeted at the right problems. He offers a thought-provoking observation: "It's mostly, are you solving the right problem? Are you framing the problem in a manner that the solution actually makes sense?"

Furthermore, Shri also addresses the concept of maintaining focus on your mission and exercising the discretion to say 'no.' Startups, particularly in the medical device space, do not have the luxury of frequent pivots. Making the selection of must-haves versus nice-to-haves is key.

From Circuit Boards to Brainwaves: Interview with Noctrix Health CEO Shriram Raghunathan

Build a Team That Isn’t Afraid to Challenge Assumptions

One of the most crucial lessons that echoes amongst successful medtech entrepreneurs is assembling and nurturing a high-performing team and a supportive community. Shri says: ”I was fortunate to have a lot of people around, some of whom I work with today, including my founding team, as well as mentors and advisors that offered free advice.” This isn't simply about creating a team for the sake of it, but curating an environment where every individual can contribute with their unique perspectives, enriching the overall fabric of your startup.

A strong and supportive team can act as a bulwark against the myriad of challenges and risks that come with entrepreneurship. “You don't want to be surrounded by ‘yes’ men. I get scared when that happens because I know I'm not the sharpest knife in that toolbox. And if everybody's heads are nodding as I'm speaking, then something's wrong,” Shri wisely suggests.

Beyond building a team, it is essential to foster a culture of trust and open communication. “Having people who are not just experienced but also frank, honest, and willing to have the hard conversations upfront with you pays dividends. You build that trust over time, and you wind up being much more productive as a team.” A good team does more than just execute; it challenges assumptions, broadens perspectives, and fosters growth.

You also need to give your team members the freedom to excel in their areas of expertise. Shri says: "You can't just surround yourself with people and then tell them what to do. You have to let them do what they're good at, which means setting your ego to the side, rolling up your sleeves, shutting up, and helping."

Broadening the scope beyond the immediate team, Shri also underlines the importance of cultivating relationships with a wider community: "In hindsight, I would have just said, have more people, more relationships, more mentors, around you. Reach out to more people and ask for help." A network of trusted peers can become invaluable sources of advice and support, especially during the tumultuous startup journey.

From Circuit Boards to Brainwaves: Interview with Noctrix Health CEO Shriram Raghunathan

Accelerating Fundraising With an FDA Breakthrough Designation

In an ever-competitive market, fundraising can often be a formidable hurdle for start-ups. Shri revealed how his company leveraged FDA breakthrough designation to bolster its funding strategies.

For Shri, a successful process begins with identifying the right investors. As he states: "It's not just about the check, but about the beliefs behind that check and what else they can do. Are you actually seeing eye to eye with those people?" The investor's belief in the business mission is just as important as their monetary contributions.

Validating the problem and its magnitude is a cornerstone of the pitching process when looking for investors, too. Shri shares: "When we pitch, we really take time to focus on that first piece, which is, here's the problem, here's how big of a problem this is, and here's how we validated that this is a big problem."

Securing the basics builds credibility and forms a bedrock for your future fundraising strategies. In Shri's case, Noctrix Health shot for — and hit — attaining breakthrough designation, and it really influenced the perception of their therapy in the eyes of potential investors, serving as a reassurance on the importance of their treatment. Shri shares: "It was a great validation for us and the RLS community in general when the FDA acknowledged that this is a chronic, severe, and irreversibly debilitating disease, and this therapy has the promise to address that."

Despite the high number of breakthrough designations granted, Shri emphasized the scarcity of devices that eventually make it to the market: "There have only been about 60 devices that have come out on the other side of that funnel." A stark statistic underscoring the extraordinary nature of Shri and his team's achievement.

The breakthrough designation path was also beneficial in terms of engaging with the FDA early on. Shri explains: "Putting my entrepreneur hat on, I think it's a great channel, a great pathway to engage the FDA early. And the agency has been fantastic with our requests for sprint meetings."

Iterating Towards Perfection in Medtech

Interview with CEO of Sonavex
David Narrow

David Narrow

Preview

In this interview, David Narrow, CEO of Sonavex, shares the art of perfecting product design, strategies to adeptly navigate complex regulatory waters, and the nuances of capturing the trust and interest of venture capitalists. All in all, vital lessons for every budding entrepreneur in the medtech space.

About David

Prior to co-founding Sonavex, David Narrow worked with multinational medical device companies on their commercialization and long-term business strategies as a healthcare consultant for Health Advances. David earned his B.S. in Biomedical Engineering with Highest Distinction from the University of Rochester before receiving his Masters from Johns Hopkins University. Narrow was named 30 Under 30 in Healthcare by Forbes in 2016 and 40 Under 40 by the Baltimore Business Journal in 2017.

Key Learnings From David's Experiences

- The ultimate perfection of your product design is a result of continuous iteration. Don't get married to your first prototype; keep refining it. Solicit consistent feedback through every phase, especially from end users, to make this process as cost-effective and efficient as possible.
- When navigating the regulatory landscape, leverage all of your resources and don't be afraid to ask for help from your network. Initiate early communication with regulatory bodies like the FDA to anticipate challenges and understand their expectations.
- There is no one-size-fits-all strategy when it comes to winning venture capital. Keep in mind that investment decisions are often driven by emotions and hinge heavily on your management team's credibility. Utilize your contacts to connect with the right capital partners and learn what drives them to invest.

Iterating Towards Perfection in Medtech: Interview with Sonavex CEO David Narrow

Product Design: Iterate Your Way to Perfection

No new technology emerges from thin air; every innovation undergoes its own development cycle, completed only after countless trials and errors before it is market-ready. This is especially true in the medical device space. As an experienced medtech entrepreneur, David knows that the path to a successful device is rarely a straight line.

The initial design is not necessarily the endgame, so avoid getting too attached to your prototype in the early stages of development. Investing time and resources in refining your initial designs is a necessary part of the process. In David's words: "You make these assumptions when you first start inventing things, but until your end-users actually try to implement the solution, it's all theoretical. And the rubber meets the road when you actually have these people put their hands on it. That's where the real learning happens."

But every iteration means more expenses, and as an entrepreneur, you'll need to draw the line at some point so your company doesn't bleed too much money along the way. In David's case, their team went through 26 different designs on EchoMark before settling on one and transitioning into the rest of the development stages. He acknowledges that the process is expensive, but if you don't iterate on your design based on stakeholder feedback, it'll cost you more down the line.

That's why it's crucial to manage finances wisely during this stage, which means you must move towards your ideal device with a keen eye on every penny you spend. According to David, "It's helpful to use an objective rubric, create scores based on different factors, and seek external input. Use surveys or other types of market research tools to make sure that you're in a good enough place to move forward."

David emphasizes the importance of feedback during the alpha-beta iteration phases: "Making sure that you've had the chance to get adequate user feedback is really paramount... Iterating through a device in the absence of end-user and other external feedback is a doomed mission."

He also underscores that external input is important to maintain a clear vision towards your path as a CEO. He shares: "It's also a lot easier emotionally to have objective input because so much of entrepreneurship is emotional. The highs are great, the lows are terrible."

Iterating Towards Perfection in Medtech: Interview with Sonavex CEO David Narrow

Leverage Your Network to Cross the Regulatory Chasm

According to David, the trifecta of medtech entrepreneurship starts with regulatory approval, followed by quality management and clinical trials.

Venturing into the regulatory landscape requires leveraging all the resources and wisdom of experienced mentors. David recommends tapping into the wealth of free resources, podcasts, and blog posts at your disposal. There is no shortage when it comes to educating yourself and getting comfortable with the topic.

He also underscores the importance of experienced guides who can help decode the key areas of the regulatory arena. He shares: “Across all of these, what is most important, and this is frankly with any facet of the business, is finding a coach or a mentor who can say, ‘Here's what you have to worry about now. Here's what's coming later. Here are some of the considerations”.

However, while knowledge is power, delegation is equally critical. David strongly advises hiring specialists who can effectively steer through the often-complex regulatory requirements. As he puts it: "You've got to find a functional expert, either as an external consultant or someone that you hire internally, who’s going to be able to own a lot of these processes."

Above all, David emphasizes the importance of early and ongoing engagement with the FDA. This echoes his ‘solving the problems from the beginning’ mindset. David suggests: "Engage with the FDA as soon as possible, and get a sense of what pathway they think you're going to go down and their biggest concerns...Collect that information and touch base with them". This strategy is key to understanding regulatory expectations more clearly, and consequently, anticipating potential issues that may eventually come up down the road.

The regulatory function might seem daunting, but with proper guidance, resource utilization, strategic planning, and active engagement with the bodies, you can successfully navigate the safe shores of approval and market authorization.

Iterating Towards Perfection in Medtech: Interview with Sonavex CEO David Narrow

Put Yourself in the Shoes of Your Investors

David's perspective provides a fresh approach to the complex process of fundraising for medtech startups. First, it's important to understand that venture capital is the lifeblood of any life sciences startup and a crucial phase in determining whether your ship's going to sail or sink. To secure it, however, you need more than a compelling pitch. As David underscores: "People are going to invest emotionally versus logically." That's why it's more about understanding the motivations and processes of all parties involved than just laying out empirical facts.

As David asserts, raising capital isn't a one-way street. However, he also acknowledges some guiding principles that can make the process less frustrating. The key is to realize the importance of timing, the relationships you've built, and the context in which you ask for money. Soft skills, thus, are as important as hard facts in this endeavor.

David shares: "The most important thing that I learned, and it was pretty early on, is the weight of the empathy element, really putting yourself in the investor's shoes. As an engineer, I naturally had an empirical approach to laying out a set of facts...That couldn't be further from the way things actually were."

That's why relationships and networking are pivotal. It's critical to target the right people, and as David points out, leverage your network to get the right introductions. Furthermore, understanding what drives different types of investors, like angels, venture funds, family offices, and strategic investors, is paramount.

Interestingly, one of the most effective strategies time-tested by David, as counter-intuitive as it sounds, is engaging with investors even when you're not raising capital. As David puts it: "People don't want to be aggressively sold to where you're saying - Hey, I've got this company. It's a great deal! Listen to my aggressive pitch!"

Beyond strategy, timing, and networking, the human element of fundraising can't be discounted. David posits: "So much of an investor's bet is on the management team and the founders versus the technology."

Finally, the cornerstone of successful fundraising, according to David, is meticulous preparation. His parting advice to fundraising CEOs is to map out a detailed plan and lay out their strategies, budgets, and future milestones. Plans are subject to change, however, a sophisticated approach solidifies your credibility in the eyes of potential investors.

Embracing Ambition Without Arrogance

Interview with Luminelle CEO
Allison London Brown

Allison London Brown

Preview

Allison London Brown is a seasoned healthcare executive turned startup pioneer. In this interview, she shares insights on how to best understand your strengths and weaknesses, the potential pitfalls of 'one size fits all' regulatory strategies, and innovative methods to secure capital in a risk-averse economy.

About Allison

With over 25 years of experience in the healthcare space, Allison London Brown has been involved in nearly every aspect of product development for women's health. From Fortune 50 companies like Johnson & Johnson and GE Healthcare to founding startups, she's seen it all. Now, as the CEO and co-founder of Luminelle, she's channeling her decades of knowledge into a revolutionary new device aiming to transform gynecological procedures.

Key Learnings From Allison's Experiences

- Lean into your strengths and weaknesses as a medtech entrepreneur. It's not about being an expert in all areas but about recognizing your own gaps in knowledge and having the guts to seek out partners or team members who can fill those.
- There's no 'one size fits all' strategy for gaining regulatory clearances or approvals. Look for consultants that are experienced and accomplished in your domain, but don't expect them to be superheroes.
- Medtech breakthroughs require funding, but it's no secret that fundraising is challenging, especially in the current economic climate. That's why you need to unleash your creative genius and come up with unique, attention-grabbing ways to captivate prospective investors.

Embracing Ambition Without Arrogance: Interview with Luminelle CEO Allison London Brown

Lean Into Your Strengths and Weaknesses

Being a CEO often makes you feel like you need to have a thorough understanding of every facet of your business. But let's face it, no one can be an expert in every single area, especially in the highly-regulated and complex world of medical devices. One crucial lesson Allison shares is the idea of leaning into your strengths and weaknesses, especially when your background is in a specific area, such as engineering or marketing. She shares: "I myself do have a scientific background, but I am not an engineer, so I was fortunate to find a partner who came on later to really help design something elegant and simple."

Allison also draws attention to the value of assembling a diverse and balanced team. The essence of a successful venture, she claims, doesn't lie in individual brilliance but in collective effort.

Her own strength was in her market knowledge and the relationships she had built within the women's health community. She leveraged these to connect the dots between different phases of her company. It takes more than a good idea, as she shares: "You need to have a commercial market, intelligence, pricing, marketing, R&D, and clinical. Everything has to be married at the very beginning."

Allison's overarching advice here is that the reciprocity between different disciplines and the successful combination of various expertise is the magic formula when it comes to success in medtech. This doesn't only pertain to hard skills or technical knowledge but also to understanding the end customer's needs and how to cost-effectively manufacture your product. "I think the ability to quickly tap into resources, find consultants, and bootstrap ways to get to the end result is really critical for entrepreneurs," she explains.

Embracing Ambition Without Arrogance: Interview with Luminelle CEO Allison London Brown

Domain Expertise Can Be a Double-Edged Sword

In most cases, experience is the best teacher. But there's a dichotomy to that. As Allison underscores, domain expertise can be a double-edged sword, especially when it comes to overcoming regulatory hurdles. She underlines the potential pitfall of a 'one size fits all' approach: "If you get a regulatory consultant who's already knowledgeable, they may know the people at the FDA, they may have seen things, been there, done that. But then they may apply the same rule to you that they applied to somebody else, and that might not be the right way to go."

Conversely, she also raises the risk of engaging with an inexperienced regulatory consultant in your specific area: "At the same time, if you've got somebody with no domain expertise, are they going to charge you to learn that?"

The optimal solution, as Allison herself discovered, is partnering with a firm that exhibits a broad understanding of medtech and applies a strategic approach to problem-solving versus a 'plug and play' approach.

Overall, Allison highlights that the decision to hire a regulatory partner should be a calculated one that balances domain expertise, adaptability, strategic thinking, and the ability to align with your company's specific needs and goals. The 'one size fits all' approach often falls short, while a nuanced, tailored strategy is exactly what you should be looking for.

Find Creative Ways to Raise Awareness

There are inherent challenges in raising capital, especially in a risk-averse economic environment where everybody is forced to play it safe. As an entrepreneur, Allison points out that you need to get creative in garnering the attention of both your target customers and potential investors.

Allison asserts that there are ways to shorten sales cycles, regardless of the business model. Her experience in various sectors, such as consumer goods, BTC, and BTB healthcare, has shaped her unique approach to generating demand. The COVID-19 pandemic, for instance, made it harder to get into offices and meet people, but Allison and her team figured out clever ways to promote their products, and it ended up being a catalyst for growth.

Find Creative Ways to Raise Awareness

She shares: "Marketing today is not what it used to be. It is highly data-driven. It is very much about demand and revenue generation, not tchotchkes and cute little ads anymore." In Luminelle's case, they've experimented with all channels, specifically digital demos, virtual meetings, and social media, to get the attention of their potential end users. They aimed to take some of the pressure off their sales team, which enabled their reps to focus more on selling. "We are spending more of our time right now talking about the top of the funnel," Allison shares. She emphasized that once your audience is aware of the product you're building, you can help them to better understand how it can improve their workflow.

Still, Allison's experience showed her that traditional methods are not to be dismissed entirely. "Print is not dead," she declares. Old-school tactics like sending postcards and print material to offices can still elicit responses. To get their attention, she recommends offering them something valuable, such as medical education or interesting and compelling data.

On the subject of capital fundraising, while acknowledging that the environment is brutal, Allison shares her simple strategy — use your network. "I sent emails, did videos, and sent messages out to like 400 people," she says, underscoring the importance of outreach and perseverance, and concludes: "If you are an entrepreneur and you are scared to ask somebody to write you a check, find another job."

In a difficult economic environment, medical device and health technology entrepreneurs need to be proactive and creative, not just in capturing the attention of potential investors but also catering to their target audience's needs and interests. Old methods can be complemented by new ones, and consistent outreach and networking remain central to securing capital.

Bringing the ENT Clinic to the Community

Interview with Tympa Health Founder
Dr. Krishan Ramdoo

Krishan Ramdoo

Preview

Dr. Krishan Ramdoo, founder and CEO of Tympa Health, talks about his journey toward becoming a technology innovator, starting as an ENT physician to eventually developing the world's first all-in-one ear and hearing health assessment system. He shares invaluable insights on the importance of proactive problem-solving, balancing external feedback with personal vision, and the power of tangible products in converting stakeholders to true believers in your solution.

About Dr. Ramdoo

Krishan is a celebrated international speaker, researcher, and educator with a keen focus on the intersection of medical science and technology. He is the CEO and creative mind behind the Tympa platform, an all-in-one ear and hearing health assessment system that has gained global recognition. Some of the accolades Dr. Ramdoo and the Tympa team have received include the prestigious Royal Society of Medicine prize for innovation in ENT, the Rowena Ryan prize for research into ENT, and the Hartopp-Dixon ENT award.

Key Learnings From Krishan's Experiences

- A problem-solving framework is integral to entrepreneurship. Focus on a patient-centric issue where you can identify a clear gap with the existing technology stack.
- Seeking feedback is an important virtue across every function in a startup. However, you don't necessarily have to agree with all of the external input. Balancing feedback with your vision and understanding is vital to making better decisions.
- Your ultimate goal is to transform people into believers of your solution, whether they are investors or potential users. One of the best ways to do this is by providing them with something tangible. Showing rather than telling is a much more effective strategy for conversion..

Bringing the ENT Clinic to the Community: Interview with Tympa Health CEO Dr. Krishan Ramdoo

A Proactive Approach to Problem-Solving

In the early days, Dr. Ramdoo's primary focus was on the product itself. He knew that he had to create a solution that could effectively address a real-world issue in order to change the way things were being done. So, he broke down the problem and identified the key challenge.

When it comes to assessing someone's hearing, you need to look inside the ear, but if there's something obstructing the ear, like wax or an infection, proper examination becomes impossible. Thus, he focused on developing a tool to address this middle phase, the proper examination of the ear. The otoscope, the device used for ear examinations, hadn't evolved much since the 13th century, and Dr. Ramdoo saw that as a clear opportunity for innovation.

Upon that realization, Dr. Ramdoo began with a basic proof of concept and went on to win an innovation prize, which he then used to gather broader feedback from colleagues. "If you've got something tangible to show, it just helps people understand it," he says.

Dr. Ramdoo has always kept patients – his end users – front and center. He aimed to make healthcare more efficient, ensuring that only patients requiring intervention ended up in the specialist's office. He spent the first 12 to 18 months diligently refining the product before trying to raise awareness for what he was building. Operating heads-down in stealth mode allowed him to stay focused on product development, which was crucial for shaping the direction of Tympa and fine-tuning its value proposition.

Once he nailed the gist of what he wanted to solve and how he was going to address it, Dr. Ramdoo consistently sought feedback and iterated accordingly. By focusing on feedback, even from colleagues initially skeptical of his product, he was ultimately able to develop a device that could substantially improve ENT care.

Bringing the ENT Clinic to the Community: Interview with Tympa Health CEO Dr. Krishan Ramdoo

The Importance of Active Listening and Balancing Feedback

Dr. Ramdoo's willingness to actively seek opinions and listen to others was pivotal in the refinement of Tympa's product and strategy. He says, "You may think you have the best idea in the world, but if you're unable to accept feedback, then you're never going to evolve your product. If people give feedback, it's for a reason."

But, this is a nuanced subject. Regarding feedback, Dr. Ramdoo reiterated, "It's essential to carefully evaluate the input you receive from others. Seek out those who will be honest with you and try to understand their perspectives."

Any big idea faces negative and positive feedback early on. Sometimes, the negative feedback can be accurate, coming from a good place, wanting to prevent you from wasting time and energy on something that may not pan out. And sometimes, as Dr. Ramdoo puts it, "People may have concerns about potential changes or how your product could affect their work or business."

While feedback is crucial, that doesn't necessarily mean you have to agree with everything you hear. Balancing feedback with your overall vision and understanding the motivations behind the responses you receive can help you make better decisions. If you're onto a solution that will ultimately help patients in a demonstrable way, then it might be best to tune some things out and press on.

Despite some initial resistance, Dr. Ramdoo used the feedback he got to refine his approach, ensuring that Tympa was addressing a need without unnecessarily disrupting existing workflows and incentives. His ability to dissect and analyze such input was vital in developing the Tympa platform.

While some naysayers were more concerned that Tympa might disrupt the status quo, over time, it became evident that the platform actually helped specialists focus on more complex cases that required their time and expertise.

Navigating Fundraising: Presenting a Tangible, Patient-Centric Product

Having a good idea might open some doors, but to convince crucial stakeholders, showing them what you're doing instead of telling them is a much more impactful strategy. In Dr. Ramdoo's own words, "We have a physical device, and although it's a [combination of] software-hardware, just seeing it changes the mindset."

Tangible demonstrations can resonate with investors and potential users, making it easier for them to grasp the product's value and potential. Being receptive to feedback and iterating accordingly is a crucial part of the early development process. If you take the right actions during that phase, regulatory and commercial rounds become much easier.

Bringing the ENT Clinic to the Community: Interview with Tympa Health CEO Dr. Krishan Ramdoo

Navigating Fundraising: Presenting a Tangible, Patient-Centric Product

Dr. Ramdoo admits that putting together a tangible, patient-centric product was at the core of Tympa's development strategy and a significant factor in its early fundraising success. For him, raising awareness about your company has to be strategic. He says, “The best time to talk to an investor is when you're not raising money.” In the early days, the Tympa team focused on the product, keeping their heads down and trying to be as cash-efficient as possible. They were able to raise some non-diluted grant funding and a series of seed rounds, which helped the team develop a commercial product.

Today, the Tympa team is getting ready to commercialize in the US. To help ensure success, Dr. Ramdoo emphasizes the importance of thoroughly understanding the entire landscape.

“Before raising money to bring the technology to the US, we spent about a year understanding the landscape in the US, which made it easier to speak coherently about our go-to-market strategy."

With the recent FDA ruling allowing over-the-counter sales of hearing aids, Dr. Ramdoo recognized another potential opportunity for Tympa that’s similar to how eye tests are done before purchasing reading glasses. Offering quick assessments can ensure customers are appropriate candidates for over-the-counter hearing aids.

Dr. Ramdoo’s approach to commercialization revolves around effectively managing growth to sustain both the drive for success and the sense of accomplishment. Reflecting on the company's US expansion, he states, "It feels like you've almost got a startup within a startup. We kept the team very lean where everyone is doing a bit of everything because if you grow too quickly without a structure, that hunger for a sense of achievement will be your doom."

From Chaos to Order: The Journey of a Medtech CEO

Interview with CEO of Amplifi Vascular
Sean Morris

Sean Morris

Preview

Sean Morris is a serial entrepreneur who began his career in medical device sales and rapidly ascended to running the Peripheral Vascular Division of AngioDynamics. Sean's career is a roadmap of determination, creativity, and a relentless pursuit of mechanical solutions to clinical problems. In this interview, Sean shares the story — from his first job selling medical devices for AngioDynamics to his current role as CEO of Amplifi Vascular, how his novel Vein Dilation System is poised to revolutionize dialysis patient care, and the many lessons he's learned bringing innovative medtech products to market as a startup CEO.

About Sean

Sean Morris started his professional journey selling medical devices for AngioDynamics. Over his ten-year tenure with the company, Sean rose through the ranks to become the Global Vice President of Marketing and later led the entire Peripheral Vascular Division. After leaving AngioD in 2009, Sean embarked on various entrepreneurial ventures, including the founding of Veniti, which was acquired by Boston Scientific in 2018. He also spearheaded Euphrates Vascular, an innovative startup in the field of microvascular obstructions. Currently serving as the CEO of Amplifi, Sean is focusing on developing the groundbreaking Vein Dilation System to improve access sites for dialysis patients.

Key Learnings From Sean's Experience

- The responsibility in a startup ultimately rests on the CEO's shoulders — nothing is going to get done unless you do it. While this may seem daunting, embracing simplicity can be strategic to effectively tackle unpredictability. On top of that, seeking guidance from mentors and not being afraid to ask for help are important virtues for growth.
- Placing human-centric design, clinical data, empathy, and personal relations at the center of a venture is the key to providing true value to end-users.
- Engage potential acquirers and investors early on — not necessarily to sell or raise funds immediately but to understand if your startup's vision aligns with their long-term goals. Early feedback helps refine your pitch for the future.

From Chaos to Order: The Journey of a Medtech CEO with Amplifi Vascular CEO Sean Morris

Embracing the Challenges of a Medtech Startup CEO

Being a CEO, especially in the early stages of a startup, isn't about glamorous moments in the spotlight. You'll need to make tough calls and endure unexpected challenges while trying to consistently make the best decisions for your company. The role requires a deep commitment along with constant vigilance.

In Sean's words, "In a startup, as the CEO, you have got to do everything. You can't depend on anybody else to do your job for you".

Sean continues, "It's very easy to read a story around some overnight success. But if you're afraid to roll up your sleeves, do a lot of dirty work, and get into the weeds, and if you have an ego around not being willing to do certain aspects of a role, it's not usually going to work out."

However, this isn't to say you should do it alone. On the contrary, surrounding yourself with a skillful and supportive team is crucial. Sean shares, "You want to align with good people, and you want to have really good supportive investors. The smart money; not just the capital but the people that want you to be successful too."

Still, at the end of the day, the primary responsibility rests with the CEO, and this role requires that you approach every aspect of the business hands-on, be it regulatory, clinical, R&D, marketing, or Key Opinion Leaders (KOL) engagements.

Sean advocates for a streamlined approach — "Don't hire a bunch of people to the extent it's possible. Find like-minded people, maybe some advisors that are not full-time employees." In line with this, one particular analogy Sean shared is golden: "In a startup, you'll feel like you're trying to fix the car while you're driving it down the road."

Lastly, amidst all the responsibilities and under the weight of decision-making, Sean underscores the importance of seeking guidance and mentorship. According to Sean, the best mentor is someone who is supportive without being judgmental; someone who can provide insights without dismissing your questions. His candid advice is simple: "Talk to enough people to find your ideal mentor."

Effective Communication Will Carry You Forward

According to Sean, a CEO plays a dual role — understanding the intricacies of the business and communicating these complexities in easily digestible terms.

He advises not to overwhelm others with complicated terminology or technical jargon. Instead, adopt clarity and simplicity. Focus on making key points stand out and emphasize what needs to be accomplished. He stresses: "Spoon feed your comms in a way so your words are almost like bold letters. Like they're a little bit larger so it's clear what you're trying to accomplish."

Effective communication isn't just about relaying information. It's about acknowledging mutual goals and creating a dialogue. Sean emphasizes the importance of recognizing that both parties, whether it's the company or the FDA, are working toward public safety and well-being.

That's why empathy stands out as a crucial skill for a CEO, especially in startups, enabling you to understand others' needs, concerns, and aspirations. You need to read the room to ensure the message is heard while fostering trust and building lasting relationships at the same time.

But apart from empathy, empirical evidence also helps to crystalize your mission, milestones, and progress. Sean emphasizes that the most valuable thing you can deliver is clinical data on humans, whether it's a safety study or a pivotal study. "Few things will create external value as much as human data does," he says. Such tangible data can play a significant role in drawing the attention of potential investors as well as your key clinical and regulatory stakeholders.

The Importance of Establishing Early Dialogue

It's vital to initiate conversations with potential acquirers and investors early on, not necessarily for sales or raising funds, but to get an understanding of whether there's a mutual vision alignment between the parties. Such interactions can provide invaluable feedback, refining a startup's pitch to woo future potential partners.

Sean's perspective is rooted in real-world experience. He reflects on his days at Veniti, which was later acquired by Boston Scientific: "I like to get strategics on our radar sooner rather than later. And I'm not in there in a desperate way saying, 'Oh my gosh, are you going to buy us?' Instead, it's, "Hey, here's what we're working on. I want to see if it's aligned with your vision of the future."

Building such relationships is mutually nurturing in the long run. For instance, Sean has managed to get large strategic companies like Boston Scientific and Philips to invest in startups he was associated with. On that note, he also emphasizes the importance of building trust and communicating regular updates. Engaging with large multinationals isn't just about securing funds; it presents an opportunity for establishing serious credibility.

Fundraising, a closely linked concept, is another area where being proactive sets you apart. Sean advocates for an "always be capitalizing" mindset, a variation of the classic "always be closing" sales mantra. In his words: "Often, the best time to raise money is when you don't need it."

About the Author

A self-described medical device and health technology enthusiast, Scott is a Founding Partner and Managing Director of Big Sky Biomedical, a medical technology venture studio focused on designing and developing novel interventional therapies. He currently serves as President and CEO of FastWave Medical, a spin-out company founded by Big Sky Biomedical partners, which has successfully closed on nearly $20M in capital in less than a few years.

Scott is also a Co-Founder and Advisor to Crossfire Medical, a Big Sky Biomedical portfolio company, which has garnered its own share of attention and is focused on the chronic venous insufficiency arena.

He founded Medsider in 2010 with one simple goal: help ambitious doers learn from experienced medical device and health technology entrepreneurs. Scott's work with Medsider has been featured in publications like Forbes, Mass Device, MedCity News, and MD +DI.

Scott has participated in highly-popular podcasts with Dave Asprey, Skinny Confidential, Ben Greenfield, Aubrey Marcus, and many others. He's also been featured in media outlets like the New York Times, ESPN, and Men's Journal.

About Medsider

The chief aim of Medsider is to help ambitious doers learn from proven medical device and health technology entrepreneurs. These experienced founders and CEOs will show you how to:

- Improve your commercialization plans.
- Enhance your regulatory submissions.
- Strengthen your reimbursement strategies.
- Streamline your R&D efforts.
- Raise capital for your startup.
- Advance your network and career.
- And much, much more!

On a monthly basis, tens of thousands of people consume Medsider podcasts and articles. Folks just like you — men & women, CEOs & entrepreneurs, leaders & teammates, and many others who are interested in ensuring their success within the broader healthcare ecosystem. Learn more at **medsider.com**.

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