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Book your Vegas convention today. For more information, please contact Michael Dominguez at mdominguez@mgmresorts.com.
Getting Where You Need to Go

AS USUAL, IN THE WORLD OF APPS and such, I’m a day late and a dollar short. I do not like the navigation system in my car, so I use Google Maps on my phone to get where I need to go. It doesn’t send me on crazy routes and I can choose to take alternates in case of traffic. But in just one week, I heard about the Waze app quite a few times. At first, I thought we were talking about Shazam, which is how you find out the name of the song by holding your app to the source of the music. But no. Waze is GPS navigation that is crowdsourced to include “live” navigation. Avoid a pothole? Check. Cop ahead? Check. Re-routing around a parade? Check. It’s GPS on steroids, which Google bought in 2013. Check.

It used to be in the job market, you could pretty much rely on the tried-and-true methods to navigate your way to a good job or profession. Go to college, get a degree, start into an entry-level job and then move your way up. Eventually, another degree would put you in the running for a better position in the same company or for a closely-related company that would scoop you up.

But the current roadmap for a career is not so direct. There are generational gaps on what people can expect will happen to them. Currently, the average number of jobs held by baby boomers is 12. For millennials, that number is already at three to four jobs, and they haven’t even tapped out yet.

In the pharmaceutical industry, we can see more clearly than ever in this year’s annual Emerging Pharma Leaders issue that there is no hard and fast direct route for getting ahead either. This year features more titles that didn’t exist five years ago, more diverse paths these professionals took to get to their current position, and a bit more awareness and positive reflection on the skills and attitudes that got them where they are today.

Let’s plug that into our Waze for Jobs in Pharma app. This is what it would pop up:

» Follow Your Passion
» Curious About Commercial (or another part of the business)
» Build a Team and Support Its Talents
» Listen to Others
» Realize When You Need Guidance
» Loyalty Still Matters
» Gratitude

A key for Waze to function optimally is to thumbs up or thumbs down the information that appears on your screen. While, personally, I find that distracting when you are driving, if you don’t agree or disagree that you did see the pothole, police officer, or parade, then the information you pass along to the next person is going to be that much less accurate.

The Emerging Pharma Leaders Class of 2018 (see page 12) knows they didn’t have a Waze to get where they are. But, philosophically, they abide by the idea that sharing information and imparting advice will make those behind them that much more aware. Many EPLs teach, mentor, and give back to others. The following are just a few words of advice from our EPLs for those on the pharma journey:

» “I try to concentrate on enhancing their critical-thinking and building the necessary soft and technical skills that could be transferrable, such as leading project teams, communicating with non-technical audiences…”

» “Be bold, take career risks, and don’t be afraid of diversification…”

» “...seek out diverse viewpoints and insight from advocates, mentors, colleagues, etc.—especially those with different opinions and life experiences.”

» “…all of us are better than any one of us.”
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Leadership

The MBA Path in Pharma, Healthcare
Julian Upton, European and Online Editor

A growing range of MBAs with concentrations in pharmaceuticals and healthcare management are on offer in university curriculum from coast to coast. Pharm Exec looks at how three of the top programs in the US prepare their students for industry success.

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Cover Image: alphaspirti/stock.adobe.com

2018 EMERGING PHARMA LEADERS

Pharm Exec’s 11th annual list spotlights a select group of biopharma managers who are poised to help chart the industry’s path forward. We present the diverse stories of 10 rising executives—and detail how each are changing the ways leaders direct critical industry functions such as R&D, data and analytics, patient advocacy, business, commercialization, and human resources.

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Reader Feedback

Yes, we will be ready to start marketing curative therapies soon, at least for cancer, because of viable oncogenic KRAS inhibitors and immunotherapy coming into play. However, I have come across some big pharma companies who expressly informed me that "curative therapies" do not fit their business model. Not a smart thing to say to a cancer biologist with expertise in drug design that is also a patient activist.

Anonymous

"Marketing Curative Therapies: Are We Ready?"

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FDA Launches Major Push for New Antimicrobials

The critical need for new medicines to combat infectious diseases that fail to respond to current medical treatment is prompting FDA to join with other federal health agencies and the biomedical research community to advance the science, regulatory policies, and reimbursement strategies to support innovation in this area.

A main problem is that current payment and coverage policies for new drugs encourage widespread use of the product to generate a sufficient return on investment to companies sponsoring research on new treatments. But to remain effective against lethal pathogens, new antimicrobials need to be used very sparingly, cutting revenues in the process.

These financial obstacles have curbed industry investment in developing new antimicrobials. The Pew Charitable Trusts reports that as of June only 42 new antibiotics were in clinical development to treat serious bacterial infections. Just one in five, moreover, are likely to succeed, and only a handful have potential to address serious resistance problems, such as gram-negative bacteria, which cause particularly hard-to-treat infections.

To address this crisis, FDA Commissioner Scott Gottlieb recently unveiled a 2019 Strategic Approach for Combating AMR (antimicrobial resistance) at a meeting last month organized by Pew. The plan includes policies and programs to encourage development of new drugs, diagnostic tests, and vaccines; to promote responsible stewardship of antimicrobials in animals and humans; to improve surveillance of antimicrobial use and resistance; and to advance research for developing new tools, standards, and policies in this area.

Reimbursement critical

Key to spurring innovation in this field is to devise new reimbursement strategies to support the development of products that would be prescribed and used on a highly limited basis. In a June statement, and again at the Pew conference, Gottlieb outlined proposals for devising innovative milestone payments and subscription fees for developers of products targeted at multi-drug resistant organisms.

To maintain a robust pipeline for antibiotics, Gottlieb recognized the need to “change the perception that the costs and risks of antibiotic innovation are too high relative to their expected gains.” One proposal is a subscription-based model that charges hospitals a flat rate or licensing fee for access to a certain number of doses each year of a new antimicrobial. By creating a predictable revenue stream, this kind of “pull incentive,” Gottlieb explained, would “create natural markets for drugs targeted to rare but dangerous, multi-drug resistant pathogens that can threaten human health.”

FDA is working on pilot programs or demonstrations of such reimbursement strategies with the Centers for Medicare and Medicaid Services (CMS) and other health and research agencies, such as the Gates Foundation, the Center for Medicare and Medicaid Innovation, and the Biomedical Advanced Research and Development Authority (BARDA), along with insurers and payers. These might include add-on payments for new technology, including antibacterial drugs that meet public health needs.

FDA’s initiative for combating AMR also includes a new five-year plan to support antimicrobial stewardship in veterinary settings. A main aim is to curb the use of antibiotics to promote animal growth. Another part of FDA’s plan involves improving surveillance of antibiotic use in humans and animals to track infections more quickly and help determine when antibiotics should be used and then discontinued. This involves refining standards for transmitting data on antimicrobial sales and on-farm product use. Equally important is support for developing in vitro diagnostics able to detect disease rapidly, identify appropriate treatment, and track resistance. FDA also seeks to clarify standards for transmitting lab test results related to antimicrobial use and resistance.

JILL WECHSLER is Pharmaceutical Executive’s Washington Correspondent. She can be reached at jillwechsler7@gmail.com.
A More Focused Approach to Targeted Pain Therapies

To help combat the nation’s opioid epidemic, FDA is promoting a more tailored approach to developing and testing effective analgesics, with the aim of bringing less addictive pain treatments to market more quickly. This is part of a range of strategies for reducing excessive opioid use and misuse, while ensuring patient access to effective treatments for pain and addiction.

FDA’s latest step involves issuing a series of guidance documents that map out specific methods for developing more targeted pain and addiction treatments, including abuse-deterrent opioid formulations and analgesics with low- or no-opioid formulations. To set the stage, FDA is withdrawing a 2014 draft guidance on developing drugs and biologics with analgesic indications, explained FDA Commissioner Scott Gottlieb in a recent statement. The old advisory will be replaced by at least four new guidances in the coming year that aim to shift sponsors away from development programs with multiple large studies designed to support new products with broad indications for treating general chronic pain.

The new advisories will recommend that sponsors study one or two populations with an eye to gaining more expeditious approval of drugs or biologics that treat specific kinds of pain in certain patients. An initial guidance will encourage using this approach in developing low-opioid pain therapies that “demonstrate clinically meaningful reduction” in exposing patients to opioids in treating acute pain.

Another document will provide a new framework for evaluating risks associated with the intentional misuse or abuse of new opioid therapies. A third guidance will support the development of extended-release local anesthetics to replace oral systemic opioids in certain situations. And the agency will further advise on developing non-opioid pain therapies to provide safer long-term treatment of chronic pain.

The new advisories will recommend that sponsors study one or two populations with an eye to gaining more expeditious approval of drugs or biologics that treat specific kinds of pain in certain patients.

States expand transparency and disclosure requirements

Just as biopharmaceutical companies are mastering the complexities of the five-year-old federal Open Payments program, state governments are enacting a host of additional marketing and disclosure rules and restrictions on industry interactions with healthcare professionals (HCPs). This stepped-up action on the local level undermines a main promise of the federal program: to avoid a proliferation of diverse state and local reporting requirements that would be difficult and costly for companies to meet.

A main thrust of state disclosure laws is to curb spending on drugs and medical products. Nearly 30 states and the District of Columbia have enacted or are considering new laws to limit pharma marketing activity, require licensure of sales reps, expand clinical trial disclosures, restrict drug advertising, and limit price increases, reported Amie Phillips Pablo, associate director for compliance operations at Novo Nordisk, at CBI’s recent annual Transparency and Aggregate Spend Conference in Washington, D.C. A new law in Nevada requires detailed data from manufacturers of “essential diabetes drugs” to justify and curb prices. California now requires advance notification of price hikes greater than 16% a year and sets limits on payments for new specialty drugs. Similar measures are emerging as gubernatorial races are heating up in nearly 40 states. Drug take-back programs, disclosures related to co-pay cards and rebates, more stringent gift bans, and requirements to adopt marketing codes of conduct are also prominent. A “big new area” for states, added John Oroho, executive vice president at Porzio Life Sciences, is to require local licensure or registration of pharmaceutical sales reps.
Vienna’s Vision on Health Regulation in Europe

What will come out of Austria’s shakeup of European pharma rules?

Vienna’s tradition as a powerful European hub lives on: just like 150 years ago, when the city hosted a breakthrough meeting on the emerging technologies of 1868, it is aiming to do the same in 2018. Back then, it was the crucial International Telegraph Conference that established common regulations for international service. Right now, in the face of rapidly developing healthcare innovation, it was the location for a string of meetings intended to bring a new sense of order to the regulation of medicines.

Early in September, Austria, the current president in office of the European Union’s health council, brought to its elegant capital dozens of ministers, senior officials, and diplomats from across the continent for an ambitious and broad-ranging two-day review of norms, ranging from paying for innovative medicines to making a success of digital health. And as the month moved toward its end, Vienna again welcomed further batteries of officials in a bid to get some real action out of all the talking it generated.

The health council meeting took as its starting point the growing challenges of assuring access to innovative medicines—the focus of ministerial concern since the Italian presidency in 2014, supported in recent years also by the UN High Level Panel on Access to Medicines, the World Health Organization (WHO) Fair Pricing Forum, an Organization for Economic Co-operation and Development (OECD) Health Ministerial last year, and the European Commission’s own expert panel on investing in health. And the tone of the Austrian presidency’s attentions was evident from its formal invitation, with frequent references to “a significant increase in spending for high-priced medicines,” to “growing pressure to sustainably maintain the high quality of care in Europe,” to “differences between member states in availability of innovative medicines, and “evidence … that many newly authorized drugs do not provide any (additional) patient-relevant benefit.”

To tackle these challenges, it is “necessary to adopt a more specific approach in the general debate,” according to the presidency. Its declared goal is “to identify and implement relevant and concrete measures.”

One such area where these “concrete measures” may be introduced, according to the presidency, is in doing something about the “often unstructured” exchange of information between approval authorities and payers, leaving the organizations that have to pay for medicines suffering an information deficit and uncertainties over upcoming costs.

Another difficulty identified by Austria is “the fact that there is no mechanism to disclose pricing models or the level of research and development expenditures”—subjects where information is “often hampered by confidentiality clauses.” Access to information on public money spent on the development of a medicine would make it possible to use the public contribution as an argument in pricing negotiations, it says.

Elsewhere, the presidency highlights criticisms about inadequate levels of evidence to demonstrate patient benefit, studies suggesting limited value in newly authorized drugs, and weak criteria for pricing and reimbursement decisions. Expanding the evidence criteria for approving new medicines could ensure that additional patient-relevant outcomes are measured in the approval process, it suggests.

Uneven access

The presidency focused particular attention on questions of wide availability of new medicines. “Despite the fact that the vast majority of innovative medicines are centrally approved, there are strong timing differences in the availability of new medicines between the EU member states,” it says. “Significantly deferred” market launches in some member states average up to two years after the granting of authorization, it complains. In other words, the current EU rules do not provide adequate supply requirements for the whole EU market. One recommendation the presidency makes is for a stricter interpretation of the existing rules so that manufacturers would risk losing their authorization if a new medicine was not widely marketed. This, it says, “could provide an additional incentive to speed up the market launch of authorized medicines in Europe.”

What are seen as malfunctions of the EU’s incentive schemes for drug research also come under the Austrian spotlight. It homes in on
the lack of control on some manufacturers’ use of the orphan drug scheme to gain unjustified advantage from it. One of the targets is “the fact that it is possible to extend therapeutic applications for active substances with orphan designation at any time without a new authorization procedure.” The active substance may be used for a much larger patient population than originally indicated in the application for orphan status, and the revenues generated cast doubts on the eligibility of such products for favorable financial treatment, in the presidency’s view.

On digital health, the Austrian concern is that Europe is still far away from exchanging data across all areas of their health systems, and insufficient use of the potential benefits is being made. Barriers to interoperability in standards, formats, compatibility, reliability, or accessibility have not been overcome. As a result, the objectives for optimizing care and research will remain unattainable, it warns.

In addition, Austria is continuing to work toward agreement on the proposed—and highly contentious—new rules for coordinated health technology assessment, and to promote the adoption of a recommendation on strengthened cooperation against vaccine-preventable diseases.

**Strategy sessions**

To push forward this ambitious agenda, Austria recalled senior EU officials to Vienna for several working sessions in late September. A meeting of national directors responsible in each of the member states for drug policy started by exploring how to improve the availability of medicinal products—and included discussions on incentives in the pharmaceutical system, and “a strategic discussion on the importance of the pharmaceutical policy for current political debates.” The problem of access in specific European markets featured prominently, with particular attention to the supply obligations, following up on the informal council meeting.

This was followed by a session with the broad title of “Matching Health Needs and Pharmaceutical Research—How to Set the Research Agenda for Public Health.” The costs of R&D of pharmaceuticals are often co-financed by public funds, but because public health authorities have insufficient knowledge of the global structure of companies’ R&D funding, they cannot actively steer research toward unmet medical needs, said the presidency. So it wants to create a platform to improve exchange between national health and research administrations, universities, funds, and international organizations.

There were also meetings in Vienna of a cooperation mechanism among European medicines agencies on legal and legislative issues, the coordination group of national medicines agencies for mutual recognition and decentralized drug authorization procedures, the Network of Competent Authorities on Pricing and Reimbursement, and “learning meetings” of the EMA’s Pharmacovigilance Risk Assessment Committee, its Pediatric Committee, and its Committee for Medicinal Products for Human Use.

**Gains in offing?**

How much will all this achieve—above all in the three months that now remain until Austria hands its presidency over to Slovakia? Closer cooperation among national authorities on information re-

One area where these measures may be introduced is in doing something about the “often unstructured” exchange of information between approval authorities and payers.
This year’s class of Emerging Pharma Leaders embody the many changes that pharma has made to navigate the many complexities in the industry. Newly-created titles that oversee functions that have only come into higher priority in the past five years; executives that have traversed non-pharmaceutical paths to bring different perspectives to their current position; and those that realize the most successful executives are the ones that recognize talent and bring their successes forward.

This year, Pharm Exec received over 100 nominations, and the final 10 selections were judged in a blinded process by three members of Pharm Exec’s Editorial Advisory Board, and a former Emerging Pharma Leader representative. Judging criteria was based on the nominee’s current role; progression of their career; education and extracurricular activities to enhance leadership; and specific case examples. The final 10 are those individuals that have exhibited the qualities, knowledge, and skills that show they have what it takes to make the tough decisions that will continue to face manufacturers in the coming years.

In many of the profiles you will read, and many that you have read in the past, you can’t help but notice some similarities. These individuals share a passion for their profession and they are vested in directly touching patients’ lives. In no other industry do we see this level of commitment, personal reward, and true belief in the difference science and medicine make to the world.

Congratulations to this year’s Emerging Pharma Leader alumni and thank you for sharing your inspiring stories.

— Lisa Henderson, Editor-in-Chief
**A ‘Data Hippie’ at Heart**

Christopher Boone, VP, Head of Real-World Data & Analytics, Pfizer

When Christopher Boone’s children ask him for career (or life) advice, he simply tells them to “always follow your passion,” and though he says they leave the conversation perplexed, due to its lack of clear direction, he feels strongly that it’s advice that has served him well.

By following his passion, Boone now serves as VP and head of the Global Real-World Evidence Center of Excellence at Pfizer. It’s a position that fittingly pulls together all of his previous experiences, and maybe most interestingly, it is a job that didn’t exist five years ago—a testament to the changing landscape of the pharmaceutical industry.

“Candidly, there is no structured academic or professional training to prepare for this job,” says Boone, who holds a PhD in public affairs from The University of Texas at Dallas; a masters in healthcare administration from The University of Texas at Arlington, a bachelor’s degree in business administration; management information systems from The University of Tulsa; and several executive certificates from Harvard University’s John F. Kennedy School of Government.

“One cannot create a standard candidate profile [for this position]. Unfortunately, it’s not like I could identify an existing leader who has mastered this job and suggest, ‘Hey, teach me what you’ve learned in today’s environment so that I may be successful in this role.’”

One characteristic that has made Boone successful is his insatiable desire to learn and attempt new endeavors. It’s how he landed as the CEO of the Health Data Consortium, a public-private partnership working with the White House and the US Department of Health and Human Services focused on advancing open health data in the US under the Obama administration.

It’s also how Boone would join Avalere Health as a VP spearheading real-world informatics and digital strategies. And, before that, in various health informatics and patient advocate roles at the American Heart Association, Cook Children’s Health Care System, and other Texas-based integrated health systems.

While he was always interested in data and technology, Boone didn’t have a true passion for the general application to purposes that did not improve human life. One of his personal drivers for pursuing transformation within healthcare using data and technology was a life-threatening, health-related incident that happened with his mother. Boone says it could have gone much smoother for everyone involved, from the doctors and hospital administrators to his mom and family, if the appropriate health data-sharing technologies were in place.

“At the time, I was relatively early in my career and convinced that my destiny was to be a CEO of a hospital system,” he says. “And I was putting all the pieces in place to achieve that vision, such as working on my masters in healthcare administration and being active in many civic organizations. However, it was that moment that I realized that I could do something greater by enabling the healthcare world with informatics and data. I felt like it was my calling and knew we really needed to do something to transform the industry.”

In each position Boone has held, it has opened his eyes to another perspective or tool that he should pursue to make him more effective. “Honestly, I would love to tell you that I had this master plan for how all of my passions and interests would converge, but I’d be lying—I only wish I had that foresight,” he says. “The only objective I had was to continuously press forward with pursuing my passion, my calling if you will.”

Boone knows that to be successful, you do not always need to be the smartest, but you do need to build a team of very smart and talented people and provide them with the tools to succeed in their respective fields.

“The key to any great leader is to know thyself, which means recognizing and embracing your own strengths and weaknesses,” he says. “I know that if I have a great team with the appropriate mixture of talents and skill sets, then we can do great things.”

Boone credits this perspective to his time playing football growing up, where you are taught to go out on the field with 10 teammates, each with a specific role, responsibility, and skill and to perform collectively to the best of their abilities. Boone also credits his humble beginnings.

“I grew up in a relatively poor community in southwest Dallas called Oak Cliff,” he says. “When you have that type of life experience, it tends to manifest itself into a certain level of humility when you...
are leading people, but it also allows you to better connect with people from all walks of life because you see something in everyone. Clearly, I don’t come from a privileged background, so I don’t see myself as any better than the next person; but I do have the utmost gratitude for the extraordinary opportunities I’ve been blessed to experience, and seek to enable others to accomplish the same.”

Boone’s passion for health data doesn’t stop at the office. He is a featured speaker on the topic at a number of different venues and conferences; has an active Twitter account—at DataHippie—where he shares his knowledge; serves on a number of nonprofit boards supporting the cause; and acts as an adjunct professor of health informatics at the University of Cincinnati. Teaching the next generation of leaders might be one of Boone’s most challenges jobs, given the fast-changing industry. But the fact that he is in a position that was created less than a decade ago, it also makes him the most qualified.

“There is definitely a tendency for students to want to jump right into the highly technical aspects of the course,” says Boone. “But the reality is, the digital world is evolving rapidly and getting more and more automated, which means by the time they are out of school, their core technical skills may be obsolete. I try to concentrate on enhancing their critical-thinking and building the necessary soft and technical skills that could be transferrable, such as leading project teams, communicating with non-technical audiences, and actually solving real-world problems using data.”

— Michelle Maskaly

From Bench to Business

Hong Cheng, Head of Research Strategy & Effectiveness, Sanofi

Imagine being in your early 20s, enrolling at a university in another country where you didn’t know the language and moving there alone. Pretty scary, right? That’s exactly what Hong Cheng did, which eventually led to her current position as the head of research strategy and effectiveness at Sanofi Research and Development in Massachusetts. Surrounded by a family of artists while growing up in China, Cheng’s dad didn’t want her to go into the art industry. Instead, as she tells it, “he wanted me to do something different.” Lucky for both of them, Cheng’s mother worked at a pharmaceutical company and after spending one day shadowing her there as a little kid, Cheng fell in love with science—and the white lab coat, a traditional symbol of a bench scientist.

Cheng holds a PhD in biochemistry/organic chemistry from the University of Maryland, and conducted her postdoctoral research at Harvard University Medical School. While she says being in a research lab was important to help craft her skills and education, her passion was more about helping people. Cheng wanted a career where she could make, and see, a direct impact.

That’s when she entered industry, starting at a small biotech as a scientist. As Cheng moved to larger companies, she also took on more responsibility, including project leadership, and teams-building and management. Meanwhile, she quickly realized that in addition to the science behind the drugs, she wanted to learn the business side of industry.

To achieve this, Cheng attended the MIT Sloan School of Management, earning her executive MBA in 2015. Cheng credits this experience as being one of the best educational lessons of her life, and something she encourages others to pursue. “They said, ‘a scientist’s view is very narrow. We see the science, but we don’t see the broader view of the industry,’” recalls Cheng of the time before she started the program. “During orientation, they said, ‘this program is going to transform you.’ I didn’t believe it.”

But Cheng admits the instructors did deliver on their promise, noting that because it wasn’t a healthcare-specific MBA program, there were people across all industries in the classes, allowing for more diversified learning. “During the program, I began
to realize that one really had to think not just about the science, but how to integrate scientific discovery with the demand of the industry growth.”

This is why when Cheng mentors younger scientists, she encourages them to understand the business perspective. “It makes you become a better leader, communicator, and drug developer,” says Cheng. “Most people who come talk to me about their career, my advice is that first you need to work diligently to really understand the science and how drug discovery works. Then go and learn the business thinking to help you be able to articulate strategy, drive for efficiency, and be more effective. The majority of the time I see a scientist do a lot of great science, but they don’t know how to communicate effectively to make upper management understand the business impact of what they are doing.”

Cheng’s passion for building the next generation of scientists and drug discovery strategists stretches across the world. In fact, she played an important role in building Sanofi’s global research organization, establishing the Global Research Leadership Team, and formulating the company’s research strategy. She worked closely with the oncology leadership group in rebuilding Sanofi’s preclinical pipeline in cancer. Cheng also played a key role in strategic planning for Sanofi’s research presence in China.

When she’s not speaking at a global conference or discovering new drugs, Cheng lends her skills to helping biotech startups with guidance on raising funds, marketing, and articulating their strategy. Cheng is particularly focused on supporting companies run by female CEOs, and serves on a panel of mentors for Springboard, a non-profit organization whose mission is to help women CEOs be successful.

It can get a little clichéd, but people often say “follow your passion,” and that’s exactly what Cheng has done when it comes to shaping her career path. “I never imagined I would go to business school,” she says. “I was a hardcore scientist. I never had a goal of becoming a CEO or CFO.” But Cheng’s passion to go outside the box and make a bigger impact led her down a path she never dreamed of. “I have to be passionate and believe in it, if I am going to do something.”

— Michelle Maskaly

A Mission to Innovate

Kathryn Corzo, VP, R&D Global Project Head, Isatuximab, Sanofi

It would be easy to attribute Kathryn Corzo’s career path in the biopharma industry to two distinct influencing forces—and leave it at that. One was her father, an engineer, who taught Corzo from a young age that there was always a way to solve and fix a problem no matter how complex, which instilled in her a love of science and technology. The other was when a close relative was diagnosed with cancer at a young age. Corzo was already studying pharmacology at Massachusetts College of Pharmacy and Health Sciences, where she would earn a pharmacy degree, and had started working at the Dana-Farber Cancer Institute in the experimental therapies unit, but the experience of watching a loved one undergo “extremely difficult” treatment ingrained in her a personal mission and focus that continues today: steer efforts in drug development to bring novel and urgently needed therapies to patients with cancer.

Both of those examples serve as logical stage-setters for a career in pharma and medicine, but as Corzo’s journey shows, when peeled back to reveal the diverse trajectories and connections along the way, there is usually much more to the story. Those early, defining influences and events all circle back and contribute to what Corzo says is a deeply-rooted purpose to grow and accelerate innovation from the ground up.

“I love startup opportunities, even in large companies,” says Corzo, who today works for Sanofi as VP and R&D global project head for isatuximab, the company’s late-stage investigational drug for multiple myeloma—a new indication to Sanofi—and lead cancer candidate in its oncology-hematology pipeline.

Corzo originally joined Sanofi in 2010 as associate VP of global development operations and strategic planning, attracted by the opportunity to get in the door as the Paris-based drugmaker was reinventing its global oncology business, establishing head-
quarters for a new cancer unit in Cambridge, Mass. Earlier in her career, Corzo was integral to two other starting-point endeavors in big pharma. The first was at Roche in Basel, Switzerland, where she was a market manager for a number of countries and then assumed a business development role during the beginnings of Roche Molecular Systems. Corzo was part of the startup team and contributed to the development and launch of Roche’s genome sequencing tool, the precursor to today’s standard next-generation sequencing technologies. She also managed a portfolio of drugs that included the cancer therapy Neupogen. Later, Corzo returned to the US to become a key part of Lilly’s inaugural entry into oncology. Working in what she called a “startup environment,” Corzo played a significant role in the development and commercialization of blockbuster cancer drugs Gemzar and Alimta across several indications, helping to build Lilly’s oncology business in various assignments—from clinical research to medical affairs to sales leadership—over nearly 12 years at the company. In between Lilly and Sanofi, Corzo even got a taste of the more traditional startup world, serving a stint as senior director, clinical liaison and medical communication, for epigenetics-focused startup Syndax Pharmaceuticals.

“I’m not a person who has stuck with a single line of growing my career in a particular function or a particular expertise,” says Corzo, a native of Massachusetts, who grew up in the town of Andover. “What I’m able to bring my team is an agnostic view in the sense that all expertise and perspectives mean something to me. …When you just work in R&D, you’re a bit isolated from what happens commercially—particularly from a market-access perspective.”

This appreciation of the value chain has guided Corzo at each of her big pharma stops, where she has built multifunctional expert teams in several areas. For example, in her global program head role at Sanofi, she has merged strategies across preclinical, biomarkers, clinical development, biostatistics, regulatory affairs, biologics CMC (chemistry, manufacturing, and controls), commercial, market access, medical affairs, and other functions such as digital.

Over the course of her career, Corzo’s ability to manage complex programs in varied and dispersed markets was vital in the development and launch of four major cancer therapy brands. She hopes isatuximab will be the fifth. Corzo has shepherded the advancement of isatuximab, a monoclonal antibody, from pre-proof of concept to a clinical program that now includes four pivotal Phase III trials, the first of which was completed recently evaluating the drug in combination with other cancer agents. Isatuximab has been given orphan-drug designation in the US and European Union for patients with relapsed/refractory multiple myeloma. A regulatory filing is possible in the next six months, according to Corzo.

“In a way, it’s like a mini-CEO role,” she says of the project head responsibility at Sanofi, where, in the case of isatuximab, Corzo directs program execution across more than 50 countries. “I feel very accountable for the significant investment that we’ve made in this asset, and also making sure as we develop the asset, that patients around the globe will have access to it.”

In positioning isatuximab as such, should it win approval, Corzo credits her team’s commitment—having overcome “major challenges” to get to this point—and what she calls Sanofi’s unique “project-centric culture.” She’s glad as well, she says, for the supportive vision of Sanofi’s new R&D head John Reed, who joined the company in July after five years at Roche. “Our team was one of the first [at Sanofi] to have a patient advocate participate on the project team to provide insights,” says Corzo. “And we brought our commercial and market-access colleagues in early on in the project, right after proof of concept, so that we could work those into the development strategy. I believe that good drug developers are not just those that have clinical insight.”

Corzo also stresses the importance of industry-academia collaboration. In the leaner stages of isatuximab testing, she helped establish an agreement with the University of California, San Francisco (UCSF), which performed preclinical, translational, and clinical work—generating insights that ultimately led to one of isatuximab’s Phase III studies. Corzo and her team have formed other research partnerships to assess combination therapies or biomarkers, including with the International Myeloma Foundation. “The future is around collaboration,” says Corzo, also pointing to the need for greater relationships with regulators and health insurers. “Because patients are waiting. Patients are waiting for new therapies and new innovation.”

Internal initiatives within pharma can impact this effort as well. Corzo was recently selected as one of 40 executives across various disciplines and cultures in Sanofi to participate in the company’s new innovation group, called Ignite. The leaders are connected with the global innovation accelerator ecosystem inside and outside the organization. Corzo, who fondly remarks of “the number of mentors that have
helped guide my career and were willing to take a bet on me,” now mentors female entrepreneurs through programs at MIT and the Springboard platform. And with her sights on opportunities to assume greater business responsibility in new drug development and boost her analytical skills, Corzo is currently enrolled in the Executive MBA program at MIT Sloan School of Management, with graduation next June.

It seems the married mother of one, a daughter starting college, is following her own advice to new professionals entering pharma, perhaps inspired to pursue a similar leadership track that she did. “Be bold, take career risks, and don’t be afraid of diversification,” says Corzo, an avid marathon runner, who has participated in races on all seven continents. “It’s important for a leader to recognize progress, whether it’s success or failure. Because, either way, we are advancing scientific progress and we are one step closer to helping patients who need our commitment to developing new therapies.”

— Michael Christel

Paying it Forward

Greg Griesemer, SVP, HR and Communications, G&W Laboratories

“Are you good with people, have no marketable skills, and want to make a lot of money?” Those were the exact words in a newspaper ad that Greg Griesemer answered after graduating college—Franklin & Marshall with a pre-law degree. Already accepted to law school, Griesemer made the choice to forgo that route and instead pursue the opening with a staffing recruitment agency, much to the delight of his parents.

“They were really psyched at that time, recalls Griesemer, 43, with a laugh. “After a private college education, deciding to go into a commission-based sales role—they didn’t see the return on investment.”

But little could anyone predict then, Griesemer’s early experience as a headhunter (he got the job) would be a springboard to an expansive and difference-making career in talent and HR leadership in the pharmaceutical and healthcare industries, with the Pennsylvania native looking back on those years as critical in shaping his professional identity.

“I answered that crazy ad, and when I sat down for the interview, the gentleman across from me said, ‘I’m not going to teach you how to recruit. I’m going to teach you long-term consultative selling, where the relationship is at the center of everything that you do,” says Griesemer. “That is a foundational item for me that still carries through to today.”

Griesemer is currently senior VP of HR and communications at G&W Laboratories, a company specializing in the development, manufacturing, and sales of generic pharmaceutical products, including topical creams, ointments, lotions, suppositories, oral liquids, and oral solids across a number of therapeutic areas. His pivot to pharma began in 2002, when Johnson & Johnson, then looking to beef up its staffing group supporting the New Jersey operations, hired him into their central talent identification team, liking Griesemer’s recent background at the time recruiting for engineering and operations positions in pharma and medical device. After almost seven years at J&J, including promotions into a variety of recruiting leadership roles and ultimately to director of the company’s global recruiting operations, Griesemer went on to Endo Pharmaceuticals as senior director of talent acquisition and HR operations.

He then segued to the broader healthcare world, joining insurance giant Cigna as talent director, and followed that with a stint in the diagnostics space with Ortho Clinical Diagnostics, before landing back in pharma. At each strategic stop, Griesemer says he’s held firm to the principle of “paying it forward”—not just for the next person that would step into his position, but in building strong and lasting networks and connections along the way.

“One lesson I learned from my father, is always leave things better than you found them, especially before you give it to someone,” says Griesemer, whose father was a factory worker for 35 years. “I
remember when I was 10 or so, I saw him out back washing and detailing the car he just sold. That really stuck with me all these years. I’ve had the benefit of being able to experience different organizations, and I’d like to think that I’ve applied that value as I’ve moved from one to the other.”

Several company-scale examples offer proof. At J&J, Griesemer was part of the core team that led the evolution of its consolidated staffing arm from a 35-person team in 2002 focused on hiring for the NJ-based operating companies, to a centralized, global function of over 200 employees hiring across 18 countries by the time he left in 2009. At Endo, he was a key HR contributor during a fundamental shift in the company’s business strategy, which was moving from pure-play pain management to a holistic pelvic healthcare focus. Griesemer joined Ortho Clinical Diagnostics shortly after The Carlyle Group acquired it from J&J in 2014, directing the staffing of critical functions needed for the business to operate as a stand-alone entity. He developed hiring, talent management, and diversity and inclusion strategies—helping shape the company for a future sale or IPO.

Griesemer joined G&W Labs in August 2016 and quickly rebuilt the company’s HR function—from people and policy to process and systems—over the course of nine months. The HR infrastructure at the time was admittedly broken, having never been harmonized as G&W diversified its portfolio with acquisitions from Teva and Actavis in the prior years.

“We got lean very quickly in HR,” says Griesemer, who works out of G&W’s headquarters in South Plainfield, NJ. The company of roughly 750 people also has locations in Pennsylvania and North Carolina. “[But] I’ve always led small but powerful teams to get a lot done in a short period of time. I’d rather have a Navy SEAL Team Six than a battalion.”

A nimble structure and approach may be more effective in today’s larger business climate for generics, an industry “under assault,” according to Griesemer. Generic drugmakers in the US have had to navigate headwinds such as pricing pressure, consolidation of competitors and customers, and a more competitive market due to FDA approving a record number of new generics. “As part of the HR leadership team, regardless of the role you play, you have to be a businessperson first, HR person second,” says Griesemer, who, in 2013, completed the HR Strategy Program at Cornell University. “You need to have a broader view of the ‘HR system’ that you think will work well with the environment that you’re in.”

With a framework in place, it then becomes a matter of enabling employees to more comfortably embrace shifts in the industry and business, says Griesemer. “It’s our job as the HR function to engage them in a way that they’re enrolled in the change that they’re experiencing, not just passive receivers.”

Griesemer, a single father to two daughters, age 7 and 9, believes good HR leaders and teams, in any industry, during periods of what he terms “deconstruction” on the macro level and internally, are those that recognize what motivates their employees inside and outside the company, and understand the “whole-person” picture in the context of ownership and accountability in employee development.

“That allows people to bring their full selves to work and emotionally feel good, even if they’re in a time in the industry or a company that’s not overly positive,” says Griesemer.

“I do think there is a fine line with HR-driven initiatives from the center. I’d rather figure out how to continually equip managers to drive the engagement at their team level—and focus on how people are feeling.”

Griesemer also points to the importance of employees self-managing the experiences needed to develop as roles and responsibilities evolve. That could include things like forming a “personal board of directors,” if you will, where Griesemer encourages employees to seek out diverse viewpoints and insight from advocates, mentors, colleagues, etc.—especially those with different opinions and life experiences.

In Griesemer’s line of work, it ultimately comes down to the human element. And that goes for those who manage the process as well. For Griesemer, he cites the always well-timed guidance from his mother and others in giving him perspective as he embarked on his latest challenge. “She would say, ‘you need to pull the bow back to shoot the arrow forward.’” A tinge of schmaltz, yes, but Griesemer believes those simple moments of wisdom have reflected in the career decisions he’s made to this point, including G&W, which next year celebrates its 100th anniversary as a values-based, privately-held, family-owned and operated company.

“I really feel like I’m where I need to be and in the chair I need to be in,” he says. “I’d like to continue to help organizations through the pains associated with growth and change.”

— Michael Christel
The People’s Court

Liz Lewis, Chief Counsel and Head, Patient Advocacy, Takeda Oncology

In a quickly-evolving biopharmaceutical world, a host of new titles have emerged to address the intentions, as well as the necessities, for the leaders of Pharma 2020. Titles range from the impressive, ie., Director of Thought Leadership; to the pragmatically existential, say Chief External Innovation Officer; to the currently practical, Chief Digital Officer. And some just fall into place based on experience, expertise, and promise. It is this category where we find Liz Lewis as chief counsel and head, patient advocacy, for Takeda Oncology, based in Boston.

Upon entering college, Lewis pursued a law degree. Nothing out of the ordinary for an intelligent woman, but she then chose a very specific area—a pharmaceutical specialty as a reimbursement attorney. With her JD in hand, Lewis was offered a job at a law firm because, as she says, she “knew the difference between Medicare and Medicaid.” Lewis was later recruited by another law firm, where she became a partner in a relatively unheard specialty field, representing pharma companies and tackling their compliance issues.

In 2002, Lewis joined Millennium Pharmaceuticals to create a legal structure to support the company’s transition into the commercial arena. Millennium was acquired by Takeda Pharmaceuticals in 2008, and was left largely independent to operate as its own integrated pharma company, with CEO Deborah Dunsire at the helm. In 2014, after integrating Millennium into the global R&D footprint, Takeda formed Takeda Oncology, it’s oncology commercial business unit. That is when Lewis’ current role was created. Since that time, she has evolved patient advocacy into a global, strategic business function that, according to the executive, includes patients in every part of the drug development process and allows them to contribute as thought leaders on areas of value and access.

Lewis is candid about the connection between the legal function and patient advocacy. At first glance, it might not seem that a lawyer’s take on patient advocacy would be a natural fit, she told Pharm Exec. “Lawyers tend to look at issues with a skeptical lens. ‘What could go wrong?’ ‘What does wrong look like?’” But Lewis elaborates that the two actually have a lot in common. “They need to have a strategic business focus,” she says. “The two functions overlap and complement each other in many ways and both serve a diverse group in the company. Having an enterprise view into both has been very progressive.”

The serendipity with Lewis’ background couldn’t have been a better stroke of cosmic genius. Her father was a medical doctor and Lewis remembers tagging along on patient rounds with him at the hospital. Her mother had a chronic eye condition, and Lewis accompanied her on doctor’s visits, communicating and advocating for her needs. They were living in Massachusetts during the development of managed care and medical access—topics that Lewis says provided a constant stream of dinner time discussions. Her choice for law was influenced by the discussions around that table, and the importance of access to medicines and medical care for patients; she was passionate about working at the intersection of patients and science.

Lewis says her journey has been an incredible evolution from when she started to where she is today. Along the way, she has had mentors who were able to help her make better decisions and navigate the terrain. At her second law firm, another female partner helped Lewis as she developed the pharmaceutical practice group. When Lewis had her first child, her mentor provided invaluable guidance on how to balance a demanding career while maintaining a fulfilling personal life. “I’ve had the benefit of incredible people, so I feel it is important to give back,” she says. “I mentor within and outside of Takeda, which is a lot of work, but it’s also rewarding.”

Lewis, who supports Takeda-sponsored gender diversity as well as initiatives within the life sciences, has spoken frequently about promoting female leadership; she has represented the company at events honoring female leaders, including the recent announcement of the first recipients of the Massachusetts Life Science Center’s MassNextGen initiative, for which Takeda was the anchor sponsor. Her goal is to help individuals achieve their highest potential and she is also committed to helping groom the next generation of women and men in science by promoting STEM and skills that translate into corporate careers to high school students.

“It takes a lot of resiliency and ability to change and be flexible,” says Lewis. She believes the indus-
try has undergone huge changes on many levels. Where departments were much more siloed, now an enterprise perspective is necessary; patients that were sick and reluctant to speak out, now are making their voices heard, and are encouraged to do so by regulatory authorities; where pricing, access, and reimbursement were not part of the dialogue, they are now recurring topics in all stakeholder discussions.

But with the patient advocacy movement, Lewis says the evolution has also brought inconsistency. “Patients are asking to be more involved in drug development decisions, as well as encouraged by the FDA,” she says. But from the DOJ (Department of Justice) and OIG (Office of the Inspector General) perspective, how companies support patients from an access standpoint is a point of monitoring.” Lewis notes that every pharma company’s approach to advocacy varies, as do the approaches of the actual patient advocacy groups, and there is no one-size playbook. But she says, “At the end of the day, if you don’t develop for patients, if they can’t use your therapy, then that’s a problem. We have to preserve our ability to do that and operate at a high level with high standards.”

Access and costs vs. access and value are two different lenses, explains Lewis. “Is this too much money? What does it cost? How does it impact patients’ needs? This is a real change in the industry and we are all grappling with this right now.” But for Lewis, she says her two teams are talented and well-prepared. “I manage and push and challenge the teams to truly understand the boundaries and our business partners, because that’s what makes both departments successful.”

Lewis credits Takeda for its evolution and accelerated vision, adhering to the core values of the company, called “Takeda-ism” (integrity, fairness, honesty, and perseverance), to ensure its commitment to quality and that the company does the right thing at all times. “I am most proud of what I’ve done to change the two organizations,” she says. “For legal, to evolve the function to reflect and support global legal responsibilities, and in advocacy to rewrite the function and take it from a more relationship-based function to a strategic and substantive part of the business. To take what was status quo and working well for the company and be a change agent has been a very gratifying professional experience.”

— Lisa Henderson

Bridging Science and Solutions

**Shao-Lee Lin**, Executive VP, Head of R&D and Chief Scientific Officer, Horizon Pharma

Since her early teens, Dr. Shao-Lee Lin has been immersed in science and medicine, working in a lab as part of her magnet high school curriculum, learning principles and techniques that became part of the foundation of her far-reaching scientific career.

Now, as the recently appointed executive VP, head of research and development, and chief scientific officer for Horizon Pharma—she started in January—Lin is excited about her new role as she looks with gratitude on her past experiences for future guidance.

“I joined each pharmaceutical company I’ve worked during an inflection point—a time when each was undergoing a transformation—and had the opportunity to contribute to scientific growth as well as toward building a strong, diverse team that could have a lasting impact,” Lin told Pharm Exec. “It was these experiences that drew me to the opportunity at Horizon, where I could help drive the next phase of the company’s transformation and apply the experiences I’ve had throughout my career.”

Lin was an executive medical director, global development at Amgen when the company was undergoing exponential growth. During her nearly nine years there, Amgen grew by well over 10,000 employees.

“Amgen was my transition from academia to the biotech industry,” says Lin. “I learned a lot, including how to develop medicines across a number of therapeutic areas as well as the importance of understanding medical practices around the globe to best ensure that the medicines we developed were accessible to the patients we served.”
In 2012, Lin joined Gilead at a time when it was embarking on what was considered by many a bold, if not risky, approach to chronic hepatitis C. “One of the tremendous draws for me was that Gilead was talking about cures for a chronic illness like hep C,” she says. “The company made a significant investment in the acquisition of Pharmasset, which they felt was the missing link in creating this cure, despite facing tremendous criticism from Wall Street. It was that kind of institutional courage—taking the leap to do something they believed in from a science-based perspective and push the envelope to find a cure in a chronic illness—that was incredibly attractive to me.”

Lin served as VP, immunology and respiratory development at Gilead, and by the time she left, the company had achieved its hep C success—the drug Sovaldi.

A mentor from Lin’s Amgen days recruited her to become the VP, global immunology and renal development at AbbVie in 2015. “AbbVie was in one of these amazing transformative periods,” says Lin. “The patent cliff from Humira was on the horizon. It was an immunology company, which was solidly my foundational background as a scientist and a physician, and that gave me the opportunity to contribute very rapidly.”

Lin was promoted a year later to a corporate officer level as VP, therapeutic areas, development excellence, and international development. In just under three years, she built and led a team of therapeutic area and international development heads that brought a next-generation hep C cure to market; filed for the first medicine for endometriosis since 1990; and witnessed a new approval in multiple sclerosis. Lin’s team, responsible for acquiring and advancing programs through the pipeline, also expanded the immunology area by identifying and aggressively advancing two “pipelines in a program,” each delivering in Phase III and demonstrating even further potential with Phase II results in additional indications.

As Lin reflects on her experiences at AbbVie and in other industry positions, she is grateful for how each has contributed to what she brings to her current position. She describes her days at Amgen as “building bridges” and noting, “it takes many people building bridges together to be successful.” From Gilead, she learned “how to build the plane as we flew it and to take calculated risks and apply the 80-20 rule to get stuff done.” And at AbbVie, it was all about “making possibilities real, building teams, and ensuring processes supported the programs and the people.”

Today, at Horizon Pharma, Lin brings these experiences and skills of building successful teams and effective processes to the ever-changing world of drug development.

“This is my first time working with rare diseases, and I know we have to look at development in a different way. At the current pace, with over 7,000 rare diseases, it would take thousands of years for us to find and develop medicines for each of those diseases,” she says. “At Horizon, we have a culture that strives to do things differently and build teams that can break down those traditional barriers to progress and get drugs to clinical stages faster.” In the few months Lin has been at Horizon, she has helped further the company’s strategic shift into R&D by beginning to build new processes and teams that reflects the company’s culture to take calculated risks.

Lin can clearly look back even further than the pharma industry for the insights she draws on today. “I started out in the lab and in academic medicine and thought that I would stay there,” she reflects.

Lin was born in Taiwan. She grew up in an immigrant household in some tough neighborhoods in the US. Lin reflects back on her early public school days with respect for the dedicated teachers who captured her interest and imagination with science. Her undergraduate degree is in chemical engineering and biochemistry from Rice University and her MD/PhD is from The Johns Hopkins University School of Medicine and was funded as part of the NIH sponsored medical scientist training program. Lin was a clinical scholar and scientist at The Rockefeller University. Along the way, she says she met “amazing mentors” who made unique contributions to medicines that touched patients. But she said she grew more interested in seeing how discovery made it all the way through to help patients.

“The part where you actually make the scientific discovery into a drug was a big black box to me,” says Lin, and thus she took the leap into industry. “Joining pharma was really eye-opening. As a physician in academic medicine, I thought I really understood what teams were. In academia, you are brought up as part of teams in lab settings or in a hospital setting where, as the physician, you have a defined stylized role. You write orders and they get carried out,” she laughs.
Lin says in industry, it’s a different dynamic and context. “It distills into this one concept, and my personal mantra, that all of us are better than any one of us. There is so much at stake—potentially a decade of work to develop a molecular candidate to become a therapeutic medicine, and many hundreds of patients who volunteer their time and accept risks while participating in the clinical studies, or the billions of dollars that are spent to bring a drug to market,” she says. “The stakes are high and the results are so important to patients. It’s critical to have continuous, deep input to make sure that you are bringing your team and stakeholders along with you, so you can get the end result right and bring meaningful new medicines to improve patients’ lives.”

Lin says she loves what she does, both personally and professionally. She keeps in touch with her academic roots and has consistently served as an adjunct professor at teaching hospitals localized to each of her positions. Her physician practice keeps Lin grounded, and she always puts patients first in what she strives to do in R&D.

Her advice to those entering the industry: “It’s not about plugging in your individual expertise into a framework; that’s just the first piece. I would encourage people to network as early and as often as possible to meet people from all different areas that you can draw on when you are trying to solve problems. The more ideas you have access to, the more opportunities you have to bring solutions.”

— Lisa Henderson

The Path of Curiosity

Bernat Olle, CEO, Vedanta Biosciences

Dr. Bernat Olle knew from the day he started his PhD—in Chemical Engineering Practice at MIT—that he would enter the industry after his studies. It wasn’t any great plan, he says, “it was just an intention, just about following my curiosity.”

After completing his thesis research in bacterial fermentation, Olle duly made the move to the entrepreneurial realm at Boston-based PureTech Health, a biopharma group that translates academic science into new medicine through both new ventures and an internal pipeline. Making that shift from bench to new venture creation was “neither particularly difficult nor particularly easy,” Olle says, but he was fortunate to have in his colleagues, PureTech founder and CEO Daphne Zohar and co-founder David Steinberg, two teachers of “Entrepreneurship 101.” With them, Olle would serve a nine-year apprenticeship in starting new biotechs, learning, among other things, how to evaluate technologies, assemble teams of scientific cofounders together around an idea, how to write and pursue intellectual property, how to negotiate contracts and licenses, and how to finance a company from private investors or pharmaceutical partnerships.

During his time at PureTech, Olle became very interested in understanding how emerging research on the human microbiome field could be used in developing new medicines in a range of applications. After examining more than 120 technologies in the microbiome field and assembling a team of academic pioneers, in 2011 Olle co-founded Vedanta Biosciences (with Dr. Kenya Honda of the Keio University School of Medicine) to focus on using rationally defined consortia of gut bacteria as a therapeutic modality. It was, he says, “a return to my research roots.”

Back then, the idea of using consortia of live bacteria as drugs had no precedent. Olle and Honda proceeded to demonstrate that the idea was biologically sound, that the approach was patentable, and that manufacturing processes could be conceived and scaled to produce GMP-grade drugs based on bacterial consortia. In the process, they established a blueprint for how to develop this modality of drugs, positioning Vedanta as the leader in the microbiome field. In 2015, Johnson & Johnson licensed the company’s VE202 program in inflammatory bowel disease for up to $339 million in potential milestones. In December last year, Vedanta initiated a Phase Ia/Ib, first-in-human clinical trial of VE303, its lead candidate for the treatment of recurrent C. difficile infections. In the meantime, Olle was awarded as one of 2013’s Innovators of the Year by MIT Technology Review Spain.

While the responsibilities of entrepreneurship have pulled him in new directions, Olle still feels “very connected” with the science. “Obviously, I’m not doing experiments myself, but I still spend a sig-
significant amount of time around the R&D team,” he says. “And I like to read a few scientific papers every week to keep up with what’s going on in the field.” But Olle finds the business of leading a company—fundraising, recruiting, setting the vision, and preserving the culture—as rewarding as the science. “I never resent spending time on these activities,” he says. “Take recruiting. I love it when you see your hunches in interviews being proved right later on. It’s great when someone you thought could grow into a really good manager actually goes on to become one. Or when you see that smart recruit who was very shy finally finding his or her voice, speaking up and challenging ideas and becoming a bigger part of the team. I really enjoy that part of my role.”

For Olle, what’s important as a leader isn’t a particular style of leadership. As he notes of his PhD mentors at MIT, one was charismatic and diplomatic, the other quite blunt and direct, and both equally effective. “What matters is having people’s best interests in mind, period. This is really the root of everything,” says Olle. “If that holds, the style that you choose for managing becomes less important. If your team knows you fully support them, they will stop worrying about where they stand and spend their mental energy figuring out how to solve problems and doing a great job.”

Olle is proud of his team’s efforts in bringing a completely new drug modality to the clinic for the first time. “Now we’re starting to get data from humans and we’re working to show that this modality can be truly efficacious and safe, but just getting to this point is a big achievement.” Going forward, he still has the same drive and curiosity that was awakened in him as a schoolboy in Catalonia by a dynamic chemistry teacher.

“I’ve been given a once-in-a-lifetime opportunity to work on a really big idea that could have an impact in medicine—namely, creating a new type of medicines from our microbiome,” Olle says. “I don’t take the opportunity for granted.”

— Julian Upton

**Multi-Growth Strategist**

Nadeem Rehmat, Chief Operating Officer & Head of Business Development, PharmEvo Pvt. Ltd

Across the many and varied functions that Nadeem Rehmat has performed during his 23-year pharma career, a constant theme has been business development (BD) and partnering strategies. He honed his BD skills at Pakistan’s CCL Pharma during the late 1990s and early 2000s (back when BD was not recognized as a specialty function in the country), and since 2003 has been applying them with great success at PharmEvo, a Karachi-headquartered company developing, producing, and marketing therapies in areas such as cardiovascular, gastroenterology, respiratory, and oncology.

Rehmat began his career as a medical rep with G.D. Searle in the mid-’90s, after completing a degree in pharmaceutical sciences followed by an MBA. Combining sales rep work with his education in pharmaceuticals and business was the “best way to enter the industry,” he says. “It gave me a clear advantage and supported me in understanding the needs of healthcare professionals and patients.” But he credits his early move into BD with giving him a “360-degree understanding of pharmaceutical operations.”

Rehmat has gone on to exercise a multi-disciplinary approach by supplementing his BD activities in a range of roles at PharmEvo, including positions in international marketing, regulatory affairs, market access, licensing, pipeline portfolio management and, most recently, as chief operating officer. He has also handled various projects in medical devices, biosimilars, nutraceuticals, and phytocuticals.

On the global scale, the pharma market in Pakistan is still small at just over $3.7 billion, but with a population set to rise to 250 million by 2030, the recent introduction of a government health insurance system, and more disposable income for healthcare products, there are reasons to be op-
timistic about its future, says Rehmat. Although there are signs it is slowing down, the Pakistan market achieved a compound annual growth rate of 12% between 2012 and 2017. PharmEvo’s own growth has significantly outpaced this. Since joining in 2003, Rehmat has helped the firm transform from a small company with a turnover of less than $1 million to an international, $80-million healthcare organization with offices in 12 countries across Asia, Africa, and Central America. In the last five years, it has achieved a CAGR of almost 23%. The company’s sights are now set on moving into Europe. PharmEvo, says Rehmat, “has a good set of values, encourages performance, and has given me the liberty, the training, and the resources to perform at my best.” He adds: “There are not many companies in our region that are aiming for EMA approval or WHO pre-qualification. What is unique about PharmEvo is that it continues to push ahead of its competitors.”

Rehmat is looking forward to seeing how pharma will be shaped by technological developments in the next five to 10 years. “An increasing demand for medicines; more informed patients; the potential of big data on R&D and pharma’s ability to understand big data; robotics and artificial intelligence—all these factors will transform the industry.” However, he says, “The industry must learn to blend these new technologies into its business model. It is still working in a very conventional way.” Rehmat remains humble about his own achievements. “My true moment of pride is yet to happen—it’s an ongoing process. No success has been big enough to claim it so far,” he says.

Rehmat acknowledges the mentorship of Dr. Ha- roon Qassim, PharmEvo managing director, who has been “a coach professionally and a friend personally, guiding and supporting me to experiment with ideas.” And he has been long inspired by two leaders from his home city of Karachi, former Schering-Plough CEO Fred Hassan and biosimilars pioneer Safaraz K. Niazi. Following in their footsteps means no less than making a sizeable impact on the global industry. In the meantime, there are still things Rehmat wants to learn; he would like, for example, to go back and study at “a world-class business school.”

His humility is engaging, but Rehmat’s success speaks for itself. He is recognized as one of Pakistan’s leading lights in BD. Colleagues place him among the top people in his field; they say there are few who understand BD in Pakistan as well as he does. Moreover, he is admired for his diversified, end-to-end industry expertise and his “passion, courage, and tenacity.” There is little doubt that these qualities will remain in evidence as he helps to steer PharmEvo toward newer horizons in Europe and beyond.

— Julian Upton

Mindful of the Many

Raymond Sanchez, SVP, Global Clinical Development, Otsuka Pharmaceutical Development & Commercialization

W hen Raymond Sanchez left his clinical and academic position at Yale University to pursue a career on the commercial side of the business, he faced a lot of doubt from his then-colleagues. But the decision was fueled by an internal passion he knew he couldn’t ignore—the desire to help more patients on a larger scale.

Many years later, Sanchez’s decision was validated.

“I was at a CVS pharmacy, and they alphabetize medicines so they can access them quickly, and I’m standing there and all of a sudden I see the Abilify bottle on the shelf,” he recalls, referring to the drug that treats the symptoms of psychiatric conditions such as schizophrenia and bipolar 1 disorder. “That was such a sobering moment, because I said to myself, ‘My goodness. I played a role in bringing that medication to patients who desperately need it.’”

Throughout his career, that’s all the now-senior VP of global clinical development at Otsuka Pharmaceutical Development & Commercialization wanted—to help patients suffering from psychiatric disease.
Even at a young age, Sanchez says he remembers always having an interest in human behavior and the brain. In fact, while still in high school, he was conducting research at the University of Miami on the affect noise had on the behavior of monkeys, and often participated in science fairs. “The brain was always something fascinating to me,” says the Northwestern University graduate, who spent time at Harvard before enrolling at Northwestern’s Feinberg School of Medicine.

When it came to medical school, Sanchez had to make a choice: neurology or psychiatry. He picked the latter, because as he explains it, he really wanted to treat the whole person and neurology was more tactical.

“If you asked me in medical school [if I was going to work for a pharma company], I would have said, ‘no way,’” Sanchez says with a laugh. “I’d say, ‘I just want to treat sick patients.’”

But after spending about six years in the Yale School of Medicine’s Department of Psychiatry, as an intern, resident, chief resident, fellow, and then instructor, Sanchez knew he wanted to do more, and that his first-hand experience and knowledge could help patients on a larger scale and not just those he was seeing at the university.

“People spend billions on assets and drug development, but don’t always look close enough at the teams or other aspects of a trial,” says Sanchez. “One of the issues in trial design or studies is that it may look good on paper—you have the right patient profile, you develop a strong protocol that is actually patient-centric.” But, as Sanchez notes, it may not actually be practical, a realization you can’t find in a textbook or academic paper.

“Part of the success in developing a drug is understanding this, and having had that practical opportunity to treat patients, you know what worked and what didn’t work, and you can relate and relay this information,” he says. “You can look at a proposal [for a clinical trial] and see the danger points and wire trips. Not having that clinical background experience can really minimize the effectiveness of the development.”

Given Sanchez’s fascination with the brain and his commitment to treat the whole person, it’s no surprise he takes the same approach when it comes to leading and managing his team. In fact, he uses mindfulness and dedicates time and money toward developing the people in his groups. For example, Sanchez brings in an outside personal and professional development coach to work with them.

“I’ve had amazing mentors in my history,” he says, adding that he wants to create that same opportunity for others. “I want to nurture enthusiasm and develop an energizing environment that is productive and exciting. We have created that environment and it’s something that attracts people to the company.”

Part of that nurturing, Sanchez says, is identifying an individual’s talents and developing them for other opportunities, as not only their career and interests grow, but also as Otsuka expands and needs additional leaders and skill sets. In fact, the day Pharm Exec spoke with Sanchez for this article he was preparing for a reception honoring someone he helped groom and was now about to take on a new leadership role at the company.

“You have to keep an open mind and open heart to be successful and happy,” says Sanchez. “You have got to listen to that inner voice and follow your passion.”

— Michelle Maskaly

Transformative Leadership
Harout Semerjian, Executive VP, Chief Commercial Officer, Ipsen

After graduating in biology from the Lebanese American University in 1993, Harout Semerjian couldn’t wait to “get out into the world and make an impact, fast.” He started his career carrying the bag as a rep for Solvay Pharmaceuticals in Beirut, Lebanon, before moving to Canada and joining Novartis in Toronto for a field role in 2001. Soon after, Semerjian took his first head office job in market research at Novartis in Montreal. After working in sales and sales management, the head office role was a revelation. “I sat in a room with the big players and was now asked to listen instead of talk,” says Semerjian. “I did that for two years and loved it as I had access to what I didn’t know.”

He thought Canada would be his final stop, hav-
ing arrived with a one-way ticket. But he remained restless for advancement and in 2004 enrolled in the Cornell–Queen’s Executive MBA program. The next couple of years, he says, were “probably the most testing time in my life.” Semerjian and his wife had just had their first child; their second was born before he completed the program and he got a new role. The experience “created a whole new meaning of focus and prioritization,” he says. Achieving that “Holy Trinity”—pursuing a career, going back to university, and establishing a family—is something he remains proud of today.

Semerjian went on to enjoy a steady rise through the Novartis ranks. He joined the global Gleevec team in the US in 2007, then moved to Denmark in 2009 as head of the company’s oncology business unit, before serving three years as general manager of its Nordic-Baltic Oncology Cluster. He was VP and region head of oncology for Novartis’s Middle East Cluster from April 2013 to December 2014, before moving back to New Jersey as VP and franchise head of its hematology business.

After 16 years at Novartis, Semerjian joined Ipsen in February 2017, moving with his family to London. His contribution was quickly felt. In the last 20 months—first as EVP and president of specialty care international region and now as EVP and chief commercial officer—he has overseen a period of unprecedented growth across Ipsen specialty care’s three franchises: oncology, neuroscience, and rare diseases. He has helped to steer an impressive list of products to market or to regulatory approval, including the carcinoid syndrome diarrhea treatment, Xermelo (EC approval), and Dysport, for the treatment of lower limb spasticity in adults (FDA approval). He drove the launch program for Cabometyx for the first- and second-line treatment of adults with advanced renal cell carcinoma; the drug is now reimbursed in >20 markets outside the US. Established products such as Somatuline and Decapeptyl continue to grow in a rapid manner, helping more oncology patients and gaining share in their respective markets.

Together with his executive leadership team colleagues, Semerjian is helping transform Ipsen from a small biotech to a global biopharmaceutical group. In 2017, its oncology portfolio achieved 32% growth, making it one of the fastest-growing oncology companies and breaking into the top 20 companies in terms of sales.

Semerjian believes in creating environments where it’s safe for people to make mistakes and learn. “Innovation by design means you get it wrong nine times out of 10. But that shouldn’t mean taking the safe option. You have to be prepared to take calculated risks,” he says. “The mission is still critical. There will be negative aspects, but to succeed you have to believe in the mission and lead the team forward while course correcting. The healthcare industry is still one of the best industries where you can make a positive impact on patients and on the world. It really transforms you.”

For Semerjian, good leadership is about passing on the skills and insights he has drawn from his own mentors. Early in his career, it took some time for him to realize that senior leaders “are actually very open people.” He explains: “They’re open to new starters saying, ‘I’d love to pick your brains—can I take 15 minutes of your time?’ I never had a mentor who said no. Now I try to do the same. I coach on a daily basis, and even coach people outside of my group. It’s my way of passing on those gifts.” Above all, Semerjian wants his teams to realize that “it’s possible to rise from a rep in Beirut to chief commercial officer of the third-largest French pharma company.”

A colleague notes Semerjian’s “relentless commitment to building high-performing teams, adding key external talents, and energizing them to elevate the collective ambition.” When he moves to a new role, he gets calls from colleagues wanting to join his team. “It’s not just about loyalty,” Semerjian says. “It’s about knowing they’re embarking on something that’s going to be bold and fun at the same time.”

The industry has changed dramatically during Semerjian’s career, but “it’s no better or worse, just different.” The curiosity that has driven him this far is still as strong as ever. “The innovation rate overall is still strong, a lot stronger with things like artificial intelligence and predictive learning. It’s really exciting and I want to be part of it.” He adds, “I want to be doing this for a long time to come.”

— Julian Upton
For any life sciences company bringing its first product to market, the “commercialization to-do list” is long and punctuated by one critical strategic decision after another. What are the variables driving your launch strategy? What tools should you have in place to support marketing and sales? How can you ensure compliant transparency reporting and mitigate risk? Often in as little as 18 months, you’ll need to pull together – or access – an entire commercial organization and infrastructure. So where do you start?

Hear from a panel of emerging biopharma executives who have faced these challenges, and more, as they built their commercial operations function from the ground up. They will share best practices and lessons learned based on their experiences launching in the US and in Europe.

Key take-aways:

- Understand how to identify and plan for the investment you’ll need to bring the product to market (and gain stakeholder support)
- Determine how and when to ramp up the building blocks of your commercial infrastructure with a ‘just-in-time’ execution
- Discover ways to develop an efficient and effective commercial operation that can scale appropriately with the trajectory of your launch

Presented by: Sponsors by:

For technical questions about this webinar, please contact Kristen Moore at kristen.moore@ubm.com
In a 2014 article for *Pharm Exec*, pharma business consultant and MBA tutor John Ansell noted that the previous decade had seen “a marked increase in the variety of specialist pharma MBA courses on offer.” Four years on, as these programs continue to grow in number across the US (and the world), potential students who are lucky enough not to be too restricted by cost, location, and/or ability may find choosing the right one a tricky prospect.

Websites such as find-mba.com and MBA Crystal Ball help to make the selection easier. Find-mba this year highlighted six US institutions in its global “Top Business Schools for Healthcare/Pharma/Biotech 2018,” while MBA Crystal Ball listed 21 schools in its “Best MBA Programs for Healthcare 2017,” which span the country from UCLA’s Anderson School of Management to Cornell University’s Johnson School of Business. As helpful as they are, such rankings require some further investigation, as each school’s pharma/healthcare offering can vary from fully specialized MBA programs to a series of elective courses. For example, where Boston University’s Questrom School of Business offers a specialized Health Sector MBA, UCLA Anderson students choose to specialize in healthcare through elective courses in their second year.

*Pharm Exec* spoke to program leaders from three of the top universities offering MBAs with pharma/healthcare concentrations to outline the structure of their courses and to consider the question that may challenge pharma-oriented students as they pursue the MBA path—that is, to specialize or not to specialize?

### Choosing the Right Track: Pharma & Healthcare MBAs

A growing range of MBAs with concentrations in pharmaceuticals and healthcare management are on offer. We look at how three of the top programs in the US prepare their students for industry success.

*By Julian Upton*
Saint Joseph’s University (Philadelphia, PA)
Saint Joseph’s University (SJU) developed a Pharmaceutical Marketing MBA track as far back as 1991. Its current AACSB-accredited Pharmaceutical & Healthcare Marketing MBA requires the completion of 24 two-credit courses for a total of 48 credits. Core business courses—“designed to ensure that all students in the program have that common body of knowledge necessary for advanced study in business”—include Product Management, Pricing, Supply Chain Management, Pharmaceutical economics, and Global Corporate Strategy (with students traveling to Ireland in July 2019). The electives include Pharmaceutical Strategy, Creating Effective R&D, and Health Policy.

Key to the SJU model is flexibility; it offers online and in-person (weekend) program delivery to meet the needs of working, adult students. As such, students tend to have a wide range of experience.

“On average, our students have 11 years of pharma and healthcare industry experience, which takes them typically into a manager or director role,” says Terese Waldron, director, Executive MBA and Industry-Focused MBA programs at SJU. “But we are also seeing students that are in their late forties and fifties coming back to school, looking for a second or third act. Students can take up to five years to complete their program if they need to. They can opt out of the program for a year if they’re on maternity leave, for example. There are nuances related to our flexibility that I think are missing from other models and other competitors.”

The SJU program also differs from most of its MBA competitors in its heavier focus on pharma and healthcare—around 50% of the class work. As the SJU literature maintains, “it’s not just an MBA with a concentration—it’s a program designed for professionals with established careers in sectors such as pharmaceuticals, biotech, medical device, diagnostics, and healthcare.” Waldron adds that “our accounting faculty, our finance faculty, and our management faculty all teach their courses through the lens of the pharmaceutical and healthcare industry. So, there’s a great deal of focus and less distraction in the classroom. The content is truly relatable and actionable for many students seeking some early ROI. The value that the students can get in the classroom can be applied as soon as they go back to work on Monday morning.”

Rutgers Business School (Newark, New Brunswick, NJ)
Rutgers’ Pharmaceutical Management MBA program was launched in 2000, instigated by a Novartis seminar in the late 1990s that highlighted the concern that the MBAs the industry was recruiting still needed further training in pharma and healthcare. Given New Jersey’s position as “the Mecca of the US pharmaceutical industry,” it was suggested that NJ-based Rutgers develop a suitable program. “We didn’t know at first how long the program would last,” says Mahmud Hassan, PhD, the program’s director, “but quickly we were amazed with the quality of the applicants.”

With industry assistance, Rutgers developed a curriculum with six pharma-specific courses: US Healthcare System and Managed Markets, Legal & Ethical Issues of the Pharmaceutical Industry, Pharmaceutical Industry Structure & Dynamics, Pharmaceutical Marketing Research, Pharmaceutical Product Management, and Managing the Pharmaceutical Sales Force. (A course in market access was later added to the curriculum.)

The Rutgers program can be pursued on either a full- or part-time basis, requiring 60 hours of course work to complete the MBA degree, including 18 hours focused on pharmaceutical management. While the course does not admit anyone with less than three years full-time work experience, “that experience can be in any industry: IT, consulting, finance, marketing, pharmacy,” says Hassan. “But it’s important to have real-world experience.”

The average age of Rutgers’ pharma MBA students is around 29. Students in the full-time program are given paid summer internship placements at the end of the first year. “There is a big demand for the intern positions,” says Hassan. “Most of the students come back to start the second year of the program with a full-time job offer.”

As well as offering courses taught by “high-ranking and highly qualified pharma personnel who are either retired or still active in the industry,” Rutgers sponsoring companies, such as Bristol-Myers Squibb, Johnson & Johnson, Bayer, and Novartis, invite the students to their sites once a month to keep them informed about the current environment. “The students that come out of our program do not need further training or orientation in pharma — they are ready to go,” says Hassan.
“Most of the students come back to start the second year of the program with a full-time job offer.”

Columbia Business School (New York, NY)

Columbia’s renowned MBA program offers electives in Healthcare and Pharmaceutical Management (HPM), which include Innovation in Global Healthcare, Healthcare IT Principles and Opportunities, and Pharmaceutical Drug Commercialization. The school does not offer a specialized healthcare MBA track, but is a general MBA program “that gives students options to take as many or as few courses as they want concerning healthcare,” says Professor Linda Green, HPM faculty director. “There’s a whole slew of things that students can take advantage of to tailor their experience at the school to their specific interests. We’re extraordinarily flexible in that regard.”

The HPM track offers extra-curricular activities such as lunch and learns and an annual healthcare conference. Columbia’s guest speakers comprise a “Who’s Who of industry leaders,” says Green, including CEOs of major companies, major hospitals, and government representatives. “We also have a very active alumni group, so there’s a tremendous amount of interaction and networking with industry.”

There is no shortage of applicants for Columbia—Green notes that it is “really hard to get into the school.” Generally, Columbia students have been out of their undergraduate degrees for four to five years and all have some career background. Almost all the students do an internship, and, as for subsequently finding a job, Columbia “has one of the best employment records of any school.”

Specialization level

While MBA programs such as the ones outlined are noted for the quality of their pharma and healthcare concentrations, potential students and employers may question how much concentration is necessary. Scores of past and present executives have led pharma and biotech firms with a “traditional” MBA under their belt.

Columbia’s Green says, “Our feeling at the school is that an MBA is supposed to be a generalist degree to prepare you for the world of business. A specialized MBA that takes away some of the flexibility compromises this idea. Anything you teach that’s very specific to an industry right now is likely to be outdated very rapidly.” It’s much more important, says Green, to prepare students “with general perspectives and tools and frameworks for understanding the world of business.” The Columbia MBA, she adds, “prepares students for the long run, both while they’re within our full-time program and also as alums.”

While he notes that, on the Rutgers program, students “from a science background tend to do better,” Hassan also says that employers in the industry “do not really emphasize the need for pharma experience.” More important, he says “are original, clear thinking and good leadership qualities. You need to be able to combine skills in finance, supply chain, economics, accounting, and business all in one.”

Waldron says, however, that for people who choose to stay in the pharma industry, “there’s no substitution for the model that SJU offers.” SJU data points to up to 80% of its students being promoted before they even graduate. “That is unheard of in most industry standards,” she says. “We believe that it’s the program concentration that gives them that differential.” The SJU model also continues to evolve to reflect the ongoing transition of the pharma and healthcare sectors. “We have an integrated approach, which creates a greater value and understanding of the entire healthcare space,” Waldron says.

This broad approach means that, for students wishing to make a career change down the line, the SJU MBA “can take them anywhere.” Waldron adds: “Pharma is still one of the most respected industries in the world and it has given business some of its best practices. It’s no shortcoming to make that selection and then make a career change later on. It’s about equipping a student to be more holistic in their approach to a particular industry, and that’s a transferable skill.”

Whether a student opts for a specialist or a more traditional MBA, Green reminds us that “the value of the MBA very much depends on the school and its reputation in general.” That so many of the US’s top schools are featuring pharma and healthcare tracks in their long-established MBA programs is certainly a positive development for the industry. While many of the graduates of these programs are still a little too young to have reached the very top positions in the industry, we can surely expect to see them making a difference in the years to come.
Japan is — and will remain — the second largest market for branded pharmaceuticals and innovation. Continued investment in development and commercialization of pharmaceuticals in Japan is creating many opportunities and growing the potential for multinational biopharma companies. This is driven in part by ongoing regulatory and government initiatives that reward innovation, shifts in population demographics, and increased disease awareness and identifiable patient populations, amongst other factors.

Join IQVIA Japan as we discuss how to seize these opportunities and the strong potential outlook for the market in the coming years.

Key take-aways:
- To obtain the information about the market in Japan
- How to seize the opportunity in this strong potential market
- The potential of the market in Japan in coming years

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For technical questions about this webinar, please contact Kristen Moore at kristen.moore@ubm.com
Medical Affairs’ Search for Meaning

The need to look beyond the function’s traditional performance measures to the one that really matters—patient outcomes

“Between stimulus and response there is a space. In that space is our power to choose our response. In our response lies our growth and our freedom.”¹ This quote from Victor Frankl perfectly reflects the mindset of great medical affairs teams in pharmaceutical companies at the moment. The time is now, and it is for the medical affairs function to determine if it wants to have a bright future and be a true partner and a leading value driver.

For pharma organizations in the past, the commercial function was the only lead in setting and driving the strategy. Medical affairs, in addition to the license-to-operate function, provided mostly on-demand medical information services, as well as support on an ad hoc basis in key external experts’ engagement and internal and external medical education. The key performance indicators (KPIs) and the resulting perceived value were related to these support activities, and were expressed in in-consequential metrics, including but not limited to the number of visits to external experts and the number of evidence-generation activities and publications.

Redefined role

Innovative specialty and ultra-specialty pharma companies have recently invested heavily in expanding the medical affairs function, due to the complexity of therapeutic areas and medicines, with more and more medical affairs colleagues working in the field, while at the same time improving the quality and impact of those medical teams. They, in essence, are internal experts employed by the company. This dynamic changed the scope and value of medical affairs dramatically. From our perspective, however, the purpose of being (raison d’etre) for medical affairs is to ensure the best patient outcomes via shaping the practice of medicine through evidence generation and scientific exchange activities, and enhancing patient access to the best available treatment by demonstrating its value to payers, physicians, and patients.

The only way to achieve best patient outcomes for the medical affairs function is a true peer-to-peer partnership with external experts, scientific societies, academic institutions, and research groups, as well as the entire medical community involved in patient care. In order to become a partner, you need to be considered as a peer in a specific therapeutic area.

But what can make a good pharma medical affairs professional a peer to an external expert, in addition to having in-depth scientific, clinical, and medical knowledge in the relevant therapeutic area and medicine(s)? The answer is an ability to understand patients’ needs, think across therapeutic areas, assess clinical value, analyze risk versus benefit, and exploit technological advances.²

In addition, a sustainable, trustful, and successful partnership is only possible in cases where external experts engage with medical affairs professionals as peers; have confidence in our unbiased data; look to us for our medical expertise and scientific reference; and want to involve us and collaborate in evidence generation, policy shaping, regulatory, and patient access activities, as well as listen to us at scientific forums, because we own the science they value. Medical affairs has a huge ethical responsibility in creating this trusted and sustained partnership.

Insights unlocked

Medical affairs is the only function to systematically provide the physician’s perspective to the drugmaker.³ The medical science liaisons (MSLs) bring these insights back into the company, based on a peer-to-peer discussion. By listening carefully to the medical community, the medical strategy will be adapted with the patient outcome as the sole goal. Indeed, the best medical professionals, physicians, and medical professionals of pharma companies alike, always have the patients’ needs at the forefront of their minds and actions. They always see the disease through the patients’ eyes and help the company to transform patients’ needs into their deliverables. This is non-negotiable and medical affairs should proudly represent this point of view.

In turn, higher investment in headcounts and quality, with a
specific focus on external scientific exchange and education activities (by MSLs), the quality of the output, and the greater responsibility regarding evidence generation activities to fill evidence gaps has led to an increased demand from the business to measure the value of medical affairs.

Many companies developed KPIs, measuring the number of external engagements with targeted experts per quarter, the number of publications in peer-reviewed journals based on evidence-generation activities, and the number of medical education events or advisory boards. These numbers are extremely important for internal tracking and benchmarking but do not fully reflect the real value of the leadership role of medical affairs. They, instead, result in a “KPI trap,” where medical affairs produces ever-bigger dashboards that do not reflect the true value, leading to a misunderstanding and a perception of medical affairs as a cost center.

That returns us to the pragmatic challenge of the medical affairs function, having to show the value and impact to the business first, and, next, to the patients, physicians, and payers. Relevant value measurements should be related to mainly two deliverables and supplement traditional numerical KPIs.

» Access to our medicines for the right patient at the right time.
» Shaping medical practice based on evidence generated in collaboration with external experts and payers to optimize patient treatment and outcomes.

Which relevant measurements should be considered in the future? With respect to quantitative and qualitative KPIs, we do not think it is an either/or question. Great MSLs and medical teams will need both quantity and quality. It doesn’t matter how good your science is; if you are not meeting regularly with the key external experts (KEEs), your impact will be limited. We believe “traditional KPIs” such as number of publications and advisory boards or number of field visits and interactions per MSL should still be measured and put into a dashboard to understand and benchmark the quantitative output of what we do; but these, what we will now define as “traditional numerical KPIs,” should not be used as the justification of the medical affairs function and its activities.

Value and impact measurements—like documented examples of change in medical practice; inclusion of a medicine in a protocol or formulary based on trusted evidence and confidence; independent external expert feedback of the value of the medical affairs function—are the new ways forward as they better reflect the desired outcomes for patients.

By implementing this approach, the need and request to justify the existence of medical affairs is no longer necessary, because the value and impact on patients’ outcomes as the ultimate goal of the pharmaceutical company will be clear and obvious.

The value and impact measurements are the result of the overall value proposition framework of medical affairs. In our view the medical affairs value proposition framework consists of five interrelated elements:

1. Excel in pharmacovigilance
2. Shape the practice of medicine by evidence generation and building on this through scientific exchange activities, with the objective to develop strong value propositions. These activities, as well as the medical affairs strategy in general, need to be highly relevant to the current and future business and always should stay two steps ahead on pre-launch planning to lead the rest of the company.
3. Drive strategy by science and insights. The medical affairs function ensures the incorporation of medical practice and patient insights into the drug manufacturer’s strategy.
4. Enhance patient access to the best treatment available by demonstrating value to payers, physicians, and patients;
5. Provide a talent pipeline for evolving tasks across the company.

Pharma companies often unintentionally create “silos” within their organizations, where medical affairs, sales and marketing functions, and clinical research don’t share critical data in time, and only rely on loosely organized cross-functional teams. When this is the case, medical affairs does not get the information it needs to develop...
productive external relationships. Companies must include medical affairs as a full partner in all stages of the drug life cycle, from R&D to commercialization, and should grant medical affairs full access to essential information from all parties involved in this cycle. Only in this way, can this function truly make a difference, create an equal playing field, and address patient and physician needs.

**Trusted exchange**

Imagine a world where pharma companies have a real peer-to-peer discussion based on mutual trust coming from studies and data with the patient in mind. This is the direction the life sciences industry is going. Medical affairs owns this space of building trust. There are no multiple truths. The data and the science speak for themselves and should lead to a consensus between the larger medical world and the pharma industry.

Innovative organizations do not sell drugs as an endpoint and a goal by itself, but are leaders and indispensable partners in improving patients’ lives through well-informed physicians, based on a broad scientific consensus. Since patients are not quantifiable, numerical KPIs as sole measurements of medical affairs’ value are something of the past.

Patient outcomes should become the only measurement on which medical affairs and, as a consequence, the larger pharmaceutical company should be judged in the future. Medical affairs is in the unique position to lead this evolution.

**References**

1. Frankl, V. E. Man’s search for meaning, Beacon Press, 2006
If you think about the stereotypical big-city internship, the image of a college-aged student fetching coffee may come to mind.

But that was definitely not the case for Armand Avetisian, who spent the summer of 2018 as a business development intern at EpiVax Oncology in New York City, where he worked side-by-side with the company’s CEO and Co-Founder, Gad Berdugo.

“It was a very unique experience working directly with the CEO on strategic direction,” says Avetisian, who is pursuing his master’s degree in biomedical engineering at Columbia University, where he’s slated to graduate in December. “I learned a lot about the business side of things, which is what I needed to work on. ... I would hear stories from my friends that have supervisors a year or two older than them and here I am sitting next to the CEO. It really helped take me to the next level.”

Avetisian’s internship was made possible by the New York City Economic Development Corporation’s (NYCEDC) LifeSci NYC Internship program. The program is a core component of NYCEDC’s $500 million, 10-year LifeSci NYC initiative to accelerate growth of the life sciences industry and to create 16,000 new, good-paying jobs. The goal is to attract and prepare a diverse range of NYC students for careers in the life sciences sector and to ensure that it has a wealth of talent to fill the industry demand for high-quality jobs.

It was the first official year for the program after running a successful pilot internship in 2017. Host companies ranged from early-stage startups to large pharmaceutical and biotech organizations, as well as other companies such as advertising agencies and public relations firms that serve the life sciences community.

Doug Thiede, senior vice president of life sciences and healthcare at NYCEDC, explains that as the internship program evolves, it will create a community within the NYC life sciences ecosystem that will build on the previous year’s progress and experience.

To help drive this evolution, NYCEDC held various business-type events prior, during, and after the internship program for participants to come together for networking and learning.

“We hope that when they come out of school, they go back to work at an organization in the New York City life sciences,” says Thiede. “It is really a building block for the future.”

Facilitating success

The program is a win-win for the companies and interns involved, organizers believe. For Avetisian, who previously focused on the research side of the industry, it wasn’t just about helping make his skill set more well-rounded in today’s environment, but it also diversified his career options.

“It opened my eyes up to a ton of different career paths,” says the born-and-bred New Yorker. “I can stick with more research or go into everything from business development to venture capital and investing. This opportunity gave me a great skill set that I can use to launch my career.”

For the companies, particularly those such as EpiVax, which recently opened offices in NYC, the program allows them to explore the local resources.

“I was sent at least a dozen strong resumes,” says Berdugo, whose company is developing precision cancer immunotherapies based on mutanome-directed neo-epitopes. “The talent pool was really impressive.”

Interns can sometimes get a bad rap with upper management, but Berdugo encourages C-suite executives to work with younger, aspiring leaders, describing Avetisian as a quick learner, good communicator, intelligent, and having a positive attitude, all of which is essential when working in a start-up environment.

“He knows he has a job offer when he graduates Columbia,” says Berdugo. “The door is always open.”

Crash Course in Strategy

New life sciences internship program has high-level mission

Gad Berdugo, CEO of EpiVax Oncology, and business development intern Armand Avetisian.
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