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Pharma's budding opportunity

Why the industry is forming bonds with CBD

Meagan Parrish, Senior Editor

No single molecule has likely ever generated as much buzz in the wellness market as CBD.

Cannabidiol — commonly known as CBD — is one of the primary, non-psychoactive compounds found in the cannabis plant. A recent loosening of regulations for CBD has triggered an explosion of over-the-counter dietary supplements touting so many therapeutic uses for the molecule, it almost sounds magical.

Not long ago, cannabis products were widely viewed as a threat to the pharma industry, partly because of the competition they could pose within key therapeutic areas such as pain management. But these days, the smoky cloud of suspicion around marijuana and its derivatives has begun to clear, and pharma companies are getting poised to take a hit off the high-growth industry of CBD.

But even prior to new rules on the federal level, CBD sales were booming in parts of the country where marijuana is legal. In February, analysts at Cowen, a Wall Street investment firm, estimated that Americans spent about $2 billion on CBD products in 2018, mostly to treat anxiety, pain or sleep issues. By 2025, they predict that the market value will swell to $16 billion, partly fueled by rising beliefs in the effectiveness of cannabis compounds.

"In the 90s, when you read stories about it, the words 'medical cannabis' were always put in parentheses. But I don't think there's any question about the medical benefits of

cannabis anymore," explains Philippe Lucas, vice president of global patient research and access at Tilray, one of Canada's biggest medical and recreational cannabis companies. "What I have seen over the last few years is that there is now a general acceptance of the overall comparable safety of cannabis, especially when compared to opioids, benzodiazepines and even OTC drugs."

In 2017, around 191 million prescriptions were written in the U.S. for opioids. Because many CBD users are looking for alternatives to prescription pain medications, the opportunity for that segment of the market alone is enormous.

Therapeutic targets

Conditions being tested in clinical trials with CBD

- Pain
- Post-traumatic stress disorder
- Arthritis
- Schizophrenia
- Autism spectrum disorder
- Anxiety
- Heart failure
- Substance abuse disorder
- Epilepsy
- Glioblastoma
- Crohn's disease

Naturally, pharma companies have taken notice of the potential of CBD. In 2018, the U.S. Food and Drug Administration approved the first pharmaceutical drug with CBD as a primary component. According to ClinicalTrials.gov, there are now about 100 studies underway examining the impact of cannabinoids, the class of cannabis compounds that includes CBD, on a wide range of ailments — from heart disease to central nervous system conditions.

Yet, to a large extent, cannabis remains on the fringes of the pharma world. But there are signs that could be changing.

Last year, Sandoz dove into the space when it struck a development and marketing agreement with Tilray — the first deal of its kind between a Big Pharma company and a cannabis partner, and a sign of a turning point between the two industries. More deals are likely on the way. All throughout the CBD supply chain, scores of companies — from drug development to delivery — are readying themselves to hook up with pharma's top dogs so they can jointly cash in on the growing "green rush."

THE WONDER WEED

It's well known that marijuana was used as a medicinal plant for centuries throughout the world. But in the 1930s, American attitudes towards marijuana soured as its use became increasingly associated with immigrants and minorities. By 1937, the growing anti-pot

> "There is fundamental evidence that CBD can be helpful for many diseases."
>
> — Ann Allworth

hysteria triggered new regulations that effectively made marijuana illegal for medical and recreational uses.

In the 1990s, however, the medical potential of this ancient plant crept back into the healthcare consciousness as patients began smoking it to combat the harsh side effects of chemotherapy, among other health issues. Although the primary focus was on potential of THC (tetrahydrocannabinol, the compound in weed that produces a high) to treat a variety of ailments, the flurry of cannabis research has also brought CBD to the forefront of drug innovation.

What is it about CBD that makes it such a potent weapon against a wide variety of health troubles? According to Ann Allworth, a former medical school professor with a PhD in biomedical sciences with a focus on cell biology, it's all about how marijuana compounds target the endocannabinoid system, which overlays every system in the body.

"This is what's unique. The endocannabinoid system coexists with cells in all systems of our bodies," Allworth explains. "This includes reproductive, endocrine, cardiovascular, urinary, nervous, immune, skeletal, muscular and even our skin."

The discovery of the endocannabinoid system started in the 1960s when an Israeli researcher set out to decipher why weed made people high and laid the groundwork to scientists finding receptors now known as CB1 and CB2 all throughout the body. Allworth says that when marijuana compounds like CBD hit those receptors, they can help restore balance to the body's different systems when the associated endocannabinoid system is impaired. Unlike many conventional medicines for tough-to-treat diseases that only ease symptoms, Allworth says that activating these receptors can, in many cases, fix the root of the problem on a cellular level.

"The bottom line is that the endocannabinoid system works to create balance in all systems of the body," she says. "This is why CBD works for a wider range of conditions than any other medicine known."

Like so many die-hard converts in the CBD industry, Allworth's foray into cannabis products started with a personal ailment. After being diagnosed with an autoimmune disease and told by her doctor that she would have to be on steroids for the rest of her life, Allworth went hunting for alternatives. Friends eventually steered Allworth in the direction of CBD, which she says, caused her symptoms to vanish. Now, Allworth has launched a new company called Cannabis Education Solutions, which is aimed at teaching healthcare professionals about the endocannabinoid system and promoting curriculum reform to medical schools so that more incoming doctors understand the role it plays in the body.

"I think one reason it's not taught is because when some people hear about the endocannabinoid system, they think it's something the medical marijuana industry cooked up to sell their stuff," she explains. "But there shouldn't be any stigma around CBD. There is fundamental evidence that CBD can be helpful for many diseases."

FROM THE STREETS TO THE SUITES

Like Allworth, Marcelo Reinhardt, the director of business development of C2 PHARMA, an API manufacturer, became a believer in CBD after feeling the effects for himself.

"I have back pain and had been taking painkillers for at least three or four years," he explains. "I started using CBD oil out of curiosity and now I haven't taken any painkillers in several months."

Established in 2014, C2 PHARMA has begun unveiling the latest offering in its API portfolio: highly potent and pure CBD. C2 PHARMA hasn't started selling CBD just yet, but the company has locked its supply chain into place — from cultivation to distribution — and is readying itself to be a go-to source for pharma companies looking to purchase high-quality CBD for drug development and manufacturing.

"We want to position ourselves as one of the leading sources for CBD, and all other cannabinoid APIs for the pharma industry," he explains. "We will extract and isolate the APIs under all the compliance guidelines for pharma and will be ready once they want to launch products with CBD."

C2 PHARMA, based in Luxemburg, currently has more than 100 customers for its APIs, including over 15 Big Pharma companies. Reinhardt says that even though rules around CBD are still prohibitive on a global level, the company is focusing on establishing itself in the regulated market, where the potential is biggest.

"I think it's going to be huge," he says. "And there are a lot of players trying to get a piece of the action now."

> "CBD works for a wider range of conditions than any other medicine known."
>
> — Ann Allworth

According to Reinhardt, dietary supplements made by the hundreds of companies that have popped up to produce CBD oils, gummy bears and more, are the "low hanging fruit." The real ball game is in the pharma-sphere, where entry is more difficult but the rewards are higher. Now, many companies like C2 PHARMA are looking at ways to expand their pre-existing portfolios to include CBD offerings.

California-based CURE Pharmaceutical, for example, has developed an innovative oral film technology that the company believes could represent the future of improved drug delivery. The company already offers several high-potency dietary supplements and has established a partnership to manufacture a generic form of Viagra using its CUREfilm technology. Recently, CURE also broadened its Drug Enforcement Agency license so that it can research cannabis plant extracts and CBD.

Although there are a lot of entryways into the CBD market, Jessica Rousset, chief operations officer at CURE, says that the company's ability to get high doses of medications into easily dissolvable films will give CURE a niche edge in the booming market.

"The future on the cannabis side is not in cultivation — that's the race to the bottom," she says. "The future is in drug delivery."

Rousset says that CURE is not yet disclosing the details of any partnership discussions with pharma companies, but they are happening. Currently, however, the U.S. industry is still stymied by regulatory confusion over CBD and concerns that new FDA rules could alter the landscape of the market.

"We have a lot of companies coming to us wanting to make CBD products," she says. "But we are an FDA-registered facility — we don't operate under state laws — so we are actively pursuing the manufacturing of CBD products within federal guidelines."

DAZED AND CONFUSED

Although rules around marijuana are still a messy patchwork of contradicting federal

and state regulations, the U.S. is at least trying to develop a sensible framework for CBD.

One major turning point came in December, when President Trump signed the latest Farm Bill into action, which included a provision that legalized CBD when it's derived from hemp under specific growing conditions (with a low concentration of THC). The bill also preserved the FDA's authority to regulate consumer products containing CBD. Although cultivation, distribution, and possession legality is determined by state and federal laws, the FDA is tasked with deciding if CBD pharmaceuticals are safe for consumption, how OTC CBD products should be labeled and importantly, whether CBD should be treated as a dietary supplement or a pharmaceutical ingredient.

The issue took center stage in early June when the agency held a public hearing for CBD stakeholders in an important first step towards deciding how to sheriff the "wild west" CBD market. From the onset of the meeting, it was clear that the FDA has a daunting task in front of it — and the stakes are huge.

So far, the FDA has been looking the other way as companies add CBD to food products and has only cracked down on a few dietary supplement manufacturers for potentially making false labeling claims. But because the FDA approved a pharmaceutical drug derived from CBD last year — GW Pharmaceuticals' treatment for rare and severe forms of epilepsy in children called Epidiolex — the agency could decide that CBD should only be treated as a drug and not allowed in OTC products. For now, the agency will likely attempt to find a balance between allowing continued access to OTC CBD without undermining its established clinical trials process for pharmaceutical drugs.

But after 10 hours and presentations from over 100 speakers from various corners of the CBD industry including manufacturers, healthcare professionals and patients, the hearing left many feeling more lost than ever. Although many speakers touted the compound's safety, several also warned about the inherent dangers of marijuana and a lack of credible research on CBD. The agency's acting commissioner, Ned Sharpless, said in his opening remarks that although the FDA recognizes the intense public interest in CBD, there are still "critical questions" about the safety of cannabis compounds.

The only clear consensus was that everyone wants the agency to find its footing in this market quickly. But so far, the FDA has not laid out any kind of roadmap for making regulatory decisions for CBD and the market could be waiting for months (or years) before it's operating under clear rules.

> "The future on the cannabis side is not in cultivation...the future is in drug delivery."
>
> — Jessica Rousset

OH CANADA

While the U.S. marijuana market stumbles along, unsure of what the future holds, Canada has surged ahead with a legal cannabis industry that will rake in an estimated $7 billion this year. It's no surprise then that Canada has become the home of some of marijuana's biggest players, including companies that are blazing new trails into neglected niche therapy markets.

Ontario-based Cardiol Therapeutics, for example, has become one of the only biotechnology companies focused on developing cannabinoid-based treatments for the massive heart failure market. David Elsley, the company's president and CEO, says he first became interested in CBD after coming across research that discussed the role of using the compound to fight diastolic heart failure — a segment of the cardio drug market that hasn't seen a significant treatment advancement in 30 years.

In particular, Elsley says that what makes CBD effective in treating conditions such as heart failure is its anti-inflammatory properties and the way it works through the immune system to relax blood cells and lower blood pressure.

"When we look at this molecule through a heart-disease lens, we see a protective molecule," he explains.

Cardiol is now working with two pharma companies, Dalton Pharma Services, a CDMO with expertise in cannabinoids, and Noramco, which specializes in production for controlled substances, to help bring its CBD-based treatments to market. Currently, Cardiol is in the process of commercializing a pharmaceutical CBD product with zero-detectable THC — what Elsley calls the "new gold standard" — that the company will market in the EU, Canada and Latin America.

For the U.S. market, Elsley says the strategy is to work with the FDA to win approval for its heart failure medication, following the same regulatory process as the epilepsy treatment that got the green light last year.

Scores of other biotech companies have also jumped into the race to create pharma-grade

CBD treatments, with a new focus on synthesizing the molecule from sources other than marijuana (which might allow companies to bypass that tricky regulatory landscape).

Last year, Boston-based Ginkgo Bioworks, which has worked with big name companies like Bayer, made a $122 million deal with a Toronto-based cannabis producer called Cronos, to harness marijuana's DNA and make lab-grown cannabinoid strains. Ultimately, the goal is to target the pharma industry with lower-cost cannabinoid compounds with medicinal potential.

But the biggest deal in the industry so far was struck between Sandoz, the generic arm of Novartis, and Canada's Tilray. Last year, Tilray became the first cannabis company to have an IPO on the U.S. stock exchange, and was one of the top 10 performing IPOs of 2018.

As part of its agreement, Tilray will leverage Sandoz's industry know-how to educate Canadian physicians and pharmacists about medical cannabis. The companies will also develop and co-brand Tilray's extract products — and according to Lucas, having the Sandoz logo on its products is like winning a seal of approval in the eyes of healthcare professionals.

"This raises the level of confidence that insurers, doctors and prescribers have towards our cannabis products," he says.

The partnership also represents the potential of what pharma can do to transform the world of CBD.

THE PHARMA FACTOR

Although the CBD market is busting at the seams, it still lacks an air of legitimacy on a mass scale. At the recent FDA hearing, several speakers pointed to studies that have shown that OTC CBD products often don't contain the exact dosing that their labels promise. As more companies crowd into the CBD market and rush to get products into stores, these low-quality offerings could soon rattle consumer confidence, and send patients looking for more reliable options. This, of course, is where pharma comes in.

In the risk averse world of pharma, where high-purity is paramount, drugmakers have an opportunity to leverage the industry's manufacturing standards and edge out lower-quality products. The consumer demand is there. But what the CBD industry needs is higher standards, especially if it's going to win over healthcare professionals.

"We ultimately benefit from pharma taking part in this industry and removing the remaining stigma around cannabis," Lucas says.

One of the biggest challenges Allworth sees for pharma entering more wholeheartedly into the cannabis space is that the industry might have to change its mindset from

> "We ultimately benefit from pharma taking part in this industry."
>
> — Philippe Lucas

researching single molecules to looking at the entire plant. Marijuana is thought to have over 100 cannabinoids, and many healthcare professionals believe that they work best when taken together.

"I think the most beneficial way is with all the terpenes, flavonoids and cannabinoids together," Allworth says. "Because Big Pharma is focused on single molecule remedies, it's going to be difficult to achieve the same results with just CBD."

The CBD market may not be pharma's typical gig but the opportunities to work with smaller drug developers to commercialize innovative products are piling up. Although none of the companies interviewed for this article would disclose specific details about any partnership discussions they may have underway, they all showed a strong interest in buddying up with players in pharma to help commercialize their goods.

There's also a lot of hope that pharma won't just help these companies soar to new heights, but improve access for patients as well.

"We understand that with pharma, we're going to see more refined cannabis products enter the market. But they could improve patient experiences or maybe even help reach an older population that has never tried cannabis," Lucas says. "With the formal medicalization of this substance, I honestly hope that patients will have more access to these whole plant medicines."

The overlooked element of cleanroom specifications

How applying cleanroom standards to compressed air systems can provide clarity and reliability

By Jenny Palkowitsh, Operations Manager, Trace Analytics and
Chad Larrabee, Global Product Management Leader, Ingersoll Rand

To ensure end-product quality and safety it is necessary for pharmaceutical manufacturers to build quality standards and reliable monitoring plans into their processes. Compressed air systems, while critical to many manufacturing processes and cleanroom environments, are often overlooked in risk management. This is, in part, due to the lack of specific regulations that can leave manufacturers at a loss on how to correctly monitor these systems. One way to provide clarity and reliability to the manufacturing process is to use cleanroom standards for compressed air systems.

RECOMMENDATIONS

The International Society for Pharmaceutical Engineers (ISPE) Good Practice Guide specifies, "in cases where the gas is entering a classified area, it is required to at least meet the room classification limits established for the cleanroom environment" (2016). Additionally, the most recent US FDA Guidance for Industry Sterile Drug Products Produced by Aseptic Processing – Current Good Manufacturing Practice recommends that "compressed gas should be of appropriate purity… and it's microbiological and particle quality after filtration should be equal to or better than that of the air in the environment into which the gas is introduced."

Using the guidance of the US FDA and ISPE GPG, pharmaceutical manufacturers can properly evaluate the quality of their processed gases including nitrogen, oxygen, argon, carbon dioxide, and compressed air.

Compressed air used in cleanroom environments should match the quality levels required by that room.

Chad Larrabee, Global Product Management Leader of Ingersoll Rand and GPG: Process Gases co-chair, explains that the compressed air used in cleanroom environments should match the quality levels required by that room (2019). This mirrors the recommendations made by the US FDA. By implementing a monitoring plan, pharmaceutical manufacturers can ensure that their compressed air quality maintains the determined levels.

The International Organization for Standardization (ISO) published a standard for compressed air quality that contains 9 parts. This standard, ISO 8573:2010 is commonly used for compressed air applications. Despite this, pharmaceutical manufacturers often favor cleanroom specifications over ISO 8573-1 to conform to their cleanroom facility. It can be useful to translate ISO 8573-1 specifications into cleanroom classifications to facilitate communication with manufacturers and other distributors. The following chart depicts how the two compare and can be used in conjunction to avoid confusion.

COMMON USES OF COMPRESSED AIR

The ISPE Good Practice Guide asserts that a logical method for determining the requirements of a facility's compressed air quality is to review the role of the gas in the process. Process gases and compressed air are used in a variety of ways depending on the product manufactured. While some facilities use compressed air in direct contact with products to clean, aerate, or move them through the processes, others use process gases in fluid pumps that take products through the production and filling processes. Nitrogen generators or compressed air can be used for packaging or blanketing depending on the result required. Process gases can also be used to spray or coat a product, or as an ingredient of the product itself. The amount and type of contact that products have with compressed air or process gases informs the risks associated and necessary monitoring plans for a system.

CONTAMINATION AND RISKS

The ISPE Good Practice Guide recommends a risk based assessment which evaluates what might go wrong, what will probably go wrong, and identifies the potential consequences of these risks (ISPE GPG, 2011). It is important for manufacturers to consider the unique risks for each facility. When compressed air is introduced to the environment, it must also be controlled and monitored as it can have an impact on the cleanroom and products themselves. Therefore, controlling contamination means controlling the total environment (McFadden, 2007).

According to ISO 8573-1 and ISPE, the common contaminants in process gas or compressed air are nonviable particles, water, oil, and microorganisms (viable particles). Each of these contaminants put products and systems at risk and require regular testing.

Cleanroom specifications set guidelines and limits for particle quantities in ambient or environmental air. Most compressed air intakes are located outside of the cleanroom and therefore that air is not monitored or controlled. Compressor systems draw in unfiltered ambient air for the compression process where particles, water, oil, and/or microorganisms can contaminate the final compressed air if proper air treatment is not applied at the point-of-use. In fact, one cubic meter of untreated compressed air can contain close to 200 million dirt particles and other substances (Nexflow, 2018).

Pharmaceutical manufacturers, in particular, who do not employ an oil free air compressor should monitor for hydrocarbon contamination. An excess of oil aerosol can accumulate to eventually form liquid oil. This can cause an immediate system shut down. Hydrocarbons are oily liquids and vapors that can be hazardous to consumers and products. These are regularly found in some cleaning solutions and sometimes in compressed air systems as lubricants. If ingested, hydrocarbons can cause consumer illnesses. Additionally, when the system heats up, lubricants can create oil vapors. Because oil has a low vapor pressure, it is extremely hard to get rid of contamination once it occurs. Many facilities employ an oil-free compressor to avoid contamination, but while the compressor does not add oil to the air stream, this does not completely remove the possibility of an oil contamination since ambient air being ingested into the compressor can contain hydrocarbons such as exhaust fumes. Proper filtration and regular testing are still required because ambient air can contain hydrocarbons such as benzene and toluene, cleaning supplies can release hydrocarbons, and compressor systems can harbor industrial oil.

Water contamination can be detrimental to the longevity of a compressed air system by causing the corrosion of pipes,

Water contamination can be detrimental to the longevity of a compressed air system.

tubing, and other system functions. Repairs and replacements for water damage are extremely expensive and time consuming. Moisture also provides a suitable breeding ground for microorganisms to grow and flourish. To address this issue, pharmaceutical manufacturers often use desiccant driers to remove moisture from the compressed air, however when regenerated, the process creates desiccant dust, small particles which should be removed with a particulate filter just after the dryer (Larrabee, 2019).

Bacteria, yeast, and mold contamination put end-users and exposed employees at risk. When microorganisms are starving for nutrients, they produce exotoxins. Exotoxins, even in very small amounts, can cause illnesses (like botulism) in consumers. Some bacteria can also produce non-viable products like endotoxins. These secondary metabolites that are very harmful to consumers. Countless products have been recalled due to microbial contamination. Sterile filters are often employed to prevent viable particles from impacting end-products (Larrabee, 2019).

Whether contamination is from non-viable particles, water, oil, or microorganisms, any contamination can induce a shutdown, cause a recall, or require equipment replacement and re-validation. The loss in revenue and product alone can be detrimental to a brand, but the loss of confidence from consumers is even more damaging. Brand reputation is difficult to build, but easy to lose. Because of these damaging consequences, pharmaceutical manufacturers must strive to implement quality processes into their systems, prevent contamination from occurring in the future, and regularly test their compressed air systems.

CONTROLLING AND MONITORING

According to Chad Larrabee, Global Product Management Leader of Ingersoll Rand, predictability and repeatability are the most important factors of any quality plan in pharmaceutical manufacturing. Because of this, it is critical to design a monitoring and sampling plan that allows facilities to catch potential issues before damaging any products (Larrabee, 2019).

Sampling frequency and locations will depend heavily on the individual risk assessment created by the facility. Some manufacturers choose to test quarterly to account for seasonal changes, while others choose to test before and after maintenance is performed. This ensures that no contamination was caused during maintenance either from personnel, cleaning materials, or systemic changes. Annual testing is an option for manufacturers, however this does not provide adequate data for trend analysis and is representative of the system only at the time of sampling.

The ISPE Good Practice Guide provides the following chart as a helpful recommendation of sampling plans per contaminant:

When working with an accredited laboratory, sampling and testing compressed air can be a simple process. Depending on classes required, different equipment can be purchased or rented. It's important to ensure that your laboratory can meet your individual needs and that they report the analyses in a way that meets the require cleanroom classifications. Trace Analytics, LLC can test to a wide variety of specifications including ISO 8573-1, ISPE Good Practice Guide, Cleanroom Classifications and custom specifications. Ingersoll Rand provides oil free compressed air systems certified by TUV for class 0 according to ISO 8573-1:2010 meaning the compressor adds no oil to the air stream.

To provide reliable compressed air and gas quality, many pharmaceutical manufacturers choose to apply cleanroom standards to their process air. This is achieved by analyzing facility risks, reviewing the role of air or gas in the process, understanding the major contaminants and the risks they pose, and implementing a monitoring plan.

What's behind all the M&A deals in pharma?

As far as M&A deals go, 2019 started off with a boom

By Meagan Parrish, Senior Editor

As far as M&A deals go, 2019 started off with a boom. In fact, two of the first big deals announced — Bristol-Myers Squibb's $74 billion purchase of Celgene and AbbVie's $63 billion takeover of Allergan — put 2019 on track to be a record year for M&A activity.

All told, the top 10 deals announced in the first half of this year also have a total value up 47 percent from of the top 10 deals in the first half of 2018. And Chimera Research Group estimates that 14 of the biggest biopharma deals in the first half of 2019 are worth a whopping $173 billion — not including some of the earlier announced deals that closed this year (such as Takeda's $58.6 billion acquisition of Shire).

What's behind all the deal making?

According to Amanda Micklus, an analyst with Informa Pharma Intelligence, a pharmaceutical research and analysis firm, many of the key drivers are similar to what the industry has seen in past years, but emerging trends are bringing companies together as well.

NEW THERAPEUTIC AREAS

Hooking up with another company has traditionally been a way for top pharma players to expand their portfolio into new therapeutic areas. In recent years, cancer care has been top-of-mind for pharma companies as several groundbreaking treatments, such as immuno-therapies, have burst onto the scene.

"Oncology-focused deals have been standing out among the major deals this year," Micklus says.

> "Oncology-focused deals have been standing out among the major deals this year."
>
> — Amanda Micklus

Micklus points out that some of the sector's most notable cancer-driven acquisitions have included BMS' deal with Celgene, Pfizer's $11 billion acquisition of oncology specialist Array, Eli Lilly's $8 billion purchase of Loxo Oncology and Merck's $2.2 billion buy of Peloton Therapeutics.

Besides oncology, another therapy area behind big deals lately is immunology/inflammation, as evidenced by Novartis' deal with IFM, along with several assets in that area that BMS is also gaining from Celgene. But companies have also been looking to get their feet wet in other hot markets such as gene therapies. One of the biggest deals in that arena so far is Roche's $4.3 billion merger with Spark Therapeutics.

Micklus notes that gene therapies are not only bringing drug developers together, but creating a wave of mergers throughout the supply chain. This year, Thermo Fisher announced that it is buying Brammer Bio, a viral vector manufacturing company for gene therapies. Drug delivery powerhouse Catalent also struck a $1.2 billion deal this year to buy Paragon Bioservices, another viral vector manufacturing company.

THE PATENT FACTOR

With scores of blockbuster drugs falling off the patent cliff in the next few years — AbbVie's $19 billion-a-year Humira is already facing biosimilar competition in the EU and will face it in the U.S. in 2023 — pharma companies are also looking for new drivers of revenue growth.

Micklus notes that companies are looking for ways to "diversify portfolios and bring in more marketed products that have already have established sales."

BACK TO BASICS

In decades past, pharma companies opened up their portfolios to different market segments like consumer goods, animal health and medical devices. Now, many big name companies are divesting their non-pharma business and refocusing on making breakthrough drug treatments.

"A lot of these big pharma companies inherited these businesses through other mega deals in the past and they have tried to participate in these markets but it's a total different type of regulatory environment, the patent life for products is different,

> "Pharma companies should brace themselves for changes."
>
> — Amanda Micklus

and it's just a different landscape," Micklus notes. "Now they are returning to pure play pharma and innovative drug development."

SMALLER IS SOMETIMES BETTER

Mega mergers are nothing new in pharma. In fact, pharma has had more $40 billion-plus deals in the last 10 years than any other industry, according to Bloomberg.

But now the emphasis is on "bolt-on" acquisitions of smaller biotech startups.

"I think we're going to see a slow down in mega mergers," Micklus predicts. "Anecdotally and from what I've seen, mega mergers haven't done great things for R&D productivity. I think instead we're going to see more bolt-on deals that are therapy driven."

INNOVATIVE PARTNERSHIPS

Pharma companies are not also just gobbling up the buzziest biotechs on the scene. Often, they're striking different kinds of partnership deals that allow them to invest in the company, and bring their commercialization and marketing know-how to the table, while letting the smaller company maintain independent operations.

One example is Gilead's recent announcement that it is entering a nearly $5 billion research and development collaboration with Galapagos, which specializes in small molecule treatments for inflammation, fibrosis, osteoarthritis and more. As part of the deal, Gilead will gain access to Galapagos' portfolio of compounds and drug discovery platform, while Galapagos will receive an investment that allows it to expand its R&D.

In a way, Micklus says that these deals show that Big Pharma companies understand the importance of allowing startups to keep their innovative biotech culture even when they've entered into a deal with a major company.

DIGITAL HEALTH

With digital innovations at the forefront of changes within pharma, companies are also looking for deals that will give them an edge with the latest tech.

Some pharma companies are striking partnership deals with companies that offer AI, machine learning and other tech advances to improve their own capabilities in areas such as drug discovery and clinical trials.

In other cases, medical tech companies are also joining forces to create a more robust entity. In June, Dassault Systems, a French software company, made a deal to buy Medidata for $5.8 billion. New York-based Medidata, which provides cloud-based and software services for clinical trials and works with 18 of the top 25 pharma companies.

SPEEDBUMPS?

With the pharma industry — and in particular, drug prices — in the national spotlight, political or regulatory changes could potentially tone down this M&A party. At present, legislative leaders from both sides of the aisle are floating several different kinds of regulations to bring down the price of pharmaceuticals but it's unclear what the impact of these potential new rules could be on the industry.

For now, Micklus says "pharma companies should brace themselves for changes."

"I don't know if any kind of action on drug pricing is going to deter M&A, but there could be some action on that front soon," she says.

Pharma's damaged reputation

Can pharma fix its image problem?

By Meagan Parrish, Senior Editor

Say the words "Big Pharma" outside of the industry and images of life-saving drug discoveries rarely come to mind. Instead, the public perception of pharma is often shaped by issues like drug costs, prescription drug abuse, the supposed dangers of vaccines or corporate greed.

One would think that when you're in the business of saving lives, it would be easy to stay in the public's good graces. But despite the good intentions of most pharma companies, the actions of a few bad actors continue to cast a cloud of mistrust over the entire industry. And pharma's image in the public eye has suffered.

In 2018, Gallup asked Americans to rate their perception of over a dozen sectors in the U.S. — out of all the business industries, pharma came in last. Reputation Institute (RI), a consulting firm which devotes a yearly index to measuring the reputational standing of major pharma companies, also found that between 2017 and 2018 the industry's reputation declined by 3.7 percent — its first drop in years.

While changing public perception may seem like an intangible goal that's out of the hands of everyday companies, it should nonetheless be top of mind for pharma firms looking to keep their businesses healthy.

What can pharma companies do to win the public over? Here's a look at why reputation matters and how companies can make sure the value of their work doesn't get tarnished by the industry's bad image.

WHY PHARMA SHOULD CARE

It only takes one misstep or scandal to sink a company's reputation, which can rattle shareholder confidence, hamper employee recruitment and cause a company to lose credibility. In the most extreme cases, unsavory behavior can cost pharma companies big.

Mylan, for example, was at the center of a hailstorm of criticism after it raised the price of EpiPens, a life-saving allergy treatment, by about 400 percent between 2010 and 2016. As public outrage over the price hikes hit a fevered pitch in 2016, Mylan's market value took a massive dive — between August and November the company's stock dropped from about $49 to $34.

In the midst of the public scrutiny, the Department of Justice also discovered that Mylan had been misclassifying EpiPens as a generic to lower its Medicaid rebate payments — which prompted a lawsuit and a $465 million settlement with the government in 2017. As part of the settlement, Mylan had to pay the higher rebates, which, along with generics entering the market, hit EpiPen sales revenue hard. In the third quarter of 2017 alone, analysts estimated that EpiPen revenue fell by $184 million — down 57 percent from the previous year.

On the flip side, pharma companies who are at the top of their reputational game have shown time and again that good governance can be a key driver of profitability and success. Analysts at RI, which measures reputation across numerous industries, have continued to find a strong link between reputation and a company's bottom line.

PHARMA'S MOST AND LEAST REPUTABLE COMPANIES

RI's 2018 RepTrak ranking is based on a survey that asks respondents to describe their feelings about 22 different drugmakers.

AT THE TOP	AT THE BOTTOM
1. Sanofi	18. Takeda
2. Genentech	19. Mylan
3. Celgene	20. Merck
4. AbbVie	21. GlaxoSmithKline
5. Biogen	22. Pfizer

"People increasingly care about intangibles just as much as they care about products," says Meghan Burke, a research analyst with RI. "Markets are saturated these days. And if companies are not differentiating and putting value on reputation, they will lose out to competitors quickly."

REPUTATION VS. BRAND

We all know when a company has a bad rep — or when just the mention of its name invokes suspicion and mistrust. These days, one of the most conspicuous examples of a company name becoming damaged goods is Monsanto, which has been the target of public scorn for years for producing genetically modified seeds and a potentially cancer-causing weed-killer. This toxic legacy is why Bayer dropped the Monsanto moniker from its products after merging

with the mega-chemical company last year. However, analysts continue to speculate that the negative connotations associated with Monsanto could haunt and possibly hurt Bayer for years.

But there's more to reputation than just the brand association. According to Dr. Nir Kossovsky, CEO of Steel City Re, an insurance company that specializes in reputational risk, the pharma industry has grown increasingly interested in the issue of reputation in recent years — but companies often confuse it with marketing and public relations.

"Brand is the promise made by a firm to its stakeholders," Kossovsky explains. "Reputation is how that promise is received and interpreted to create informed stakeholders expectations."

Kossovsky says the trouble starts when there's a mismatch between the expectations of stakeholders — which includes customers, board members and regulators — and what the company is delivering.

For pharma, Kossovsky points to six unique reputational issues that can vex a company's good name: ethics, innovation, safety, sustainability, quality and security. If a company isn't living up to their promises in these areas, its reputation will take a hit, which could anger stakeholders and lead to economic, and importantly for pharma, political losses.

THE CHALLENGES FOR PHARMA

When gauging reputation in pharma, RI takes a slightly more emotional approach by conducting a yearly survey that asks respondents four key questions about the industry's top 22 companies: Do they have a good feeling about that company? Do they admire the company? Do they trust the company? And do they find the company reputable?

To ensure that the respondents are representative of the "informed general public," RI tracks down about 2,600 people in the U.S. who say they are at least somewhat familiar with the industry. After starting with its four key questions, RI then drills down into more specific perceptions of the company, asking respondents about how they view each company's governance, leadership and general performance.

The results are used to rank the industry's top-performing companies for reputation, while also offering key insights into how the public defines reputation for pharma.

Between 2017 and 2018, RI found that there was a significant erosion of trust in pharma: In 2017, 48 percent of respondents reported that they gave pharma "the benefit of the doubt" — last year, that number fell to 35 percent. Over half (54 percent) of those surveyed in 2017 also said that they trust pharma "to do the right thing" — in 2018 the rate plummeted to 40 percent.*

According to Burke, the 2018 data showed that pharma has a major "depth of understanding" issue.

"Normally we like about 30 percent of respondents to have some familiarity with the companies. In pharma, the average is only 20 percent," Burke explains. "And we notice that when familiarity rises, so does reputation."

RI has also found that the drug pricing debate has had a negative impact on the industry.

"With pharma, the highest impact on reputation is the question of whether or not companies 'offer products and services that are a good value for the money,'" Burke says. "For this question, pharma scores very low…and has lost five points on this issue since 2017."

According to Kossovsky, part of the problem in pharma is that companies often rely too heavily on regulatory compliance to gain public trust.

"As long as pharma companies view their regulatory arm as their biggest stakeholder, that is where the bulk of their efforts are being placed," he says. "That may help explain why the industry has not been very communicative and why it has not developed better strategies around ethics and innovation."

REPUTATION REHAB
Quick tips for pharma companies

Put patients at the center of everything: Every employee should be thinking about patients regardless of their role.
– Zeba Khan, vice president of Corporate Responsibility, Celgene

Prioritize ethics: Good governance is the single most important driver of reputation — and this is where pharma companies struggle the most in the eye of the public.
– Reputation Institute (RI)

Be open and transparent: Listen to your stakeholders' concerns and work with them to address issues.
–Khan

Celebrate your corporate brand: Use all media to control the narrative about your company. Purpose driven companies with enhanced brand strength have a higher reputation.
–RI

Collaborate with advocacy groups, medical institutions and government: Use collaborations to help support drug development, improve patient access to treatments, and provide emotional support to patients and their families.
–Khan

Invest in programs that make a positive impact: When these programs align with your strategy and brand, everybody wins.
–Khan

TRANSFORMING REPUTATION

What can drugmakers do to form a solid strategy for boosting reputation?

Inside the company

When looking at the companies who get the highest scores in RI's annual "RepTrak" survey, several key patterns emerge. At these companies, policies focused on good governance, robust sustainability practices, connecting profits to purpose, strong ethics and celebrating the company brand have helped weave a positive public image.

For Celgene, which got the third highest score in RI's 2018 RepTrak survey, one of the biggest factors contributing to the company's good standing is its focus on patients to drive "bold pursuits in sciences as well as the creation of transformational medicines."

"Celgene has reinvested a major percentage of its revenue back into R&D each year, with an average of more than 38 percent being reinvested over the last five years — one of the highest rates of any company in any industry around the world," says Zeba Khan, the company's vice president of Corporate Responsibility.

Celgene has also positioned itself as a top company for employees. In addition to focusing on diversity and inclusion with its hiring practices, Khan points out that the company promotes benefits like its flexible work arrangements, increased paid parental leave, and paid caregiver leave, among others — which are all efforts that helped land the company on Forbes' Top 10 List of the World's Best Employers in 2018.

Sustainability has also been a top priority for Celgene and the company has announced four measurable environmental goals to hold itself publicly accountable. Khan says that Celgene has already hit two of its 2020 targets: purchasing renewable electricity and waste reduction.

"Reaching these goals is good for the environment, and it helps us improve our bottom line," Khan says.

The global level

What's good for the world can also be good for business — which is a fact that many top drugmakers have leveraged wisely. It's also a key point underscored by Access to Medicine Foundation, a nonprofit devoted to motivating Big Pharma to tackle global healthcare challenges.

Access to Medicine publishes several indexes that compare which major pharma companies are more successful at providing wider global access to medicines and vaccines in lower income countries, and at innovating new treatments to fight antibiotic-resistant super bugs. The indexes are widely reported on in major media — and by changing policies to move up in the rankings, Access to Medicine says that companies can use the indexes to improve their reputation. The organization also notes that pharma companies can use these efforts to boost sales by tapping into emerging markets.

"It's a way for companies to reach more patients with the understanding that the traditional business model of 'high margin, low volume' may not be the best way to succeed in emerging economies," explains Damiano de Felice, Access to Medicine's deputy director of strategy. "High volume might be better in the long run."

> "A company needs to understand what drives its reputation and what that value is."
>
> — Dr. Nir Kossovsky

According to de Felice, the top drugmakers on the indexes are companies that discuss global health issues on the board level, and systematically work to improve the affordability and accessibility of their products for people living in lower-income countries. These companies also understand that despite the value of their products, they still have to sell their image to the public.

"The general perception is that pharma creates just a win for the companies and not society," de Felice says. "We see that many investors and stakeholders now frame the conversation around the 'license to operate' … and the importance of pharma maintaining that societal contract so that their business is a win-win for both."

CASTING A SAFETY NET

Kossovsky's distinction between branding (the promises made to stakeholders) and reputation (how those promises are interpreted) is critical when it comes to knowing how to manage reputational risk. One option companies can explore is getting insurance to protect the business from reputational damage. Kossovsky's company, Steel City Re, provides a comprehensive risk management solution that includes reputational insurance.

In pharma, Kossovsky says that this kind of insurance can help cover a company from a variety of potentially damaging situations such as an ethical breach (if a rogue employee releases a drug that's not safe); innovating drugs that are shown to have bad side effects later; cybersecurity problems such as being hacked; supply chain dilemmas; or a failure in the company's governance to oversee and predict a crisis.

Insurance options from firms like Steel City Re can shield companies in two ways. First, it helps protect short-term cash flows.

"One part of our insurance is the instrumental value, which tells creditors that the short-term cash flow is protected because there is contingent capital. This improves bond ratings and risk profiles, which raises your earnings multiple," he explains.

Secondly, insurance can create "expressive value" for the company.

"The expressive side tells about the company's governance, which indicates that a firm is in control of the big six risk areas and is more likely to behave in a way stakeholders expect. It says that the products are safer and that regulators can manage your company with a softer touch," Kossovsky explains. "It indicates that you can trust the company because you can trust the leadership."

Kossovsky says that by just going through the process of getting reputational insurance, a company can better pinpoint where it's most at risk.

"A company needs to understand what drives its reputation and what that value is," he says. "Then if they make decisions to mitigate those risks, they'll get a return on investment for doing so."

THE KEY TAKEAWAY

According to Kossovsky, what is relatively unique about the pharma industry is the prevalence of "vicarious risk."

"This is when the bad behavior of one firm tarnishes many others," he says.

In pharma, the image of the industry is too frequently being controlled by the media. In an age when information is dispersed at a breathtaking clip, social media discussions dominate the public consciousness and people love to be outraged, the odds of swaying opinion can seem insurmountable.

But challenges always have a way of presenting opportunities. For pharma, that means getting in the conversation — using social platforms and the media to tell your company's story and controlling the narrative around your brand. And if one company succeeds, it can help buoy the entire industry, and may even transform the discourse around the industry's toughest issues. If, for example, the general public better understood the value of drug research, they would be more likely to accept pricing.

"If the stakeholder community expects companies to produce new products that have not been built before, and that do a better job of treating disease more effectively for a larger population, they will be more tolerant of the cost of innovation," Kossovsky argues.

And as many of the industry's top firms have shown, there are ways to break through the noise and effectively tell your company's story.

"Communicate your accomplishments, but also the challenges you've faced and how you are working to solve them," Khan says. "This is key to gaining trust."

Pharma Finds Balance

Despite negative public opinions and heavy demands, survey respondents indicate rising satisfaction and pride in their work

By Karen Langhauser, Chief Content Director

For the 15th consecutive year, *Pharma Manufacturing* readers have provided insightful feedback on their careers through our annual survey. We probe our readership to share their unfiltered thoughts in order to gauge both the financial and emotional health of their pharma careers.

Their responses, placed in the context of current industry happenings,

help us to piece together a bigger picture of pharma.

HAPPY DESPITE CRITICISM

A 2018 Gallup Industry Ratings Poll found that 53 percent of Americans have a negative view of the pharmaceutical industry; in fact, of the 25 different business sectors in the survey, only the federal government was held in lower esteem than pharma.[1]

Fortunately, external opinions do not appear to be swaying pharma's internal satisfaction. According to our readers, job satisfaction in the pharmaceutical industry is actually on the rise — more than 91 percent reported their satisfaction levels within the range of "OK" to "very high," which is better than recent previous survey years.

What is the greatest threat to your job security?

	External financial pressure on company (expiring patents, failed products, etc.)	Continued internal cost-cutting measures	Possible plant closing	The trend toward outsourcing	The diminished relevance of my skills due to the changing technologies and industry focuses	Personal issues with coworkers or supervisors
2018	20.7%	43.2%	5.4%	7.2%	6.3%	n/a
2017	39.6%	37.6%	8.9%	5.9%	7.9%	n/a
2016	25.6%	53.8%	11.5%	2.6%	6.4%	n/a
2015	21.20%	41.1%	16.6%	13.3%	8%	n/a
2014	20.2%	50%	11%	6.6%	4%	8.3%
2013	30.4%	42.8%	8.7%	4.8%	6.3%	6.9%
2012	29.9%	39.8%	8.3%	7.9%	6.6%	7.5%
2011	47.1%	21.3%	14.2%	8%	3.1%	6.2%
2010	30.3%	31.6%	13.9%	7.4%	4.3%	12.6%
2009	39.6%	32.6%	11.7%	7.8%	2.2%	6.1%

In some cases, results varied by respondent demographics. Gender did not seem to be a factor in happiness, however salary made a difference. The survey found that 62 percent of those making over $100,000 reported "high" to "very high" satisfaction rates, while less than 13 percent of those making $60,000 or under reported the same level of satisfaction.

When broken down by industry segments, those working for consulting companies reported the greatest amount of job satisfaction, with a dramatic 81 percent ranking their satisfaction levels from "high" to "very high." Those working in process control/validation were the least happy (only 27 percent ranked satisfaction levels from "high" to "very high").

Overall job satisfaction continues to rise in the U.S., but only just recently (in 2017) surpassed the 50 percent mark — so despite being in the public hot seat, the pharma industry is well above average.[2]

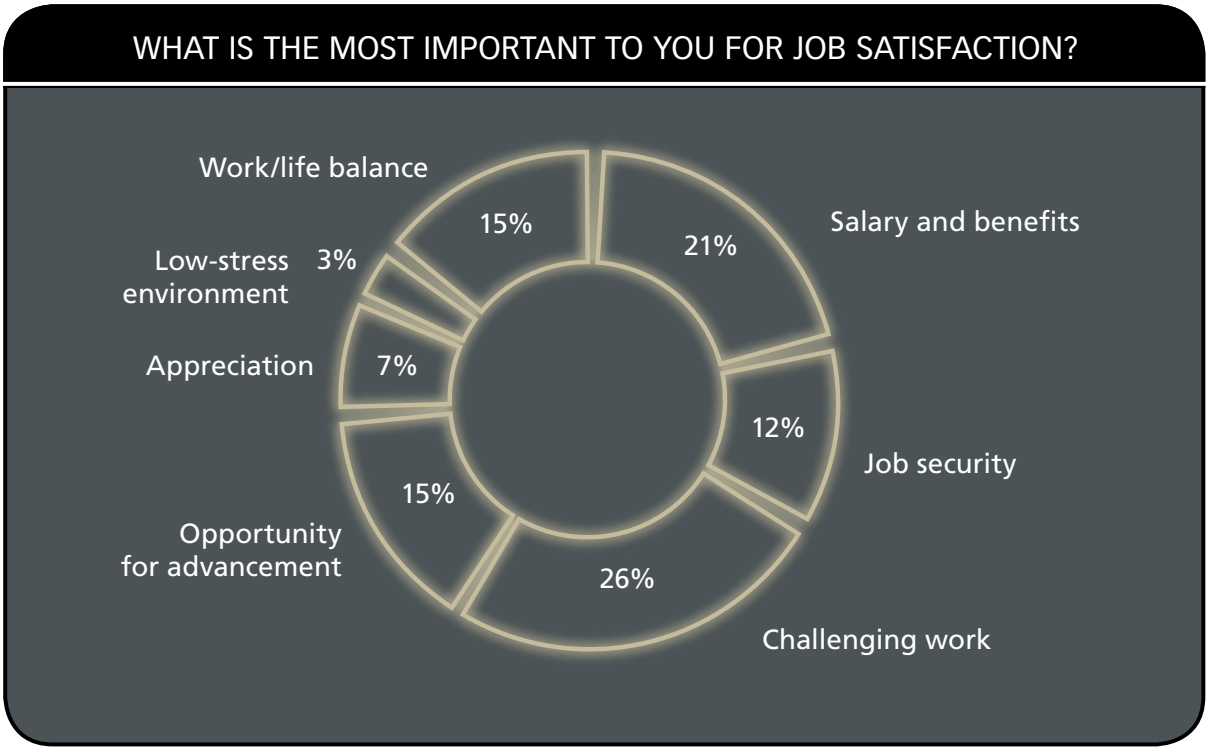
What's driving this satisfaction? According to those surveyed, various factors (see chart next page) — but one respondent summed up a common sentiment with this write-in: "Working for an ethical company in a field that provides significant benefit to customers in regards to quality and length of life — satisfaction from knowing that my work has a tangible impact on people's lives."

WHAT SATISFACTION LOOKS LIKE

Because the definition of "satisfaction" can vary by individual, our survey asked readers which specific factor contributed most to their overall happiness. "Challenging work" was the highest-ranking factor, and has been throughout the history of the survey. This was closely followed by "salary and benefits." This year, "work/life balance" edged out "opportunity for advancement" to take the No. 3 spot.

These results were corroborated by a write-in question that asked respondents to elaborate on what satisfies them most about their current position. Many respondents solidified their previous answer, pointing out how much they enjoy the challenge and diversity of the work they do. "Freedom and control over my projects; solving unsolved problems," said one respondent.

Despite the long hours and stresses of the job ("There is an endless opportunity to get things done," said one respondent, positively), numerous respondents were pleased to have flexible hours and autonomy in the workspace. Even though less than 15 percent noted "opportunity for advancement" as the most important contributor to satisfaction, many testified to their happiness with the opportunity to excel at their companies.



"There are ample opportunities for advancement. The work is quite challenging with aggressive timelines that need to be met — I look at this as a positive, " said one respondent.

Encouragingly, many are finding fulfillment knowing their work has a direct impact on patients. They respect the commitment of their colleagues and those in the field towards this common goal.

"Being part of a team that launches products which improve treatment outcomes and overall quality of life," said one respondent.

Also, we are happy to report that pharma still has a sense of humor, as respondents said "lunch" and "ergonomic work chairs" were also sources of job satisfaction.

WHAT ABOUT THE MONEY?

Compensation remains strong, stable and congruent with a healthy 2018 U.S. economy as a whole. Similar to last year, just over 25 percent of those surveyed have gross annual salaries between $100,000-150,000, with the next largest group (19 percent) making $150,000-200,000 annually. And 13 percent of respondents indicated their salaries are above $200,000.

According to survey results, tenure, education and gender factor into salaries. The majority (83 percent) of those who report gross yearly salaries exceeding $100,000 have more than 10 years of experience in the industry. Just over 39 percent of the

surveyed females reported gross yearly salaries exceeding $100,000, while 61 percent of men fell into this bucket.

Additionally, 62 percent of those who report salaries exceeding $100,000 have postgraduate degrees.

In this year's survey, 66 percent of respondents reported getting raises last year, with most (71 percent) seeing an increase of 3-5 percent. Just over 12 percent of those who reported earning raises said their salaries were increased by more than 10 percent.

The 66 percent of pharma reporting increases are claiming slightly higher raises than they did in year's survey, which is contrary to what is happening on global level. A Korn Ferry 2018 Salary Forecast predicated that, adjusted for inflation, employees around the world were expected to see lower wage increases, averaging just 1.5 percent, down from last year's prediction of 2.3 percent.[3]

HARD WORK & BALANCE

Pharma's healthy salaries do not come without a healthy dose of obligation. Although more respondents than in past years said they took vacation time, 53 percent of respondents still left vacation days on the table last year. This trend is on par with other U.S. industries. According to a U.S. Travel Association's study, America's vacation behavior is improving; but 52 percent of employees reported having unused vacation days at the end of 2017.*4*

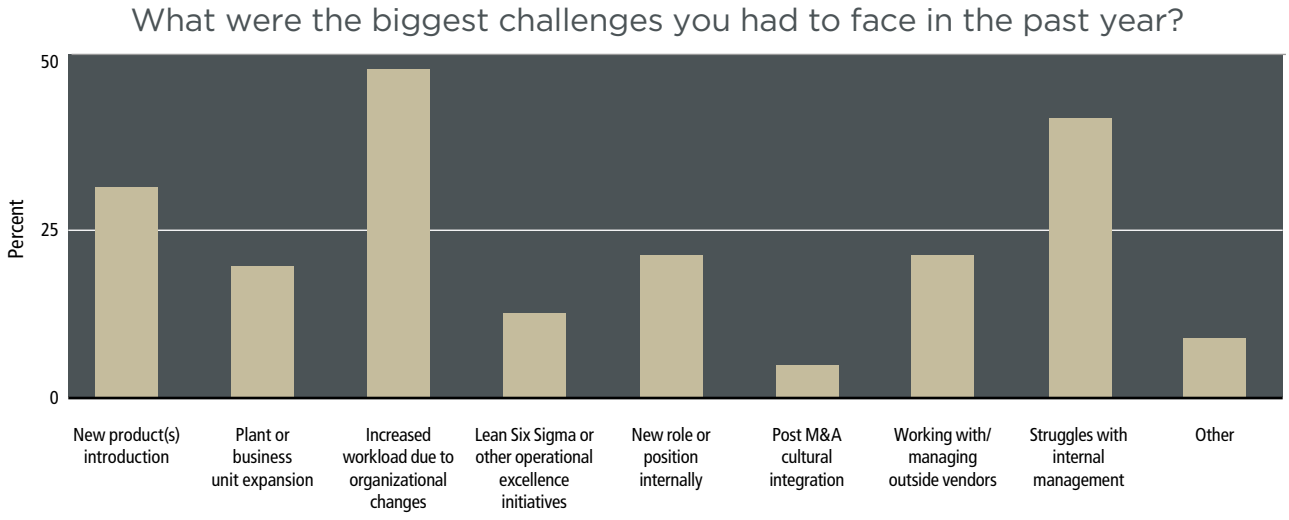
Although work/life balance is still low on the list of priorities for pharma, it's growing in importance. In 2016, only 4 percent of those we surveyed pointed to "work/life balance" as the most important factor for job satisfaction; this year that number jumped to 15 percent.

This year we asked readers how many hours they worked each week — a question we haven't asked since 2013. Not much has changed in that six years; only 12 percent of respondents are working a traditional work week (between 30-40 hours). Over 50 percent of respondents are working 41-50 hours per week, and over 32 percent are working a whopping 50+ hours per week.

WHAT'S STRESSING YOU?

Stress comes with the territory, especially for those in the business of saving lives. The good news for pharma is that stress levels are dropping. According to the survey, 54 percent of readers have what most consider a "normal" stress level (feeling overly stressed only some of the time at work), while just 19 percent feel overly stressed most of the time — and both categories are down a few percentage points from last year's survey.

Stress seems to be coming from both external or internal sources. When asked the

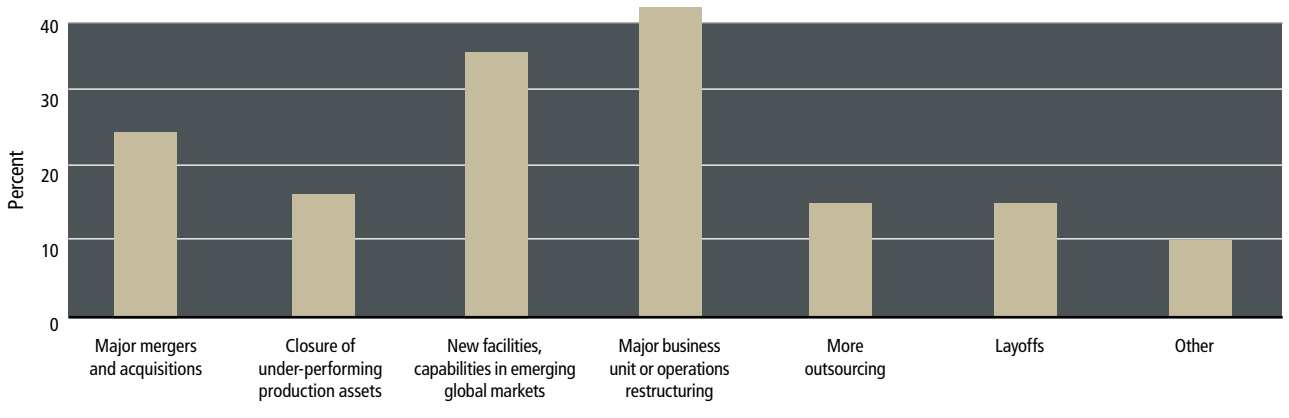


biggest challenge they had to face in the past year, 49 percent of respondents noted "increased workloads due to organizational changes," while 41 percent pointed to "struggles with internal management."

Pharma is not immune to external struggles either. When asked what current market and competitive forces affected their companies, 42 percent of respondents noted "major business unit or operations restructuring." This answer has remained in the top spot since we started asking in 2014. This was closely followed by 36 percent who said their companies have been affected by the "launch of new facilities and capabilities in emerging global markets."

The impact of major mergers and acquisitions continued their decline in this year's survey, with only 25 percent of respondents noting the effects of M&A on their companies.

Despite obstacles, survey results reflect continued positive attitudes about job security. When asked if they were more or less concerned about job security, only 31 percent



noted an increase in concern. While similar to last year's numbers, these percentages are way down from previous years (52.5 percent in 2016 and 48 percent in 2015).

Those who were wary of job security pointed to "internal cost-cutting measures" (43 percent) as their biggest threat. "External financial pressure on my company due to expiring patents or circumstances surrounding failed product development or regulatory approval" took the second spot this year, but dropped to 21 percent from last year's leading position of 41 percent.

Declining woes about patent expirations could have several potential explanations. According to the National Pharmaceutical Services (NPS), there were simply more potential patent expirations in 2017 than 2018. Additionally, expiring large molecule patents require biosimilar drugs — not only is their development more complex and expensive, their entry into the marketplace is heavily plagued by patent dance delays.

TELL IT LIKE IT IS

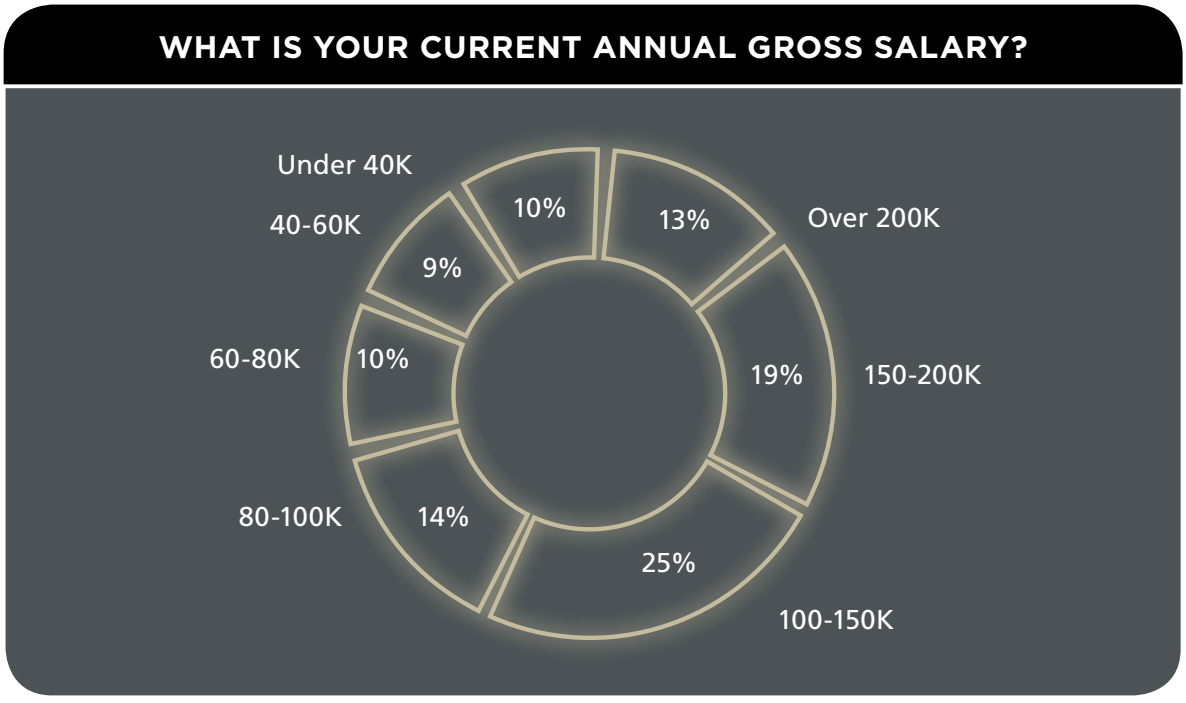
When given the opportunity to elaborate in an open-ended question asking what makes them least satisfied about their current position, pharma did not hold back.

Some complaints were about the industry as a whole. Many mentioned pharma's hesitation to adapt and change in general, while others were more specific about the industry's reticence. "Changes in technology not embraced as fast as I would wish, old analytical methods and techniques are still being used," said one respondent.

Several voiced their concerns about pharma's image problem and the "politics" impacting the industry. "Much of the discussion about the pharma industry being negative and driven by poor behavior of a few bad actors rather than being perceived and driven by the majority that are behaving appropriately," said on respondent.

Internally, many are up against high workloads, high stress and long hours. Expectations are clearly lofty to the point where a handful of respondents described them as "unreasonable."

And management does not appear to be helping. Similar to years past, management and senior leadership bore the brunt of the criticism, with respondents pointing to management's lack of communication, lack of transparency, lack of decision making, and lack of appreciation. "The politics of senior and upper management. Never really going through the trenches, but seemingly know everything about the day to day workload each department has. They do not take the time to actually LISTEN to employees who do the 'grunt work' and hear how the day to day workload really is," commented one respondent.



Some also mentioned the lack a of clear path to advancement within their companies. In fact, 46 percent of respondents said they do not receive meaningful feedback on job performance on a yearly basis.

And to the handful of respondents who said that what satisfies them least is the amount of meetings they have to attend: Preach! We feel your pain. Also, a big shout out to the person who claimed their biggest challenge was communication with our publication — our bad.

STAYING ON TOP

Given the extremely competitive pharma industry, employees can't afford to stagnate. While respondents expressed concerns about their companies as a whole falling behind when it comes to adopting new ideas and technologies, most appear to have faith in themselves and their colleagues. One respondent said the best part of his/her position is the "quality of the talent I get to work with" — a sentiment that was echoed by numerous respondents.

And many respondents spent last year dealing with change — 21 percent said their biggest challenge this past year was "adjusting to a new role or position internally." Despite changing circumstances, it appears that most respondents found a good fit — they are confident that their skills and training match the demands of their positions. According to survey results, 66 percent feel their skills and background are well suited to current responsibilities. Just over 20 percent admit that although they are being asked to do some tasks outside their skill set, they are generally able to execute them without specific training.

While research tells us that about 70 percent of learning on the job occurs informally,[5] formal training, especially in a highly regulated industry such as pharma, still plays a big role. According to our survey, 54 percent say their company offers access to a formalized program of training to support business or operational excellence goals.

SURVEY DEMOGRAPHICS

This year's study yielded 373 total responses. Examining demographic profiles revealed by *Pharmaceutical Manufacturing's* respondents, participants were predominately North American-based (70 percent), with the remainder of respondents dispersed in Asia (8 percent), Europe (6 percent), India (4 percent), and the Middle East, Africa and Latin America.

This year, 78 percent of survey respondents were male and 22 percent female. The majority of respondents (76 percent) were 40 or older, with most possessing degrees in pharmaceutics, chemistry or chemical engineering. According to survey results, 20 percent work in quality assessment and QC, 17 percent in manufacturing and operations and 16 percent fill R&D rolls. Corporate management, academia, consulting, process control and regulatory functions were also represented.

Industry longevity dominated, with 80 percent of responding readers having seven or more years of industry experience — and an impressive 44 percent of total respondents boasting more than 20 years of pharma industry experience. Interestingly enough, despite all the grumblings about management, 67 percent are in supervisory roles themselves, with 15 percent in charge of supervising more than 15 people.

Respondents represented the true diversity of our readership, with 16 percent from Big Pharma, 16 percent from small and mid-sized specialty manufacturers, 14 percent from generic pharma, 10 percent from contract pharma and 9 percent from biopharma. The remainder, including consultants, vendor/solution providers and all others, accounted for about 35 percent of the total.

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