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Taking the lead in pandemic preparedness

Pharma can use its pandemic response momentum to set the pace for a more prepared future

By Karen Langhauser, Chief Content Director

As the pandemic began to take hold last year, the pharmaceutical industry placed a collective foot on the accelerator in the race to stem the serious public health emergency, while at the same time tapping the brakes on its usual competition-based model.

Pharma's rapid and unified response to the call for novel coronavirus treatments and vaccines highlighted the depth of the industry's scientific and technological strength — showcasing the true potential of an industry that, in less urgent times, has been embedded with rivalries.

But pharma's successful pandemic response is only part of a much larger picture. Our "new future" will demand that the world rethinks its approach to pandemic preparedness.

The pharma industry is armed with the science, the technical know-how and the global platform. Now it has the experience of responding in real-time to one of the most rapidly-spreading pandemics in modern history. When the dust of COVID-19 finally settles, can pharma gather up its "lessons learned" and use them to help the industry rise as a leading voice in pandemic preparedness?

COLLABORATIVE RESPONSE EFFORTS ARE WORKING

Examining the timeline between when the genome sequence of SARS-CoV-2 was shared by Chinese researchers and how fast pharma progressed on vaccines would lead anyone with knowledge of the industry's inner workings to conclude that pharma's response exceeded expectations. And

> **Hopefully the lesson learned is that we need to invest in the ability to respond as quickly as possible to an emerging infectious disease because we don't want to go through this again.**
>
> — Clem Lewin

the backbone of these accomplishments was collaboration.

In spring of 2020, news coverage highlighted numerous high-profile vaccine-related partnerships involving the pharma industry, many of which were public-private pairings.

Pharma companies with promising SARS-CoV-2 vaccine candidates, including Moderna, Sanofi Pasteur and Johnson & Johnson were the first to announce funding grants and expanded collaborations with the Biomedical Advanced Research and Development Authority (BARDA). In April 2020, the National Institutes of Health (NIH) announced a massive public-private partnership between federal researchers and 16 pharma companies, among them vaccine giants GlaxoSmithKline, Sanofi, Merck & Co. and Pfizer.

But for most larger vaccine manufacturers, a relationship with government agencies — with the end goal of preparedness for public health threats — is nothing new.

Part of Clement Lewin's role as associate vice president Head BARDA Office & NV Stakeholder Engagement at Sanofi Pasteur* involves managing Sanofi's relationship with BARDA — which, until COVID-19, has been primarily related to pandemic influenza. The drugmaker has had what Lewin describes as a "very close and productive relationship with BARDA" that dates almost as far back as BARDA's inception. In fact, the first product supported by BARDA to earn an approval from the U.S. Food and Drug Administration was Sanofi Pasteur's H5N1 influenza vaccine — which, in 2007, became the nation's first vaccine for the deadly virus.

[*Lewin was interviewed for this article by *Pharma Manufacturing* in 2020; Lewin now serves as a principal at CSL Vaccine Consulting]

"For [Sanofi], it's not a new way of working, but obviously in this situation — a public health emergency — we are working even more closely with partners to move things forward quickly," says Lewin.

Responding to the urgency of a rapidly spreading public health threat requires speed. And speed, in the pharma industry, can be achieved with strategic collaboration.

For Sanofi, the collaboration went beyond public-private partnerships, extending to rival vaccine maker, GlaxoSmithKline. In the pairing — one that GSK CEO, Emma Walmsley, called an "unprecedented collaboration" — Sanofi agreed to supply its COVID-19 antigen, a genetic match to proteins in the virus, and GSK agreed to supply its pandemic adjutant technology, which could enhance the immune response.

Perhaps most impressive about this partnership is not the fact that it united two competitors — collaboration in the pharma industry, especially in the development stage, is certainly nothing new. In this case, the novelty is in the speed in which two rivals with a collective worth of over $200 billion, made a deal.

"If you look at our partnership with GSK — it's two of the largest vaccine companies coming together very quickly to try to meet a public health emergency. In those discussions there was this spirit of collaboration because we all know how important this is," says Lewin. "Within Sanofi, I have not heard any discussion of how much this is going to cost us or how can we profit — it's how are we going to respond to this — and I think that speaks to the industry itself," Lewin adds.

James Mayne, vice president of science and regulatory advocacy at Pharmaceutical Research and Manufacturers of America (PhRMA), says the increase in collaborative spirit has been inspiring. "Seeing an industry that is both large and complex and, at times, competes within itself, pull together with all oars going in the same direction for a very important purpose like this has really been impressive and makes me proud to be a member of this industry," says Mayne.

BROADENING THE SCOPE OF PANDEMIC PREPAREDNESS

Collaboration has been key to pharma's exceptional pandemic response. But once the industry moves beyond reacting to a public health emergency, pandemic preparedness will be necessary to ensure the world is ready for the next outbreak — whether it be additional waves of novel coronavirus, or an entirely new threat. Will the momentum gained during COVID-19 continue, bringing about a future where pharma collaborates to create a world more prepared to respond to infectious diseases?

It could be too early to speculate.

"I think we would all agree that it will have a durable effect on industry and how we practice. Right now, the industry is in a read and react mode — an 'action mode'

Key names in infectious disease response and preparedness

NON-PROFIT

WHO (1948)
The World Health Organization is a specialized agency of the United Nations with the primary role of directing international health within the UN leading partners in global health responses.

GATES (2000)
The Bill & Melinda Gates Foundation is a private foundation founded by Bill and Melinda Gates with a global mission to enhance healthcare and reduce poverty, and a national focus on expanding educational opportunities and access to information technology.

CEPI (2017)
The Coalition for Epidemic Preparedness Innovations is an international non-profit coalition with the goal of developing vaccines to stop future epidemics.

PUBLIC

NIH (1887)
The National Institutes of Health, an agency of the U.S. Department of Health and Human Services (HHS), is the primary government department responsible for biomedical and public health research.

NIAID (1948)
The National Institute of Allergy and Infectious Diseases, one of the 27 institutes and centers that make up NIH, conducts and supports research to better understand, treat, and ultimately prevent infectious, immunologic and allergic diseases.

DARPA (1958)
Defense Advanced Research Projects Agency is an agency of the U.S. Department of Defense responsible for the development of emerging technologies for national security.

USAID (1961)
The United States Agency for International Development is an independent agency of the U.S. government that is primarily responsible for administering civilian foreign aid and development assistance, which includes a focus on combating infectious disease.

BARDA (2006)
The Biomedical Advanced Research and Development Authority, part of the HHS Office of the Assistant Secretary for Preparedness and Response, was established to aid in securing the nation from chemical, biological, radiological, and nuclear threats, as well as from pandemic influenza and emerging infectious diseases.

— and not so much in 'after action' mode of analyzing what we've learned from the experience," says Mayne.

"Exactly how that learning gets synthesized and pulled into new practices, approaches and strategies — I think that book has yet to be written."

What most can say for certain, however, is that concern over the threat of pandemic outbreak has long loomed within the industry and beyond. For years, experts from all sectors have been warning of impending pandemics. (To date, Bill Gates' 2015 TED Talk on pandemic preparedness has over 41 million views). Heeding the call of the warnings, there have been countless simulations, conferences, workshops and committees assembled to evaluate and improve global pandemic preparedness. Academia, government and private industry has had prominent seats at these tables.

Unfortunately, what the vast majority of these events have had in common was the unsettling conclusion that the world was woefully underprepared for a pandemic.

One obstacle — despite incredible advancements being made in medical science and technologies — is that planning for pandemics still involves guesswork. Many of our pandemic models and frameworks were based on the predication that the

next pandemic outbreak would be a form of influenza.

In the U.S., the threat of pandemic influenza has gotten the lion's share of attention — and funding. The 2018-2022 budget for the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) — which is the overarching coordinator of federal efforts to enhance public health emergencies preparedness — designated pandemic influenza as the largest threat-specific investment. Across National Institutes of Health (NIH), BARDA, Strategic National Stockpile (SNS), and FDA, spending on pandemic and seasonal influenza was estimated to be $5.7 billion over the five-year period.

In fact, in December 2019, just prior to the global outbreak of COVID, Sanofi Pasteur was awarded $226 million from BARDA to expand pandemic influenza production capabilities at its Swiftwater, Pennsylvania facility.

Emerging disease pandemic preparedness outside of pandemic influenza — for coronaviruses, for example — adds logical and financial challenges.

"Facilities you would use for pandemic influenza are up and running because of seasonal influenza but when it comes to emerging infectious disease vaccines, how do you keep a plant going if you don't utilize it?" says Lewin.

"It's not just a financial issue, it's that you can't keep a factory warm without producing anything — these are biologicals, they are complex processes, so you can't just start up the machinery overnight. Figuring out how to do this for emerging infectious diseases has proven to be challenging," Lewin continues.

This has led government agencies, as well as non-profits such as the Coalition for Epidemic Preparedness Innovations (CEPI) and the Bill & Melinda Gates Foundation, to invest in the development of platform-based technologies that ideally could be leveraged to produce vaccines against multiple threats, including both emerging and known infectious diseases. Because these technologies would also enable standard manufacturing processes and facilities to be used for the production of non-pandemic vaccines, plants would not sit idle during non-pandemic times.

And yet, despite the flexibility and scale that could be made possible through innovative platform-based approaches, a recent Johns Hopkins Center for Health Security project focused on vaccine platforms concluded that emerging infectious diseases "will never represent a major market with large financial rewards and minimal opportunity costs."

Lewin adds that there's a certain amount of funding that needs to be provided by

> **The current pandemic may have finally served notice on humanity that it has to take viruses seriously now, and in the future.**
>
> — Barry Holtz

government when asking private companies to devote resources to diseases that may not materialize as threats. "There's no market for theoretical emerging infectious diseases," he says.

But, as we have learned from COVID-19, that does not diminish the importance of investing in them.

Lewin speculates that the current pandemic could lead to emerging diseases carrying more weight in the future.

"It does illustrate the importance of thinking of emerging infectious disease response in the same way the U.S. and other countries have thought of pandemic influenza response. Hopefully the lesson learned is that we need to invest in the ability to respond as quickly as possible to an emerging infectious disease because we don't want to go through this again," he says.

COLLABORATING WITH GOVERNMENT

As every TV commercial likely reminded you, "these are unprecedented times."

Pharma has cast aside its competitive nature and has seen, first-hand, the importance of investing in infectious disease. But if the industry is to be a leader in crafting better pandemic preparedness on a global scale, efforts will have to persist long after vaccines are available and the pandemic abates.

Most agree that pharma shouldn't go at it alone. Recent events have certainly shown that collaboration is the most efficient path to results. Dedicated, collaborative programs spearheaded by governments and philanthropies will be needed to advance future pandemic preparedness. Post pandemic, one thing we could see — and arguably should see — is an increase in public-private partnerships. But is this easier said than done?

The government has acknowledged the importance of these partnerships. According to a recent statement made by now-famed National Institute of Allergy and Infectious Diseases (NIAID) director Dr. Anthony Fauci, "We always need a pharmaceutical partner. I can't think of a vaccine,

even one in which we've put substantial intellectual and resource input, that was brought to the goal line without a partnership with industry."

In the U.S., there are several government agencies and projects that can provide various degrees of funding, technical assistance or resources for pharma companies looking to engage in the emerging infectious diseases and pandemic preparedness space. Names that are now more mainstream, such as the U.S. Department of Health and Human Services' Office of Pandemics and Emerging Threats (PET), BARDA, the Department of Defense's Advanced Research Projects Agency (DARPA), and the U.S. Agency for International Development (USAID) are open to partnering with the pharma industry in areas such as R&D, new technologies or manufacturing.

The COVID-19 pandemic has raised the profile of a lot of these agencies, creating a larger awareness of the partnerships and funding available. Chris Stanley, president and principal consultant at Harmony Consulting, submitted a request to BARDA on behalf of a client in the spring of 2020 and was told that BARDA had received close to 2000 COVID-19 related applications since that February. This is seven times the amount of submissions the small agency — who is currently limiting requests to COVID-19 products and technologies only — receives in an average year.

But yet, in non-pandemic times, companies are not exactly lining up to partner with government agencies on pandemic preparedness and potential medical countermeasures (MCMs). "It's usually a bit of a selling job that has to be done because, you know, working with the government presents its own challenges," says Stanley. In his position, Stanley devotes a considerable amount of time — much more so in these past few months — to helping companies get grants from the government for medical countermeasures.

In some ways, it's a bit of a Catch 22. In Stanley's experience, government agencies, such as BARDA, focused on MCMs are historically more interested in repurposing existing drugs already in development, rather than investing in early stage development. And yet, the "further along a company is in development, the less interested they are in working with the government," says Stanley. "Why would commercial stage companies want a large government contract and all the headache that comes with it?"

As such, the bulk of the partnerships Stanley ends up facilitating are clinical stage companies strapped for cash — partnerships born out of the need for non-diluted funding to keep the company afloat.

But Stanley, like many others, is hopeful that the pandemic might lift the stigma

> **There's money and support to be had here and you can do some good for your country — maybe for the world — at the same time.**
>
> — Chris Stanley

surrounding government partnerships within the pharma industry.

Aside from funding, partnering with organizations such as BARDA can offer pharma companies access to subject matter experts with long resumes of pharma experience. Through its TechWatch Program — which allow companies to pitch ideas — BARDA provides detailed feedback, including advising companies on where data may be lacking and what studies may still be required, what further discussions need to occur, and possible regulatory pathways. Importantly, BARDA also can connect companies to interagency partners within HHS, including FDA, CDC, and NIH, where the timing may be better suited to begin a working relationship.

And while timelines are accelerated right now due to the current health crisis, even during normal times, launching a partnership with BARDA is fairly efficient. "The whole process takes around to six to nine months from the time that you say, 'Hey, I want to approach BARDA' until the time they issue a press release saying that they have signed your contract," says Stanley.

Pharma's willingness to explore these types of partnerships can go a long way in terms of future pandemic preparedness in the U.S.

"There's money and support to be had here and you can do some good for your country — maybe for the world — at the same time," says Stanley. "I think that will appeal to a lot of pharma companies now."

PHARMA IS POSITIONED TO LEAD

"The current coronavirus pandemic may have finally served notice on humanity that it has to take viruses seriously now, and in the future," says Barry Holtz, former president of iBio CDMO, now serving as chief science officer for a new company called Phylloceuticals.

Awareness of the dangers surrounding infectious disease is high during a public health emergency but as treatments and vaccines progress and the world gradually returns to normalcy, the threat that pandemic preparedness will fall to the back

burner looms large. Pharma is uniquely positioned to make sure this doesn't happen.

"Pharma companies have shown that they can be agile and that they have the technical knowledge to respond quickly," says Holtz.

And not only does the industry have the expertise, with extensive networks and operations spanning the entire world, it has the reach. Pharma taking a strong role in continuing to generate both public and political awareness will be key to future pandemic preparedness efforts.

"Pharma is best-suited to use its political influence to lead this preparedness effort, because they understand all facets of research, clinical testing and supply chain dynamics," says Holtz.

Pharma must encourage leadership on a global level to support a continuum of research, manufacturing and distribution related to infectious disease.

"Without all of this in place, viruses will outpace our ability to respond," says Holtz.

The current pandemic has also shown the importance of science-backed information. PhRMA, the industry's leading trade group, has been a strong voice in disseminating information about pharma's pandemic response efforts.

"There are a tremendous number of sources of information on this — not all of them reliable — so we've tried to pull together credible information and collate it in a way that allows us to speak at an industry level," says Mayne.

In addition, PhRMA has coordinated communication between pharma and policymakers. "We are on the phone weekly with leadership at R&D organizations within member companies and making sure we are coordinating efforts and communications with regulators and the administration," says Mayne.

In order to truly push the needle on the way the world views infectious disease, conversations about the importance of medical countermeasures and pandemic preparedness will need to continue beyond the COVID-19 pandemic. And these conversations should be backed by actions, likely spearheaded by larger pharma companies, that include sustaining a level of donations, investment and collaboration.

Our new reality will have a new set of heroes. Pharma has the chance to stand among them.

Puerto Rico pharma: Battered but unbroken

The post-Hurricane Maria effort from the pharma industry is a story about resilience

By Karen Langhauser, Chief Content Director and Meagan Parrish, Senior Editor

Ask someone what it was like in Puerto Rico the night Hurricane Maria barreled into the island, and often, the answers take on a surprisingly calm tone.

Sure, it was loud. The winds roared at over 155 miles per hour. And there was the sideways rain — something many had never seen. But although some stayed awake all night and watched as Maria showed no mercy, many managed to sleep.

For most on the island, the real drama began the morning after.

"It's as if you went to sleep in the 21st century and woke up in the 19th century," Marco Monrouzeau, CFO and general manager of Neolpharma, headquartered in Caguas, PR.

The morning after Maria hit Puerto Rico, it looked as though the island had been pummeled by bombs. Trees were scattered like toothpicks on the streets. A massive storm surge plunged parts of the island underwater. And all of the forms of modern technology we rely on were suddenly gone — no power, no internet, no phone service. Puerto Rico was on its own — and the scramble to find resources had begun.

News (whether accurate or not) was spread primarily by word-of-mouth and sporadic radio broadcasts. Occasionally, someone would find a functioning cell tower and people would cluster around it in cars, desperate to connect with the outside world. Lines to get water, food and gas were horrendously long. And all of these new challenges had to be managed amidst the sudden need to rebuild.

At first, many stayed close to home, clearing debris from local roads, repairing damage to their houses, and checking in on neighbors. But for many employed by one of the island's dozens of pharmaceutical plants, there was a notable exception to this post-Maria routine: They were at work. In fact, some hadn't left their facilities during the storm. Luckily, many pharma companies were able to provide employees with much-needed post-storm supplies. But perhaps more importantly, going to work gave people some semblance of normalcy after their lives were so violently disrupted.

The post-Maria effort from the pharmaceutical industry, like that of Puerto Rico as a whole, is a story about resilience.

The pharma industry in Puerto Rico is up against unprecedented challenges: The Commonwealth's crippling debt, an unstable power grid, the rapid consolidation of manufacturing facilities and a changing tax structure. On top of this, Maria has sparked worries about the future growth of manufacturing on the island.

As Puerto Rico approached the one-year anniversary of the most destructive storm in close to a century, *Pharma Manufacturing* editors headed to the island to meet with industry leaders and tour major manufacturing facilities to find out how pharma companies are recovering. Their message? The industry may have been battered, but "¡Puerto Rico se levanta!"

BATTEN DOWN THE BATCHES

For Puerto Rico, September of 2017 was a painful cliché. Just two weeks after Hurricane Irma left more than half the island without power and nearly 50,000 without water, Maria made landfall — a crushing

MANAGING DISASTERS

Key takeaways from industry leaders in Puerto Rico

Stock up: Make sure your water and energy reserves are always full and have enough to keep your facility operating off the grid for a prolonged period of time.

Have spare parts: Be ready to fix broken generators or other key machinery on your own.

Have IT know-how: So many systems are now automated and online, it's crucial to have a professional available who can quickly solve IT-related hiccups.

Establish a clear chain of command: Know who's going to be in charge in case of an emergency.

Track employees: Have a plan to account for everyone at your facility if phone service is disrupted.

Line up contractors: Establishing good relationships with contractors will help with rebuilding when you need them to prioritize working with you over other companies.

> **There was a need to supply direction, so we took that leadership role.**
> — Idalia García

example of what it's like for an entire island to be kicked when it's already down.

Hitting the island as a Category 4 storm, and now considered the worst natural disaster to affect Puerto Rico in history, Maria's 155-mph winds wiped out what was left of the electrical grid, grinding through wounds already opened by Irma.

Arthur Deboeck, general manager at Galephar Pharmaceutical Research, had one word for Maria: Ugly.

"As an engineer, I'm accustomed to building. Maria was hard because you had to slowly, but surely, watch the destruction unfold," he explained.

For those managing pharma plants on the island, their responsibilities were twofold: Not only did they have to worry about their own homes, but they also had to prepare for the storm's effects on their facilities, workers and, ultimately, patients.

It's basic practice for manufacturing plants in Puerto Rico to have Standard Operating Procedures (SOPs) for both disaster preparation and recovery. The plans are specific, and executed by hurricane task forces — a group of people who are trained to stay on-site during the storm. The task forces spent the evening of Sept. 20, 2017 taking care of critical utilities, reinforcing failing doors and windows, relocating inventory as needed and keeping key personnel updated on the facility status.

Some facilities manufacturing biologics, such as AbbVie and Amgen, were not able to halt all their processes, and thus continued manufacturing through the storm, relying on generators for power.

Although most of the pharma facilities were structurally safer than many homes, the stories of those who stayed on-site were chilling.

"This is where I slept during the storm, while the rain water seeped into the room, soaking the floor around me," said Kerry Ingalls, vice president of site operations at Amgen, as he gestured to the table we were sitting at in Amgen's Juncos conference room.

East of Juncos, at the Galephar facility in the coastal city of Humacao, Deboeck told us about how he covered his chief of security's post-Maria psychological treatment after the worker witnessed the two-story windows of the administrative building exploding around him during the storm.

In times of crisis, a sense of order is often the most comforting asset — most site leaders agreed that a crucial benefit of the disaster preparedness plans was the structure they provided.

"I think a business continuity plan provides a clear chain of command," said Idalia García, vice president and site director of CDMO, Avara Pharmaceutical Services -Arecibo. "Who's the leader? What are the roles? This was critical to keep people calm and provide direction. People were in a state of shock but they were willing to work. And the team showed them what to do and what we were going to accomplish."

SOLVING A PROBLEM LIKE MARIA

But even the best of plans could not combat the power of Maria. The short-term impact of the storm on the pharma industry was daunting. However, the industry was strategic, and at times, even fiercely creative in sourcing solutions.

Contrary to public perception, Puerto Rico has endured surprisingly few catastrophic hurricanes — the last storm that came close to matching the intensity of Maria was Hurricane Hugo in 1989. Perhaps the biggest adjustment to make post-Maria was the loss of essential communications — cell service and email especially. These communication issues, combined with the physical obstacles caused by flooding and downed trees, and the sheer demand for essentials, made securing resources and workers a challenge.

After companies did their best to locate employees and ascertain their safety (most used radio communication via satellite) there were several issues that needed to be addressed. The knowledge that pharma facilities were manufacturing drugs, and in some cases, controlled substances, meant that security was a top priority — especially at night as darkness fell on the areas surrounding the plants.

"Even though we added some additional security people, they were here alone without perimeter lighting and without monitoring systems to see what's happening around them. I was also concerned that our security gate was affected," Monrouzeau noted about the Neolpharma site.

The Pfizer site in Guayama got assistance from an unlikely source — inmates from the neighboring low security detention center, who helped repair the plant's exterior fencing after the storm. And Pfizer repaid the favor too, allowing the center to fill their

1. The authors (Karen Langhauser, left; Meagan Parrish, right) meet with Marco Monrouzeau, CFO and general manager, Neolpharma. **2.** A power pole in San Juan. **3.** Post-Maria damage outside Neolpharma. **4.** Damage caused by Maria to a conference room at Neolpharma. **5.** Old San Juan. **6.** The authors get a tour of Amgen's biomanufacturing facilities in Juncos. **7.** Damage caused by Maria to an office room at Galephar. **8.** San Juan. **9.** Old San Juan. **10.** A roundtable discussion at Amgen. Seen here (from left to right): Alejandro Blanco, general manager, Becton, Dickinson and Company; David Thompson, site director, AbbVie Biologics Ltd, Barceloneta; Kerry Ingalls, vice president, site operations, Amgen-Juncos; and Juan C. Kuang, vice president, manufacturing, Amgen-Juncos. **11.** A door in Old San Juan showing the saying: "Puerto Rico se levanta" —a local rallying cry that means "Puerto Rico rises."

potable water tanks at the site to keep the inmates hydrated.

To help with the lack of power, all of the facilities had contingency plans — most of which involved diesel-powered generators. Unfortunately, these generators were meant for brief outages — days, typically. None of the companies thought they would need to use their generators for months, like they did after Maria.

This continuous operation also gave rise to other problems no one anticipated.

"One thing we learned is that we need to identify the critical materials that we might need, such as spare parts for generators. For example, we needed oil filters and then we couldn't find any — they weren't available on the island," Monrouzeau said.

And then there were the unexpected challenges most don't think of initially: With no power or internet, banks were closed, and ATMs and credit cards didn't work. Suddenly, life was cash-only and that cash was hard to come by. While larger establishments, such as Amgen, have their own credit unions on-site, other plants had to get creative.

Medical technology company, Becton, Dickinson and Company (BD), for example, flew in a corporate jet full of cash. Deboeck took an even more hands-on approach at Galephar, personally driving $50k from San Juan to his plant in order to pay workers.

FILLING IN THE GAPS

There was notable reluctance among all interviewed to criticize the government's response to Maria. Instead, the general mindset was that of self-reliance. Pharma companies were more than willing to assist the government in "connecting the dots" as Alejandro Blanco, general manager, BD puts it.

The pharma industry knew it had to proactively take matters into its own hands and it collectively stepped up to not only assist employees, but the government and community at large.

"Someone had to provide a structured approach to manage an emergency, and our role was to take that lead," García said. "As you can imagine, the government was busy with other things. There was a need to provide a defined direction, so we took that leadership role."

After the storm, Amgen worked with the Puerto Rico Water Authority and supplied resources to fix a pump that services the nearby community. The drugmaker also supplied diesel to local gas stations. When a supermarket generator broke down, Amgen sent technicians to fix it so the store could continue operating.

> **After this I have become an even bigger fan of our colleagues. They put the interests of Pfizer even before their own.**
>
> —Víctor Batista

"There were different ways to mitigate some of the gaps that were created," Juan Kuang, vice president, manufacturing, Amgen, said. "We came up with plans to handle whatever factors we could."

Pharma companies also did something unexpected for a such a highly competitive industry — they worked together.

For example, there was a sudden constraint on gases like nitrogen and oxygen, that are essential for pharma manufacturers, after one of the island's main supplier's facility was damaged during the storm.

"Companies started talking to each other and created a supply chain for gases. Once one of us found a route, we shared with the other companies and could even share some of the product as we were getting it to the island," Kuang explained.

Getting personal

Strong relationships with suppliers and contractors proved essential to helping the pharma industry overcome the deluge of obstacles that rained down with Maria.

Neolpharma, for example, had contractors on-site the day after the storm, dealing with flooding and roof issues — Monrouzeau attributes this quick service to loyal, long-standing relationships.

Amgen gave props to the support and expertise they received from companies such as CIC Construction Group, which provides construction services for the biopharma and medical device industries in Puerto Rico.

Gustavo Hermida, president, CIC Construction Group, says he had 70 percent of his employees back to work the day after Maria, and 100 percent within a few days.

"We have an action plan to make sure we can respond immediately to customers. Our company has close to 650 employees around the island and we can react quickly," Hermida said.

Notably, not one pharma leader failed to praise the efforts of the pharma workforce post-Maria. Despite suffering extensive personal losses, employees were traversing

tree-strewn roads and using the little gas they had to show up to work.

"After this I have become an even bigger fan of our colleagues," said Víctor Batista, general manager, Pfizer-Guayama. "They put the interests of Pfizer even before their own."

In return, pharma companies looked out for the wellness of employees, too. Pfizer provided free kits with portable generators, propane stoves and portable gas tanks to all its employees, and then distributed the extra to critical contractors and nonprofits, giving away 2,200 kits in total. Amgen opened a temporary gas station and laundromat on-site. The majority of companies fed their employees and families meals, as well as provided other essentials, such as hygiene kits, water, batteries, diapers and ice.

"It was important to provide them a better and more comfortable place than they had outside, so that they could come to work and focus on contributing," Batista concluded.

BEYOND THE STORM

In the fall of 2018, as a Category 4 hurricane closed in on Hawaii, Honolulu's mayor made a public statement to reassure the city's residents.

"We do not want to see here what happened in Puerto Rico," Kirk Caldwell said. The statement illustrated how, even though a year has passed, Puerto Rico was still synonymous with "disaster." In fact, repairing the industry's public image may prove to be more difficult than rebuilding its infrastructure.

Part of the holdup is that the effects of Maria are lingering throughout the island. A year later, signs on highways that long ago blew away hadn't been replaced. At some intersections, inoperable traffic lights hung precariously. Parts of rooftops in the hardest hit areas are pounded into pieces. And some were still without power.

Although most pharma facilities were up and running within weeks, some of the sites we visited were still rebuilding a year post-Maria, with walls, floors and windows under construction.

According to estimates from the Puerto Rican government, the full cost of repairs from Maria could reach $139 billion. For pharma companies, the costs were significant as well.

A month after Maria, Amgen estimated that its hurricane-related costs could reach $165 million. According to Monrouzeau, Neolpharma, which has a much smaller facility, submitted an insurance claim for $5 million after the hurricane to cover the cost of repairs and business interruptions.

> **I didn't choose to come here 35 years ago only to leave because the wind is blowing a little bit more.**
> — Arthur Deboeck

Monrouzeau admits that Neolpharma also lost one-third of a customer account due to production delays — and all of the company representatives we spoke to said there were concerns from customers. But most companies were able to reassure customers they could maintain business as usual.

"We were expecting major equipment — a compressing machine — and when it came, we sent our customers a video of that," García said. "So, companies could see that we were doing our work to deliver our commitments and be back on our feet."

After seeing the damage Maria caused, it's difficult not to wonder if pharma companies still see Puerto Rico as an attractive destination for manufacturing. Those who attended our Amgen panel were dismissive of the idea, however, that Maria will have a long-term impact on the health of the industry.

"I've watched the indicators that keep track of the risk of industry decline — taxations, royalties by patent expirations, mergers, where sites are closing, etc. This has all been an ongoing process, but those issues have been ongoing for 30 years," said Carlos Serrano, a capital partner with Reichard and Escalera Law Firm. "But the industry just evolves."

What's it going to take to overcome the public perception that Puerto Rico is a place in peril? Right now, it's all about proving that the industry has learned from all of these storms and is even better prepared for what comes next.

ANOTHER MARIA? BRING IT ON.

Storms like Maria don't come around often. But global warming has also increased concerns that strong hurricanes could become more frequent.

Either way, all of the company leaders we spoke to said they have updated their SOPs for hurricanes and have strengthened their business continuity plans in case of another blackout. Many have increased reserves for critical resources and are looking at new ways to ensure their supply of electricity will be stable. For most, that will likely mean switching to co-generation, or combined

heat and power. These kinds of systems are generally located near the point of consumption and recycle wasted heat to produce heating, cooling and electricity from a single source.

Blanco says there has also been a lot of knowledge sharing in the industry so that others can learn from the experiences of companies on the island.

One year after Maria, the goal was to shake the image that Puerto Rico is in a state of disaster. Those in pharma hope the storm will showcase the industry's ability to roll with the punches and bounce back stronger than it was before. No matter how many challenges the industry is up against, it's determined to maintain its footing as a high-tech hub for pharma manufacturing.

"The reality is that what we built on this island cannot be done overnight," Batista said of the industry's long history and staying power.

If companies in Puerto Rico have anything to say about it, the industry won't be un-done overnight either — and for now, it's going to take a lot more than Maria to unearth their commitment to the island.

"I didn't choose to come here 35 years ago only to leave because the wind is blowing a little bit more," Deboeck said.

Plugging the manufacturing cracks

How to ensure COVID learnings are put into practice for good

By Bryan DeBois, Director of Industrial Artificial Intelligence, RoviSys and David Sprinzen, Director of Marketing, VANTIQ

COVID-19 has shined a spotlight on the cracks in pharmaceutical manufacturing. Even before the pandemic, life sciences experts had warned about the risks of a globally concentrated supply chain where pockets of raw materials and active pharmaceutical ingredient (API) suppliers in other regions of the world left pharma companies and patients particularly vulnerable to a sudden manufacturing stoppage. Any production disruptions, they said, could have catastrophic effects on human health.

Their concerns were borne out with the sudden emergence of the novel coronavirus, which not only disrupted manufacturing but also led to widespread supply chain shortages as the pharma sector was focusing its attention on developing new therapeutics and vaccines for COVID-19. However, in an industry where companies make drugs that are life-saving, downtime is not an option.

Technology that can make data actionable in real-time has been a boon to pharma companies during COVID-19. It has helped them keep employees healthy and safe, adjust to smaller teams and react to issues faster. But that technology should not be tucked away in a server closet once the pandemic subsides. It solves issues that pharma manufacturers can no longer ignore.

INITIAL EFFECTS AND LESSONS

COVID-19 dealt a blow to pharma manufacturers that were already facing a skilled labor shortage and running reduced crew

In an industry where companies make drugs that are life-saving, downtime is not an option.

shifts. As the virus spread, these reduced work crews became skeleton crews as many employees either became sick or were hesitant to come into facilities because they feared infection. Manufacturers were forced, for social distancing reasons, to reduce staffing even further, keeping non-laboratory and plant-floor workers at home.

The new distance requirements, while a safety necessity, inevitably slowed down production processes. A McKinsey poll of more than 300 research and development functional leaders, including chief medical officers from over 50 global companies in the sector, estimated that productivity has declined by 25-75 percent due to remote working.[1] As companies adjust to remote work environments along with reduced lab capacity, clinical and product development pipelines are suffering.

Pharma companies continue to scramble to come up with employee protection solutions to mitigate health risks so their people can return to work safely.

In the face of a virus that spreads rapidly when people work in close quarters, pharma companies improvised an assortment of stopgap protection measures such as routine temperature checks, staggered shifts, and limits on personal interaction where sites remained open. This was trial-and-error in real time because employees working in laboratories and manufacturing sites were on the front lines with the pandemic threatening their own health.

REAL TIME IS THE NEW NORMAL

As the industry looks to apply lessons learned, one clear takeaway is the need for solutions that will improve business resiliency. It's no longer enough to rely on traditional safeguards companies put in place during "normal times" to ensure general safety standards and protect workers doing the delicate work of biologic manufacturing against standard illnesses. COVID-19 has reminded us there is nothing standard about a pandemic.

In the past, pharma companies weren't under such pressure to respond to issues in real time. They were accustomed to taking the necessary time required to collect and review data on their products or the performance of their equipment. In

With the right IoT technology monitoring their workplace and workforce, managers at a pharma facility can sense, analyze, and act upon data in a single view – and all in real time.

the face of challenges like COVID-19, that timetable needs to speed up. An employee with a fever that goes undetected risks triggering an outbreak that could lead to a total shutdown of the manufacturing site. Such information is critical, and manufacturers need to be able to have it immediately so they can respond quickly and with agility.

For comparison's sake, consider the unfortunate example of the meat-packing industry which was relatively slow to react to the new health risks posed by COVID-19. Several meat and poultry processing facilities suffered multiple outbreaks that led to closures as thousands of workers got sick with the virus.

Had those sites been equipped with effective contact tracing technology, they would have been able to understand how employees were moving through their environment. Technology would have helped them learn where people had been, who they interacted with, which rooms they spent time in, and whether they adhered to physical distancing rules.

Further, they would have been in a stronger position to enforce safety compliance, making sure that employees wore masks or were sanitizing their hands correctly.

Many companies are now connecting thermal imaging cameras into their Internet of Things (IoT) network to measure body temperatures and monitor employees as they enter the facility. As people walk through the door, the systems can flag anyone with a high temperature for further evaluation. Importantly, this occurs in the moment, not after someone has been walking around for an hour and interacting with other workers.

The upshot: Facility managers will be able to detect and respond to potential trouble in minutes, not hours.

All in all, such a system contributes toward achieving the larger goal of creating a safer, more secure environment for employees.

SITUATIONAL AWARENESS

Situational awareness isn't just for pandemics, however. It is no easy feat, as it depends upon collecting information from the environment, focusing on events taking place in real time and then converting that data into actionable insights.

As the pharma industry considers how to develop better business resilience in the post-COVID-19 era, situational awareness needs to remain a critical component of any recovery strategy.

Real time is part of the broader digitalization trend underway the last few years as more organizations connect to IoT and deploy sensors and devices that collect information from their environments. Even gateways and edge devices now have logic running anywhere and everywhere. With this extraordinary amount of data, companies can apply artificial intelligence to extract meaningful

5 Benefits of working in real time

1. Workforce health and safety
Businesses making use of real-time data now have a way to ensure the wellbeing of their workforce. Instead of waiting until an employee falls ill before sending them home — at that point, you're already behind the infection curve. IoT-based monitoring solutions that send back real-time data allow managers to track the health of employees, based on up-to-the-minute data. Managers can act preventively to send home employees showing early signs of fatigue or illness.

2. Workplace health and safety
Real-time data also allows the early detection of any hazardous conditions that could potentially harm the safety of the workforce. In the event of an incident, such as a carbon monoxide leak or a fire, management can gather instantaneous updates on the status of the problem and location of workers in the facility. Real-time information also helps with the oversight of more routine safety-related norms around the maintenance and sanitization of equipment.

3. Minimizing production downtime
Instead of waiting for something to break, companies can now spot early signs of technical malfunction, mobilizing repair teams as needed to intervene before a situation worsens and systems and machines break down. Organizations reap additional cost and health benefits since they no longer need to staff as many technicians on site. At the same time, they reduce potential health risks that may arise since fewer employees are required to work in a facility.

4. Integrated maintenance
Manufacturers often find themselves running disparate systems where it's hard to communicate and share data internally. But with real-time data, the deployment of sensors and devices around a site will immediately inform managers of any urgent operational decisions they need to make — from DEFCON-1 emergencies down to nuts and bolts situations, such as whether to keep the power on in a room or shut off a piece of equipment for the night.

5. Resource management and efficiency
In any complex factory, there are so many steps in production that a single change can affect operations at all the other points on the assembly line. Based on real-time data collected along each point on that line — for instance, an alert that a particular piece of equipment needs maintenance — managers can adjust any step or multiple steps in order to improve performance.

Digital is still a long way from becoming central in life sciences interactions.

understanding to be more proactive when it comes to operations and strategy.

That means any organization can now receive alerts for everything from an industrial accident to an active shooter on site, to the previous example: identifying someone who may be carrying a virus onto the plant floor. This situational awareness can be connected to DEFCON-style modifications in plant operations, orchestrating near-instant changes to policies, systems, and workflows with a single button click.

All of these developments are shifting the capabilities of businesses as they enter a new age of the real-time enterprise. The inputs can come from current existing enterprise business systems, mobile devices, web browsers or other inputs. These myriad pieces of sensory data reveal a lot about the work environment. It might be about a particular machine's status or conditions related to the broader business environment. The information gets contextualized, combined and correlated so that the organization can apply best practices and truly operationalize its data.

What's more, these new applications don't require a database and so, don't suffer performance hits that might arise if they were required to store data for subsequent analysis. And since they are built to leverage IoT, AI and edge technologies, they can literally sense and react to events as they take place.

PAPER IS DEAD — OR IT SHOULD BE

Digital is still a long way from becoming central in life sciences interactions.

Indeed, many pharma manufacturers still rely on paper records for batch processes. However, paper can get lost, and a batch without a record cannot be sold. Currently, a review of paper records requires someone to be present at the facility. That's not a recipe for increased speed and agility.

Moving to real-time technology systems does not require ripping out or completely replacing enterprise systems. But manufacturers need to be able to cross-pollinate and better orchestrate their current systems to foster smarter

coordination and accelerate average response times. As we reimagine work processes in a post-COVID world, anything that can reduce unnecessary physical contact is worthwhile. Ideally, companies should be able to build an alert that notifies a reviewer when a completed batch record's exceptions are ready to be reviewed digitally. However, as the future takes shape, it will feature increasing reliance upon digital tools that provide greater situational awareness.

DOING MORE WITH LESS

Another lesson learned from COVID-19 is technology's ability to do more with less. That must continue, even as staff come back on site. Nowhere is this need more pronounced than when it comes to maintenance teams. While pharma manufacturers have traditionally counted on their maintenance teams being able to travel to multiple facilities, the quarantines, lockdowns and limitations on travel has hampered flexibility.

Here's where technology compensates for the loss of physical manpower. Solutions that allow remote monitoring of assets and bring together data associated with those assets will transform how maintenance teams do their jobs. They'll now have clear insight into how the machines on the plant floor are functioning. What's more, operators on plant floors will be able to use mobile forms built into the platform to augment the total picture — including descriptions of what they're hearing, seeing, and even smelling from their equipment. All of that feedback would get routed to the appropriate maintenance team.

Pharma learned hard lessons in the past several months. But while this pandemic may be unique, the experience vividly underscores the need for comprehensive solutions that combine automation and human interaction.

There's been much conversation about what adapting to the new normal will require as manufacturers shift to recovery mode. Pharma companies that are equipped to respond quickly and take the proper steps are going to be the winners —and smarter, situational technology solutions will be key.

REFERENCES

1. McKinsey & Company. "COVID-19 implications for life sciences R&D: Recovery and the next normal." May 13, 2020.

Steering through turbulence with IoT

How pharma can navigate disruptions by applying Internet of Things technology to supply chains

By Jay Welsh, Principal, Consulting; Srihari Rangarajan, Senior Manager, Consulting; Nicholas Zarling, Senior, Consulting, EY Supply Chain & Operations, Ernst & Young LLP

Uncertainty and changes to industry trends have created a difficult environment for the current pharmaceutical supply chain. But with challenge comes opportunity.

Pharmaceutical companies are facing challenges that stem from a rise in mergers and acquisitions, a shift to outsourcing of business functions, changes in patient trends and complications with operations.

The surge of mergers and acquisitions and increase in business function outsourcing has forced many underlying business functions to rely on incompatible, legacy data systems. This has led to fragmentation of data across manufacturers, distributors, pharmacies, hospitals/health systems and third-party logistics suppliers.

Additionally, the rise of personalized therapies has been a common trend within the industry. Therapies, such as individualized cell and gene therapies, increase supply chain complexity as future manufacturing is customized and made to order. This shift to customized treatments requires precise product temperature and location tracking to be viable. Within operations, a lack of visibility into manufacturing, aging assets and an underutilized workforce are impacting organizations' ability to produce and transport drugs efficiently. In fact, product losses due to issues such as temperature variations during transit are costing pharmaceutical companies over $15 billion a year.[1]

The current challenges within the supply chain have been further magnified through

The shift to a more intelligent, well-networked supply chain will help organizations cope with disruptions like COVID-19.

the disruptive force of the COVID-19 pandemic. The outbreak has directly impacted the logistics of supplying drugs to patients, disrupted the ability to plan and schedule production, and further complicated forecasting of demand and capacity.

Organizations can navigate industry disruptions by applying Internet of Things (IoT) technology to improve how drugs are produced and supplied to patients. The adoption of IoT will enable a more nimble supply chain that allows for rapid response during industry turbulence.

EMBRACING THE DISRUPTION

We are entering an era where emerging technologies are reaching maturity. IoT has become far more than a futurist prediction — it's now the backbone of the connected world and a fundamental component of smart manufacturing and the modern supply chain.

IoT will allow data to flow seamlessly from operations and equipment into the hands of workers, management and executive leadership, providing end-to-end visibility and enabling real-time, evidence-based decision-making. The ability to connect, track and analyze processes from sourcing to storage and administration will provide an audit trail of compliance while improving control over inventory and delivery. Analytics will further advance the insights available from IoT data to promote drug product quality, reduce lead times, predict equipment failures, estimate downstream product needs and optimize capacity utilization.

Further, IoT will aid in the integration of supply chain data with other functions of the pharmaceutical value chain, including marketing, sales, finance and R&D. Capturing and analyzing supply chain data on shipments, usage, returns, claims and clinical outcomes will provide real-world evidence on drug efficacy. These insights can help pharma deliver the right product to the right patient at the right time.

In this pharma supply chain, changing stakeholder needs and industry trends are met effectively in real time. Leveraging IoT technology improves visibility across the supply chain and enables a more nimble approach to serving patients. The shift to

a more intelligent, well-networked supply chain will help organizations cope with disruptions like the COVID-19 pandemic.

ADDRESSING PAIN POINTS

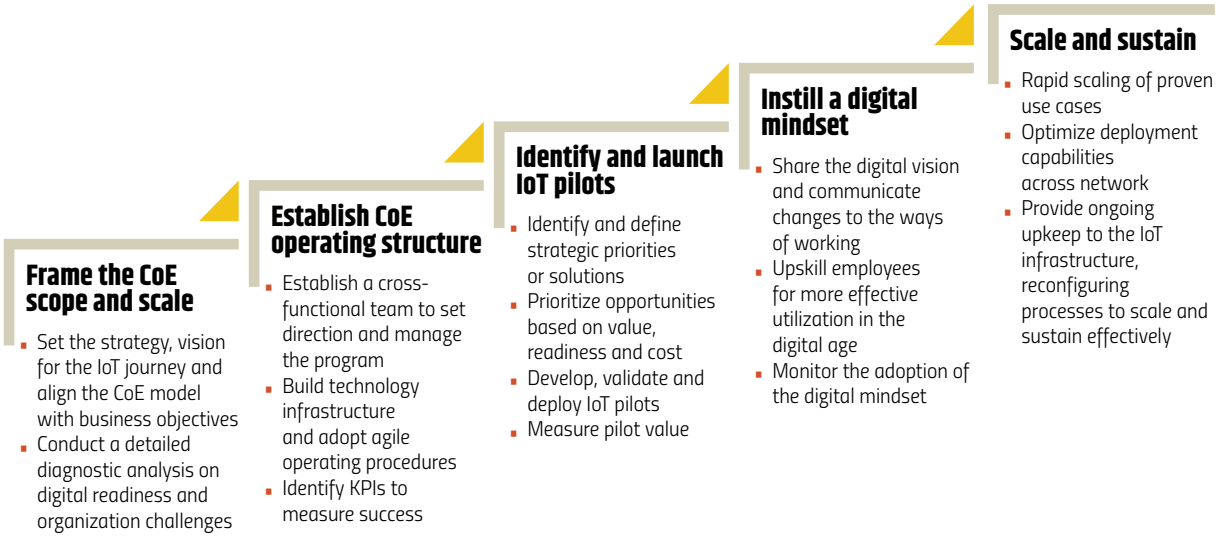
IoT has the potential to improve pharmaceutical supply chain visibility and productivity by connecting various data sources, enabling insights and providing optimization opportunities.

A combination of hard and soft sensors will enable organizations to capture data on often-overlooked variables, such as machine utilization, equipment health, process conditions, energy consumption and interplant logistics. Deploying sensors to the highly utilized equipment on a fill-finish line allows manufacturers to monitor equipment uptime in an area where downtime directly impacts the quantity and timeliness of product reaching the patient. Unlocking new data points also allows for the monitoring of critical assets, such as autoclaves and centrifuges, while providing insight into process conditions, such as moisture content in a lyophilizer.

The improved data availability from IoT enables employees to monitor operations away from the production floor and even remotely. When used for reporting, this available production data enables a smart factory that is capable of monitoring operations in real time to improve the physical process control of drug production and material flow.

Outside of interplant operations, IoT enables organizations to integrate the flow of data from suppliers to customers by using cross-platform open source data

Pharma's IoT journey with a Center of Excellence model



Thirty percent of IoT projects fail in the proof-of-concept stage.

frameworks. This will allow for individualized therapies, such as cancer treatments, to utilize a fully connected data infrastructure to efficiently transfer information between unaffiliated entities such as hospitals, laboratories and logistics centers. The ability to control the flow of data and bring different sources together also creates value within the organization's internal operations. Combining different data types unlocks insights not previously available. This new, connected digital ecosystem will enable delivery of treatments to patients in a faster and more secure way.

The use of analytics can further magnify the value unlocked by applying IoT to the pharma supply chain. Analytics, such as machine learning and artificial intelligence (AI), can predict equipment failures, forecast batch yields, sequence equipment efficiently and estimate downstream product needs. In fact, it is estimated that more than 50 percent of pharmaceutical and biotech manufacturers will employ prescriptive analytics and AI by 2021.[2] The availability of this forward-focused information enables smart manufacturing practices that improve overall equipment effectiveness (OEE), increase revenue and boost workforce productivity.

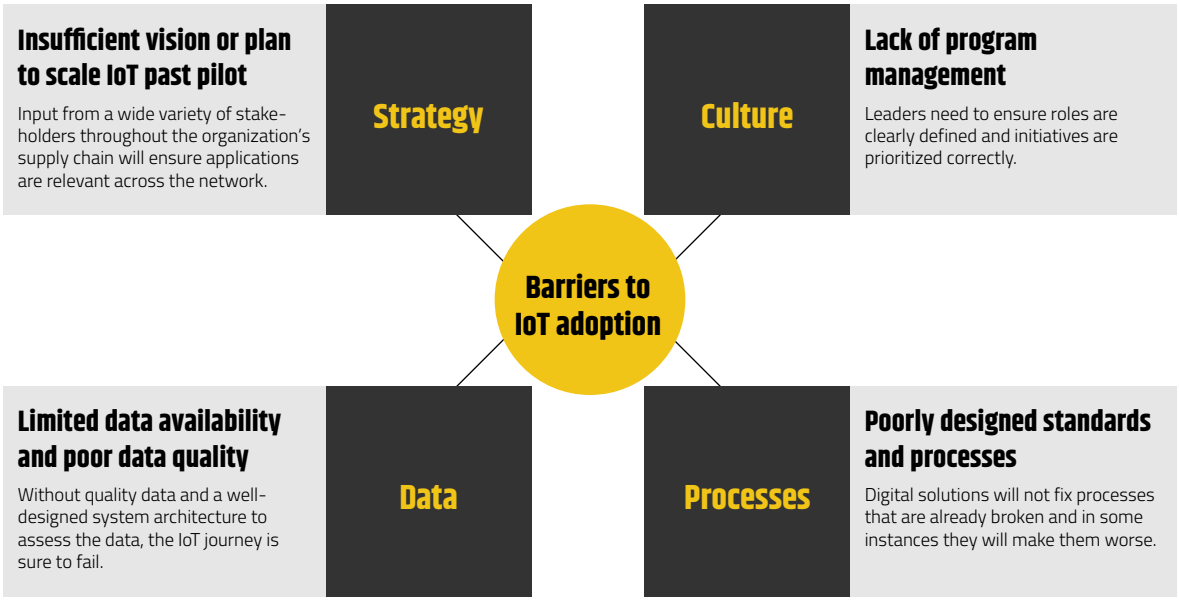
Augmented reality/virtual reality (AR/VR) further increase the value a supply chain will see from a digital IoT transformation. These technologies allow for improved data visibility in a hands-free environment, more effective trainings for operation employees and the ability to support and problem-solve operation critical employees remotely.

Embarking on the IoT journey will act as a supply chain accelerator by bringing the plan, source, make and deliver functions in closer alignment with the strategic imperatives of the organization as it becomes nimbler and more responsive.

THERE ARE NO SHORTCUTS

Thirty percent of IoT projects fail in the proof-of-concept stage. This isn't a reflection of the technology; there are many successful deployments. However, too many businesses try to begin the journey despite badly implemented processes, unclear roles and responsibilities, poorly designed organizational setup and other

Barriers to adoption



issues. These problems need to be resolved before the push to digital can begin.

Embarking on an IoT journey is a significant, company-wide responsibility demanding the dedication of substantial resources and investment across multiple departments. Because the groups of stakeholders come from fundamentally different worlds, it is critical to establish a common ground from the beginning. Creating an IoT Center of Excellence (CoE) will align strategy with execution by ensuring shop floor stakeholders are able to provide thought leadership and direction to the team executing on the IoT journey. Enabling team members to work in parallel with end users fosters an environment of continuous learning and communication.

Adoption is equally as important as execution. The organization is only able to extract the full value from IoT technology if it is effectively used throughout the supply chain. To adopt the technology in the most impactful way it is important to consider necessary changes to SOPs and ways of working. This concentration on adoption ensures the program maintains a forward focus on scalability and the realization of value.

THE IOT JOURNEY

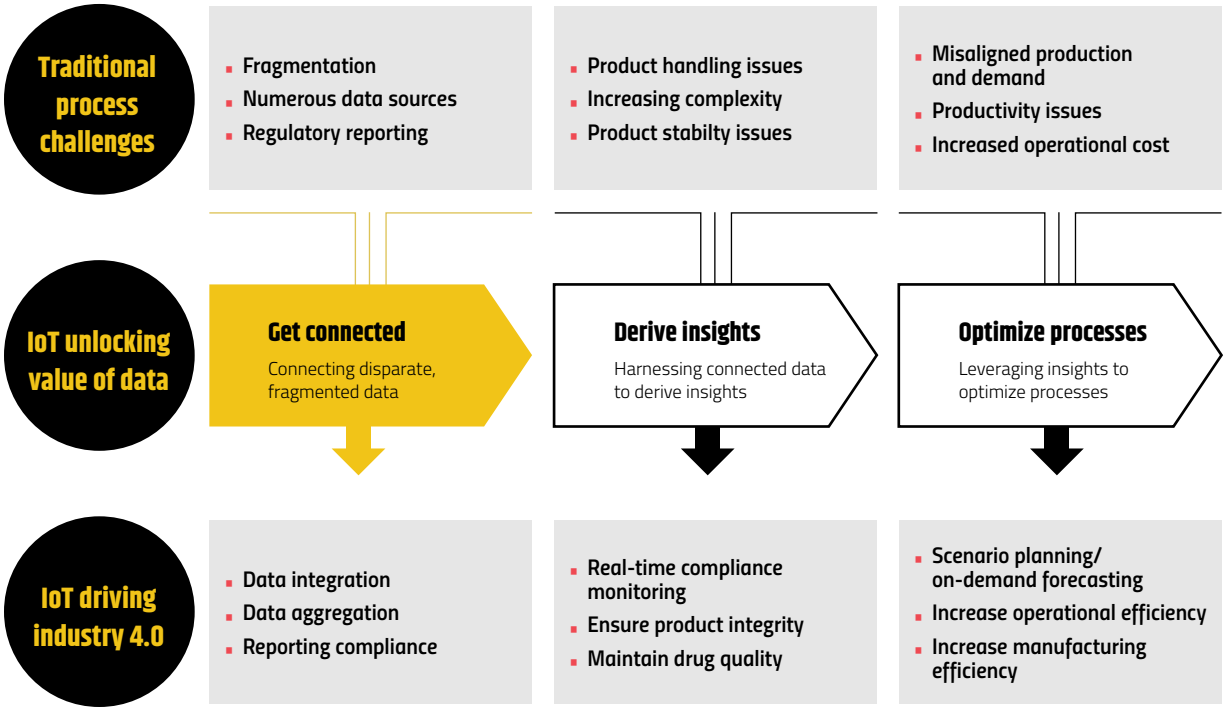
Frame the CoE scope and scale: Pharma organizations should first build a foundation by understanding the current context and future direction of the supply chain in which the CoE will operate. A detailed diagnostic analysis is conducted to understand

digital readiness and identify where digital capabilities align with challenges facing the organization. This first step on the digital journey sets the expectation within the organization on what level of investment and type of infrastructure improvements will be required.

Establish the CoE operating structure: Now that expectations and direction have been set, the organization needs to design its operations to be able to execute. Within the CoE, reporting lines and team structures should be redrawn with digital in mind to create cross-functional teams that eliminate siloed work. Agile training will enable these cross-functional teams to efficiently deliver capabilities that empower employees throughout the supply chain. To enable CoE members, agile SOPs that align with the digital mindset and ensure transparency should be implemented. Measuring the success of the CoE is also important. Leadership needs to define and monitor key performance indicators (KPIs) to understand the team's achievements and identify improvement areas.

With the agile ways of working established, pharma organizations must prepare technological infrastructure by identifying a development platform, defining system architecture standards and building analytics capabilities. Cross-platform data

IoT addressing critical pain points



The time is now for companies to make a move or risk spending years struggling to catch up later.

frameworks should be implemented to enable the flow of data between different source systems and entities. To ensure the right decisions are made it is important to align the direction of the organization with its current digital maturity and technology needs. An assessment can help steer decisions that directly impact the development feasibility of IoT applications.

Identify and launch IoT pilots: With a solid operating structure established, the next step is to define strategic priorities for IoT initiatives. A top-down/bottom-up approach allows the steering committee and shop floor end users to set the direction, reducing the likelihood that a one-off solution is developed. Many organizations that are working to improve smart manufacturing capabilities will conduct an assessment of current operations and prioritize quality control, energy monitoring, predictive maintenance and materials management for IoT application development. When deciding on pilots it is important to consider criteria like ease of delivery, network applicability and business value.

After opportunities are identified and agreed upon, it is time to execute on developing the IoT applications as pilots or proofs-of-concept. The pilots are important for gathering stakeholder feedback and should be measured to demonstrate business value before the solution is scaled throughout the organization.

Instill a digital mindset and conduct change management: Running a successful IoT transformation program is not just about tools and technology; it's also about the people. A digital mindset is crucial for building a performance culture that delivers and adopts digital solutions effectively. This digital mindset needs to be adopted at all layers of the organization to create ownership and ensure effective communication. For shop floor employees, digital working methods need to be implemented that maximize the effectiveness of IoT technologies while enabling workers to focus on higher value add activities. Conducting a current-state shop floor team capability assessment will allow the organization to understand where training is required. A training road map or plan should be devised

that includes interactive exercises on how to use the new technology. Outside of IoT adoption, it is important to upskill employees to perform tasks outside of their current skill sets.

Scale and sustain: Without upkeep, a digital transformation is sure to fail. Deploying IoT solutions on a large scale will impact all functions, including finance, human resources, sales and R&D. It is important to work with these areas of the business to ensure all functions are pursuing the digital journey with a similar mindset and integration points are considered.

Scaling best practices and sustaining a digital transformation requires resources to maintain system architecture, monitor application usability, document business impact and follow application life cycle management processes. Scaling and rapidly deploying IoT capabilities across manufacturing and supply chain operations will directly impact the return on investment (ROI) for the CoE and IoT program.

TAKING THE FIRST STEP TOWARD THE GIANT LEAP

The time is now for companies to make a move or risk spending years struggling to catch up later. To best understand the opportunities inherent in IoT adoption, companies should begin to assess which areas of their supply chain are best suited for the technology. A clear plan that ties into the company's overall strategy and creates buy-in from stakeholders can provide that first step.

Success will require a lot of experimentation. Setting reasonable expectations at the start, promoting frequent conversations between developers and users and providing competent training will facilitate the trust needed to achieve the vision of an intelligent, networked future supply chain. If all done correctly, IoT can help the supply chain adjust to shifts in industry trends and navigate unforeseen disruptive forces like COVID-19.

REFERENCES

1. FedEx, "Harnessing Big Data to Transform Pharmaceutical Logistics." Dec 2018.
2. IDC FutureScape: Worldwide Health Industry 2020 Prediction. 2019.

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