IIoT in the pharmaceutical industry

Bringing products to market faster in a highly regulated industry using Microsoft IIoT technologies

White Paper
IIoT in pharmaceutical manufacturing enables improved efficiency, cost, and business models.

Industrial companies that use the power of connected technology not only provide better service at a lower cost but deploy entirely new business models. In comparison to other industries, the pharmaceutical industry has been conservative in adopting industrial IoT (IIoT) technology.

Errors, unstable environments, and failure to meet stringent regulations can incur serious liability and be detrimental for patients and manufacturers alike. For those reasons, the solutions that recent technological advancements have enabled haven’t been as strongly realized within the pharmaceutical industry, especially at the manufacturing level.

But for pharmaceutical companies to remain competitive, they should embrace IIoT; process manufacturers across every industry recognize the need for better data and data management as it directly translates into more informed, strategic decision-making. Within the pharmaceutical industry, IIoT offers the potential to mitigate risks with data provenance, modernize medication delivery with improved chain of custody, and lower costs with predictive and prescriptive maintenance of machines and equipment.

One example of why IIoT is pertinent in pharma came to light in the early stages of the COVID-19 vaccine distribution when insufficient planning and inadequate temperature control in the cold chain resulted in millions of spoiled vaccine doses. While the particulars of the COVID-19 response encouraged haste, these difficulties are neither new nor rare and reinforce the value of stringent regulations in this industry to ensure positive patient outcomes.

Given the pharmaceutical industry’s highly regulated nature, the data management, analysis, and predictive solutions that IIoT offers is exactly what pharma companies should rely on to streamline their data and processes to minimize margin of error. Any technology that will ensure improved quality control, report patient data, minimize workplace hazards and risk, and help companies meet stringent regulations, is one worth embracing.

### Key benefits of IIoT in the pharma industry

**Azure’s pre-qualified platform:**

- **Expedites the certification process**
- **Brings products faster to market**
- **Scale out more efficiently**

IIoT in the pharmaceutical sector brings products to market faster in a highly regulated industry.
In addition, the solutions IIoT bring are particularly well-suited for the industry since they present resolutions for commonplace stalemates: guaranteeing chain of custody, ensuring consistent production on the shop floor, etc. Examples of successful IIoT deployments may include connected equipment, smart packaging, cold-chain monitoring, and/or sample lifecycle management—all of which increase accuracy, expedite processes, and ultimately save pharmaceutical companies money by mitigating costly mishaps and downtimes.

Another key change within the industry that makes it conducive to realizing accuracy and success through IIoT is the departure from the patent cliff. Traditional companies’ patents lasted 20 to 25 years, leaving only, on average, five to seven years for companies to earn a profit. With the removal of the patent cliff, pharma companies have an opportunity to bring products to market faster, minimize lost revenues, and save lives.

Lastly, the onset of the COVID-19 pandemic and its subsequent, unprecedented vaccine development poignantly accelerated urgency for modernization of manufacturing infrastructure and digitalization of operations. Things are moving fast and becoming increasingly sophisticated, so companies that do not get on board will have difficulty keeping up.

Such insights and discussions have led pharma companies to wonder how they can capitalize on a market that’s rapidly changing by leveraging IIoT. To answer this question, it’s important to explore the challenges that the pharmaceutical industry currently faces.
Life-critical quality demands and auditing requirements pose challenges for pharma

Between rigid regulations, collaboration with a myriad of businesses to ensure chain of custody, and responsibility to ensure quality control from the time drugs are made to the time they’re administered to patients, pharmaceutical companies grapple with a plethora of challenges.

Furthermore, pharma uniquely deals with products with life-critical quality demands and attendant auditing requirements with massive consequences in fines—and human lives—should failures arise. Digitalization and adoption of IoT helps pharmaceutical manufacturers to not only streamline certification, but also mitigate associated chain of custody and quality risks. In turn, companies can avoid adverse outcomes such as damaged reputation, drop off in revenue, or legal action.

IIoT adoption offers a more reliable, sophisticated approach to manufacturing by offering a way to document and oversee production by cloudifying the qualification process and overall operations.

Additionally, the byproduct accounting and waste stream consequences of the manufacturing processes are considerations less common in other industries. Nearly every material and process within pharma is biologically active, which is unusual for other manufacturers and presents added risk.

To start, volatile chemicals and challenging manufacturing processes make manufacturing extremely expensive and risky to handle materials and equipment. Equipment failures that cause production to go offline can result in costly losses and cleanup efforts, like factory leakage of hazardous materials, mechanical damage, chemical deterioration, excessive voltage, and unstable environments that create safety risks for workers. Furthermore, any of these scenarios can potentially result in audits.

Add to that, improperly produced medication can prove to be toxic and lethal, and insufficient environmental conditions can be dangerous for both drug manufacturers and patients. Counterfeit medicines, drug theft, and ingredient substitutions can cause a cascading effect of devastating consequences, and adverse outcomes undermine trust in medicine and damage a company or manufacturer’s reputation when it comes to trust and reliability. Furthermore, equipment failures and contamination create serious conundrums for pharma companies from both a financial and a safety standpoint.

Moreover, pharma companies struggle to achieve ultimate control over operations outside facility walls—especially when it comes to optimizing time to market, reducing waste, and managing shipment delays. Transportation of drugs to pharmacies, hospitals, and patients’ doorsteps may require precise temperatures and other ultra-specific environmental conditions. As such, temperature fluctuations, issues within chain of custody, and conveyance loss can not only cause
a batch of drugs to expire, but become hazardous, too.

Additionally, the modern patient is more proactive about requesting medicine, therapies, and participation in clinical trials that they’ve researched themselves—and they demand transparency into drugs and manufacturing processes. This has forced pharma companies to rethink their sales approach and more heavily invest in digital marketing practices to target patients directly and appease their concerns.

Marketing efforts aside, research and development (R&D) is more expensive than ever before, making it a complicated feat.

Asset Administration Shell (AAS), a key concept of industry 4.0, plays a vital role for big pharma as it’s the conduit for shared data and information within the industry in a standardized, electronic manner. The exchange of data between production, engineering tools, assets, and process systems ensures chain of custody, provides context and description of medicines via electronic labels, and supplies documentation of pharmaceuticals.

Many times, pharmaceutical firms that look to R&D while supporting production are forced to overextend their finances due to investments made ahead of demand that never come to fruition. For example, a mild influenza season may mean wasted flu shots or mass production of a flu shot for the wrong variant.

Another example is the case of the millions of doses of Johnson & Johnson COVID-19 vaccines that were destroyed as a result of human error at the Emergent BioSolutions facility in Baltimore, Maryland. Workers at the Baltimore plant, which manufactured two different COVID-19 vaccines, mistakenly mixed vaccine ingredients, resulting in an immediate halt in production and investigation.

With the intelligence of IIoT, the conflation of the two vaccine ingredients could have been avoided. IIoT is capable of alerting workers when incorrect ingredients are mixed, sounding alarms when specific vials aren’t meant to be filled by bioreactors, and more. Although IIoT requires upfront investment, had the facility previously embraced IIoT in lieu of relying on outdated quality control, they could have mitigated such disaster.

But, in circling back to the industry’s hesitancy towards embracing IIoT, stringent regulatory challenges make the act of deploying certain IIoT technologies feel like uncharted territory with respect to compliance standards in cloud-based environments. To date, there are few examples of successes within this space and even fewer successful figureheads willing to speak openly about their transition.
Why should pharma companies adopt IIoT?

The technological alternatives that IIoT provides offer potential to modernize manufacturing monitoring, drug discovery, and drug transportation. Smart devices and machine-to-machine communication technologies reimagine conventional production practices and the disruption of drug manufacturing.

Pharma companies that deploy IIoT into pharmaceutical manufacturing can bring solutions to the following value streams:

- Patent engagements
- Clinical trials
- Supply chain maintenance
- Supply chain optimizations via Analytics and dashboards

Such solutions can accelerate the time it takes their products to hit the market, detect errors across the value chain sooner, and allow companies to hasten their production timelines and go-to-market activities.

IIoT technologies allow pharmaceutical manufacturers real-time visibility on data within operations. Although the industry has benefited previously from industrial monitoring devices, real-time status was not widespread.

At the crux of the importance of IIoT, though, lies the need for improved safety—both in the manufacturers creating pharmaceuticals and the patients taking them.

Companies that embrace a network of connected devices and monitoring sensors gain faster and more accessible access to precise control over their production environment; they’re able to ensure optimal conditions for biomaterials and chemicals while ensuring safe and smooth production via improved equipment performance and reliability. Digital dashboards work with IoT monitoring sensors to aggregate facility data and alert maintenance crews if abnormalities or issues occur.

The advent of real-time data funnels has improved regulatory compliance and given companies the ability to predict and isolate issues or anomalies before they incur cost and stall operations down the line. In collecting data in real-time, cloud capabilities also enable companies to sample, reproduce, test, and alter tests in other environments as needed. Without the process optimization capabilities that Azure cloud offers, pharma companies wouldn’t be able to conduct automated and structured experiments in a running production.

The advent of real-time data funnels has improved regulatory compliance and given companies the ability to predict and isolate issues or anomalies before they incur cost and stall operations down the line. In collecting data in real-time, cloud capabilities also enable companies to sample, reproduce, test, and alter tests in other environments as needed. Without the process optimization capabilities Azure cloud boasts, pharma companies wouldn’t be able to conduct automated and structured experiments in a running production.
IIoT also supplies solutions for unplanned equipment shutdowns. Preventative maintenance of equipment gives pharma manufacturers greater control over production operations and helps companies manage their supply chains and product delivery logistics.

Although many pharmaceutical manufacturers aren’t ready to revalidate production facilities, many are interested in implementing functionality components to optimize and smooth the transition that inherently comes with IIoT integration.

With Azure Edge services, such as Azure Stack, IoT Edge, and RTOS; manufacturers won’t need to rely on sensor networks alone and can build a connected agile factories. Such services allow manufacturers at the shop floor level to customize their infrastructures to support IIoT through the cloud in a more agile way.

These services also allow manufacturers to deploy their cloud workloads to run on IoT edge devices which results in quicker reaction time to local changes and, in turn, increased operational reliability. Additionally, Azure cloud technology allows manufacturers to control which data aggregates into the cloud and which data remains on-premise. In doing so, manufacturers can still operate within their respective cloud ecosystem and simultaneously benefit from incremental validation.

With Azure services, pharmaceutical manufacturers won’t need to worry about losing connectivity in production lines or having the ability to cache data—a crucial challenge that’s proved to be a stalemate for manufacturers at large.

Cloud technology brings pharmaceutical manufacturers insights consistent with industry 4.0 and industry 5.0, and, in turn, revitalizes their digital infrastructure, operational efficiency, and ROI.

**The benefits of deploying pharma IoT sensors**

IoT sensors, no matter which industry they’re deployed in, boast two advantages: they improve business outcomes, and they’ve been trialed in other industries. For pharma, this means companies can avoid trial-and-error and accelerate to best practices and learnings, which is ultra-important in risk-averse business environments and highly regulated industries such as pharma.
Pharma IoT sensors are critical to helping pharma manufacturers gain a contextual view of their operations. Pharma IoT monitoring sensors loop all facility data into a single dashboard, which allows teams to monitor suboptimal production conditions and adjust maintenance requirements as they see fit.

A single, digital dashboard can supply insights on everything from vacuum pumps, heat exchangers, and air compressors. Pharma IoT sensors can outfit drug packaging, factory walls, or machinery to connect machinery across production lines and offer continual status updates on environmental indicators and equipment.

When connected with a climate control system, IoT sensors trigger automatic shutoffs in case of hazards such as a toxic substance leakage, and the system will alert staff so they can evacuate while remote technologies simultaneously monitor facility conditions. When it comes to transportation and storage, IIoT sensors allow pharma companies visibility on chain of custody, too.

**IIoT solves decades-old issues of ensuring chain of custody while in transit**

Ensuring chain of custody within drug transportation is an extremely sensitive endeavor that’s prone to human error due to repetition and frequency of data input requirements. Tackling this challenge is necessary for several reasons: drugs that require a controlled environment with a specific temperature range can expire, be stolen or replaced with facsimiles, or damaged while in transit. Furthermore, inaccurate drug storage can destroy sensitive molecules that they contain and potentially lead to adverse effects in patients.

To solve this, pharma companies have begun tagging shipments of drugs with pharma IoT connected sensors to track batches while they’re in transit. Smart labels and radio-frequency identification (RFID) track each batch, meanwhile GPS-enabled vehicles supply twenty-four-seven updates on location, offering more visibility on shipment.

Increased visibility on shipments via connected devices facilitates inventory control, quality assurance, and assurance of production speed, all of which help pharma companies track their costs and meet stringent quality expectations; tracing the source of supplies has become critical to supporting the speed of production and ensuring quality.

IIoT helps keep pharma companies organized, too. Even everyday IoT sensors can signal when customer’s stocks are at low levels and alert companies to prepare for restocking. In turn, companies mitigate the need to stock extra supplies to prevent a shortage. In this way, data informs decision-making on how much product to keep in stock by identifying when batches have passed expiration dates.
When batches are recalled, IoT location devices identify where containers are within a supply chain so that pharma companies can swiftly and completely remove that batch from circulation.

Beyond that, data analytics allow pharmaceutical companies to pursue traditional operational efficiencies and productivity by gleaning data from IoT-connected devices to determine potential cost overruns, as well as which components of their operations yield the most inefficiencies.

IoT and IIoT’s ability to meet quality standards, document processes digitally, and reduce the overall margin of error is critical to pharma companies’ ability to maintain consistent regulatory compliance while transporting drugs and other medical devices.

**Microsoft’s pre-qualified cloud expedites GxP validation**

There are several moving parts to meeting regulations within the pharmaceutical industry. Ensuring that a company meets existing standards can be a massive undertaking and includes areas such as documentation for clinical protocols, facilities, trainings, computers, software, and general record logging. Quality Management Systems (QMS) and Quality Assurance (QA) set up clear guidelines on the release of drugs, as well as storage and procedural protocols.

Within every industry, there are regulations and standards for best practices that are otherwise referred to as Good “something” Practices (GxP). GxP standards regulate the traceability and accountability of products through detailed documentation and logging around manufacturing processes and development.

Such guidelines are clear when it comes to recalls, audits, and inspection of abilities. For instance, a change control is a written procedure that mandates that pharma companies describe the effects of a changed step or ingredient that could alter the drug or affect product quality. Regulatory bodies such as the Food and Drug Administration (FDA) and European Medicines Agency (EMA) regularly conduct scheduled and random standardized and observational inspections to verify compliance.

Although strict, guidelines within the pharmaceutical industry help companies assess the risk that a specific change in process poses, as well as the risk that deviations or non-conformities present. GxP is federally mandated in the U.S., but meeting industry standard does more than clear the bar for pharmaceutical companies.

Adhering to federal regulations boosts a company’s reputation and brand, helps them maintain operational consistency, and has proven to reduce recalls and rejects. For those reasons, it’s in every company’s best interest to meticulously document company-wide data ahead of compliance checks, but also as general best practice. Electronic records help mitigate fraud, help companies trace operational changes, and ensure that their computerized systems achieve compliance in an effective manner.
IIoT in the pharmaceutical sector brings products to market faster in a highly regulated industry

Azure Services expedite GxP validation

Traditionally, certifying a pharmaceutical manufacturing facility is an extremely tedious and drawn-out process; one that requires copious amounts of paper-driven documentation that needs to be signed off by an auditor.

Microsoft is keenly aware of the cost of re-certification, which is why its cloud solutions embed internal functional boundaries around process and decision-making improvements into the software. To that end, Microsoft’s wide offerings, certification, openness, and documentation efforts significantly accelerate this process and save pharma companies time, resources, and effort—allowing them to focus on what matters most.

Azure service’s information technology better supports pharmaceutical compliance and change management by providing a certified solution, which contains IT implementation details that can be modified without triggering re-certification.

Microsoft Azure Services is the only service that can expedite GxP validation by simplifying certification and guiding manufacturers through the exercise of validating applications required to meet specific standards. For example, infrastructure hosting certifications provide a roadmap that allows companies to expedite the time it takes them to complete their certification.

Alongside Microsoft’s cloud products, Microsoft provides resources for IT and quality assurance professionals to help them understand Microsoft’s compliance features and capabilities. In our Compliance Whitepaper, you’ll learn how Microsoft helps companies manage security, risk, and governance within current standards such as ISO27001, SOC1/SOC2, HIPAA, and more.

Additional resources, such as the GxP Guidelines on Azure help partners navigate compliance standards within the pharmaceutical industry but offer a wide set of frameworks to help companies adopt a foundational, multi-purpose design of their own.
Bayer leverages AI and ML to optimize operations

By sensing and responding in real-time, AI-powered automation boasts the capability to optimize equipment and processes. In comparison to human-operated machinery and production, manufacturers run into a host of problems.

For one, there’s a scarcity of expertise since it takes years—even decades—for operators to develop adequate expertise needed to consistently improve operations. In addition to that, some optimization opportunities for manufacturers are short-lived and are too brief for operators to maximize.

Lastly, ever-evolving and intricate systems make it difficult for operators to ensure stability, which makes optimization extremely difficult. All this to say, the fault lies in traditional control systems, as they’re inflexible, rigid, and unable to consider all observable data.

Microsoft’s Project Bonsai offers a solution for outdated, static control systems. Project Bonsai is a low-code AI development platform that enables engineers to hand-craft automation using their expertise. It doesn’t require any data science expertise, and it allows engineers to leverage graphical tools and digital simulation to train AI and then deploy it.

Bayer, one of the largest multinational pharmaceutical and life sciences companies in the world, deployed Project Bonsai to reduce steam usage in its industrial evaporators. Currently, Bayer operates industrial evaporators for CP Active Ingredient production. Steam, a required resource in the process, is expensive, and its previous classical control method didn’t respond well to external disturbances not yet modeled in the MPC controller, resulting in wasted steam.

Before Project Bonsai, Bayer leveraged Aspen Plus Model, an AI model which the company trained to control an evaporator process simulation. With Bayer’s new trained control system, AI takes Bayer’s operator know-how and conjoins it with data to make high-value decisions based on optimum setpoints.

Bayer utilized ASPEN Simulation Software from AspenTech to expedite, secure, and optimize upstream midstream, and refining processes in the cloud. With the simulator, Bayer was able to deploy design, analytics, and utility tools to better manage cost, energy, operational safety, and operational efficiency within its facilities.

The simulator also yielded more accurate AI-powered models for Bayer by both optimizing complex assets across a myriad of objectives and fostering more secure data sharing between functions and across the value chain.

Lastly, the ASPEN simulator also brought faster updates to planning models for Bayer.

From there, Bayer worked directly with the automation solution company, Emerson, to direct Steam Flow SP and Pressure SP to flow into Emerson’s DeltaV Distributed Control System (DCS). DeltaV rests between two levels: L3 and L4. 52% of implementation contains OSIsoft PIMS underneath, and the ensure system runs on Azure. As a result, DeltaV isn’t on premise or isolated, allowing customers to cloudify and consolidate their systems.

Implementation Platform: A control system that makes ‘smart decisions’

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<th>Decision-making agent for optimum setpoints</th>
<th>Actions: Steam flow SP, Pressure SP</th>
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<th>Distributed Control System (DCS)</th>
<th>Actions: XV, FV, MOTORS</th>
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Data from the DCS funnels into the plant via Motors, XV, and FV. Various measurements, such as FC, TI, and PI, flow from the plant, through DCS, and into Microsoft’s decision-making agent.

As a result, high-pressure steam flowrates are automated adjustments, accomplishing a reduction in process variations. Now, Bayer can maintain EFT liquid levels within an optimal range. Additionally, the system can successfully manipulate parameters to reduce steam usage.

Bayer and Microsoft leveraged machine learning (ML) to filter, monitor, and control observable states and disturbances to remedy this. ML minimizes the number of states needed and discards states if Microsoft cannot attain their corresponding sensors within the plant.

Microsoft and Emerson’s partnership extends beyond Bayer

Pharmaceutical manufacturers at large—including Bayer—have historically faced issues related to equipment failures that don’t surface until they’ve significantly impacted operations, failure to detect when equipment isn’t running to specifications, and difficulty in accurately planning for planned outages. Additionally, the manufacturing industry’s workforce is depleting at an alarming rate, which translates to sudden losses in expertise for manufacturers.

To tackle this, we partnered with Emerson to create One Commercial Partner (OCP) catalog solutions that consist of the following: connected services for values, connected services for steam traps, and connected services for heat exchangers (to name a few).

As part of Microsoft’s alliance with Emerson, Microsoft and Emerson hoped to achieve the following:

- Drive incremental value for customers
- Leverage respective market leadership positions to differentiate from competitors
- Establish a unified posture around digital transformation scenarios
- Increase access to IT and OT organizations

Emerson’s service offerings include health monitoring, performance monitoring, condition monitoring, product as a service, and engineered connected services to help companies like Bayer decide, see, and act on their historical and real-time data.

In turn, Azure services can help manufacturers understand how to best leverage their data in order to yield more secure, connected assets and extract more data-drive solutions from assets.

Offline secure file transfer, cellular networks, collaboration with customer IT and OT, and a traditional Purdue model establish the fundamental technology that manufacturers rely on to securely connect their assets. Critical asset variables, condition monitoring software, WirelessHART networks, and historians support site assets and applications, which steer manufacturers to know which data can be gleaned from each asset.

Emerson’s connected services revolve around the drive to increase ROI by identifying failures and avoiding shutdowns. Additionally, Emerson’s ROI strategy consists of targeting improved worker safety, planning effective security token offerings (STOs), improving the performance of various assets, effectivity utilizing staff, and meeting industry regulations.

Emerson and Microsoft’s partnership reinforces the pro-data ideals of digitalization which promote technology decisions driven by business outcomes, investment in educating the future workforce, and a more open, scalable, transparent approach to managing each company’s digital transformation.
Adamed Group, one of Europe’s largest pharmaceutical manufacturers, boasts operations in more than 65 countries and has more than 500 products on the market. To streamline its data and ground its decision-making on appropriate historical and real-time data, Adamed partnered with Predica, a consulting company and full-stack member of the Microsoft Partner Network. Predica offers specialty expertise across the Microsoft cloud platform, including application development, ML, data analytics, and overall security.

In today’s market, top of mind for any large manufacturer is effective demand forecasting across multiple product lines. However, for pharmaceutical manufacturers, specific forecasting challenges arise related to pharmaceutical demand being impacted by marketing spend, seasonality, competitor actions, and product and brand attributes. Additionally, manufacturers’ business plans need to be flexible enough to account for routine, real-time adjustments.

Adamed Group accounts for a myriad of these inputs when forecasting and adjusting their production plans. Prior to teaming up with Predica, Adamed generated 18-month forecasts via subject matter experts, which scaled poorly for the vast number of unique products that needed to be forecast individually; a time-consuming process heavily dependent on human expertise and not lending itself to transparency around data driven decision-making.

In addition, accurately accounting for all variables becomes more complicated when demand for some medicines, such as allergy medications, increases during specific months of the year. As such, it’s through the combination of precise forecasting and agile, real-time adjustments that manufacturers realize the most success.

To ensure a more organized system of forecasting demand, Adamed embraced predictive analytics and automated services to reduce margin of error, store data internally, and collect insights on every product line.

Using Azure, Predica helped Adamed merge its data sources into one data factory that could supply business insights in Power BI. To create an accurate forecasting model that was successful in consolidating internal and external data from each business area, Predica used Azure Data Factory to unify all of Adamed’s data. Azure SQL Database was used to further securely process and transform data. IoT data can be fed into the same kind of data pipeline, leveraging this pattern for a forecasting ML and reporting system.
We selected the relevant Azure services, which allowed us to address issues such as quick scalability, flexibility in the choice of programming languages for machine learning, and integration with current data sources. Looking back at the finished project, I am convinced that we made the right choice.

– Dawid Detko, Microsoft MVP and Predica Digital Advisor

Included in each forecasting demand for each product line, every model could test logistic regression and display random forest and gradient-boosted decision trees. Additionally, each forecast generated data over an 18-month period, including automatic updates each month. Eventually, Adamed deployed its own forecasting demand system onto Azure online, allowing third-party applications and Power BI to access it as well.

As a result of fully automating and centralizing its forecasting process, Adamed saved company time and resources, gained visibility into insights and data, and mitigated forecasting errors to less than 5% across every Adamed product line.

Additionally, analysts gained access to validation reports. This allowed analysts to compare the models’ output to both actual outputs and the earlier system’s output. The improved performance of the ML model allowed them to track trends and behaviors across every brand and market, and reassured Adamed on adopting IIoT.

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Lonza cut down on data collection and increased solution development time using a data management system

Lonza, a multinational Swiss chemical and biotechnical company, has been an industry leader in the pharmaceutical industry for over 120 years. Lonza Specialty Ingredients (LSI), a key business segment within Lonza, creates everything from vitamins and disinfectants to bioactives and anti-fungal treatment.

Given Lonza’s wide array of products, the manufacturing giant has an extremely complex manufacturing network. To streamline its process and ensure improved production quality, Lonza digitalized its operations using sensors, data analytics, artificial intelligence (AI), and blockchain technologies.

Lonza Specialty Ingredients deploys a process optimization group to optimize processes at Lonza sites around the world. The group comprises of experts in areas from distillation to crystallization, but the group faced several challenges. As part of their optimization process, Lonza optimization group members will travel to sites, collect data manually, speak with site operators, and more—all time-intensive tasks.

Another challenge for the team was proving a hunch they’ve had about problems based on their industry expertise. As a company known for expertise within various processes and with specialized equipment, it needed to leverage its data to articulate the unmet needs it was observing internally and externally and to justify potential opportunities to capitalize on.

Additionally, these team members lacked visibility into processes in each Lonza Specialty Ingredients site, making it difficult to gain insights on day-to-day operations—a difficult situation for any company, but especially a global one.

Lastly, operators at the sites being visited had opinions and ideas of their own because of their
local process knowledge expertise but were unable to enable themselves or empower their company with the tools to know how to analyze their operations.

To solve these challenges, Lonza Specialty Ingredients came up with an initiative named PIVOT: Productivity Improvements via Operational Technology.

The primary goal of PIVOT was to introduce operations technology to reduce the amount of time process experts had to spend perfecting each site (e.g., travel time, analysis time, raw data collection, etc.), so they could distribute more of their energy and effort into producing ideas for optimization and deliver value to each site.

The idea behind PIVOT was to provide process experts with a global data infrastructure comprised of the data from across their different production sites: everything from historical data and real-time data to data dashboards and data sets. In deploying PIVOT, Lonza was successful in creating a Global PI (product increment) infrastructure using tools such as Power BI, PI Vision, Seeq technologies, and a multi-data analysis tool titled Unscrambler.

The success of PIVOT helped the company find gaps and distribute proper resources such as people and technology. In addition, PIVOT successfully addressed each challenge: optimization programs were accelerated twofold, new opportunities were identified and evaluated, visibility was increased across every site, and local sites were empowered with tools to use their own expertise in multiple solutions.

Thinking ahead, PIVOT spurred Lonza’s engineering and operations technology team to partner with OSIsoft, Microsoft, Seeq, and Hans-Meyer-Engineering to create Productivity Improvement, which removes analysis and data collection bottlenecks for optimization projects by replacing individual local managements with a single data management system. Within a matter of months, Lonza successfully piloted the solution and migrated its entire business operations into the cloud.

As a result of migrating to the cloud, Lonza changed the way it operates and reduced costs as a result. Lonza’s employees now benefit from improved visibility on day-to-day tasks. Plus, operational pain points that once took days to solve could now be easily resolved thanks to better decision-making informed by data.

Migrating to the cloud also helped Lonza become more scalable; once a single Lonza site migrates, the company at large will know how to migrate every other site, too. As Lonza expands and its production process changes and diversifies, Lonza’s cloud infrastructure will easily scale to meet Lonza’s future business management needs, too.
Adaptive Biotechnologies teams up with Microsoft to launch next-gen ImmuneCODE database to track population wide COVID-19 immunity

Adaptive Biotechnologies Corporation, the family-led biotechnology company that pioneered life-changing immunosequencing technology, collaborated with Microsoft on a release of a detailed view of human immune response to COVID-19. The two first partnered in 2018 to spearhead the analysis of genetics within humans’ adaptive immune system, otherwise known as the T-cell receptor (TCR)-Antigen map.

ImmuneCODE, as it’s named, fosters the goal to accelerate efforts to develop vaccines, therapies, and treatments more accurately and consistently by learning more about innate human immune responses.

Adaptive Biotechnologies wrote the book on using immunosequencing and machine learning (ML) to connect the dots between map T-cell receptor sequences and diseases, useful for developing a blood test for early detection of diseases. Analysis of T-cells is made possible by complex ML algorithms running in Azure, which allow researchers to catalog and adapt learning to new virus responses.

Adaptive Biotechnologies’ testing reveals an innovative approach to combating SARS-CoV-2. Instead of focusing on the B-cell or the virus itself, as most research efforts detail, the biotechnology pioneer is focusing on where the body detects and responds to the virus most: the immune system.

Using blood samples from thousands of COVID-19 positive patients around the world, Adaptive Biotechnologies uncovered real-time imaging of the immune response based on de-identified data.

The analysis revealed diverse sets of T-cells that recognize components of the COVID-19 virus at extraordinary scale and speed. Through T-cells and their insights into trackable measures of the human response, Adaptive Biotechnologies is seeking to use such insights to treat COVID-19 and assess humans’ immunity to the virus more accurately.

Understanding the T-cell’s response to the COVID-19 virus offers an array of opportunities and insights: improved understanding leads to improved testing accuracy and a more accurate understanding of immunity periods and post-infection immunity. It also provides researchers with indications on the likelihood of a patient to react severely to the illness, the length of time in which a patient will be infected and/or contagious before they’re immune, and the efficacy that potential future vaccines and boosters present.

The ImmuneCODE database allows researchers to supply real-time updates on findings they uncover, including tracking of immune responses and promising treatments, and the machine learning IIoT solutions that Microsoft supplies made the tremendous speed of delivering this research and innovation possible.

In just a few months, Adaptive and Microsoft intend to generate data for ImmuneCODE sufficient to accurately map how the adaptive immune system responds to SARS-CoV-2 from initial exposure through clearance by using our combined immune medicine platform and machine learning, potentially providing an accurate assessment of immunity. The scale and precision with which we are now able to decode the T-cell response to the virus may fundamentally change our ability to recover from this pandemic and the way in which all viruses are studied in the future.

– Harlan Robins, Chief Scientific Officer and Co-Founder of Adaptive Biotechnologies
AI technology has proven useful in tracking COVID-19 cases and correlating with other age, gender, ethnicity, and demographic trends that may potentially affect the vaccine's efficacy. Beyond that, AI can be useful in tracking the COVID-19 vaccine while in transport—which is exactly what it accomplished for Pfizer.

Pfizer, the American pharmaceutical company, in partnership with BioNTech, developed one of the first COVID-19 vaccines approved for emergency use by the CDC. Prior to mixing, the vaccine must be stored in temperatures between two degrees Celsius and eight degrees Celsius with a shelf life up to five days, making it temperamental to handle in transport.

Given the vaccine’s requirements, safe transport that ensures chain of custody poses four major hurdles: demand forecasting to know how many to ship where and when, supply chain management to avoid bottlenecks, quality assurance along the supply chain, and adverse event surveillance for patients who receive the vaccine.

Because of the Pfizer COVID-19 vaccine’s shelf life of five days, it is imperative that every vaccine shipped to each state and other countries is used promptly. Accurate demand forecasting is useful in ensuring that a surplus of vaccines is not sent to a state where it will waste or expire. Supply chain management is crucial to avoid distribution bottlenecks, especially when working on such a sensitive timeline.

Assurance and compliance standards need to be guaranteed between pharmaceutical companies creating the vaccine and the health care administrators administering the vaccine to make sure each batch is legitimate and that each dose is administered correctly. As with any drug, surveillance of symptoms is necessary to ensure and solve unexpected side effects.

Luckily, IIoT offers solutions for each scenario. When it comes to distributing vaccines, companies cannot base decisions solely on population, or they will under-allocate in some places and over-allocate in others. To assess the number of vaccines needed within each area, Pfizer tackles it several ways.

One such way is through surveys. Additionally, Pfizer uses mobile phone user data, satellite imagery, social media posts, and government data to forecast the number of people in a location. To guarantee that each Pfizer vaccine is distributed fairly in the United States, for example, Health Analytics software cojoints zip code-level data on health status of populations, demographics, and more with surveys on vaccine acceptance to forecast demand.

Each data set conjoined with other data sets allows for more precise, data-driven predictions. From some areas in the developing world, where there may be a lack of data—such as mobile phone usage data—it makes it more difficult to make these predictions.

Forecast demand and efficiency assurance are critical for the COVID-19 vaccine since demand exceeds supply and since every batch is extremely expensive to produce and transport. Meanwhile, AI
supplies real-time tracking on each batch as they move through supply chains.

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As effective as these IIoT technologies are, they do not prevent the issue of interoperability when multiple software packages are being used among a myriad of companies. To track COVID-19 vaccines, drug manufacturers, couriers, hospitals, pharmacies, and governments must work together and share data. The problem? Most of the time, each entity or organization uses a different software solution storing the same or complementary data in incompatible ways.

Beyond that, some participants in any given logistical chain may be in direct competition with one another, which makes each group hesitant to share data. Even for companies or government groups that are more willing to share data along the value chain, the compliance, security, and regulatory mandates may prevent them from doing so. Additionally, as COVID-19 vaccines are in transport and as they are administered to each patient, doctors and pharmaceutical companies must document unusual side effects.

As helpful as these reports are in flagging critical safety issues that were missed in the trial stage, there are too many reports for humans to manually review ahead of preventing a crisis. Instead, IoT technologies can flag “yellow card” reports that document uncommon side effects and automatically search for patterns indicative of developing side effects. From here, regulators can step in and take proper action in place of manually reviewing millions of reports.

AI is useful in housing all patient communication to ensure patients receive their second dose of the vaccine, which is critical in determining the vaccine’s efficacy.

**Imperatives for success within pharma IIoT digitalization**

Complete digitalization within the pharmaceutical industry requires top-down digital support. Shop floor implementation, driven by leaders on the business level, is the key to realizing and embracing the implementation of IIoT technologies.

Fostering a digital culture that starts from the top—in an industry notoriously hesitant to implement such technologies—is the key to hastening your company’s digital transformation and reaping the benefits of tomorrow, today.

**Top three pharmaceuticals using Microsoft solutions are:**

- Monitoring 50,000 OT devices in 65+ sites worldwide
- Diverse OT (Rockwell, Schneider, ...)
- Centrally managed via 3 SOCs (US, Europe, Asia)
- Integrated with Splunk, QRadar, ServiceNow CMDB and ticketing
**Microsoft develops with compliance in mind**

Cloud computing makes it easier, faster, and less error prone to satisfy privacy, regulatory, and security compliance requirements with urgency and confidence. With a partner in Microsoft for addressing the latest standards for data privacy and security, you will be able to bring industry leading technology to bear on meeting compliance standards.

Microsoft’s cloud-first, mobile-centric philosophy supports products and services that provide customers and operators with easily accessible, secure, end-to-end solutions on a flexible platform. Through pharma IIoT, pharma companies can adhere to federally mandated regulations leveraging Microsoft IIoT technologies.

At Microsoft, compliance is at the core of every infrastructure architecture. Beyond general good practice around software development (SDLC), Microsoft offers in-scope cloud services and GxP guidelines for Microsoft Azure, Microsoft 365, and Microsoft Dynamics 365, including Power Platform.

Microsoft boasts a wide array of certifications and audits including SOC 1 Type 1/2, ISO/IEC 27001, ISO/27018, GDPR, CCPA, HIPAA, FFIEC, and 90 plus more.

Through Microsoft’s IIoT technologies, pharmaceutical companies will be able to gain increased insight into customer buying preferences and patterns, and they’ll be able to communicate with customers through multiple channels—solving pharma companies’ need to invest in customer-targeted marketing efforts.

Plus, pharma companies can embrace customer centricity and improve customer-centric productivity across their enterprise. As a result, they’ll be better positioned to create and deliver products and services more tailored to customers’ needs.

Beyond Microsoft Azure Services compliance certifications, we’re committed to helping customers comply with their own strict regulatory requirements within the pharma industry, which is why we’ve built our assets with security and privacy requirements in mind.

How ready is your company to migrate to the cloud and solve the challenges within the pharmaceutical industry using IIoT? To learn how to achieve compliance certifications in a cloud-based environment, visit the following links:

- [Microsoft Compliance Offerings](#)
- [Microsoft Office GxP Guidelines](#)
- [Microsoft Azure GxP Guidelines](#)
People to follow:

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For more in-depth analysis on how IIoT can provide solutions for all process industries and increase their sustainability efforts, read the following Azure white papers:

1 Microsoft Customer Services, “Pharmaceutical manufacturer automates demand forecasting, errors drop below 5 percent.”
2 CDC, “Pfizer-BioNTech COVID-19 Vaccine Storage and Handling Summary.”