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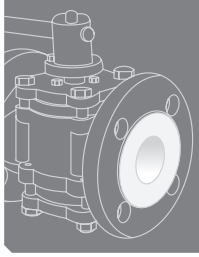

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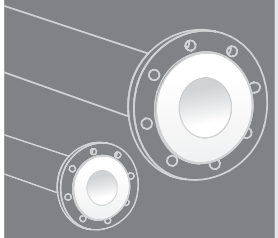

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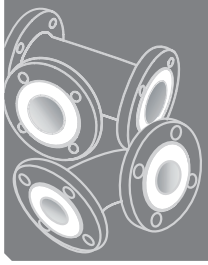

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First Release of Rs.166 Crore incentives under PLI scheme for Pharmaceuticals

Dr Mansukh Mandaviya, Minister of Health and Family Welfare, and Chemicals & Fertilizers
Govt. of India

New Delhi, India: In the bid to reduce import dependency & boost domestic production of high value formulations, critical APIs and high end medical devices, the Department of Pharmaceuticals (DoP) has released the first tranche of incentives under the Product Linked Incentive (PLI) scheme of pharmaceuticals amounting to Rs 166 crore to four selected applicants.

Under the Atmanirbharta (self-dependence) initiative of the Government, Department of Pharmaceuticals launched the PLI scheme for pharmaceuticals in 2021. The financial outlay under this PLI scheme is Rs.15,000 crore over a period of six years. So far, 55 applicants have been selected under the scheme, including 20 Micro, Small & Medium Enterprises (MSMEs). The financial year of 2022-2023 being the first year of production for the PLI Scheme, DoP has ear-marked Rs 690 crore as the budget outlay.

While appreciating the efforts of applicants, Honourable Minister, Dr Mansukh Mandaviya stated, "Working on the vision of reducing import dependency through indigenous production, Government of India is focussing on production of high value pharmaceuticals and high-end medical devices. Manufacturing of components of high-end medical devices in the country will be another big step in moving towards Atmanirbharta."

With an objective to enhance India's manufacturing capabilities and contributing to product diversification towards high value goods in the pharmaceutical sector, 3 different categories of products are being supported under the scheme.

- **Category 1:** Biopharmaceuticals; Complex generic drugs; Patented drugs or drugs nearing patent expiry; Cell based or gene therapy drugs; Orphan drugs; Special empty capsules, Complex excipients
- **Category 2:** Bulk drugs (except those 41 eligible products notified under "PLI Scheme for Bulk drugs)
- **Category 3:** Drugs not covered under Category 1 and Category 2 such as Repurposed drugs; Auto immune drugs, anti-cancer drugs, anti-diabetic drugs, anti-infective drugs, cardiovascular drugs, psychotropic drugs and anti-retroviral drugs, including In vitro diagnostic devices (applicable to 5 applicants out of 55 applicants)

The incentives on incremental sales to selected participants under these categories are at varying rate over the years ranging from

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10% to 3% (tapering at last two years of the scheme). Against the expected investment of Rs. 17,425 crore in the pharmaceutical sector over the scheme period, the scheme has garnered an investment of Rs 16,199 crore by these 55 applicants in the first year of implementation itself. Against the expected employment of 1 lakh over six years scheme period, 23,000 persons have been given employment, so far. Based on the information submitted by the applicants, about Rs.2200 crore incentives (out of total outlay of 15000 crore under the scheme) will be claimed based on the expected sales in FY 2022-23. Out of this, applicants are expected to file an incentive claim of about Rs 850 crore of incentive claims before the end of March 2023. The Department has received an incentive claim of about Rs. 544 crore from 15 applicants. Based on the evaluation, Rs. 221 crore of claims of incentives from four applicants viz. Dr. Reddy's Laboratories Limited, Biocon Limited, Strides Pharma Science Limited, Premier Medical Corporation Private Limited, were found to be eligible and 75% of this amount i.e., Rs. 165.74 crore have been released. Remaining incentives are under examination.

The DoP has also implemented two other PLI schemes for Bulk Drugs and for Medical Devices, which have achieved significant milestones in the first year of implementation.

Piramal Pharma Limited Announces Consolidated Results for Q3 and 9M FY2023

Nandini Piramal, Chairperson, Piramal Pharma Limited

Mumbai, India: Piramal Pharma Limited announced its consolidated results for the third quarter (Q3) and nine month (9M) ended 31st December 2022. For Q3 FY23 and 9M FY23, revenue from operation grew by 11% YoY in Q3 FY23 and 9M FY23, EBITDA margin for Q3 FY23 and 9M FY23 was 10% - impacted by higher operating expenses including raw material cost, energy prices, wage inflation and marketing cost. The company successfully cleared 29 regulatory inspections (including US FDA) and 155 customer audits in 9M FY23. New capabilities / capacity expansion went live at Ahmedabad PDS, peptide facility (Turbhe, India) and Riverview (US).

Nandini Piramal, Chairperson, Piramal Pharma Limited said, "Basis our recent increase in customer engagements and continued

inflows of RFPs (Request for Proposals), we believe that the demand for CDMO services, especially for our differentiated offerings remain strong. We continue to maintain our quality track record with successful US FDA inspection at our Riverview facility. In our Complex Hospital Generic business, the Inhalation Anaesthesia portfolio is seeing a healthy demand. Further, our India Consumer Healthcare business is delivering growth driven by power brands. Investment in e-commerce channel is also yielding good results. We believe in the potential of our business and in-line with our aim to grow, the Board has approved the recommendation to allot equity shares for an amount not exceeding INR 1,050 Cr., subject to receipt of requisite regulatory approvals, market conditions and other considerations."

Gland Pharma to invest Rs 400 crore on capacity expansion

Hyderabad, Telangana: Gland pharma has announced the plans for brownfield capacity expansion and setting up new capacities. The company has planned an outlay of INR 400 crore to produce biologics, biosimilar, antibodies and recombinant insulin at the Genome Valley facility. Gland Pharma invested 300 crore in February last year and will expand the facility in compliance with the national and international regulations and implement GMP guidelines for the respective product lines.Company announced the plans in the presence of K T Rama Rao, Honourable Industries Minister of State of Telangana. The said project will offer employment potential for more than 500 personnel in skilled and semi-skilled category and the requisite workforce will be sourced from nearby places. Gland Pharma's expansion of facility for contract development & manufacturing aligns with the vision of Telangana Government to position emerge as a global hub for pharmaceuticals industry.

Entod Pharmaceuticals inaugurate R&D facility

Navi Mumbai, India: Kishor G Masurkar, Group Chairman, Entod Pharmaceuticals Ltd inaugurated the state of the art advanced R&D facility to enhance the innovation strengths. Dedicating the R&D centre to the founder (Late) G V Masurkar he reminisced his passion for pharmaceutical research, therapeutic innovation & entrepreneurship that the late Founder into a pharmaceutical visionary & pioneer of his times. Nikkhil K Masurkar, CEO, Entod Pharma added, "The R&D expansion broadens our presence in the country while also acknowledging the country's specialized capabilities and potential. India has a very mature pharmaceutical market. If Indian pharmaceutical businesses wish to advance in terms of value, they should concentrate on how to deepen their own R&D and inventions. With the G20 presidency, India has an opportunity to set the global agenda and promote inclusive and sustainable industrialization and foster innovation. In particular, we feel that India's G20 Presidency will encourage innovation and substantially increase the numbers of researchers as well as public and private spending on R&D. In view of India's G20 Presidency, we believe that digital health innovation, achieving universal health coverage, improving healthcare infrastructure and delivery will continue to be

the key driving factors in 2023".

The facility has received approval from the Department of Scientific & Industrial Research (DSIR) and will focus on ophthalmic, ENT & dermatology formulation development. It will allow the corporation to further engage in new product development, formulation and molecular research.

Kotak Special Situations Fund invests Rs 1070 crore in Biocon

Mumbai, India: Kotak Special Situations Fund (KSSF), managed by Kotak Investment Advisors Limited (KIAL) has announced an investment of Rs 1,070 crore in Biocon Limited (BL). Biocon will use the proceeds to finance Biocon Biologics' acquisition of the biosimilars business of its partner Viatris to create a glbal vertically integrated biosimilars player.

Srini Sriniwasan, Managing Director, Kotak Investment Advisors Limited said, "This investment in Biocon comes at a pivotal point when Biocon is forward integrating its biosimilars business. Going forward Biocon will realize full revenues and profits from this business. With this the USD 1 billion Kotak Special Situations Fund is fully committed. India continues to offer unique and attractive risk adjusted opportunities for hybrid funding strategies."

Biocon Limited (BL) is an innovation-led global bio-pharmaceuticals company that has developed and commercialized novel biologics, biosimilars and complex small molecule APIs in India and global markets and, generic formulations in US and Europe. Biocon Biologics Limited (BBL), a subsidiary of Biocon Limited, is a fully integrated global biosimilars company that has commercialized eight biosimilars in key emerging and advanced markets such as the US and Europe and has a pipeline of 20 biosimilar assets across diabetology, oncology, immunology and other non-communicable diseases. It has many 'firsts' to its credit in the biosimilars industry.

Lupin Launches Lurasidone Hydrochloride Tablets in the United States

Mumbai, Baltimore: Global pharma major Lupin Limited (Lupin) today announced the launch of Lurasidone Hydrochloride Tablets, 20 mg, 40 mg, 60 mg, 80 mg and 120 mg, to market a generic equivalent of Latuda® Tablets of Sunovion Pharmaceuticals, Inc. Lurasidone Hydrochloride Tablets, 20 mg, 40 mg, 60 mg, 80 mg and 120 mg (RLD Latuda®) had estimated annual sales of USD 4.2 billion in the U.S. (IQVIA MAT December 2022).

Eugia Pharma Specialties receives USFDA approval for cancer drug

Hyderabad, India: Aurobindo Pharma's wholly owned subsidiary, Eugia Pharma Specialties has received final nod from the US Food & Drug Administration (USFDA) to manufacture and market Lenalidomide Capsules. The product is indicated for treatment of adult patients with multiple myeloma in combination with Dexamethaonse. It is therapeutically equivalent to reference listed drug (RLD) Revlimid Capsules of Bristol Myers Squibb

Company. The product is likely to be launched in October 2023. Aurobindo Pharma develops manufacturers and distributes generic pharmaceuticals and active pharmaceuticals.

Glenmark launches First Fixed I.V. Antiemetic Combination for prevention of Chemotherapy-induced Nausea and Vomiting

Mumbai, India: Glenmark Pharmaceuticals Ltd, an innovation-driven, global pharmaceutical company, is the first to launch in India a unique I.V. injection formulation, AKYNZEO® I.V., for the prevention of chemotherapy-induced nausea and vomiting (CINV), under an exclusive licensing agreement with Helsinn, a Swiss biopharma group company. AKYNZEO® I.V., a fixed dose combination of fosnetupitant (235mg) and palonosetron (0.25mg), will be available as a single-dose, ready-to-dilute I.V. injection. It offers prevention from both acute and delayed phases of chemotherapy-induced nausea and vomiting. AKYNZEO I.V. has been developed by Helsinn and Glenmark has exclusive marketing rights for this product in India.

Alembic Pharma to market generic antidepressant in US

New Delhi, India: The US health regulatory authority has approved marketing of generic antidepressant medication to Alembic Pharmaceuticals. In a written statement, the company has stated to have received an approval from the US Food & Drug Administration to market Brexpiprazole tablets in strengths of 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg and 4 mg. The product is therapeutically equivalent to Otsuka Pharmaceutical Co's reference listed drug product Rexulti tablets, it added. The product is therapeutically equivalent to Otsuka Pharmaceutical Co's reference listed drug product Rexulti tablets. (Source: PTI)

Sun Pharma Announces US FDA Approval for Generic Lenalidomide Capsules

Mumbai, India: Sun Pharmaceutical Industries Limited has announced that one of its wholly owned subsidiaries has received final approval from US FDA for its Abbreviated New Drug Application (ANDA) for generic lenalidomide Capsules, 5mg, 10mg, 15mg, 25mg and tentative approval for 2.5mg, 20mg. The respective product approval is based on Revlimid® Capsules, 5mg, 10mg, 15mg, 25mg and 2.5mg, 20mg as a reference product.

In June 2021, Sun Pharma had entered into a settlement with Celgene Corporation (Celgene) to resolve the patent litigation regarding Sun Pharma's generic lenalidomide capsules. Pursuant to the terms of this settlement, Celgene granted Sun Pharma a license to Celgene's patents required to manufacture and sell certain limited quantity of generic lenalidomide capsules in the US beginning sometime after March 2022. In addition, the license allows Sun Pharma to manufacture and sell an unlimited quantity of generic lenalidomide capsules in the US beginning January 31, 2026.

Chirag Patel appointed as U.S. Chair of the Healthcare and Pharmaceuticals Sector Working Group

Chirag Patel, Co- Founder & Co- CEO, Amneal Pharmaceuticals

Mumbai, India: Amneal Pharmaceuticals, Inc., a US based affordable medicines company with a longstanding R&D and manufacturing footprint in India recently expanded its presence with the initiation of its India commercial operations in October 2022. Company's Co-founder and Co-CEO Chirag Patel's has been appointed as U.S. Chair of the Healthcare and Pharmaceuticals Sector Working Group within the U.S.-India CEO Forum by the U.S. Department of Commerce Secretary Gina M. Raimondo. "It is an honour for me to have been appointed by Secretary Raimondo to help lead this significant public-private endeavour on behalf of the healthcare and pharma sector. The deep roots and expanding investments by Amneal in both countries will be crucial in ensuring that patients in India, the United States, and elsewhere can get access to high-quality, affordable medicines. We have already invested over USD 500 million in India and continue to explore opportunities to extend partnerships with government and other stakeholders to deliver outcomes that address unmet medical needs. Through this forum, we look forward to strengthening economic partnerships while also working together to resolve critical business challenges faced by the healthcare/pharmaceutical industry across both rapidly growing countries" said Chirag Patel, co-founder and co-CEO of Amneal Pharmaceuticals and Chair, Healthcare and Pharmaceuticals Sector Working Group, U.S.-India CEO Forum. ■

Four Supply Chain Management Trends: Aspen Technology

Author

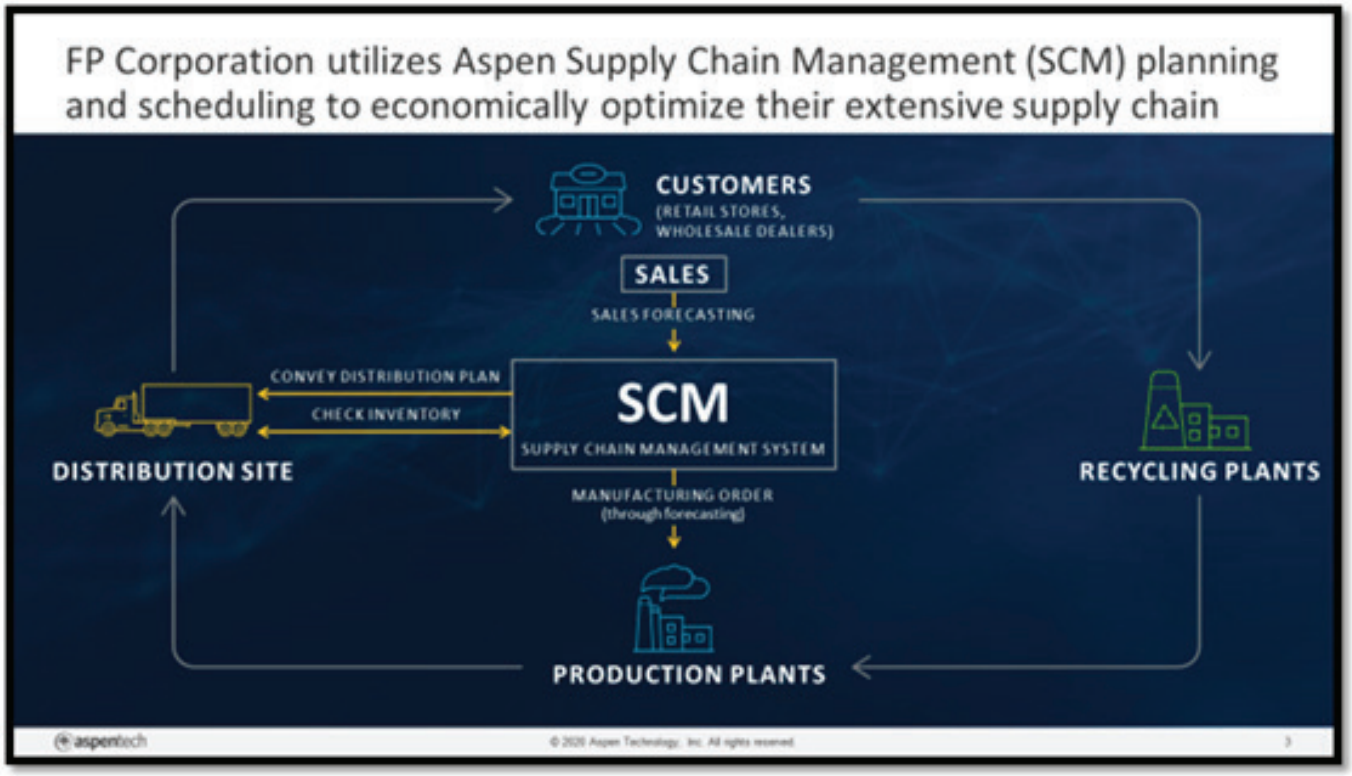
Roch Gauthier
Senior Director, Product Management
Aspen Technology Inc.

Resilient and Sustainable Supply Chains

According to Professor Yossi Sheffi at MIT, supply chain resiliency is "the ability of a company to quickly respond or bounce back from a significant disruption."

Supply chain resiliency has, in fact, become a priority for some governments.

At the same time, a renewed focus on sustainability has emerged in many chemical companies as they set new targets to reduce energy use, emissions, and waste while governments include green energy policies in economic recovery packages. The lesson from the past year is that sustainability and resiliency are two sides of the same coin.



The Aspen Supply Chain Management (SCM) planning and scheduling system used by FPCO to optimize its extensive supply chain.

Supply chain digital twins can help manufacturers achieve their resiliency and sustainability goals. For example, AspenTech's work with FP Corporation (FPCO), along with Time Commerce (an Aspen Implementation Services Partner), was recently recognized with a 2020 Green Supply Chain Award from Supply and Demand Chain Executive. FPCO is the largest maker of plastic food containers and related packaging materials in Japan.

FPCO utilized Aspen Supply Chain Management (SCM) planning and scheduling to economically optimize its extensive supply chain on an ongoing basis and consistently supply more than 10,000 types of food containers to supermarkets across Japan, support food infrastructure, and build a recycling-oriented supply chain with the goal of a sustainable society.

Managing Change through Sales & Operations Execution (S&OE) Digital Capabilities

As every manufacturing company knows, things do not always go as planned. Supply and demand

uncertainty brings forth inevitable daily events and disruptions that must be managed. This can include production quality issues, logistics delays, last-minute changes to customer orders, etc. For most organizations, the pandemic amplified supply-and-demand disruptions to a whole new level.

We are seeing a trend in the market related to manufacturers wanting to become much more agile. This is driving numerous customers to implement Sales and Operations Execution (S&OE) processes and related digital solutions. S&OE is a process that allows manufacturers to align their day-to-day activities on an ongoing basis to achieve their longer-term Sales & Operations Plans (S&OP) while also improving agility.

The October 2020 Forbes article Hexion Is Blazing New Trails in Improving Profitability, authored by Steve Banker from ARC Advisory Group, focuses on how Sales & Operations Execution helps Hexion specialty chemicals improve profitability through high operating leverage and increased productivity. The article provides some insights into how "AspenTech's collaborative platform allows the demand, inventory, production planning, capacity planning, and quality teams to interact and create better production schedules based on the inevitable disruptions that are occurring.

Extended Value Chain Integration and End-to-End (E2E) Optimization

Transportation fuels have historically been the biggest demand and end-use for crude oil. With the energy transition underway, demand for transportation fuels is expected to peak, driven by more efficient combustion engine technologies and the transition to electrical vehicles. As this happens, refiners will shift their attention from transportation fuels demands to chemical demands as a target area for future growth. This megatrend is referred to as crude-to-chemicals (CTC).

When looking at the CTC extended value chain, there are two key areas with integration opportunities. The first is the integration of the oil refining supply chain and the base petrochemicals supply chain. The opportunities here relate to exploiting process and molecular synergies to shift from producing fuels to chemicals.

The second is the integration of the base petrochemicals supply chain (e.g.

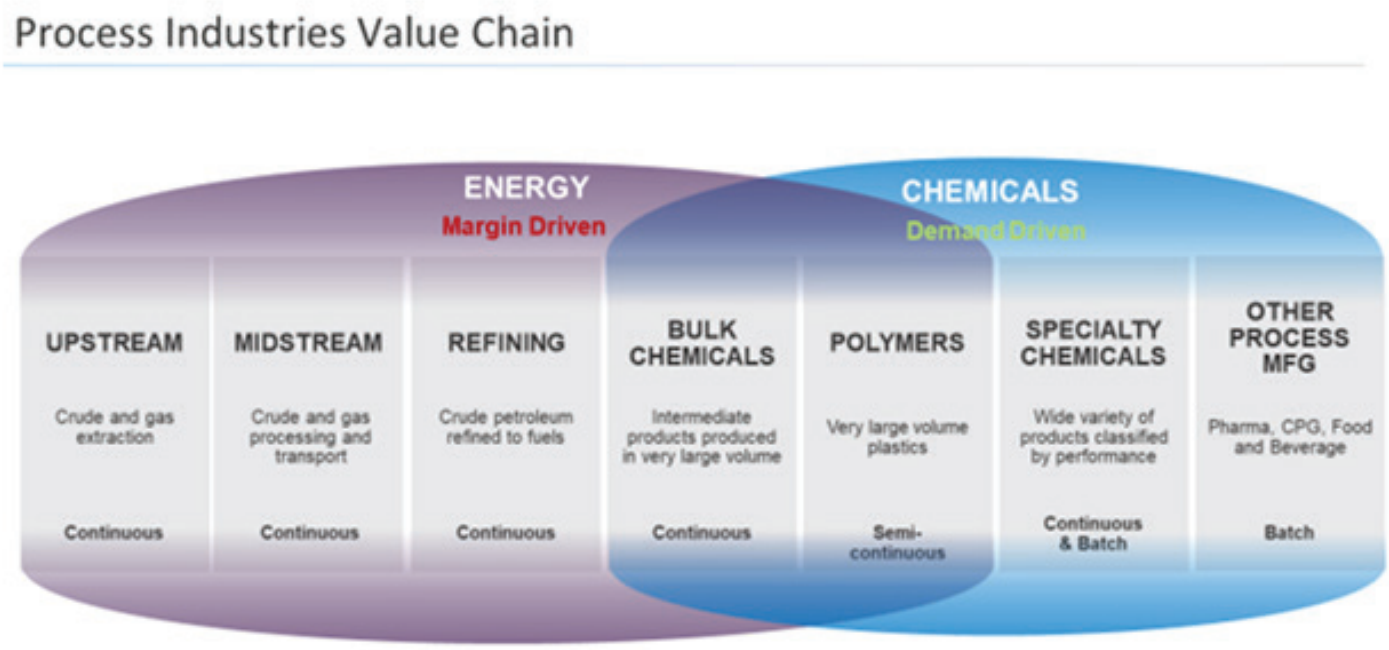
Sales and Operations Execution (S&OE) capabilities are vital because things don't always go as planned.

olefins) with the downstream derivative chemicals (e.g. polyolefins) supply chain. The opportunity here is linked to being more agile and specific in the monomers and polymers value chain planning integration and optimization to best respond to changing supply/ demand economic conditions across the extended olefins-to-derivatives value chain.

Managing and optimizing a crude/ olefins-to-polymers extended value chain is challenging, as it spans supply chains that have very different characteristics.

The upstream refining and bulk chemicals businesses are margin-driven supply chains in which the optimization opportunity consists of optimizing the operating conditions of complex continuous production processes, as well as exploiting feedstock supply and associated economics optionality.

The downstream polymers business is a demand-driven supply chain in which the optimization opportunity consists of looking at the broader business system (including changing demands for hundreds to thousands of individual finished products with



The intersection of Bulk Chemicals and Polymers is where the demand-driven and the margin-driven sides of the value chain meet and interact.

unique characteristics, the distribution network and associated modes of transportation, inventories optimized according to demand patterns and production cycles of different grades, and semi-continuous/batch/continuous production units) and determining the best way to balance supply/demand while maximizing the profitability of this overall system.

Many companies are already working on or prioritizing initiatives related to extended value chain integration and end-to-end optimization. Repsol Chemicals is one of them. Repsol Chemicals recently provided an overview of its "Control Tower end-to-end supply chain optimization" project at the November 2020 European Refining Technology Conference (ERTC). The AspenTech value chain optimization solution will support Repsol Chemicals in achieving its customer service objectives and becoming more agile to respond to market and operational changes, while doing so with full visibility into the end-to-end integrated margin across the olefins-to-polymers value chain with the required accuracy and granularity.

What-if Scenarios Analysis Leveraging Mathematical Optimization at Scale

At the core of a supply chain digital twin there needs to be a representation of the manufacturing process. Multiple complexities may need to be factored into this model, such as production switching costs, utilities, minimum run sizes, and so on. Modeling becomes even more challenging when you factor in other production or tolling sites, as well as the dependencies across sites. As you extend backwards from production into suppliers, there are aspects that should be modelled here as well including different purchase minimums, costs, and lead times varying by supplier.

Finally, you have the downstream supply chain consisting of warehouses, distribution centres and customer ship-to locations. Things get complicated when you try to factor in duties and tariffs or product substitution options. As you can imagine, it can be very challenging to model these interrelated elements in a spreadsheet—rather than using a solution designed specifically for that purpose.

The other big limitation of a spreadsheet is that it wasn't designed to do mathematical optimization at scale to solve real-world problems—taking into consideration anywhere from tens of thousands to millions of variables and constraints. Using a solution designed specifically to do mathematical optimization at scale such as Aspen Supply Chain Management (SCM) is extremely valuable because:

An optimizer will find the best answer automatically, whether the goal is to maximize profit or minimize costs across the end-to-end system.

An optimizer will recommend options that a person or business wouldn't normally consider or didn't know were even possible. That's because it can easily deal with complexity in a way that a human mind cannot. ■

Supply Chain Challenges in Pharma Industry

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The global pharmaceutical has witnessed significant growth in the last decade. At the end of 2020, the total global pharmaceutical market was valued at about 1.27 trillion US dollars. It has increased three-fold from 2001 when the market was valued at 390 billion US dollars

Pharma companies are now rearranging their operations and recovering from the COVID-19 impact. The market is likely to reach 1.7 trillion US dollars in 2025 at a CAGR of 8% from current levels.

Such robust growth was witnessed in India pharmaceutical Industry as well, as per IBEF India's domestic pharmaceutical market is estimated at 42 billion US dollars in 2021 and likely to reach 65 billion US dollars in 2024 and further expand to reach 120 billion USD dollars by 2030.

India's biotechnology industry comprising biopharmaceuticals, bio-services, bio-agriculture, bio-industry, and bioinformatics. The Indian biotechnology industry was valued at US$ 64 billion in 2019 and is expected to reach US$ 150 billion by 2025.

India's drugs and pharmaceuticals exports stood at US$ 17.57 billion in FY21 (From December 2020 to April 2021).

Medicine spending in India is projected to grow 12% over the next five years.

Challenges In the Pharmaceutical Supply Chain in India

Every business has challenges, but the challenges prevailing in the pharmaceutical Industry is extremely complicated. Pharma Industry is still relying on supply chain and manufacturing paradigms that have been around for many years. With various stakeholders involved and complex network design, it's extremely difficult to align everything for an efficient supply chain.

If we analyze the cost distribution of a pharma product it roughly costs about 30% for the supply chain & distribution alone. Where in R&D and primary manufacturing costs only 25%. Therefore, the current supply chain and distribution cost is extremely high compared to other costs. And it is likely to go up further northwards due to the following factors

- **Freight Cost**

Post covid outbreak, freight costs across all modes of transport have gone up skyrocketing by 3-4-folds when compared to 2019 levels. And there is no reliability or consistency in prices as well as service providers like Airlines, Shipping lines, truckers do not give long term rate contracts anymore, and literally, freight rates keep changing on weekly basis.

On one side the fuel costs are going up and on the other side, there is heavy equipment or inventory shortage which keeps destabilizing the supply chain plans and service providers are struggling to maintain the momentum.

Sea freight movements are extremely chaotic now and stressful due to various global issues like container shortage, backlogs in various ports, 2nd covid wave outbreak in key Asian ports, rerouting of shipping vessels, blank sailing, and avoidance of calling certain seaports is hitting the shipping movements terribly

The Airfreight movement is okay as most of the Airlines are surviving only on cargo revenue today as tourism post covid outbreak went for a toss. However, airfreight costs have gone up skyrocketing. For e.g., what used to cost INR 150 per kilo as airfreight cost to the USA per kilo in 2018-2019 has gone up to INR 450 per kilo now

Trucking costs have gone by 30-40% due to the increase in fuel cost. Combined with the shortage of drivers due to the covid outbreak has sent the trucking industry to an extreme difficult situation.

Overall, cost across all modes has gone up, and the situation is likely to continue for another 4-6 months period.



▪ Technology Investments

Pharmaceutical companies must ensure precise on-time delivery, compliance, and stability. They must ensure the cargo will turn up on time in the right condition.

Managing perishable products, degradation of the medicines as they move along the supply chain, maintaining temperature control has a heavy cost attached to it.

Many pharma companies are moving to adopt newer technologies to the fullest potential and trying to integrate various processes. Transparency and visibility are going to be a key driving factor in the ensuing years for productivity and growth. The non-visibility of inventory causes serious threats of counterfeits, loss of sale, challenges to trace products, and cannot predict the demand scenario.

Pharma companies are forced to invest in new technologies to stay afloat in their business. Managing cold storage facilities is very resource-intensive and not budget-friendly, some of the products must be stored at a very low temperature to ensure that the potency and formulation remain intact. This would need pharmaceutical supply chains equipped with specialized reefer containers for movement and the use of cold storage facilities for storage adds additional cost.

The task of bringing medicines to market is a race against time. Since the onset of the pandemic, the cold storage demand from pharma companies has increased, also flexible cold storage facilities are required now to meet the vaccine demands without any excess or wastage of vaccines. Unlike drugs, all vaccines need to be transported at cold temperatures between 2 and 8 degrees Celsius and many vaccines lose potency when exposed to higher temperatures.

Therefore, technology investment now is key to be successful and it also enables to be prepared for the future disruptions

▪ Compliance & Regulation – Choosing the right service provider

It requires a strategic approach to tackle the logistics issues like prioritizing, monitoring, minimizing, and controlling logistics risks, and its imperative that pharma companies shift the logistics cost to "Supply Chain as a Service (ScaaS)".

Due to increasing regulation and compliance requirements, the pharma industry is going through an enormous change and it needs a good service provider who can understand the pharma ecosystem. It requires a service provider who can respond to demand, provide multimodal options, cost-effective risk-based models, provide flexibility, visibility, and transparency.

The service provider with technical expertise, understanding of the regulation and compliance requirements is the need of the hour. Post pandemic, the traditional way of managing logistics is not going to be sufficient. Only an expert service provider can deliver the plans for the unexpected, reduces waste, cut costs, and can improve delivery times.

Good supply chain management can yield a 25-30% reduction in total supply chain costs. The traditional model is a highly fragmented model and is not going to help anymore as it will increase the cost further. Most global companies are now investing in an ecosystem internally to handle the complex requirements of pharmaceutical companies.

Pharma companies should have a holistic approach in identifying the service partner rather than comparing on a transactional basis.

An expert service provider who follows and deliver "Supply chain as a service" (ScaaS) offers companies end to end supply chain solutions & services from strategy to product delivery and in turn frees up the valuable company time to focus on customers and new product development and allows the company to focus on their core competence area.

Pharma companies that leverage the Supply chain as a service can quickly improve their commercial position by utilizing a lower and variable cost structure. Pharma companies can scale up their service that provides a competitive advantage in both the short and long term.

New software technologies, innovations, and digitization by the expert service providers help the pharma companies to meet their end-to-end operations, bridges the gap, and provides visibility and transparency with real-time information.

In the shorter run, choosing an expert service provider may cost more for the pharma companies but in the long run, it brings enormous value to the table and builds sustainability, and gives a competitive advantage for them. ■

Maximizing the Efficiency of Clinical Trial Supply Chain

Clinical trials are an essential part of the product development process for both pharmaceutical and biotech companies and if run efficiently can provide the company with a competitive advantage. This article discusses various key factors pertaining to an efficient and effective clinical trial supply management.

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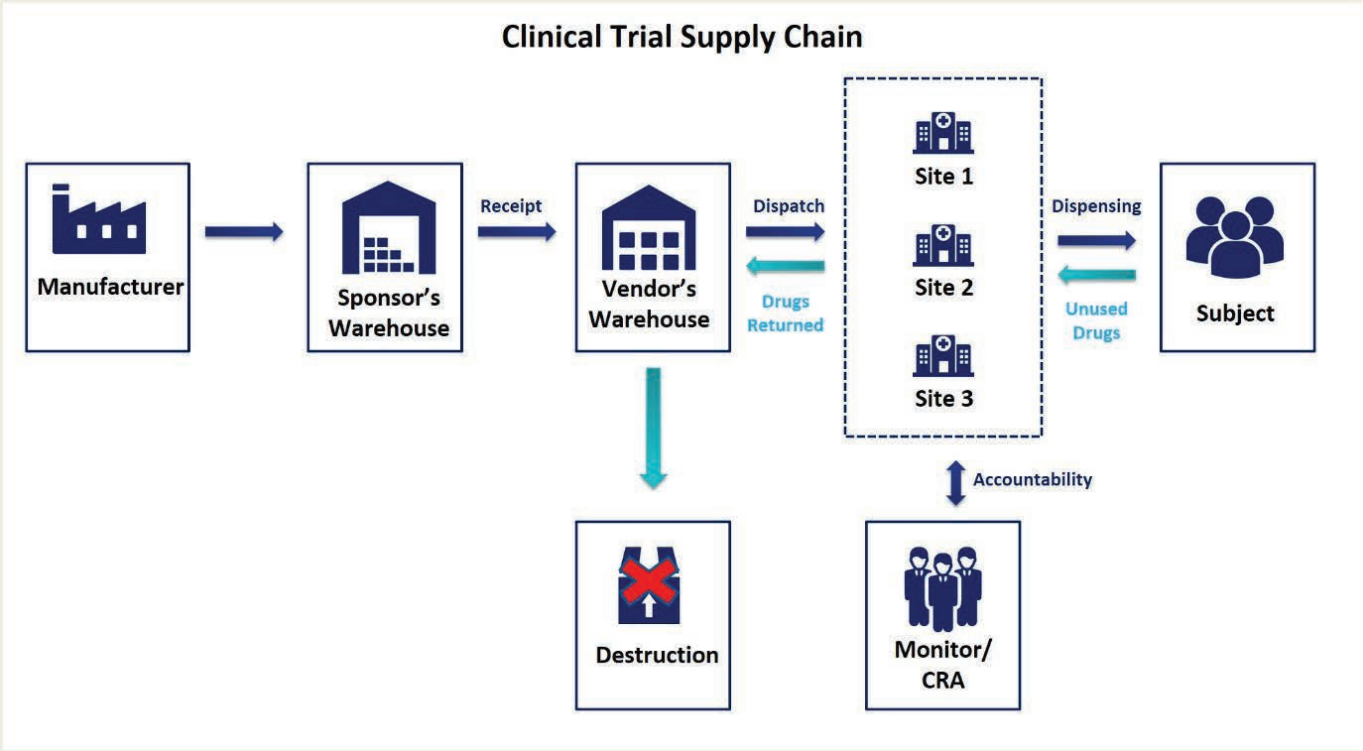
For a new drug to reach the market it has to undergo a robust clinical trial process which requires considerable amount of investment and can continue in excess of 10 years. The process involves global multi-center trials and recruiting a large number of patients to achieve the trial objectives e.g. safety and efficacy. Different types of clinical trial supplies, from investigational products to ancillary supplies are required to conduct clinical trials. The clinical trial supply chain is an integral part of any clinical trial; it constitutes packaging, labeling, storage, distribution to patients located in different geographic locations, and accountability and destruction of clinical trial supplies.

Below are the examples of Clinical Trial Supplies:

- Clinical Trial Drug Supplies:

  Investigational Product & Comparators, Background / Rescue Medication



- Clinical Trial Non Drug Supplies:

  Equipment & Lab Kits, CRFs, Blinding / Randomization Envelopes

The primary goal of clinical trial supply process is to deliver

The RIGHT SUPPLIES at the RIGHT TIME to the RIGHT INVESTIGATIONAL SITE for the RIGHT PATIENT

Although the basic principles of logistics apply to Clinical trial supply chain, it is different from Pharmaceutical commercial supply chain due to the following aspects:

- Investigational Products are still under testing hence many aspects of the investigational product are still under 'investigation' or in other words the product needs to be administered to a selective group of patients who has consented for the clinical trial. It is, therefore, extremely critical to have a controlled use of such products right from the lab where it is being produced, till the time it is consumed by the patient, while all the extra supplies are accounted for and destroyed.
- Investigational Products are exclusively manufactured and packaged depending on the trial design so they are not available off-the-shelf.
- Some investigational products eg Oncology products are very expensive and available in limited quantity, hence any wastage could affect the fate of the clinical trial.
- Each kit used at the investigational site is accounted for down to the unit

level eg tablet, capsule and it needs to be returned to the sponsor for destruction.

- The trial data is submitted to the regulatory authorities for registration hence clinical trial supply chain is prone to regulatory audits and inspections.
- The compliance level of the investigational product during the trial has a direct co-relation with the final outcome of the trial. If it is not as per the desired level, the entire trial data would be of no use. Hence, one needs to have built-in quality checks in a study design and monitor closely so that the final outcome is achieved.

Therefore, it is imperative to optimize the clinical trial supply chain process with respect to time, quality, safety & integrity, and at the same time, bring in cost efficiencies.

In order to maximize the efficiency of clinical trial supply chain, it's important to know the various challenges associated with the process and the approaches/ techniques to address them.

Geography - Multicenter/ Multinational Trials

One of the biggest challenges is the geographical location of the source and sites.

With the rapid growth in the number and spread of clinical trials, there are many multinational & multi-center trials, where multiple countries across the globe and various hospitals in those countries are involved. The clinical trial supplies need to be delivered at these sites from the source e.g. central depot. This could result in longer transit time, for example the central depot could be in USA and the sites in South East Asia.

In most of the countries, the drugs cannot be shipped to sites unless necessary approvals from Regulatory and Ethics committee are in place. Hence the clinical trial supplies cannot be sent in advance.

Global Regulatory Requirements

Regulatory requirements could differ from one country another and inadequate knowledge about it could lead to delays in customs clearance. In many countries, import license is required to import drugs and the invoice should match the import license. The labels on investigational product kits should be as per country regulatory requirements which could be country specific. For example, expiry date on the kits is not mandatory in USA but it is mandatory in India.

These situations could result in longer transit time. In case of delays in clearance, there are chances of improper handling of supplies at the custom warehouse which could ultimately compromise the cold chain and affect the quality of the product.

There is also a risk of shipments being misplaced resulting in product wastage.

Product wastage can also be caused due to inaccurate forecasting, eg supplying excess investigational product to sites with low or no recruitment, or supplying products with short expiry date. Such incidences will have an adverse impact on the outcome of the clinical trial.

Poor subject compliance can occur if the investigational product is not available as the subject will not be able to adhere to the protocol specified time regime. This will adversely affect the company's reputation as it is the social and ethical obligation of the sponsor to make the investigational product available to the patients at all times during the trial period; this is also a GCP requirement.

Substandard products resulting from improper handling may jeopardize the clinical trial outcome and there could be chances of data being rejected by the regulatory authorities.

Such issues will also delay the completion of the clinical trial and, in the worst case scenario, could lead to cancellation of the trial all together. The sponsor ultimately could incur heavy losses because of all these issues.

- Based on years of industry experience, here's a checklist which could help in developing the right clinical trial supply chain strategy. Use of a service provider (local depot)

The sponsor can appoint local depots in the countries which are participating in the clinical trial. As Clinical Trial Supplies Management is a niche area, many sponsors prefer to outsource it to the experienced partners rather than managing it by themselves. These depots are GxP compliant and provide end-to-end service from receipt till destruction of the investigational product. These depots can be audited and approved by the sponsor's Quality Assurance department. This partnership has many advantages, shorter transit time to sites being the most important advantage. The local depot can receive the drugs from the central depot after DCGI approval is received for the trial & import license is in place. Once the ethics committee approval is in place, the local depot can distribute the supplies to various sites.

Shorter transit time also ensures lower courier costs. The drugs can be shipped by the central depot /sponsor to the local depot as a bulk supply instead of supplying in bits and pieces, thus there will be fewer shipments imported for a trial resulting in less frequent customs clearance.

Appointing a local depot will give an added advantage of excellent awareness of local regulatory requirements. The supplies will be always available at the depot and can be dispatched to sites

on a short notice. The local depot can provide dedicated resources/ project team handling a particular client ensuring a customer-focused approach and prompt action.

Many clinical trials like Oncology trials require comparators, background or rescue medication. Local depot can also provide support in sourcing the comparators from the local market; this can ease the burden on the sponsor as the sponsor won't have to make arrangements for procuring it centrally and then distributing across the globe. Local sourcing will save time and ensure availability of supplies. By delegating this responsibility to the service provider, the sponsor can increase focus on the investigational product.

> Selection of the right courier partner

A courier agency with the right experience and expertise is essential for the Clinical Trial Supply Chain to succeed. Sponsor can directly or through the depot partner appoint a courier agency which is focused on the life sciences and has a proven track record in cold chain management. This will ensure on-time and safe delivery of supplies without any transit issues, e.g. excursions, off-loading. Such issues may result in product wastage and add to the overall cost as the product will have to be resupplied to the sites. The courier agency can be audited by Sponsor/ Depot partner.

The courier agency should have processes in place for conditioning / preconditioning of gel packs, preparation of insulated shippers. They should always use validated shippers and calibrated data-loggers for the shipments.

The courier agency should track the shipment till delivery and provide the POD and data logger readings to the sponsor/ depot partner upon delivery. They should ensure that the supplies are delivered to the right person. In case of any issue, the courier agency must proactively and promptly inform the client.

> Technology and Innovation

Technology and innovation play an important role in the optimization of clinical trial supply chain. Multilingual labels or booklet labels are used for multinational clinical trials. Their main advantage is the flexibility of drug supplies. The supplies can be used in more than one country or redistributed between countries. This minimizes the drug wastage and reduces the overall medication cost. This hugely helps in trials where drugs are in short supply or expensive, e.g. Oncology trials. Booklet labels also complement the use of IXRS technology and pooled supplies.

IXRS (IWR /IVR) - Interactive Web / Voice Response System is used for forecasting, randomization, drug distribution, Inventory Management etc. This system also tracks

the expiry date. As this system is linked to randomization, the drug orders are generated as per the patient recruitment and visit schedule. This minimizes product wastage and ensures the availability of supplies at sites. It also underlines the importance of using a local depot in order to manage the JIT (Just in time) delivery to the site.

Case Study

Here's a case study to help demonstrate the how a sponsor can save much of their precious time and co-ordination exercise with an experienced clinical trial supplies vendor.

In a multicentre, randomized, blinded trial number of shipments containing investigational products were sent to the sites. After using these drugs on patients at the sites, these supplies were returned to the depot on an ongoing basis by the sites. The study had a long duration of about three years. After the recruitment target and all the patient visits were over the sponsor asked the depot to provide the drug reconciliation records. As the depot had not done the reconciliation of investigational product at the time of receipt of the returned supplies they faced lot of issues in the accountability. The depot staff spent no. of days in conducting the drug accountability and found that the documentation received from sites was not adequate, mismatch between the quantities mentioned on the returned documents and the physical returned stock received at the depot. Even after spending considerable time in this activity all the kits dispatched to the sites could not be accounted for and finally sponsor had to report them as missing with a great risk of potential audit and inspection finding. This situation could have been easily avoided if the drug accountability was done on a real time basis and all the discrepancies were promptly reported and resolved.

Conclusion:

The number of global multi-center clinical trials is increasing by day. Trial design and dosage regimes are becoming complex, and so are the challenges in clinical trial supply chain. The clinical trial supply chain has evolved over the past few years. The testing phase is over; sponsors nowadays are actively looking to reduce the cost of clinical trial supply chain without compromising the quality and integrity of the trials. The sponsors can achieve this by collaborating with the service providers who are experts in their domain and can provide a customized solution to their clinical trial supply chain requirements. ■

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Internet of Things (IoT): The New Prescription for Pharmaceuticals Manufacturing and Supply Chain

The application of Internet of Things (IoT) in the pharmaceutical industry will be the next phase of growth for pharma companies. IoT refers to the networking of physical objects through the use of embedded sensors, actuators, and other devices that can collect or transmit information about the objects. Advances in wireless networking technology have made it possible to collect data from these sensors almost anywhere at any time.

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Imagine running a pharmaceuticals manufacturing company. You are not only managing the complexities of the batch manufacturing process, but also looking at plugging all gaps in your logistics chain, and ensuring complete quality to your customer. Although industrial automation and control technologies are well established in life sciences manufacturing facilities, integral information on real-time status of equipment is still not readily available to the management to take timely decisions. Moreover, stringent CGMP (Current Good Manufacturing

Practice) regulations expect top quality compliance across all your equipment.

A rising number of biologics drugs (temperature-sensitive, short shelf-life drugs) in the market would mean that you have to ensure temperature consistency and loss-free shipping from the source to the point where the drug is administered. Operating costs run high due to expensive cold chain logistics, and also because of losses due to bad handling.

The challenge is accentuated in the manufacturing and distribution of generic drugs, which constitute up to 80 percent of today's pharma market. To handle the stiff competition in the market for generics, you also need highly developed logistics capabilities with the highest efficiencies at the lowest cost.

Warehousing, a vital component in the manufacture of pharmaceuticals, is costly, and its efficiency and quality are crucial for the company's survival. Many companies choose to manage the processes internally, given the sensitive nature of the products. A McKinsey study says that warehousing accounts for 95 per cent of all pharma logistics costs.

Today, pharmaceutical companies have a compelling opportunity to adopt and profit from the game-changing technological advancement called the Internet of Things (IoT) that promises to fix all the aforementioned gaps. In an IoT environment, every 'thing' is equipped with a sensor that allows it to intelligently communicate and

interact with other objects and systems within the IoT ecosystem. The IoT environment helps pharmaceutical companies to automate and revitalise their manufacturing and supply chain management operations.

IoT extends visibility into every area of the business from development through manufacturing, transport, distribution, dispensing, and consumption. On the shop floor, real-time data from sensors will allow visibility across all areas of work, and result in improved productivity, efficiency, reduced cycle time and manufacturing costs.

Smart warehouse management systems enabled by IoT integration will bring in increased visibility, provide real-time data to track and report inconsistencies (for example, storage temperature), and ensure that the right data is available at the right time to enable the right people to act when it truly matters. In logistics, tracking drug inventory movements in real time can save billions of dollars. Smart pharma packaging can help ensure that shipments and medications are accurately tracked, and the supply chain remains fluid, efficient, and cost-effective.

According to IDC, there were 9.1 billion IoT units installed in 2013, which is predicted to increase to 28.1 billion in 2020. In such a fast-changing world, connected equipment, men and material tracking, sample lifecycle management, smart packaging, and cold-chain monitoring are among the top IoT applications suited for the pharmaceuticals industry. Investing in these transformational technologies comes with its challenges. Below are some recommendations and best practices for pharmaceutical companies to fully benefit from their IoT integration.

- Invest in supportive IoT infrastructure and be future-ready.
- Invest in IoT-based security solutions because security is paramount and workarounds are costly.
- Focus on robust change management to make sure people, processes, and responsibilities adapt seamlessly and make the transition successful.

"IoT extends visibility into every area of the business from development through manufacturing, transport, distribution, dispensing, and consumption."

- Think big, start small, fail fast, and scale quickly.
- Make sure that key decision-makers are on board and success criteria in project lifecycle are defined early.
- Perform pilots, establish business benefits through proofs-of-concept (POCs), employ Agile methodologies, choose suitable partners, and leverage expert teams to effect this digital transformation.

Looking ahead, the advances in digital technologies, ubiquity of mobile computing, dominance of social media, and a growing portfolio of smart products are sure to bring real-time actionable intelligence. Enterprises must constantly use emerging technologies to innovate, stay relevant, constantly hone competitiveness and make profits. The risks of doing nothing must be evaluated. The time for pharmaceutical companies to accelerate implementation and use of IoT platforms and solutions is now. ■

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