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CONTENTS

Foreword

Sanjeev Sachdeva,
CTO and Global Head Advisory Services – Life Sciences, TCS

Life sciences organizations are focusing at transforming their enterprise to address the challenges they face and this in turn requires harnessing the power of digital technologies. TCS works with leading life sciences companies to drive large scale digital transformation across the drug discovery and development value chain by leveraging technologies such as AI, Agile, Cloud and IoT and enabling life sciences companies accelerate their product innovation. Today as the world is dealing with a pandemic of unprecedented scale and complexity, it becomes even more important to leverage next gen technologies that can help provide big breakthroughs in epidemic containment, individual risk assessment, understanding of disease transmission and epidemiological modelling that can give the power to predict. At TCS we offer a full set of digital transformation services and solutions including advisory services, predictive and prescriptive analytics and genomics research for life sciences organizations to drive their growth and transformation agenda.

The inaugural edition of Life Sciences Advisory Insights explores how organizations can leverage emerging digital technologies to create exponential value and helping them to achieve superior business outcomes.

Personalized Medicine :
The Winds of Change in Life Sciences and Healthcare

Abstract

One of the oldest and most persistent challenges that the life sciences industry has been striving to contain is that of side effects from traditional drug treatment. The success of the human genome project and the subsequent introduction of pharmacogenomics has allowed the industry to make considerable progress in this direction through the development of personalized medicine. At the very heart of the concept of personalized medicine lies the accumulation and structuring of a massive patient data pool that contains physiological and genomic information. By accessing this data, clinicians can prescribe drugs that are tailored to meet the unique patient requirements.

This paper explores the implications that the advent of personalized medicine will have on various areas of the pharmaceutical and healthcare industries. Through innovative treatment models, personalized medicine (PM) promises to transform the industry at an infrastructural level and provide pioneering companies with first mover advantage.

About the Authors

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The Current Scenario

According to a report published by the Personalized Medicine Coalition (PMC), nearly 35% of USFDA new drug approvals in 2017 were personalized medicines[1]. Much of this observed growth in personalized medicine development initiatives can be attributed to technological advancements that have rapidly driven down computing and genome sequencing costs. This has allowed the healthcare industry to successfully identify patient subgroups and engineer drugs targeted towards them. However, simply identifying patient sub-populations and developing personalized medicine is insufficient without a sound model to accelerate and scale complete personalized medicine ecosystem.

In contrast to the voluminous batch-sized production of traditional medicine, personalized medicine production involves small-batch, and often on-demand, production of drugs. On a large scale, this requires major changes, including infrastructural transformation, and reimagined production models of largely traditional medicine manufacturers. Externally, it translates to a systematic transformation of supply chains, patient ecosystem understanding, healthcare management, and bridging of therapeutic gaps prevalent in conventional drug prescription. The associated investments with such a change, being quite extensive, hinder the personalized medicine adoption process for the healthcare ecosystem.

Another major impediment in the widespread production and distribution of personalized medicine is the lack of a clear overarching regulatory framework. The rapidly evolving gene and cell therapeutics make it further difficult for stakeholders to anticipate the kind of regulations required for personalized medicine. While regulatory authorities such as the United States Food and Drug Administration (USFDA) and European Medicines Evaluation Agency (EMEA) are in the process of developing regulatory frameworks for personalized medicine, the progress is measured.

Despite the slow pace of development of regulations for personalized medicine, various other regulations such as the 21st Century Cures Act enables advancing the medical product development and review to bring new products to patients in a timely manner. These regulations are encouraging novel clinical trial design and use of real world evidence (RWE) to support the approval of a new indication or post-approval study requirements[i].

The Forces behind Personalized Medicine

When it comes to the key drivers of the personalized medicine disruption in the healthcare sector, a large set of factors come to the fore. One such is the modified approach to drug discovery. With modern drug research increasingly focusing on comprehending disease biology and human genetics profiling, the isolation of smaller statistical patient pools has significantly improved test outcomes and could potentially reduce adverse drug reaction (ADR) incidents[ii]. Besides the scientific breakthrough in decoding the human genome, much of the advantage can be attributed to the rapid advancements in technology, data computing in particular. For instance, medical imaging has helped researchers generate valuable insights to treat chronic and critical diseases such as cancer. Moreover, the existing need to reduce patient morbidity and mortality is driving personalized medicine initiatives to achieve an efficient mode of therapy.

Another driver of personalized medicine as a practical replacement for traditional drug therapies is the availability of patient information. The use of smart devices and wearables has helped create a seemingly endless stream of data, which serves as the foundation for developing personalized medicine. In addition to publicly available information, patient-level data from EHR also provides great potential to the development and widespread use of personalized medicine.

Who are the Key Players?

The development and distribution of personalized medicine on a large scale requires the culmination of a large number of functions operating in tandem. From patient and genomic data accumulation and processing to integration into the electronic health record (EHR), the process forms an interconnected web of stakeholder responsibilities. This calls for an all-inclusive collaborative approach across the stakeholder structure. Such an effort would involve:

Providers studying available patient data, particularly the patients' molecular information, and designing treatment protocols tailored to the needs of patient sub-populations. Providers play an important role in initiating efficient patient engagements, replacing existing tokenistic involvement, that yield information instrumental in developing personalized treatment methodologies. Providers can begin to look at various areas of personalized drug administration by studying their capacity for disease management, disease prevention, and best-fit drug procedures.

Healthcare Providers (HCPs) venturing into molecular treatment studies such as genetics and biochemistry in order to better gauge possible treatment methods. Additionally, they should take into account the most recent developments in the fields of gene and cell therapy in order to provide stakeholders with a comprehensive approach towards targeted treatment.

Patients assuming an end-user role and providing valuable disease data. Patients will also play an important role in development of a comprehensive test result database for disease sub-populations by proving consent to investigational diagnosis and test-phase prognosis.

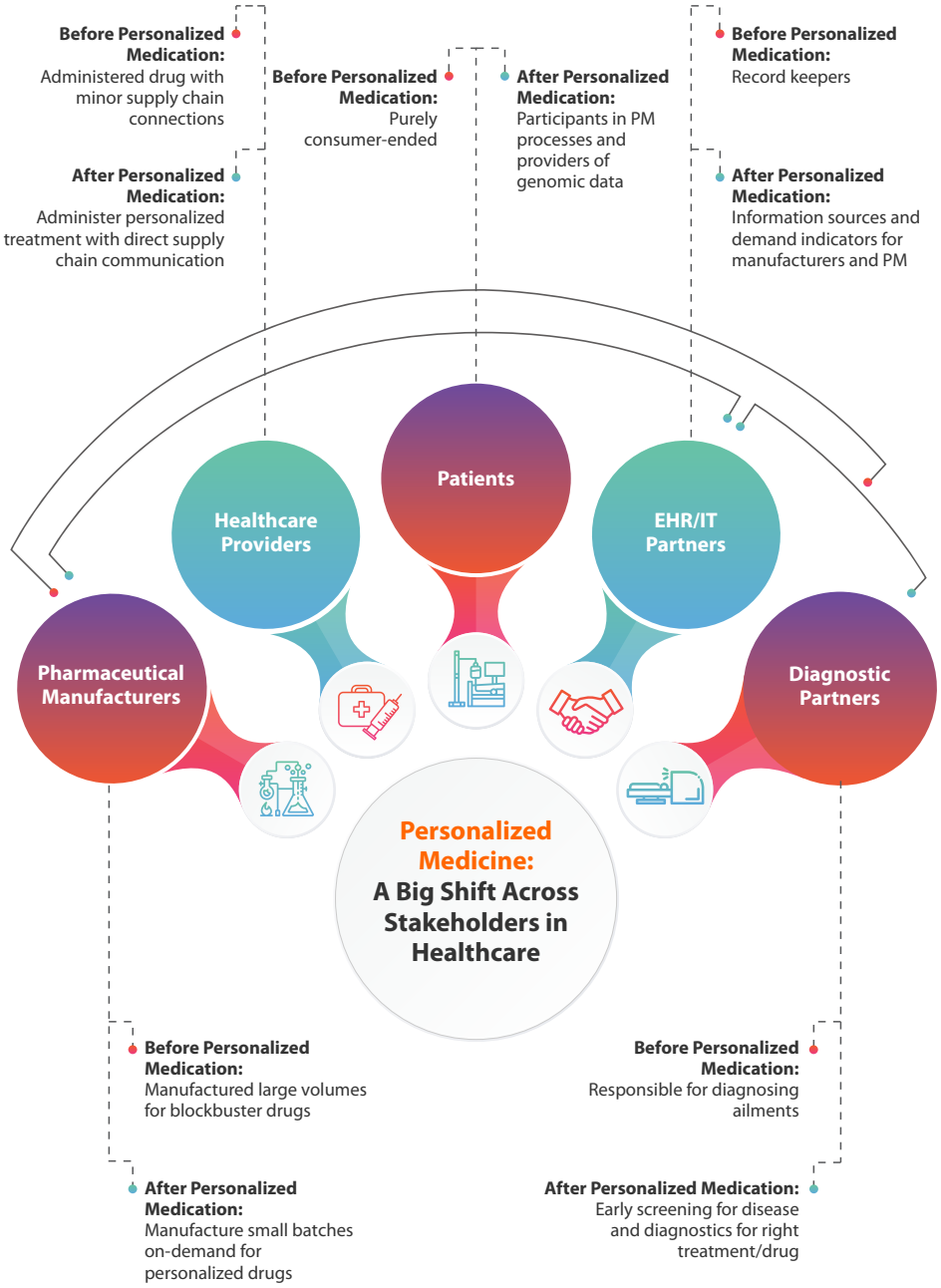
Diagnostic partners providing cost-effective technology that mixes accuracy with speed in early diagnosis, allowing for increasingly effective go-to-market strategies. Furthermore, the model needs to be scalable to be able to process large volumes of diagnostic data.

Payers rethinking financial incentives with the introduction of risk-rated premiums. This would allow payers to effectively pool risks across entire patient sub-populations while still being able to offer customized coverage of diagnostics and treatment.

Regulatory bodies developing robust compliance protocols for specimen requirements that are jointly agreed upon by stakeholders.

EHR/IT partners storing and processing the relevant data in real-time and providing manufacturers and healthcare providers with pharmacogenomics insights on patient sub-populations. This includes integrating genomic and biomarker data in the standard patient records, making it a crucial tool in the prescription of personalized medicine. IT partners will be key in the incorporation of technologies like machine learning and big data analytics in the development of personalized healthcare programs. For instance, ML algorithms are capable of identifying patterns in large genetic data sets, allowing researchers to effectively interpret genetic variations[iii]. This would allow researchers to isolate abnormalities at a cellular level and predict the onset of disease.

Such collaborative effort will prove to be a key driver in the production and distribution of personalized medicine with stakeholders gaining the first mover advantage by tapping into substantial market shares. Moreover, the pro-active approach stands to eliminate the need for currently practiced 'trial and error' methods of conventional drug treatments leading to heightened quality of life (QOL) and subsequently reduce financial repercussions.


Before Personalized Medication: Administered drug with minor supply chain connections
After Personalized Medication: Administer personalized treatment with direct supply chain communication
Before Personalized Medication: Purely consumer-ended
After Personalized Medication: Participants in PM processes and providers of genomic data
Before Personalized Medication: Record keepers
After Personalized Medication: Information sources and demand indicators for manufacturers and PM
Healthcare Providers
Patients
EHR/IT Partners
Pharmaceutical Manufacturers
Diagnostic Partners
Personalized Medicine: A Big Shift Across Stakeholders in Healthcare
Before Personalized Medication: Manufactured large volumes for blockbuster drugs
After Personalized Medication: Manufacture small batches on-demand for personalized drugs
Before Personalized Medication: Responsible for diagnosing ailments
After Personalized Medication: Early screening for disease and diagnostics for right treatment/drug

How is PM Impacting the Pharma Value Chain?

A recent survey of global pharmaceutical industry leaders revealed that 92 percent of respondents saw personalized medicine as an opportunity while 84% have a corporate agenda around it[iv]. The goal of bringing personalized medicine into the mainstream, however, requires rethinking the pharmaceutical and healthcare sector as we know it. The existing pharmaceutical value chain including production, distribution, and provision of medicine has been tailored, over the ages, to suit the conventional treatment system. This translates to disruption across various components of the value chain, the topmost of them being:

- **Manufacturing:** Manufacturing plays a fundamental role when it comes to widespread adoption of personalized medicine. Industry, thus, needs to innovate to address the changing business need. Life sciences industry is exploring newer technologies. As a result, evaluation of single use technologies such as continuous manufacturing, additive manufacturing, and portable manufacturing is beginning to mature.

3D-Printing can reduce small batch production costs to as low as a fifth of the original expense.

Since the traditional production models are not the best fit to serve the purpose of small-batch multi-product requirements of personalized medicine, drug manufacturers need to look at different modes of production. One of the most promising technologies in the area of manufacturing precision drugs is that of 3D-printing (3D-P). Being a single-use technology, 3D-P offers the required flexibility for small-batch multi product manufacturing of personalized medicine. Additionally, the approach of on-demand printing enables pharmacy-based production and holds the potential to revolutionize the ownership model across the life sciences sector.

By leveraging 3D-printing techniques, drug manufacturers can focus on the precision of formulating and "printing" drugs with properties such as automated dosage control and tailored drug release profiles. The process is suitable for manufacturing both low and high dose concentrations. 3D-P drugs can be also be customized using the size and drug combinations to suit the needs of the patient sub-populations. This method of personalized medicine production allows a great deal of freedom to design oral dosage forms (ODFs) with respect to factors such as active pharmaceutical ingredients (API) dosage, distribution and absorption of ODFs, and excipient use.

3D-printing of personalized medicine involves three commonly used techniques: printing-based inkjet systems, nozzle-based deposition systems, and laser-based writing systems. While the laser-based writing system relies on the principle of photo polymerization, printing-based inkjet system involves two techniques, continuous inkjet printing (CIJ) and drop-on-demand (DOD). The most popular of these techniques, however, is the nozzle-based deposition system. The provision of mixing drugs and polymers prior to the printing process grants it a higher degree of flexibility in terms of dosing accuracy.

- **Supply Chain:** The past decade has witnessed the optimization of healthcare supply chain to the purposes of mass distribution of drugs and centralized treatment methods. One of the ways that the sector achieved this was through consolidation of the supply chain components. Traditionally, the approach has been a "One supply chain executed many times". However, the advent of personalized medicine demands completely new capabilities to support the scenario of "Hundreds of supply chain executed once (extreme – more likely is executed few times)". The evolving personalized medicine ecosystem and the unique nature of customer distribution is forcing the supply chain industry to evolve and adapt to the personalized medicine market. It is not just the transformation of distribution models that holds the potential to disrupt the supply chain. The opportunity or need to customize treatment for individual patients further increases the complexities in supply chain.

The fundamental idea behind personalized medicine being the improvement in quality of treatment, it is safe to say that the timely, error-free delivery of the appropriate product is an important factor for such an achievement. This requires improving the supply chain control and visibility in frameworks.

Keeping these requirements in mind, pharmaceutical companies are increasingly adopting the practice of "complete chain of custody". By assuming an end-to-end responsibility of the supply chain, pharmaceutical companies can ensure that the products meet the customers' individual packaging and delivery needs. This holistic approach requires companies to possess seamless tracking of each individual product through each of the stages in the supply chain, from procurement to manufacturing to distribution. This would involve efficient management of the supply chain including monitoring details like temperature of products in transit or in storage using IoT sensors.

Personalized medicine distribution is also changing the way third-party logistics operate within the healthcare sector. One of the most noticeable trends is the introduction of 'pharmacists and patient coordinator' models that enable an integrated two-way process of personalized medication. For instance, coordinators collect blood or T-cell samples from the patient and deliver it to the manufacturer. The resulting treatment is then delivered to the patient.

Aside of the levers of the life sciences value chain, the other activities impacted by Personalized Medicine are:

Companion Diagnostics: Companion diagnostics form an integral part of patient sub-group identification and subsequent personalized treatment design. Companion diagnostics are carried out alongside the administration of a drug. These tools offer insights that help in identifying biological markers and provide vital information on the effectiveness of the corresponding drug. This is one of the fastest evolving avenues to develop innovative treatment protocols. In a bid to adopt companion diagnostics in mainstream treatment, the US FDA, in 2018, advanced a policy that backed the co-development of drugs and in vitro diagnostics[v].

Research and exploration in this area, however, experiences a certain degree of stagnancy resulting from the reluctance of pharmaceutical companies. In fact, fewer than 5% of all in vitro diagnostics are companion diagnostics[vi]. The hurdle lies in the lack of a regulatory framework, insufficiency of data, and the ever-potent threat of data breach.

Early Diagnosis: The availability of patient data, ranging from physiological to genomic, is one of the key enablers of personalized medicine. Also, this massive patient data pool brings with it the opportunity of early diagnosis and disease prevention. This kind of diagnosis will be particularly useful in identifying, mitigating, and managing diseases and conditions that may take years to show symptoms. Early diagnosis is steadily making its way into the existing healthcare framework.

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Blockchain for a Robust and Efficient Supply Chain

About the Author

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Yezhuvath Vinesh Balakrishnan works with the Tata Consultancy Services (TCS) Life Sciences unit, focusing on supply chain management. He has over 22 years of experience in supply chain management, manufacturing, process excellence, and IT management across the pharmaceutical and chemical industries. He combines process orientation and analytical abilities with an in-depth understanding of technology to develop IT solutions that drive productivity, efficiency, and governance in the life sciences supply chain and manufacturing domains. Vinesh is actively involved in numerous supply chain and outsourcing transformation initiatives, and has helped conceptualize and develop innovative solutions, and enabled process optimization. An alumni of Birla Institute of Technology and Science (BITS Pilani), Vinesh holds a graduate degree in Chemical Engineering and a postgraduate degree in Mathematics

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The life sciences supply chain has struggled with balancing risk, costs, and integrity in the collaborative aspect of its ecosystem. This imbalance can become more acute with the advent of personalized medicine as the supply chain is transitioning from one supply chain being executed hundred times to hundreds of supply chains executed simultaneously. The inherent transparency, reliability, auditability, and capacity for disintermediation, holds a lot of promise for the life sciences supply chain in the current context as well as in the future.

The supply chain has a three-flow dimension – physical flow, financial flow, and the information flow from the n-tier supplier to the pharmaceutical company to various distribution centers and partners, and then finally reaching the patient via the hospital or pharmacy.

Blockchain technology has the ability to address all three dimensions to address collaboration, cost optimization, and risk management. This technology allows companies to gain total access of the end-to-end supply chain data while ensuring that it can be securely stored and privately shared with authorized stakeholders. As a decentralized shared ledger that requires cryptographic signatures for access and modification, the blockchain can create a transparent, traceable system of recording transactions across the product life cycle.

While there are a number of applications of this technology across the supply chain, the industry appears to be focused on the following:

- **Supply Chain Security** – Driven by the need to control and eliminate counterfeit drugs in the marketplace, supply chain security has gained paramount importance. Coupled with serialization and Track-n-Trace features, there is a need to share and exchange information across a vast ecosystem. With regulatory agencies across the industry issuing new mandates to boost the integrity of pharmaceutical supply chains and eliminate fake drugs, blockchain technology could offer an industry-wide solution for supply chain security

- **Drug Tracking and Provenance** – New-age drug distribution has grown immensely in scale and complexity. Product traceability from the point of origin of raw materials/ingredients across the manufacturing sites, and then to larger healthcare ecosystems can piggy back on the blockchain to create an immutable global batch traceability, making it easier to respond to product recalls, holds, and new releases in the market

- **Cold Chain** – It is forecasted that 26 out of the top 50 pharmaceutical products will be in the cold chain. With new regulations, the entire pharmaceutical product portfolio has been deemed as temperature sensitive. Current supply chains lack instantaneous, continuous, and transparent access to end-to-end cold chain data. This results in regulatory non compliance, inability to take timely corrective actions, increased liability, loss of product and potentially, life. Blockchain could be the solution to trust the efficacy of the drugs, at the point of dosing

- **Transforming Developing/Emerging Markets** - In developing nations, the market is fragmented and comprises several hundred companies. Such small companies are beset by cash flow problems as the more financially stronger customers are on end for more than 90-day payments for delivered medicines or devices. Big Pharma, on the other end, seeks shorter credit periods, hence the small players are risk averse. Tracking the drugs on a blockchain for transaction legitimacy and authenticity could make it easier for small and mid-sized players to access credit easily as well reduce the overall turnover time

- **Trade Finance on Blockchain** - There are several points in the trading process which causes the delays in shipments and payments. For trading across borders, around 40% of the shipments get delayed due to custom clearances. The use of blockchain and smart contracts will automate the execution of business logic and bring a tremendous amount of efficiency to trade finance.

In our point of view the application of blockchain technology in life sciences can be categorized into five buckets– chain of custody, data sharing, financial supply chain, collaboration and patient engagement. It is worthwhile looking at use cases using these as the lenses of focus. The top areas within supply chain can be as that given in Figure 1 below:

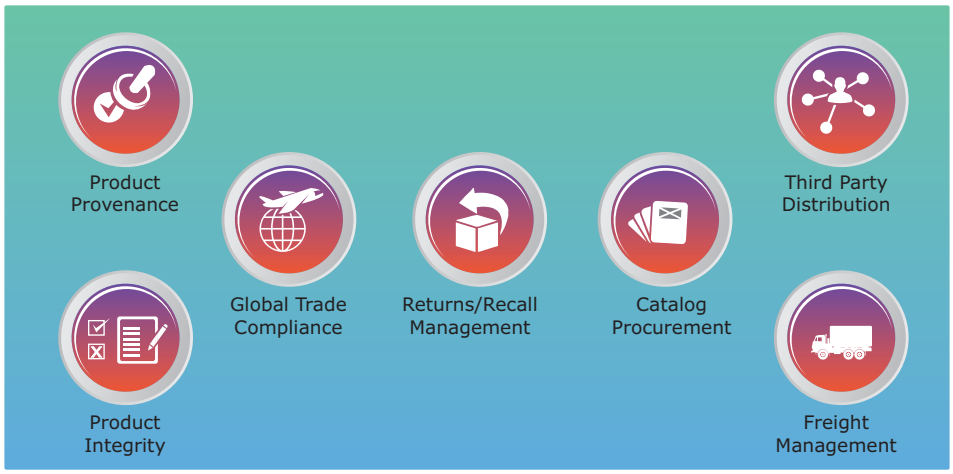

Figure 1: Top 7 Applications of Blockchain in Healthcare and Pharmaceutical Supply Chains

Life Sciences Use Cases

With the increasing importance of blockchain technology in clinical supply chains, it is imperative to be aware of its use cases within the life sciences domain:

1. Secure Product Transfer

Imagined as a system to track the movements of drugs and medical devices, using blockchain and smart contracts, coupled with the use of smart IoT edge devices, cloud ecosystems, from the point of manufacture to the point of dispense or dosage, establishes a clear chain of custody and related obligations. Blockchain will be implemented as a shared ledger for all the ecosystem participants to track and trace at unit-level drug or device in order to overcome the multiple nodes of risk, disruption and dispute. Issues of provenance, point of obligations transfer, end-to-end view will be eliminated. Cross-border transparency may persist in different forms along with shipment document permutations and combinations.

Some of the solution features are as follows:

- Triple accounting model– leveraged to reduce financial reconciliations– contracts, call offs, and settlements
- IoT integration for seamless events tracking– effective temperature data management or route management
- Secure Box Concept– applicable for VMI, Smart Cabinets, or authorized access (e.g. Field Rep can only open) using a key issued by blockchain). Hash key is used to lock and unlock boxes or cabinets (provide for secured access)

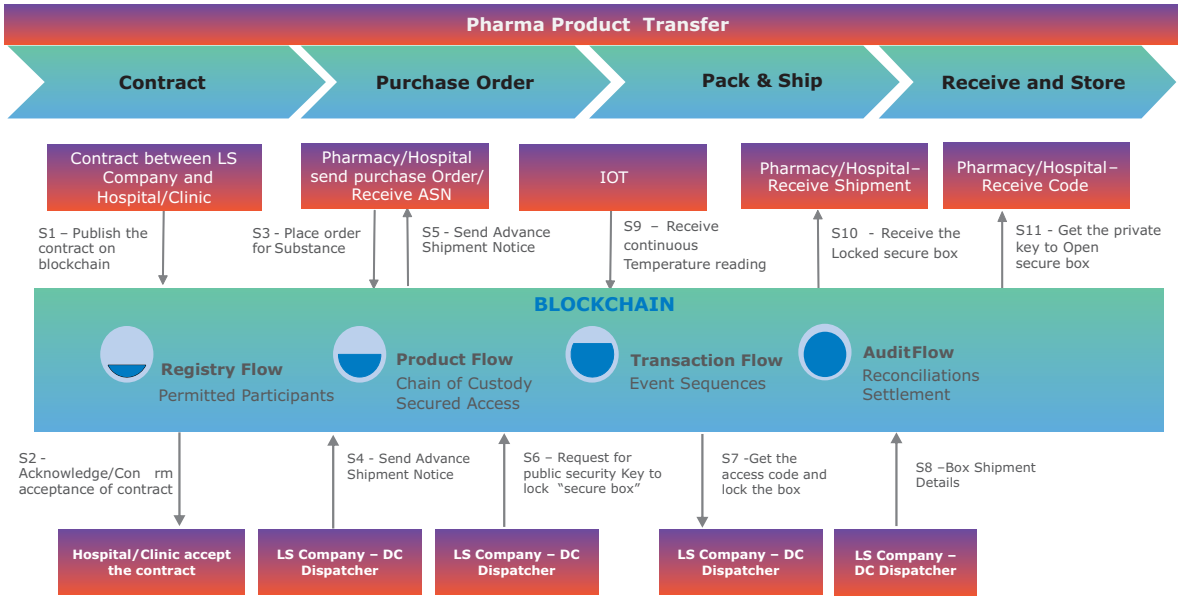

Figure2: Secure Product Transfer

Automated Smart Contract to trigger action – such as a device with a specific serial number status update as restricted for sale due to insufficient prior documentation (e.g. Sterilization Certificate not issued)

2. Surgical Implant Field Tracking

Surgical implant field tracking is imagined as a system to track the movement of devices from the point of scheduled surgery to the return of material and billing as well as long term anonymized tracking of the patient. It will improve the visibility, verification, and validation of the implant, backed by related accessories and instruments leveraging distributed ledgers, decentralization, authentication, and proof of ownership. A chronological ledger will assist in reaching a consensus on supplied products that each recipient agrees on, and acceptance of the implant with the ownership is established and recorded authoritatively through the blockchain. Automated reconciliation triggered through smart contracts will reduce reconciliation and audit schedules.

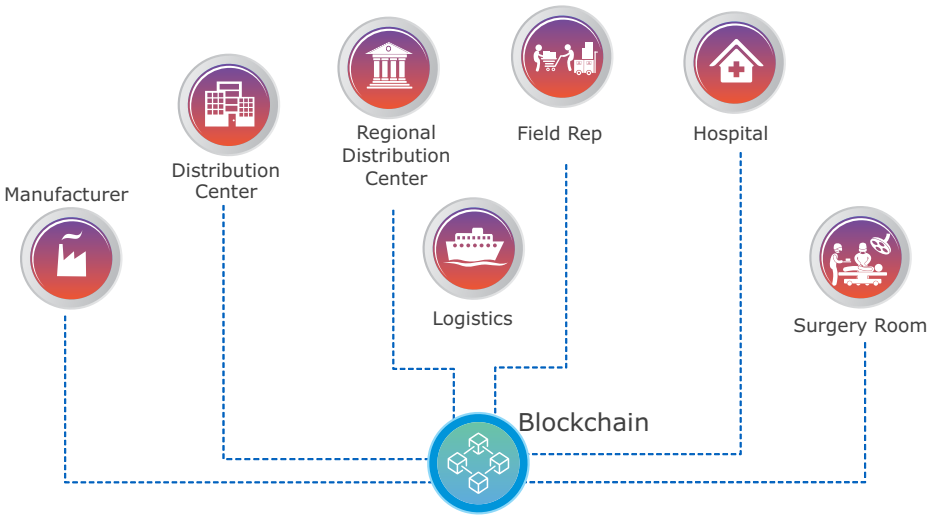

Figure 3 : Surgical Implant Tracking

3. Contract and Revenue Management

Contract and revenue management is imagined as an industry lever distributed ledger system. With a plethora of players in this ecosystem, a considerable amount of time is spent in collecting, collating, verifying, and submitting various information and claims to different parties– examples like chargeback, promotional Medicaid among other come to mind. Distributed ledgers along with smart contracts and the underlying ability for all the players to trust the data within provides an ample scope to completely reimagine and provide significant savings in the healthcare ecosystem.

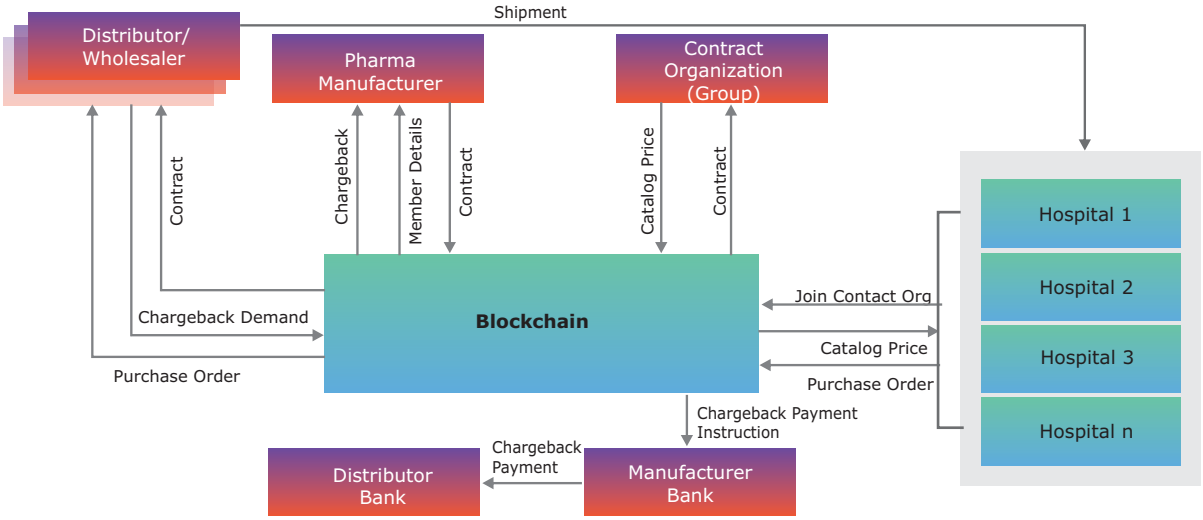

Figure 4 : Contract and Revenue Management

4. Clinical Trial Supplies – The clinical supply chain an ideal candidate for blockchain-based Business 4.0 disruption. TCS views the clinical supply chain on blockchain as ubiquitous "disruptive and transformative" applications. Data provenance that is required for business or regulatory reasons can be recorded in a secure, immutable, and auditable manner.

There are benefits of tracking medicine, providing drug provenance information, and securely collecting patient-level data under the HIPAA or other compliance laws. However, this isn't the only way by which blockchain technology can make a difference in the clinical supply chain. Secure boxes with digital locks can be used for safer shipping. Such boxes can only be opened by digital keys issued by the blockchain which ensures authorized access by say, doctors and nurses.

An industry-wide deployment of the technology can usher in regulatory changes in the blockchain. Once these changes gain the industry consensus, they can be implemented through smart contracts or automated drug reconciliation through triple accounting-based shared 'records of trust.' This can enable adherence and integration with the IoT, and will consequently drive accountability as well as faster reconciliation.

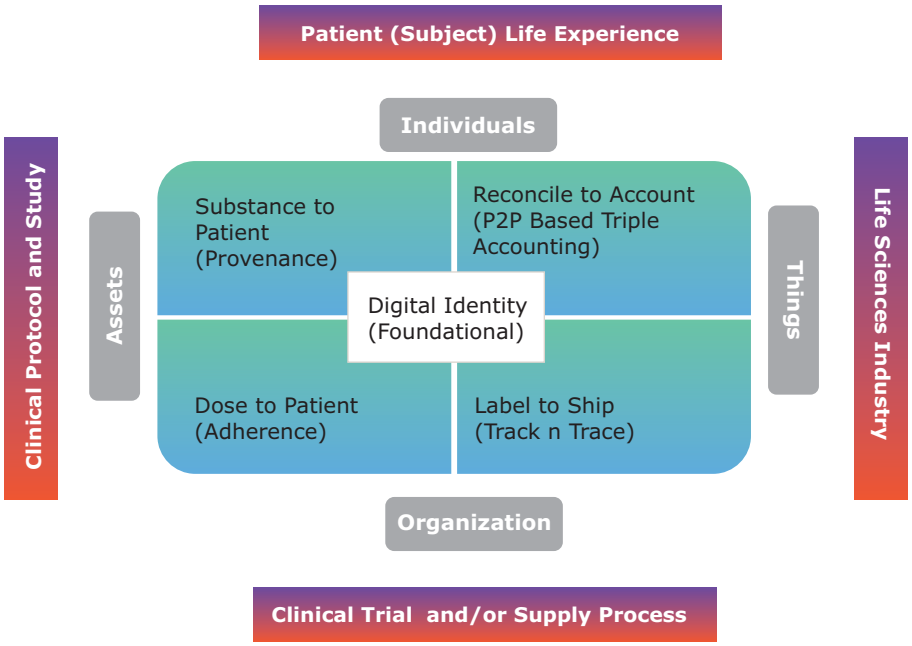

Figure 5: Clinical Trial Supply Chain 4.0 - Secure, Agile, Automated and on the Cloud

Unlike other technologies, blockchain has the potential to address the operational and business challenges at the efficiency level, transform business processes, and create a disruptive business model. Pharmaceutical enterprises today are still at a nascent stage as far as embracing the technology is concerned. While they seek to have a clearer understanding of the blockchain capabilities that are relevant to the level of transformation desired and have a solid understanding of the blockchain ecosystem, the potential impact of the technology on the target operating or business models is tremendous. It is possible to bring in steep changes, transforming the business and operating models, instill unwavering trust in lifesaving pharmaceutical products and give patients greater command to administer the clinical trial data through blockchain technology. As digitization of the supply chain increases and end-to-end processes begin to encompass external partners, blockchain technology can become the backbone of the multi-enterprise supply chain network while offering a great degree of enterprise independence simultaneously.

Reimagining Life Sciences Value Chain Using Internet of Things

Abstract

The life sciences industry, like many other industries, is leveraging the Internet of Things (IoT) to derive new value. This paper analyzes the diverse areas where the IoT can be integrated into life sciences and highlights a framework that can be used to integrate IoT technologies into products and processes and understand which IoT data must be captured.

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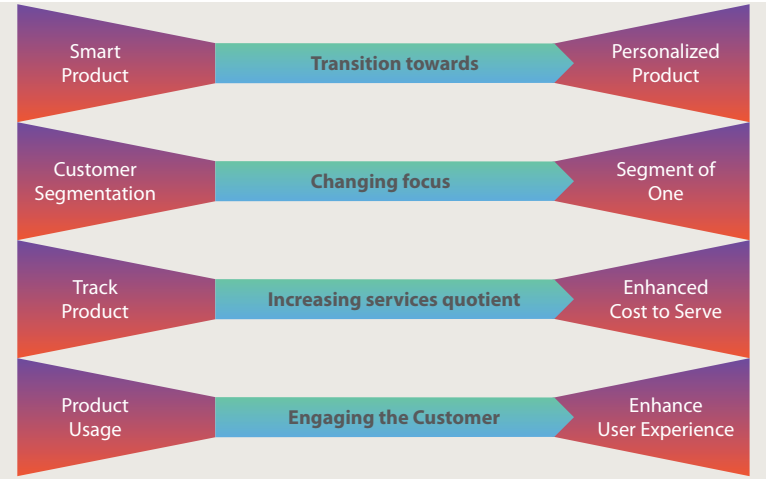
Internet of Things (IoT) and the Life Sciences Industry

The IoT promises to enable complete Digital Re-imagination™ of business models and help deliver differentiated and personalized services[1] . Three key developments are driving IoT as a force for digital reimagination:

- Miniaturization of sensors used across industries to measure or 'sense' the characteristics of real world physical environments and convert them into raw data
- Reduced costs of and advances in edge computing capabilities
- Proliferation of wireless and mobile technologies

Life sciences and healthcare companies can realize the true potential of the IoT by deploying multiple products that provide the much-needed data that can be used to diagnose consumers' health and promote a better lifestyle.

Figure 1 shows inferences from the TCS IoT survey about some areas in life sciences that the IoT will impact[2].



Inferences from the TCS IoT survey: Direction of life sciences IoT initiatives

Using the RxMxDx framework for IoT

Life sciences companies can visualize IoT opportunities along the following four distinctive themes constituting the RxMxDx framework, each with a different set of objectives and driven by different strategies:

- **Connected products:** reimaginging products and services to enable new categories of services, business models, and revenue streams
- **Connected patients:** enabling the patient to lead a healthier life with the integration and interoperability of several devices to provide collective value
- **Connected workplace:** empowering employees and business partners to be more productive through rapid integration of information and day-to-day workplace tasks
- **Connected equipment:** manufacturing equipment powered by machine-to-machine communications and driven by advanced analytics and connected operations, which optimize manufacturing operations

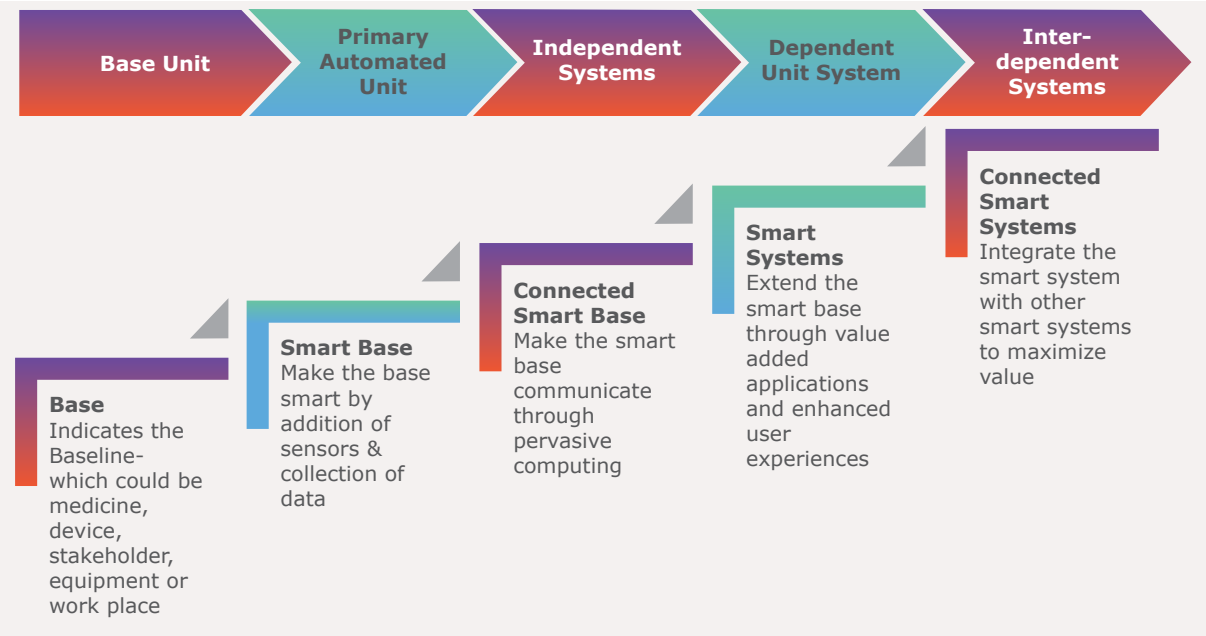
The approach or solution drivers listed in Table1 may vary based on the scenario or the context. For example, in emerging markets, several factors such as cost, scalability, flexibility, and so on may make it more prudent to use an outsourced business model for a smart logistics operation (an example of connected workplace) rather than an owned one. On the other hand, an insourced or owned model can be adopted for markets that are of strategic importance to the business.

Table 1 summarizes the key strategic drivers for each of these themes and a relevant approach to optimize results under them.

Strategy Drivers	Connected Product	Connected Patient	Connected Equipment	Connected Workplace
Data to be captured	Careful consideration and strategic alignment	Wellness driven	Vital data	Productivity-linked data
Data access and rights	Company controller	Global internet governance	Need based	Internal
Business model	Strategic	Consortium	Outsourced	Owned
Development approach	Strategic collaboration	Collaboration	Custom engineered	Outsourced

Strategic drivers for the four themes in the RxMxDx framework

After identifying the approach or solution driver, a value roadmap can be drawn up as shown in Figure 2 to chart out the evolutionary process required to provide increasing value under each of the four themes.



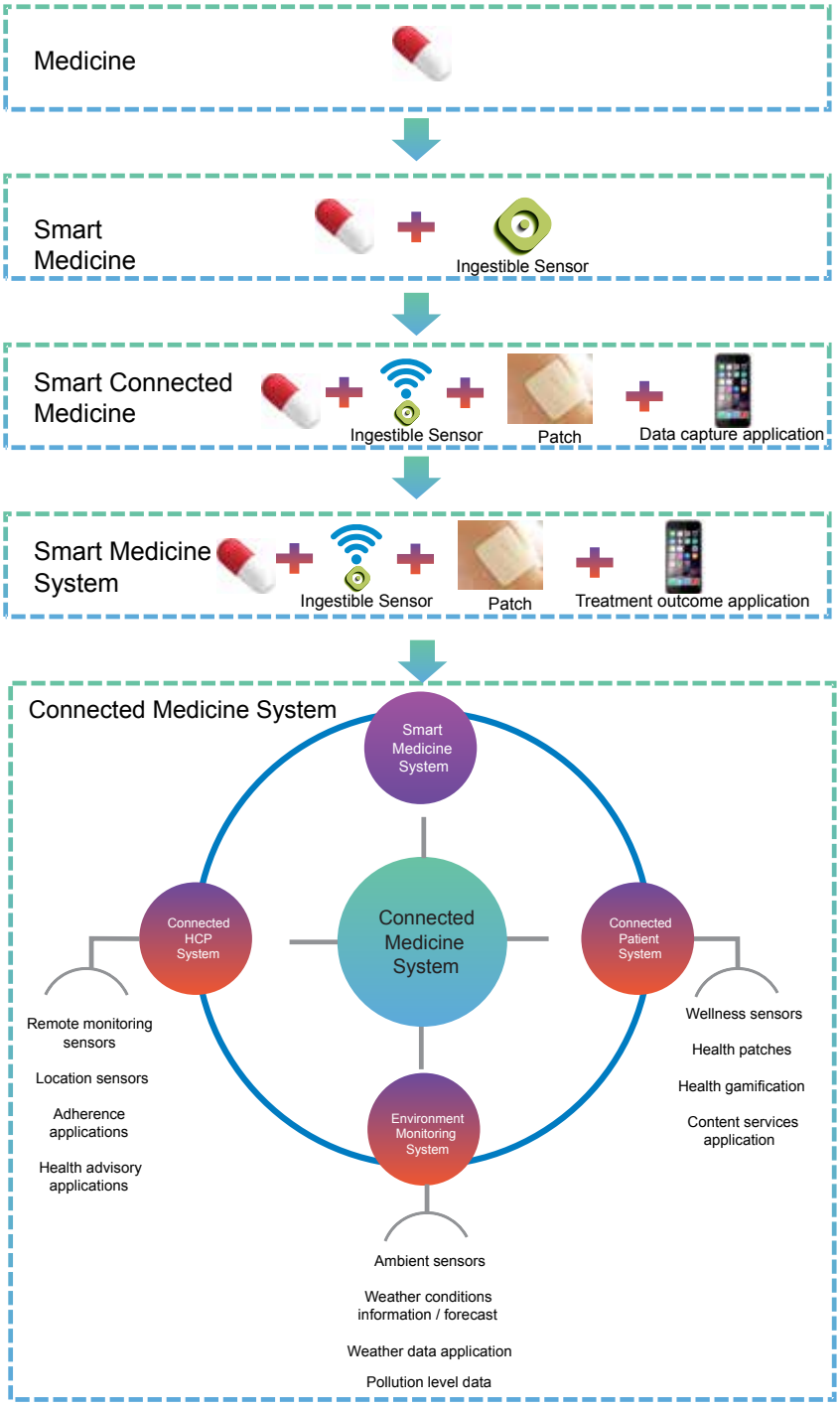
Evolution roadmap for maximizing value under the four themes

Optimizing Business Value Using the Framework

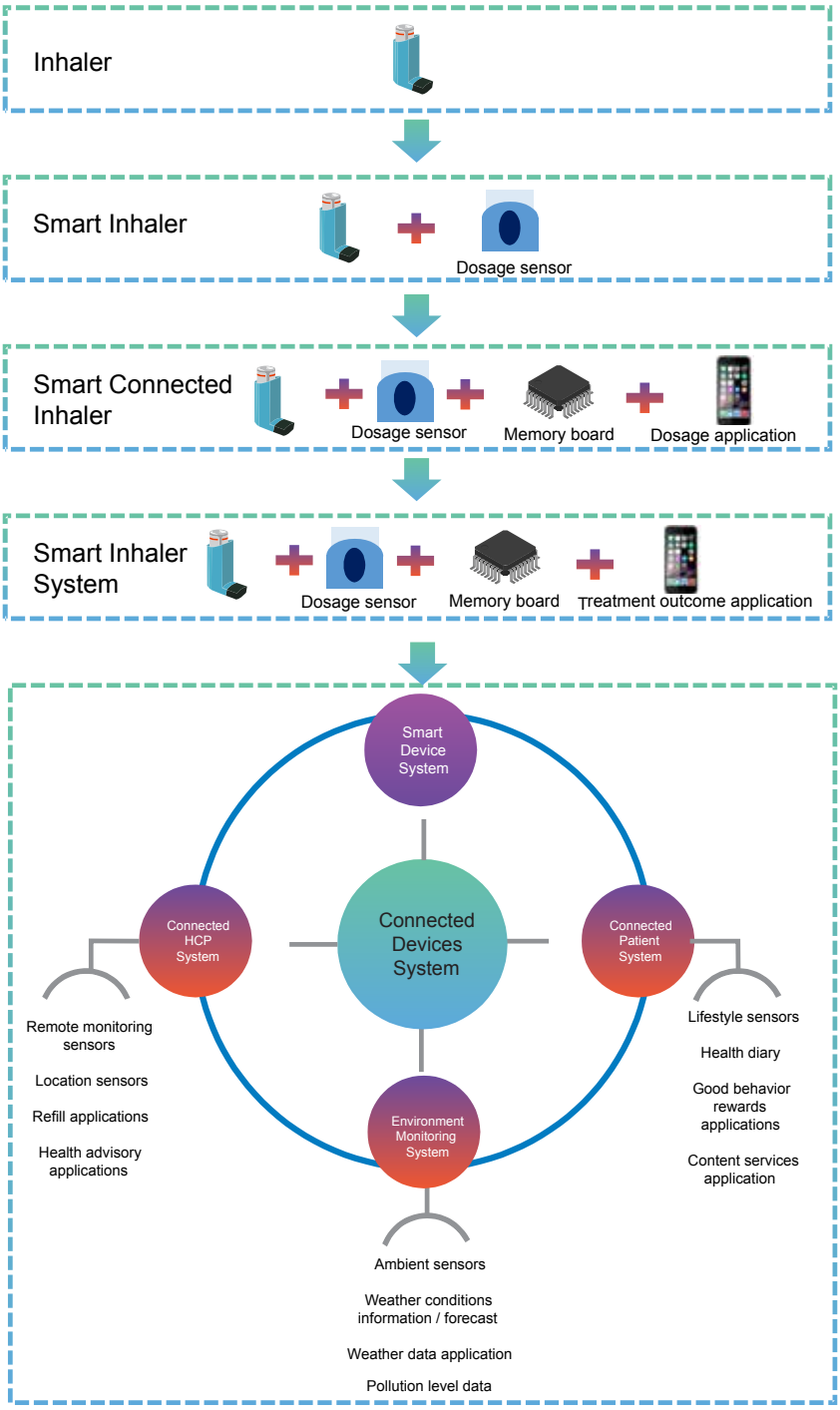
Business value is maximized when organizations move from a 'product' to a 'product-based platform-as-a-service' mindset. Already, elements of this shift are being applied in the automobile industry through connected cars and in-home entertainment systems. Life sciences companies can adopt this model too.

For each of the four themes stated earlier, let us explore some specific examples using the framework.

- **Connected products:** pharmaceutical and medical devices companies can transform the ubiquitous capsule and inhaler using a connected product system. A smart product can be created by using medicine with an ingestible sensor, such as the one by Proteus®[3]. This can be supplemented with a patch that 'reads' the information, allowing the sharing of fundamental information with the patient, physician, and care support groups. The value of this product can be increased manifold by combining the information from the patch with the patient's lifestyle information such as the level of physical activity, dietary information, and information on physiological conditions such as glucose levels and body temperature. By coupling this information with information on weather conditions that affect the illness, a connected medicine system can be developed (Figure 3).



A connected medicine system

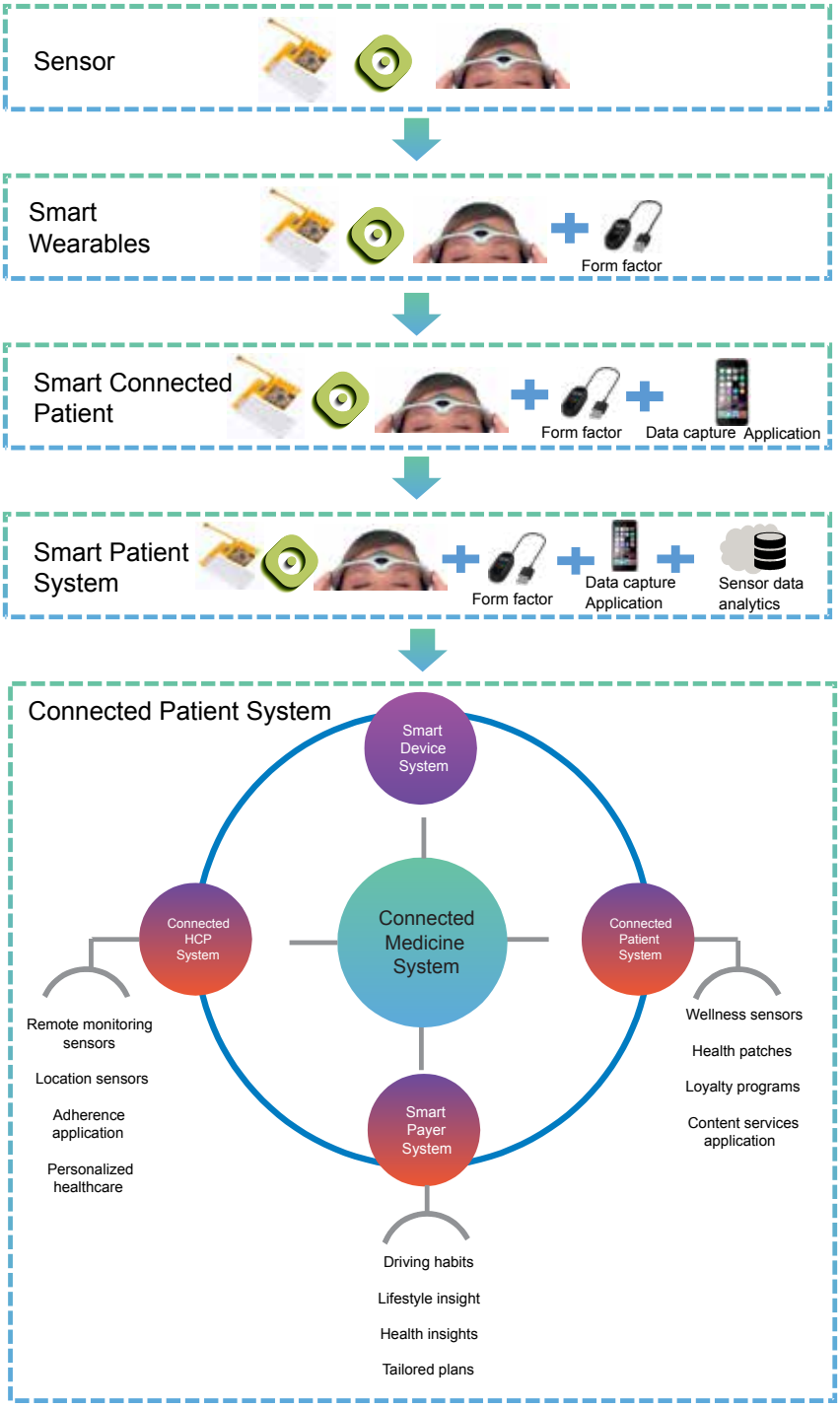


A connected medical device system.

Similarly, a connected medical device system for an inhaler can be developed (Figure 4). An inhaler with an add-on smart dosing sensor, such as Propeller[4] Health or the CareTRX sensor[5] , will help dispense prescribed amounts of medicine and share fundamental data with the patient, physician, and care support groups. Combining this information with the information on the patient's lifestyle and physiological conditions as well as external information like weather conditions leads to the development of a connected medical device system. Such an open, connected device system improves health outcomes, tracks dosage adherence, and issues early warning or alerts, based on triggers such as pollution levels.

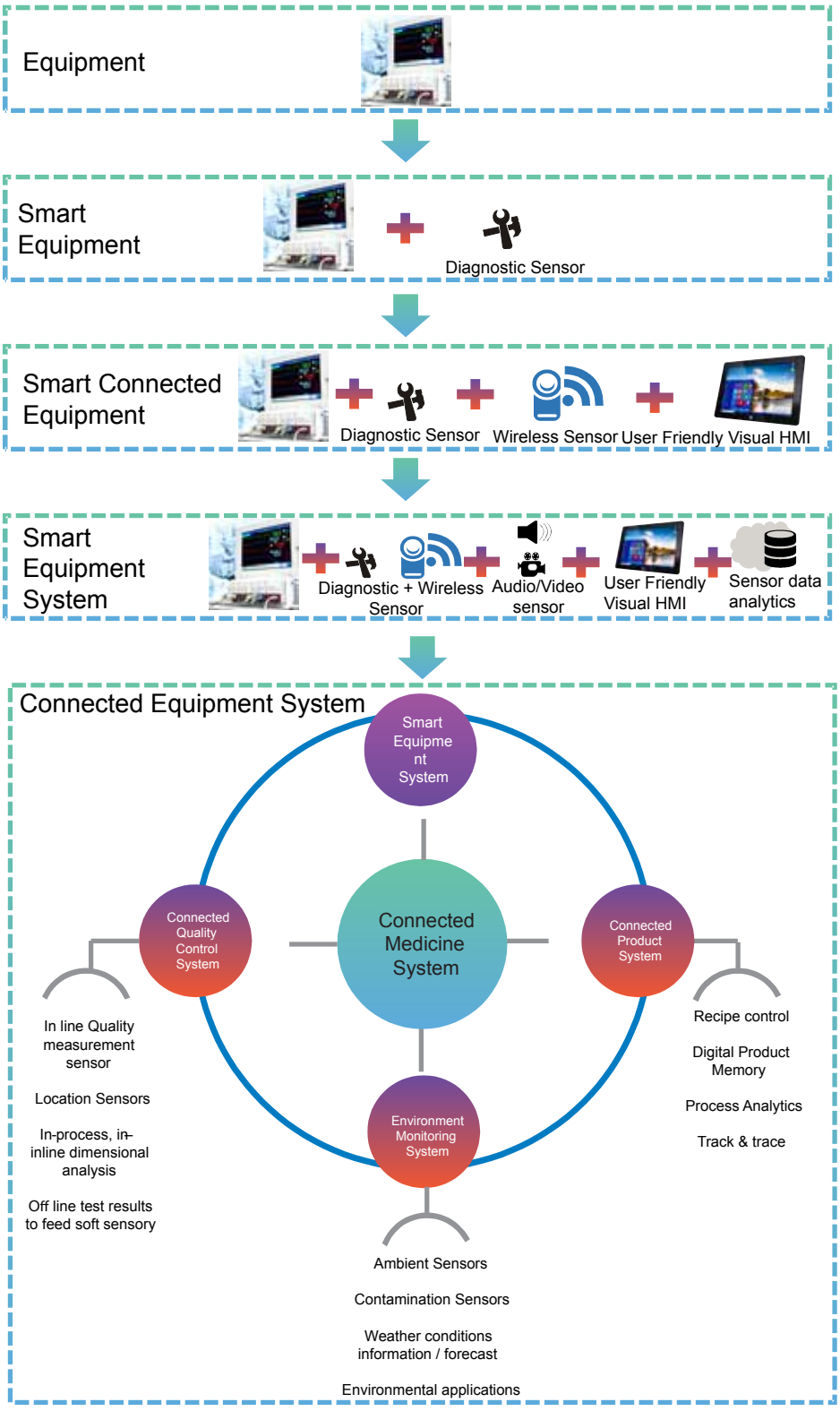
- **Connected patients:** the use of wearables, health patches, and ingestibles helps patients closely monitor and make informed decisions regarding their health. The data collected can be used to schedule primary healthcare appointments, enable online access to medical records, and analyze lifestyle factors and activity levels. Such a system when connected with other health data feed systems can:
  - Facilitate customized and personalized health feeds
  - Support the tracking of treatment outcomes
  - Help identify the probability of relapse or success of different treatments
  - Deliver tailored insurance plans and loyalty program

Figure 5 depicts a connected patient system.



A connected patient system

- **Connected equipment:** the IoT-based approach in manufacturing equipment is supported by the rise in the use of non-contact sensors to measure critical quality attributes. By using Big Data analytics and complex event processing, pharma equipment can be converted into an IoT-enabled product vending machine. Figure 6 depicts a connected equipment system.



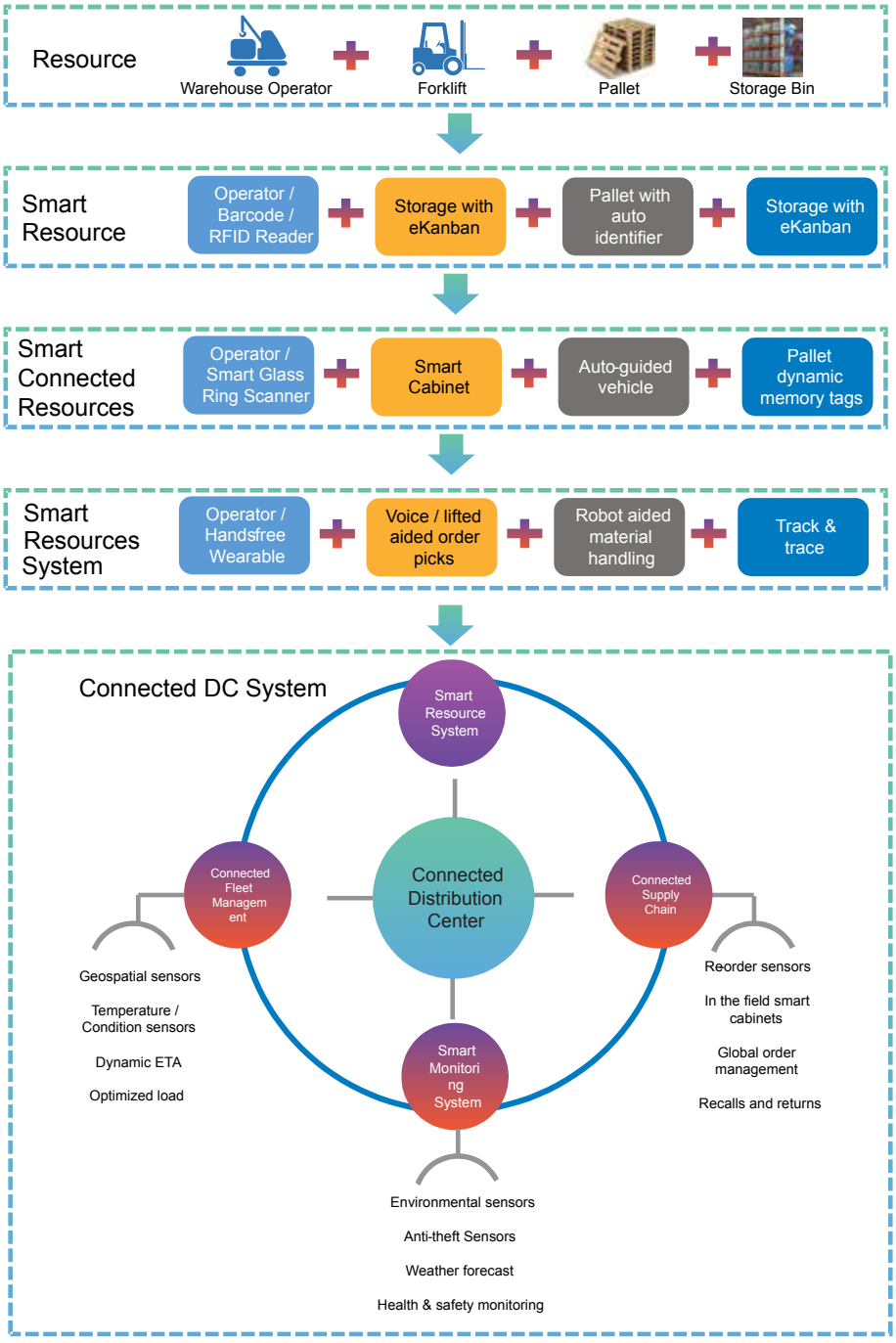
A connected equipment system

- **Connected workplace:** A connected distribution center, as shown in Figure 7, can be used to illustrate the concept of the connected workplace. The distribution center operations involve four key resources—operators, material handling equipment, storage containers or bins, and the material itself. To create a connected workplace, resources are first made smarter and connected to create a connected distribution center. For example, packaged material can be identified by dynamic memory tags that store information such as dimensions, current location, and movement history. The package can be connected to Auto-Guided Vehicle (AGV) location sensors that indicate a busy area. The AGV, after picking the material, is directed to its dock location for loading where an operator with a tablet follows instructions on the loading sequence to the truck. This connected workplace approach completely redefines the workplace by improving turnaround times, reducing equipment repair, and enhancing security.

Accelerating the Evolution of Connected Systems

The RxMxDx framework has the potential to help in the following:

- Track products from the point of manufacturing to points of dosage, implant, or test with a centralized scalable application
- Optimize and simplify the management of product life cycle activities across multiple countries for all products, intended uses, configurations, kits, and associated labeling
- Track the lifecycle of the product or service Gain insight into medical and manufacturing equipment performance
- Create safer drugs, devices, and tests
- Implement patient-centric clinical trials and ensure dosage adherence
- Underpin new business models centered around services



A connected workplace system

Conclusion

From deploying sensor-based devices to the monitoring of digital data, the IoT offers enormous potential for Digital Reimagination™ of business models, patient-centric services, and development of intelligent products. For the life sciences industry, the innovations and the emerging technology environment offer the promise of improved performance and safety. In essence, IoT will become the fundamental enabler that simplifies complexity and enhances efficiency of healthcare delivery across the entire value chain—from the point of manufacturing to the point of care.

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Pharma Quality:
Time to Transition from Fixing to Prevention

Abstract

In the pharma and biopharma industries, product quality is inspected during and after manufacture. Quality is mostly tested through inspection and fixed in case of a failure. However, without real-time monitoring, such failures sometimes go unnoticed, increasing appraisal cost and, in turn, Cost of Bad Quality (CoBQ). Breakthrough technologies, such as the tools and techniques of Business 4.0 and new age quality benchmarks, can fix these issues and reduce failures.

This paper focuses on predicting and preventing such quality failures using contemporary technologies that were not available in the past. We have tried to highlight the significant problems in biopharma upstream, tablet manufacturing, and other related industries. Additionally, the paper offers a view into solutions for these issues using the current breakthrough technologies.

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Introduction

A batch failure in the pharma manufacturing industry can cost about USD 1-2 billion1 depending on the type of drug. The cost of QA investigation (additional appraisal cost), additional cleaning, and miscellaneous costs can push the amount even higher. Moreover, a batch failure will delay the next batch. The CoBQ will include the cost of fixing internal failures and implementing CAPA.

The CoBQ will also increase the Cost of Quality, which amounts to 15-25%2 of the operation cost (see Figure 1). Per Juran2, we need breakthrough improvements to shift the needle from CoBQ to Cost of Good Quality (CoGQ). Such breakthroughs can be in the form of new tools and technologies like advancements in manufacturing technology and analytical capabilities. Nevertheless, can IT advancements help shift this needle?

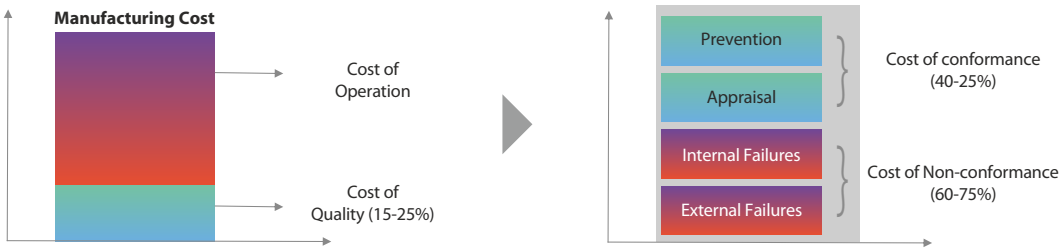

Figure 1: Cost of Quality

The answer is yes. It is possible to transform CoBQ to CoGQ today — the digitalization of quality management and its impact on people, processes and products3. New age quality benchmarks leverage connection, intelligence, and automation for better quality. Additionally, breakthrough technologies will connect and automate the process, people and systems, something that wasn't possible five years ago. A combination of Business 4.0 and new age quality technologies can enable prediction and prevention of failures, reducing additional appraisal cost post-failure.

Monitoring Failure

Upstream manufacturing processes in the biopharma industry include several parameters, physical (temperature, pH, DO) and chemical (c-source, anti-foaming agent), that are monitored periodically depending on the types of proteins and cells (bacteria/fungi/mammalian) involveda (see Figure 2). Changes in the parameters can impact protein yield and product quality. Post-transcriptional modifications particularly may affect product efficacy and safety, leading to catastrophic failures. Despite monitoring, failures occur due to legacy, disconnected, semi-automated systems. Offline analysis, which delays results, is a significant cause of failure in drug manufacturing.

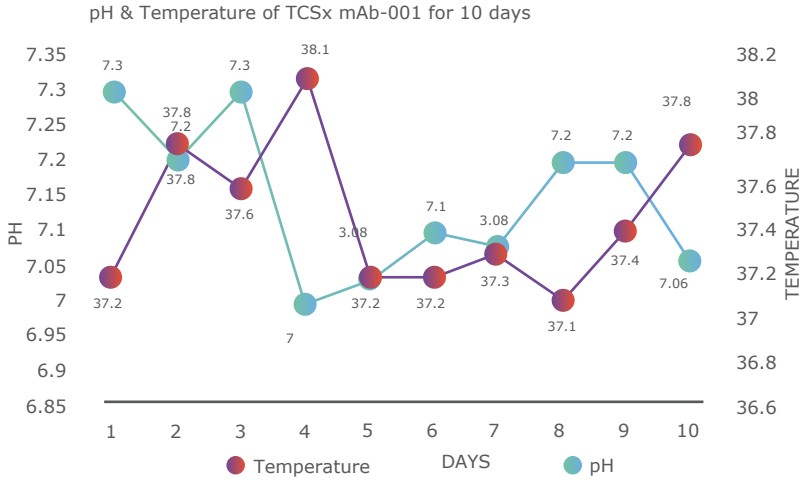

Figure 2: Data indicating mAb's pH & temperature variation over a period of 10 days

Online monitoring has been made possible by technology. Sensors and actuators monitoring production in real-time and ensuring quick intervention in case of errors have enhanced product quality. Online and at-line analyzers — in conjunction with Artificial Intelligence (AI), Machine Learning (ML), and automation — proactively and continuously scan upstream and downstream processes to detect the slightest variations in critical parameters and automatically make necessary corrections without human intervention.

However, complex upstream processes in a bioreactor can impact cell growth and productivity. Legacy systems do not allow the prediction of the effect of various components and parameters on cells. This affects the cell population and overall productivity, requiring experts to spend considerable time and effort to optimize the process. But despite such effort, process prediction overall remains a black box.

A Technological Leap

A bioreactor digital twin can overcome the challenges. A virtual representation of the process of a real bioreactor — a bioreactor digital twin of a cell-culture bioprocess helps predict cell physiology in a bioreactor environment. This can prevent complex issues and meet challenges in biopharmaceutical industries. A bioreactor digital twin can be used with AI/ ML to correlate current and historical data to draw conclusions that inform decisions about current batches.

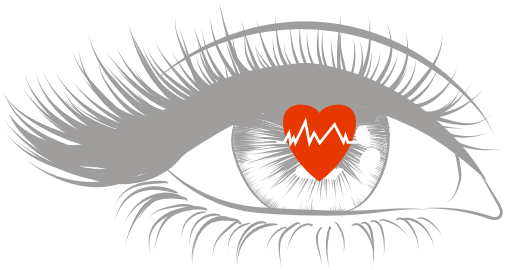

Figure 3: Google's algorithm can predict heart disease by scanning a person's eyes

We now have data monitoring technologies, sensors, and actuators that can predict changes per minute/second. Connected systems and automation allow the tracking of minute process variations. Abstract data model, graph, and DB can be leveraged for prediction-and-prevention, data crunching, and pattern finding. Just like Google's new AI algorithm can predict heart disease by scanning a person's eyes (see Figure 3), a new crop of breakthrough technologies can detect, and thus prevent, minute changes in processes.

In the tablet manufacturing industry, spots and specks are common quality issues. Spots are imperfections residing on the tablet surface, while specks can be present anywhere in a tablet (see Figure 4). Specks can either be visible on the surface or hidden within. Spots and specks appear due to leaks, over-lubricated upper punches, and undetected high temperatures. These can be grey, black or almost any other color, including white.[4]

Figure 4: Tablets having spots and specks

A batch of more than 10,000 tablets can be compressed and readied for packing before spots and specks have been identified. Based on in-process checks, the Quality team would stop further processing of tablets, investigate the batch, and finally reject it. In such a scenario, what technology or tool can help best?

Failures usually happen when they go undetected, or there is no predictive alarm in place. Right technology can save the tablet industry money, time, and resources gone to waste because of specks and spots. Ultra-fast moving cameras using visual analytics, can capture and detect a problem in tablet production, alert relevant stakeholders, or automatically rectify it. Ultra-high-speed cameras with fast data transfer and analysis capabilities can record the entire production process.

Industrial Internet of Things (IIoT) allows operators to observe and stop the process over the phone (see Figure 5). The low cost of data, now in the region of $0.021 per GB (source: AWS), makes this a feasible option. Current technology is flexible enough to ensure the storage of only useful data after a batch completion and the rejection of only 100 tablets in a batch instead of 10,000.

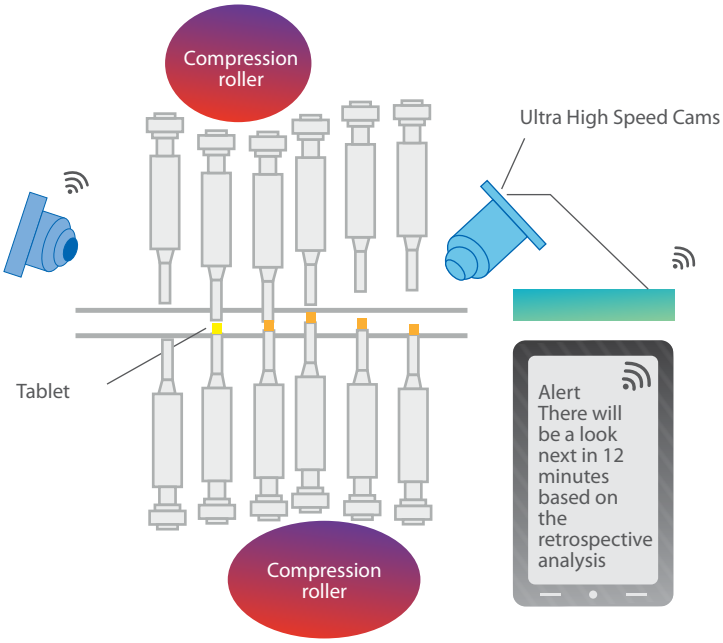

Figure 5: A high-speed camera in combination with visual analytics and AI/ML predicts failures in tablet compression

Humans typically do the repetitive work involved in granulation, drying, punching, validation, and final packing. This results in a lot of errors during manufacturing and data generation. Robotic process automation (RPA) — a software with a set of commands that communicates with the digital system to perform error-free tasks — can better execute such work and help reduce QA review time. A combination of current technologies, such as cognitive ML and deep learning with bots, will advance industry capabilities, moving from a predictive to a prescriptive model.

Benefits of Robust Prevention

While used frequently, the term 'transformation' is often misunderstood. The technologies discussed above do not transform a company; they optimize quality and manufacturing. For example, a pharma company used the cloud5 for supplier quality management (see Figure 6). All critical raw material suppliers were part of this, and Quality teams got to know of supplier changes as soon as it happened. This not only spread the quality culture for the manufacturer but also among all critical suppliers linked in the cloud.

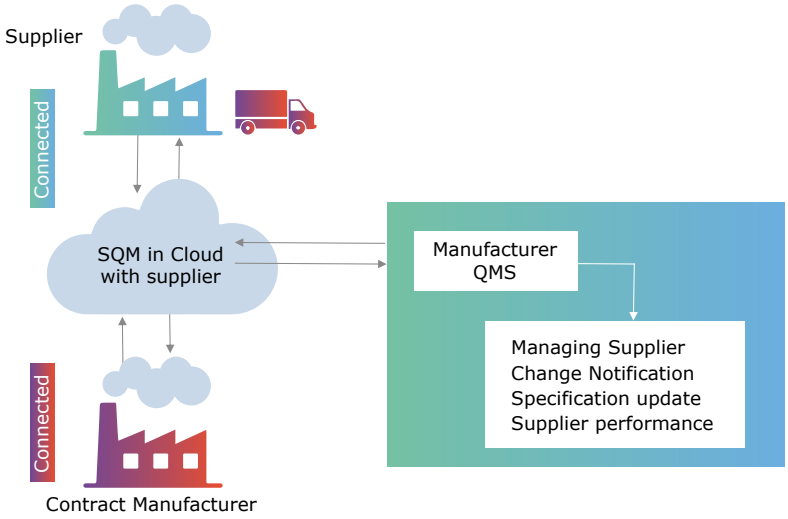

Figure 6: Cloud technology for supplier quality management

IIoT, a state-of-the-art technology, enables Quality and other stakeholders to obtain information online through mobile phones and computers (see Figure 7). A leading drug manufacturer has implemented IIoT for its Quality and production teams, enabling online process-status monitoring. Most line clearance and eBMR approvals happen over QA mobiles and tablets, reducing hold time in production and allowing the QA to monitor processes in real-time.

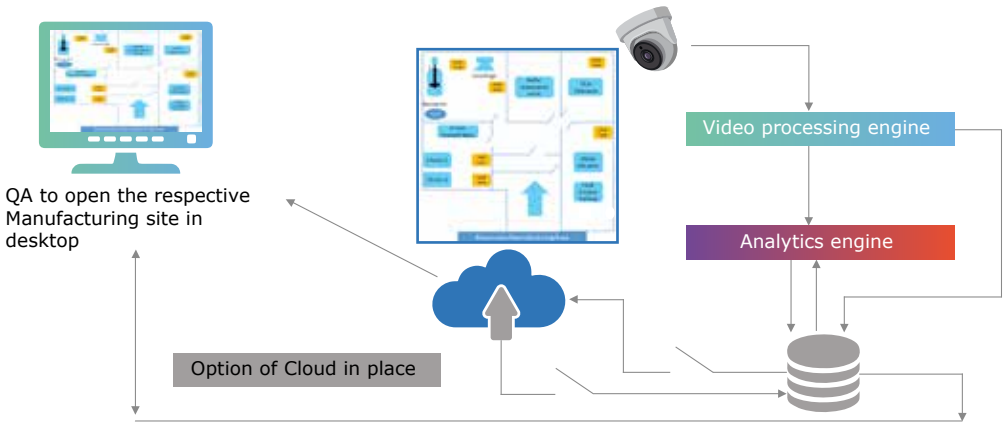

Figure 5: A high-speed camera in combination with visual analytics and AI/ML predicts failures in tablet compression

Conclusion

Quality — equipped with robust preventive and appraisal tools and technology — can prevent 80% failures. Most failures happen because of a wrong chemical or procedure being used or the lack of tools for predicting failures. Using a combination of modern technologies, such as Edge Intelligence, Digital Twins, sensorization in conjunction with cognitive computing, automation (RPA, bots), video surveillance, analytics, IIoT, cloud, and breakthrough pipeline technologies, can help make the process more efficient. Predicting and preventing failures denote no defects in products, no holds, no investigations, no deviations, and no CAPA. In terms of business benefit, this means a 60-70% reduction in CoBQ.

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Transforming Regulatory Affairs with Actionable Insights -

A Transition from Hindsight to Foresight

Abstract

A Unified Regulatory Information Management (RIM) system has helped the pharma industry achieve operational efficiency in regulatory affairs and realize significant value by reducing cycle time cost, improved global visibility, and better quality and compliance[1]. Similar progress on the Regulatory Intelligence (RI) front is the next target for the companies given the challenges from the proliferation of markets, products, information, scattered tribal knowledge, and resource constraints.

According to the Steve Gens (2018) Report, 58% pharma companies plan to enhance their RI capability and 51% of them are prioritizing RI for the next two years[2]. In another survey report, 20 of the 22 participating companies consider leveraging AI significantly in RI activities of data processing (mining, searching, monitoring, alerting)[3]. Hence, RI is poised to be the next frontier of importance, where value realization is expected in the analysis and application of intelligence.

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Rita Shah, Senior Consultant, Life Sciences, Advisory Services. Rita is a Clinical Research professional with over 23 years of experience in Pharma R&D. Rita has a PhD in Organic Chemistry from Council of Scientific & Industrial Research (CSIR) and Post doctorate Fellow in Endocrinology & Bone Metabolism from IUPUI, Indianapolis, USA.

She has more than a dozen research publications in peer reviewed journals. At TCS, Rita is actively involved in numerous R&D outsourcing transformation initiatives with the current focus on automation and helping to conceptualize and develop innovative solutions, as well as enabled process optimization.

Importance of Regulatory Intelligence (RI)

The regulatory intelligence group in pharma companies keeps track of new regulations for actionable RI. Besides analyzing, they summarize, evaluate and communicate the associated impact of the changes on product development to various relevant stakeholders for necessary action.

The entire product development life cycle is dependent on a well-defined and robust regulatory strategy. The foundation of this strategy relies on effective intelligence spanning various strategic and operational aspects, under the following categories[4]:

- **Regulatory Environment:** To get inputs for defining regulatory strategy and target product profile
- **Perceptive Intelligence:** Perspectives of industry thought leaders and various stakeholders to help companies with insights on how, when, and where to position their products
- **Procedural Intelligence:** To interpret the regulatory provisions to be consumed easily e.g. biomarker qualification
- **Competitor Intelligence:** To find the market perception of competitor products and strategize and plan accordingly e.g. to get away from risks like Refusal to File Submission (RTF), drug withdrawals, non-compliance, etc.
- **Regulatory Precedents:** To find novel regulatory approaches or deviation from normal practice (success or failure rate)

Future Perspectives: Fast evolving pharma industry has already started prioritizing RI. However, there is need to bring agility in the process to receive real-time regulatory feeds, such as updates on new legislation changes and impact, insights on regulatory position of the competitor that can offer market advantage, success rate of drug approvals and launches, timely feedback from regulators on product development for timely incorporations in product submissions, etc. Following issues keep the pharma companies from extracting such intelligence:

Extensive efforts required in the extraction of relevant insights from excessive levels of information

- Lack of confidence in the accuracy of the information, maintenance, and accessibility
- High investment in sourcing skilled resources trained to gather the right intelligence of value and understand the applicability of the information
- Time spent on the entire process of extraction, analysis, and dissemination of information

In order to sustain in a fiercely competitive world, the pharma industry has to stay updated and prepared for evolving regulatory changes and legal requirements, obtain proactive actionable insights to build robust regulatory strategies for new product development, and rapidly acquire market insights on competitor products.

Improving Agility in Regulatory Intelligence

In order to meet the current challenges, Regulatory Intelligence needs to be agile. Our vision of an agile Unified Regulatory Insights is to transform the processes of data acquisition, summarization, analysis, application, and integration. A high-performance computing powered RI Platform leveraging cognitive technologies such as RPA, NLP, and AI/ML can be used to enable autonomous data acquisition and ingestion, and abstraction of data models and content storage. Following key transformation enablers can be leveraged to transform RI:

- **Smarter Data Acquisition:** Smarter Data Acquisition can be achieved by the adoption of standards and abstracted and referenced data models, controlled ontologies and vocabularies. This will enable smart crawling, extracting, storing and indexing of the data for faster data acquisition. For example, crawling regulatory websites and other resources for instant information extraction for product label changes, or for various regulatory changes can be enabled by using industry-aligned ontologies driven by open standards.

- **Machine-First Processing:** Intelligent data contextualization, by leveraging high and faster computing cognitive capabilities, can help quickly recognize the context of the queries and extract relevant useful information. Commoditization of machine learning and deep learning allows better synthesis and AI-powered real-time analysis of information. Advanced analytics can help derive insights and produce an autonomous report from machine-driven intelligent analysis of information.

- **Smart Communication Execution:** Business agility can be achieved by the application of automated and intelligent technologies linking derived insights from smarter data acquisition with smarter communication strategy, like daily notifications, embedding insights into processes, automatic updates, and leveraging rule libraries to auto-purpose the content. This will transform RI delivery by automatically delivering the right insight to the right audiences in the right communication format, hence transforming the user experience.

Transition to Unified Regulatory Insights requires some foundational elements like:

- Defining regulatory data space/creating semantic data models and universal vocabulary

- Creating ontologies/referential to enable classification

- Abstraction of information, smart data management, and visualization

- Advanced analytics to derive impact analysis of insight

With the vision of unified Regulatory Insights in place, let us understand how such a vision can be realized in the context of Agility in Regulatory Intelligence.

a. Considering a case of a newly released guidance on new trial design considerations for oncology drugs: The system can autonomously sense for any new or changed guidance from regulatory sites, abstract the relevant information by applying controlled vocabularies, and autonomously prepare and communicate a summarized report based on predefined strategy with a link to the actual guidance document. Additionally, with the help of the rule library, it can provide hints and pointers to show the impact and follow-up actions.

b. In an another example of new guidance issued by regulatory agencies on change in content and format of labels in pediatric drugs, an alert may be sent to the identified stakeholders for necessary impact, which may include actions like the creation of new SOP or making new changes in SOPs or need for training.

The vision of Unified Regulatory Insights, in addition to identifying, summarizing, and reporting the impact of regulatory changes is to further assist in actions to be taken after impact assessment. For example, in the case of a new SOP creation, it can aid the drafting of the SOP by providing an updated version of the SOP template with prepopulated sections. For timeline-specific mandatory regulatory requirements, the system may send triggers and notifications for deadlines at fixed intervals to relevant regulatory SMEs for avoiding the risk of non-compliance.

Benefits

Unified Regulatory Insights we believe will potentially transform the entire Regulatory Affairs through:

- **Unified RI hub:** It can facilitate the end-to-end process of information/data acquisition, processing and communication, and enable data ingestion, intelligent synthesis and analysis, content storage and strategic communication. It is expected to transform the process of data/information management from manual to highly automated.

- **Efficient Processes:** The RI hub can promote a standardized approach to manage regulatory intelligence by the adoption of ontologies and semantic-based models. It is expected to increase the speed of information processing from weeks to days and hours.

- **Better Communication:** It can intelligently analyze the communication strategies as per the need and provide more dynamic and richer content rather than static insights. It can also provide high or extended granular visibility.

- **Proactive to Predictive Risk Management:** It can enable the generation of technical, procedural, strategic, and scientific intelligence, and provide inputs for product development strategy and go/no-go strategy based on calculated scores. With a predictive analysis of operational parameters, it can predict risks for better decision making.

The Road Ahead

To realize the significant value through the Unified Regulatory Insights, a minimum viable product (MVP) approach can be considered, for which it is important to consider the following:

1. Understand the need and plan to achieve the RI objective based on current challenges, desired outcomes, etc.

2. Assess where to focus, data availability, data harmonization and/or competencies available.

3. Visualize the technology investment buy-in roadmap to realize value from the platform.

4. Prioritize the capabilities to generate a high RoI.

5. Pick high-impact use cases rather than trying a big-bang approach.

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