WHITE PAPER

HOW LIFE SCIENCES COMPANIES CAN TRANSFORM INTO INTELLIGENT ENTERPRISES THROUGH PERSONALIZED MEDICINE

Abstract

In the recent past, life sciences companies have taken important steps to improve their business processes and drive greater efficiencies in drug development and commercial operations. The industry is set to embrace transformation initiatives at a faster pace in the coming years across many functional areas like commercial, clinical, regulatory, and quality. In the area of product development, companies want to streamline end-to-end processes to accelerate time to market and maintain compliance. Commercial teams continue to focus on driving smarter engagement with patients as they launch specialized products. Additionally, regulatory burdens, always a major industry concern, have become even more challenging due to the recent reorganization among government agencies and increased scrutiny. To stay ahead, the business model must change from a product-centric supply chain to a patient-centric value chain.

This paper explains how technology is driving this business model transformation. It also explains how Infosys solutions and offerings from our SAP practice can help life sciences organizations become digital, stay relevant and transform into intelligent enterprises.

Infosys®
Navigate your next

The changing life sciences industry

In the healthcare space, life sciences companies have long been perceived as manufacturers that manage their own customers. Physicians, for their part, prescribe medicines that are clinically effective and safe to use.

To stay competitive, life sciences companies must transition to a business model that is patient-centric, agile and flexible. In the new model, the focus is on health outcomes, i.e., a measurable change in the health of patients. Every stakeholder in the value chain is well-informed and plays an active role in decision-making.

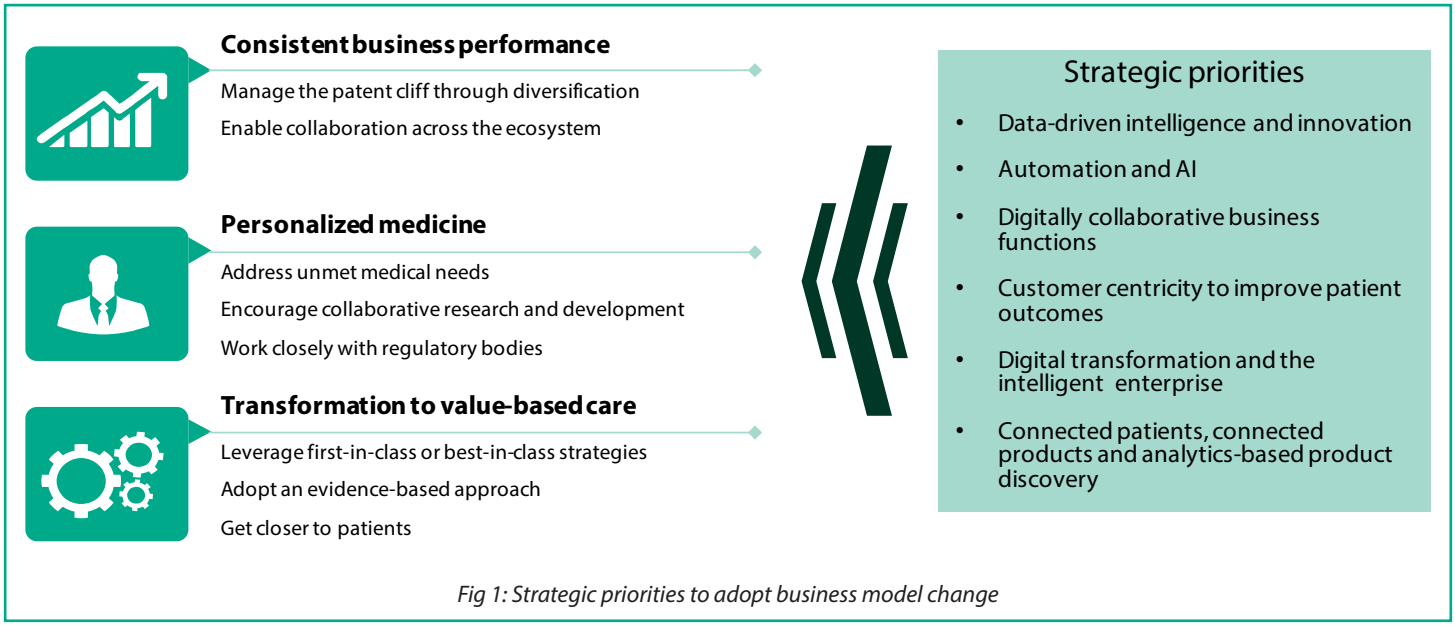


Fig 1: Strategic priorities to adopt business model change

"The life science industry has been a late adopter of most innovative technologies, despite the fact that they do have huge R&D budgets at their disposal." ***- Source, McKinsey***

What is personalized medicine?

Personalized medicine is an evolving concept in the healthcare business. It is about managing each patient's clinical, genetic, genomic, and treatment data. The objective of personalized medicine is to improve treatment outcomes and reduce adverse events, both of which are ultimate goals for clinicians as well as patients.

The field of cell and gene (C&G) therapy involves using genes and cells to treat disease. A gene is the unit of DNA that contains hereditary information passed down across generations. Together, all genes present in an organism make up the genome. Disorders or mutations in genes result in the loss or change of function in the RNA (protein molecules), which causes genetic diseases.

Gene therapy is the use of genetic material to treat genetic diseases. This may involve adding a wild-type copy of the gene (gene addition) or altering the gene with a mutation to the wild-type gene (gene editing). Gene treatment can take place outside of the body (ex vivo) or inside the body (in vivo). To introduce the new or edited gene into the genome within the cells, modified viruses or other vectors are used.

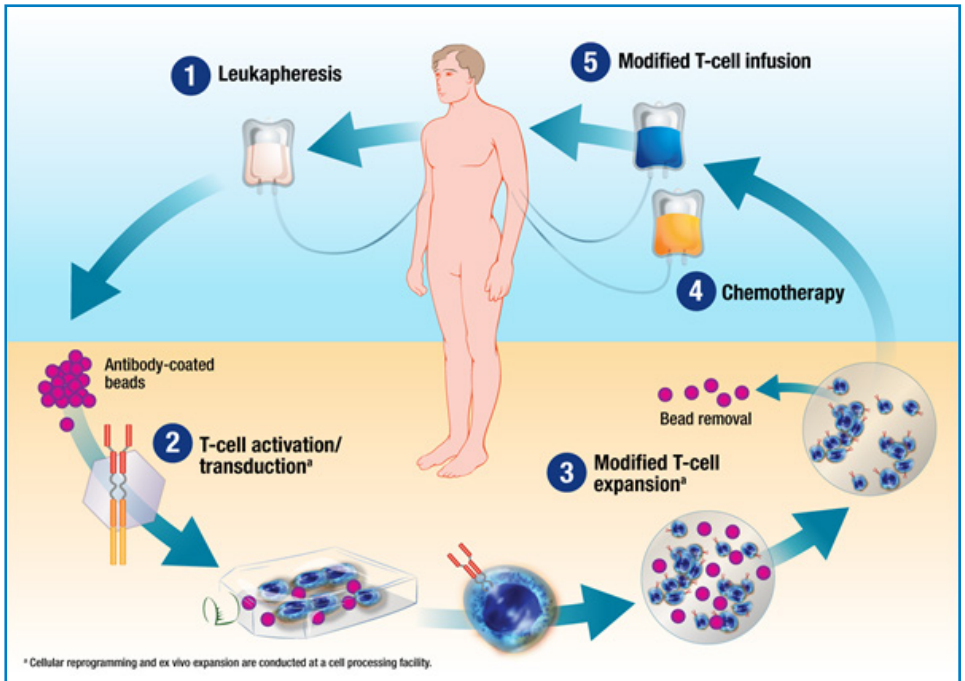


Fig 2: End to end process of cell and gene therapy

Cell therapy is the use of cells taken either from the patient or from a donor to treat diseases. Cells used for cell therapy are often stem cells, i.e., cells that can mature into different types of specialised cells.

Business processes

Manufacturing C&G products is complex when compared to traditional therapies. Traditional medical products are manufactured through a linear process from mass production and packaging till delivery to patients. Unlike this, the manufacturing of chimeric antigen receptor T cell (CAR-T cell) therapies is a highly sophisticated, circular process that is individualized for each patient beginning with extracting the patient's cells and ending with infusing the cells in the same or a different patient. Enabling patient access to C&G therapies requires close collaboration of suppliers, manufacturers, service providers, and regulatory agencies.

There are three important entities in this business process, namely, the apheresis center, the manufacturing site and the infusion center.

A patient's white blood cells are extracted through a specialized blood filtration process. These cells are then cryopreserved and sent to the manufacturing facility for processing. After strict quality testing to ensure the safety and potency of these cells, the CAR-T cells are cryopreserved. Then, the CAR-T are released and shipped to the treatment center where they are infused into the patient's blood. The entire process must comply with strict guidelines.

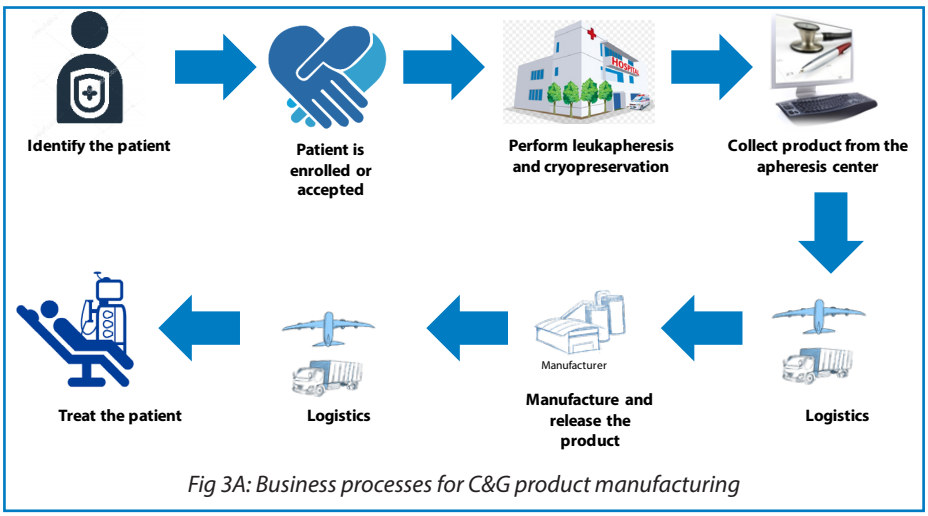


Fig 3A: Business processes for C&G product manufacturing

ERP process flow for personalized treatment

Personalized treatment is a make-to-order process where a production order is triggered by a sales order. So, the manufacturing process will begin only once the sales order is generated by the customer.

Customer service teams schedule the patient appointment upon receiving the patient request form. The production planning and detailed scheduling (PP/DS) functionality is used for capacity planning and scheduling of process order operations.

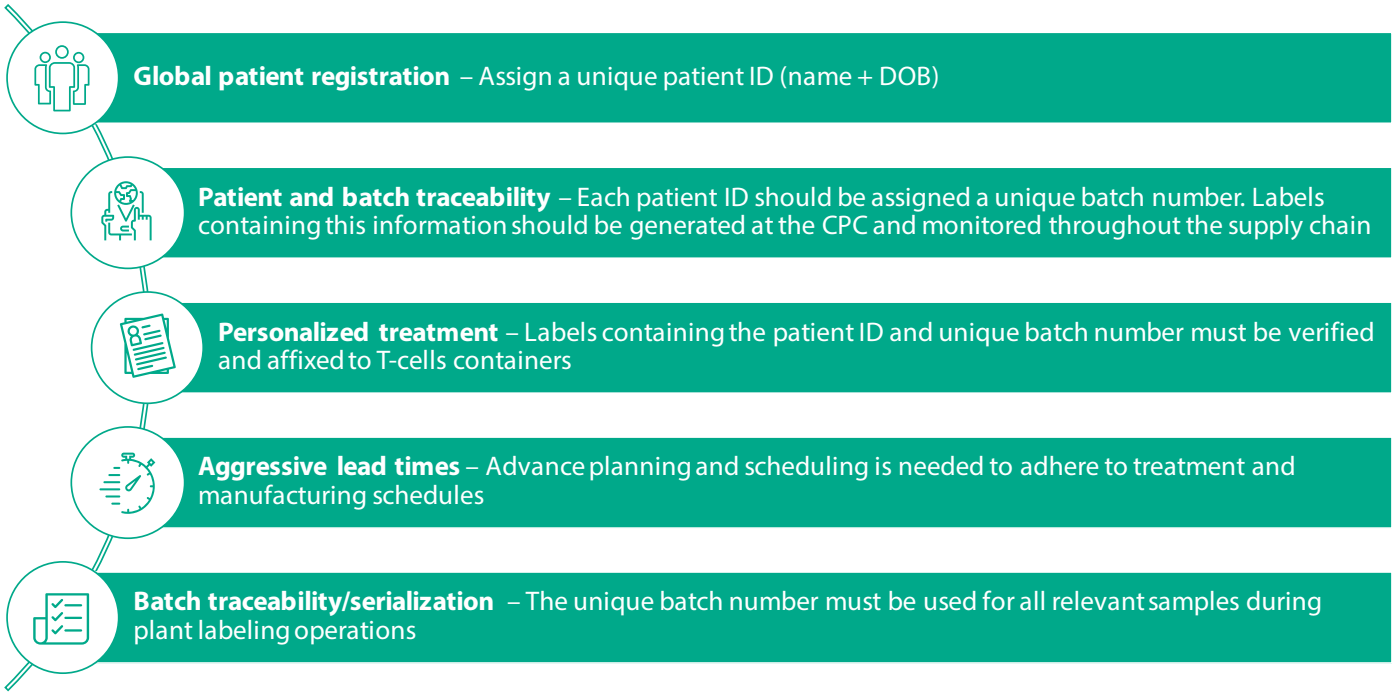


Fig 3B: Business processes for C&G product manufacturing

Once the patient's appointment is confirmed at the apheresis center, a unique batch number is generated. This represents an individual treatment number.

Then, the SAP purchase order for incoming cells, the process order for manufacturing and the sales order for the finished product are created. The unique batch number is used to represent the incoming cells that will be used as raw material to create the finished product and other dosages in the manufacturing process. Patient cells are labeled all through the supply chain process with this unique batch number and these should be uniquely identifiable with respect to the patient. As the fresh cells have a limited shelf life, an expiry check is also implemented from goods issue till process order. For certain critical operations, a chain of identity ensures that the right material and batch is used across different operations.

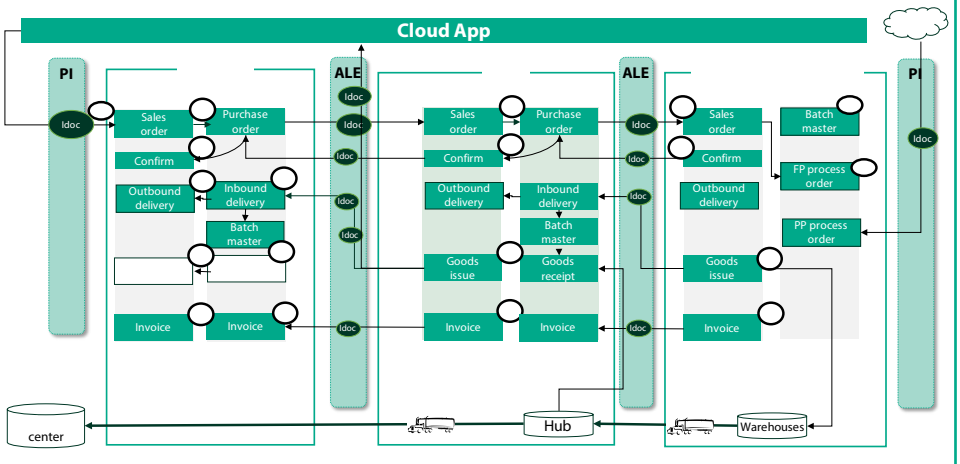


Fig 4: A cloud-based ERP solution for C&G therapy manufacturing

During shipping of the product, temperature-controlled reusable items are used that are integrated with an IoT platform to track temperature deviations. Finally, proof of delivery from the service provider is enabled to trigger final invoicing to the customer.

Business challenges

New breakthroughs in drug development are changing lives. However, there are major challenges faced by the life sciences industry that hinder personalized approaches and innovation in effective patient care. The challenges are broadly categorized based on the scientific processes involved, operational complexity in manufacturing and logistics processes, and regulatory processes as shown below:

Scientific challenges

- Small lot size/limited sample volume
- Limited availability of raw materials for process, product and test method development
- Patient-to-patient variability and cellular heterogeneity
- Complex manufacturing schemes and reagents
- Lack of long-term persistence
- Potential for insertional mutagenesis/tumorigenic potential

Operational challenges

Logistics

- Need for strong coordination between apheresis, manufacturing and patient treatment to adhere to the schedule
- Robust traceability and preventing product mix-ups is imperative
- Retrieval of shipping containers
- Retention samples add up fast

Manufacturing

- High cost of goods and labor
- Large manufacturing footprint
- Lack of patient materials for process and test method development

Regulatory challenges

- Lack of harmonized guidance between regions
- Lack of guidance for late-stage development and marketing authorizations
- Different types of regulations and marketing pathways in different regions
- Inconsistent classification of products in various regions

Fig 5: Business challenges in C&G therapy models

Apart from these, the C&G therapy model lacks maturity in a few critical aspects. It is important to address these to stay ahead of the competition:

- Lack of manufacturing controls and standard operating procedures
- Lack of product characterization early in development that can support comparability studies and late phase development
- Limited focus on process efficiency and cost of goods
- Little or no experience with multi-site studies
- Lack of preparation for marketing
- Poor understanding of global regulatory requirements

Business imperatives for personalized medicine in C&G therapy

Life Sciences firms can reframe the above challenges into opportunities and quick wins by focusing on the key business imperatives as shown in the figure below:

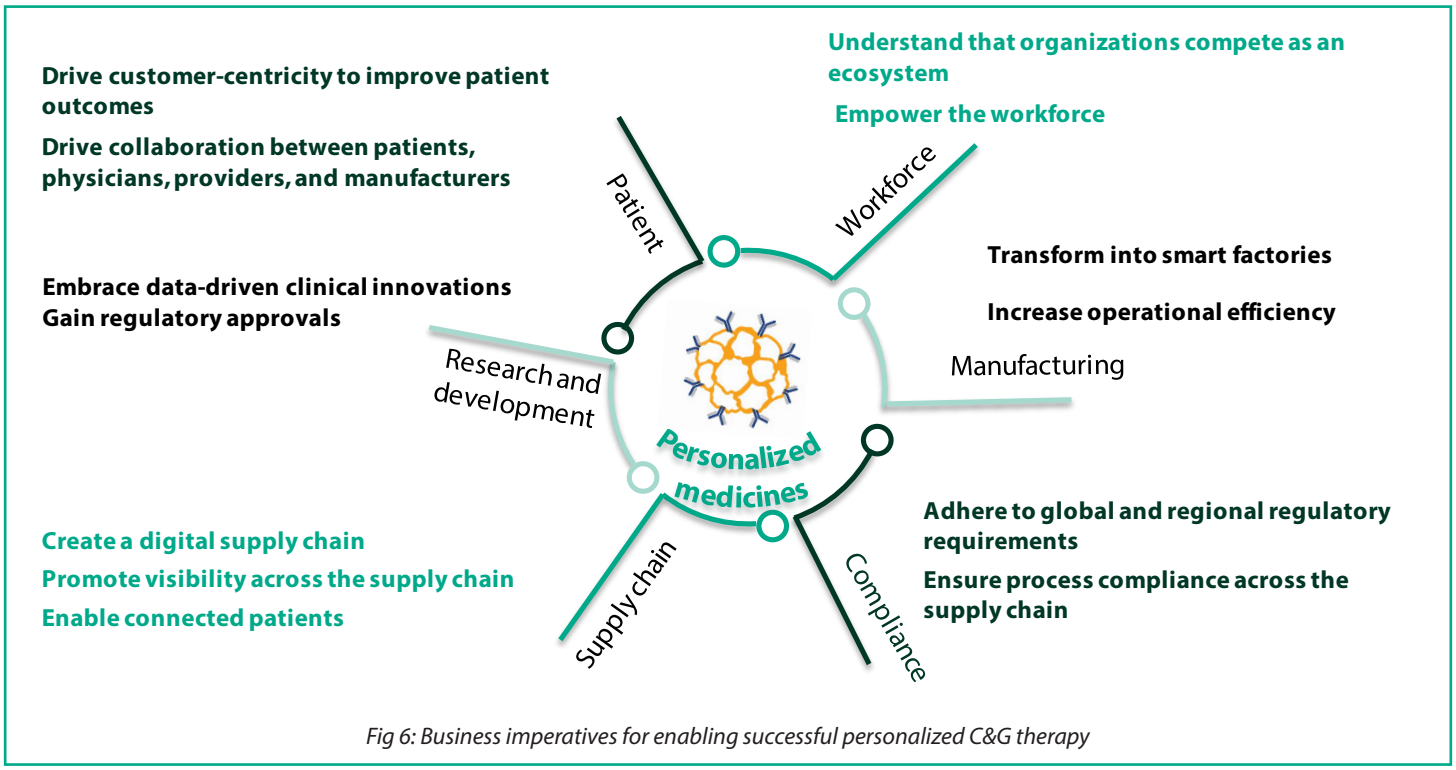


Fig 6: Business imperatives for enabling successful personalized C&G therapy

These imperatives will help life sciences companies improve patient satisfaction, health outcomes and collaboration between all the stakeholders involved during the treatment. Leveraging the right digital technology solutions such as digital supply chains, connected patients and smart factories will ensure that the organization remains competitive while adapting to the demands of the digital age.

Enabling intelligent personalized medicine processes

Moving to the SAP S/4HANA platform can help life sciences companies become digitally-ready. While the native HANA database and its underlying process efficiencies provide an immediate uplift, the SAP Cloud Platform (SCP) and SAP Leonardo enables digital innovation. By leveraging all these along with other new technologies, companies can transform into intelligent enterprises to tackle the challenges of tomorrow.

Infosys has developed the following use cases that leverage Internet-of-Things (IoT) and machine learning platforms to enable intelligent and personalized medicine processes for life sciences companies:

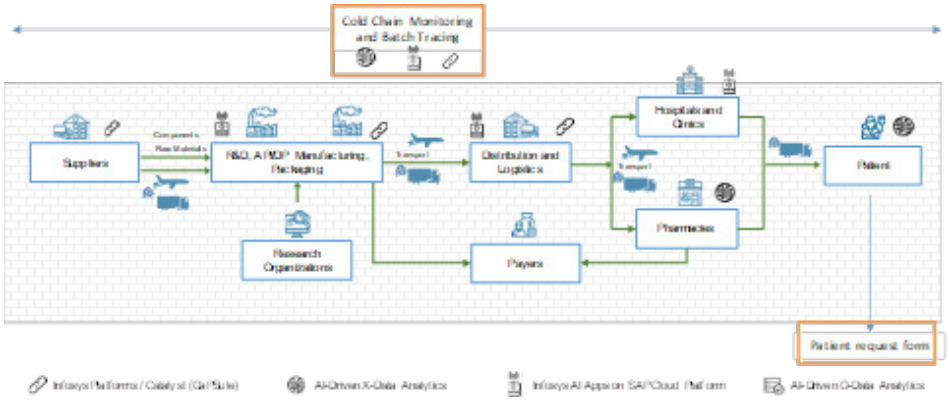
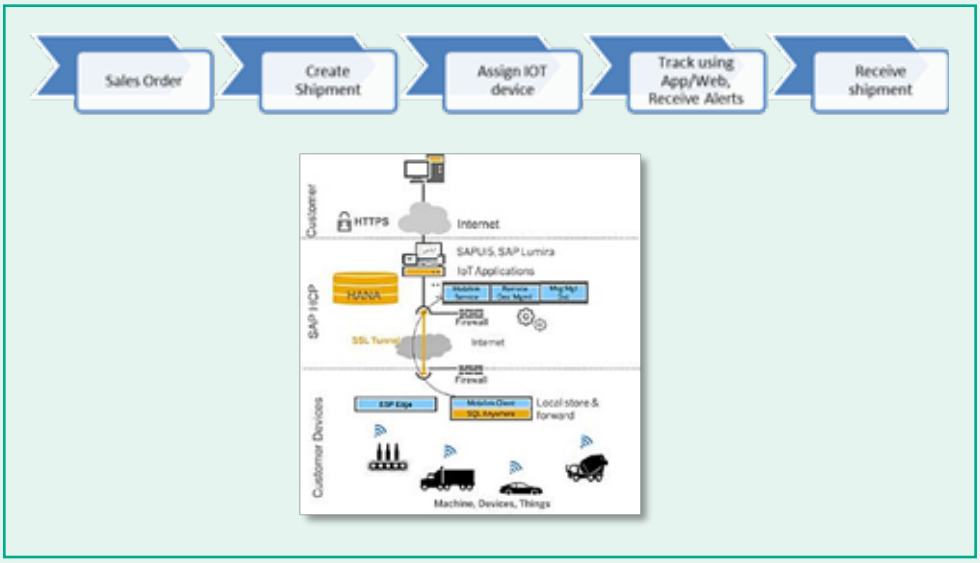


Fig 7: Infosys use case for cold chain monitoring

1. Cold chain monitoring with IoT sensors

The C&G supply chain involves several parties. Patient cells need to be transported and handled in controlled conditions. While information about the product condition resides with each individual participant in the supply chain, there are challenges in tracking temperature deviations in real-time.

Infosys is planning to develop a solution that will allow businesses to track shipments in real-time and receive alerts in case of temperature deviations so they can take preventive actions.

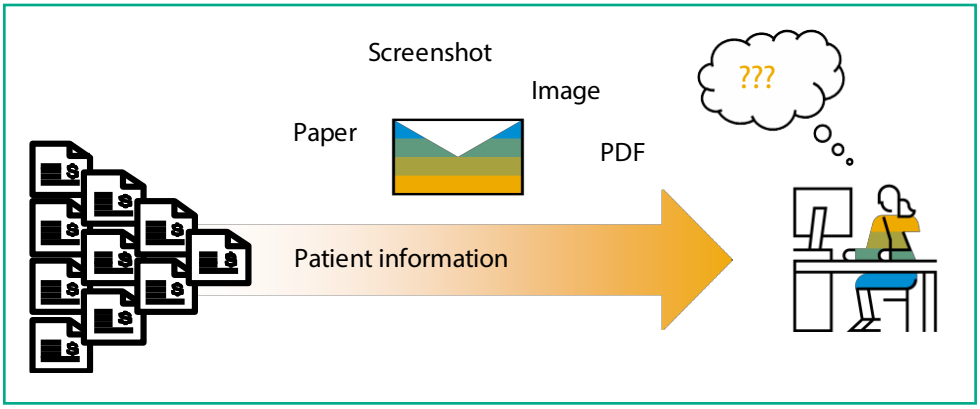


In our proposed solution, IoT sensors are placed on cryogenic packaging. These send real-time temperature data through the IoT platform. A portable gateway hotspot can be used in the warehouse or vehicles to transmit the data collected from sensors. This data is integrated into the end-to-end supply chain process and can be used for tracking, reporting and analytics. This will help businesses track products, improve visibility and enhance process compliance.

2. Auto-processing of patient request forms using machine learning

The C&G process begins with patient registration and is managed by customer service personnel. Customer service agents have to manually sort through emails/ paper-based forms that contain patient request information. As the information is unstructured and resides in various formats (paper, screenshots, PDFs, etc.), it can lead to delays in triggering subsequent process steps.

The proposed Infosys solution will leverage Optical Character Recognition (OCR) to convert information lying in patient request forms – whether this is in the form of scanned images, PDFs or text – into electronic text so that digitized data can be indexed and retrieved. To begin with, the solution would process data sets consisting of hundreds of thousand scanned documents or images in order to train and optimize the algorithms. This training dataset processing is typically done by humans to generate accurate data that can then be learned and applied by the engine, making it smarter over time.



Customer service personnel have to manually sort through emails/documents that contain patient request information.

The information is unstructured and resides in various formats like paper, screenshots, PDFs, etc.

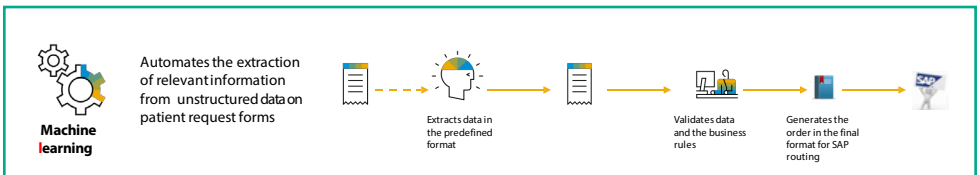


Fig 8: Infosys solution

Infosys digital footprint – How we have helped top life sciences companies

While many companies prioritize transformation into intelligent enterprises, the challenge often lies in creating the right implementation roadmap. Plugging supply chain gaps is crucial if companies are to stay ahead of the competition.

Over the past few years, Infosys has been helping clients transform their business processes by developing various proofs of concept (PoCs) that have delivered significant benefits. We help clients migrate to digital platforms coupled with digital solutions that provide greater business agility.

Infosys differentiators – Engage more to be more

Infosys has developed an overarching methodology to engage with clients through DevOps sessions, hackathons, ideation workshops, joint PoCs, etc. These provide a collaborative platform for co-innovation and encourage client participation to help achieve goals faster.

Infosys continues to create innovative solutions that leverage blockchain, IoT, predictive analytics, AI/ML, and other digital technologies. To help life sciences clients build smarter value chains, we are also working towards achieving SAP certifications for our solutions. By collaborating with SAP to design best-of-breed integrated solutions, Infosys empowers life sciences companies with a complete digital transformation experience.

Navigate your next with Infosys

Infosys works closely with clients and prospects by developing intelligent solutions, creating proofs of concepts for key process areas and helping clients realize the potential of disruptive technologies.

About the Authors

Suraj Patil, *Sr. Industry Principal - Supply Chain (Life Sciences), Infosys*

Suraj is heading Infosys SAP S/4HANA competency for Europe and has been part of various S/4HANA Greenfield transformation programs, global supply chain implementations within life sciences industry. He has played a role of Solution Architect and SCM expert in personalized medicine global implementation program at various pharma clients.

Chander Mohan Mehta, *(Lead Consultant – Supply Chain, Infosys*

Chander is the lead consultant with Infosys SAP practice. He has more than 14 years of experience in delivering large scale SAP implementation, rollout and upgrades for major pharmaceutical clients. He has worked in building significant supply chain solutions for pharma clients, with major focus in personalized medicine space. He has keen interest in enabling the enterprises with new technologies on IoT, machine learning etc.

For more information, contact askus@infosys.com

Infosys®
Navigate your next