



BUILDING A DISRUPTION-FREE DIGITALIZED SUPPLY CHAIN FOR CELL AND GENE THERAPY WITH ORACLE SUPPLY CHAIN CLOUD IN A POST- PANDEMIC WORLD

Abstract

The evolving cell and gene therapy industry in the pharma world is disrupting traditional supply chain business models. Addressing this development necessitates significant changes in the entire flow. These therapies need planning and design of optimized solutions to meet critical timelines. The biological material or drugs manufactured for allogenic process must be dispatched under stringent temperature control and timelines, keeping the chain of identity (COI) unbroken.

Infosys solutions for Oracle Supply Chain Management Cloud, part of [Infosys Cobalt](#), streamline the entire supply chain from supply planning for allogenic raw materials and other sub-assemblies required in manufacturing therapies to shipping those to logistic providers with all product genealogy details. With this, pharma companies can maintain the chain of identity across the product line and track the lots shipped.

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Introduction

Digital transformation involves reimagining systems, business processes, and data, and restructuring these to fit changing business requirements. Business process intelligence (BPI) is at the center of digital transformation. With the central focus on business processes, it accelerates

transformation by conducting in-depth process analysis during the project. It enables organizations to benchmark themselves against industry peers in order to identify potential areas for process improvement. Once the transformation reaches the sustenance phase, BPI helps improve process governance by providing

better visibility into operations and identifying instances of process deviations so that corrective actions can be initiated in a timely manner.

Business process intelligence is therefore a door opener for digital transformation and significantly improves the success rate of transformation projects



Cell and Gene Therapy in the Pharma World

Cell and gene therapy refers to the use of cells and genes to treat a disease. A gene is a DNA unit containing hereditary details

that is transferred from one generation to the next. A collection of genes is a genome.

Gene therapy refers to the use of genetic material for treating genetic diseases.

Cell therapy refers to the use of blood cells collected from donors or patients for

treating a disease. Cell and gene therapy, together, can change the way the medical world looks at defeating diseases. A combination of cell and gene therapy can provide highly targeted and personalized treatment approaches.

Allogenic Therapy

Allogeneic therapies are developed from blood cells gathered from a healthy donor and processed at treatment sites for use as raw materials in the manufacturing process. Post-production, the final product is cryopreserved and dispatched to clinical trial sites or to hospitals for patient treatments. A just-in-time delivery process, including packaging, labeling, and passing

audits is mandatory to ensure all regulatory and quality checks are met.

Pharma companies, in addition to their own internal manufacturing facility, may at times outsource the therapy manufacturing to external contract manufacturing organizations (CMOs) who are responsible for the final packaging and shipping to clinical sites. Figure 1 shows the process of manufacturing and shipping of allogenic therapies.

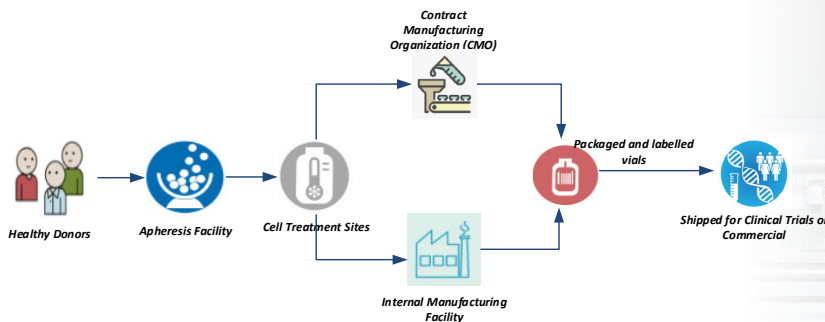


Figure 1 – Allogenic therapy process

The Need for a Supply Chain Model for the Allogenic Process

To manufacture cell and gene therapy products at scale, there is a need for an integrated solution with a seamless data sharing environment using Oracle PaaS technologies or other middleware. Maintaining the cold chain and stringent temperatures during transit is essential for the raw materials collected to produce the final drug.

The chain of identity (COI) is essential for clinical trust and patient safety. Providing COI traceability requires best-in-class enterprise software, a platform that is easily configurable and extensible. This data traceability provides a complete view of the drug throughout the supply chain from cell collection onwards until infusion to patients at medical centers.

Role of cloud technology

The challenges and risks involved necessitate the need for more digitization to integrate all operations involving patient scheduling, treatment site, manufacturing, planning, and logistics. For allogenic products, logistics plays a vital role in ensuring the therapy is administered to the right patient at the right time.

Many factors influence the supply chain flow and choice of transportation by logistic providers:

- Scheduled time for apheresis or blood cell collection
- Duration of the apheresis process
- Time of collection by logistic providers to ship to manufacturing plants
- Time taken to manufacture the final product
- Collection and distribution of the therapy to different sites and hospitals.

To ensure an unbroken COI, cloud technologies such as Oracle SCM and Intelligent Track and Trace (ITT) are integrated with systems for patient scheduling, manufacturing and third-party logistics (3PL) systems, and contract manufacturers. PaaS integration enables pharma companies to establish a seamless connection between logistics, manufacturing, and the cloud ERP system.

End-to-end integration with ITT ensures that all transaction documents (procurement/shipping) and attributes such as temperature, location of dispatch of a therapy, or any pharma ingredient can be monitored easily. This way COI is ensured between donor, procurement, manufacturing, shipping, and patient infusion.

High-Level Allogenic Supply Chain Using Oracle SCM Cloud

Figure 2 depicts a high-level supply chain including planning, manufacturing, and generating orders in Oracle SCM purchase and manufacturing modules.

Integration touchpoints at various stages of the supply chain cycle:

1. Inventory on hand sync-up with CMOs
2. Work order details with Manufacturing Execution System (MES). Most pharma companies use MES as their base manufacturing system
3. Drug shipments and acknowledgements with 3PL systems for sending shipping details to specialized courier service providers

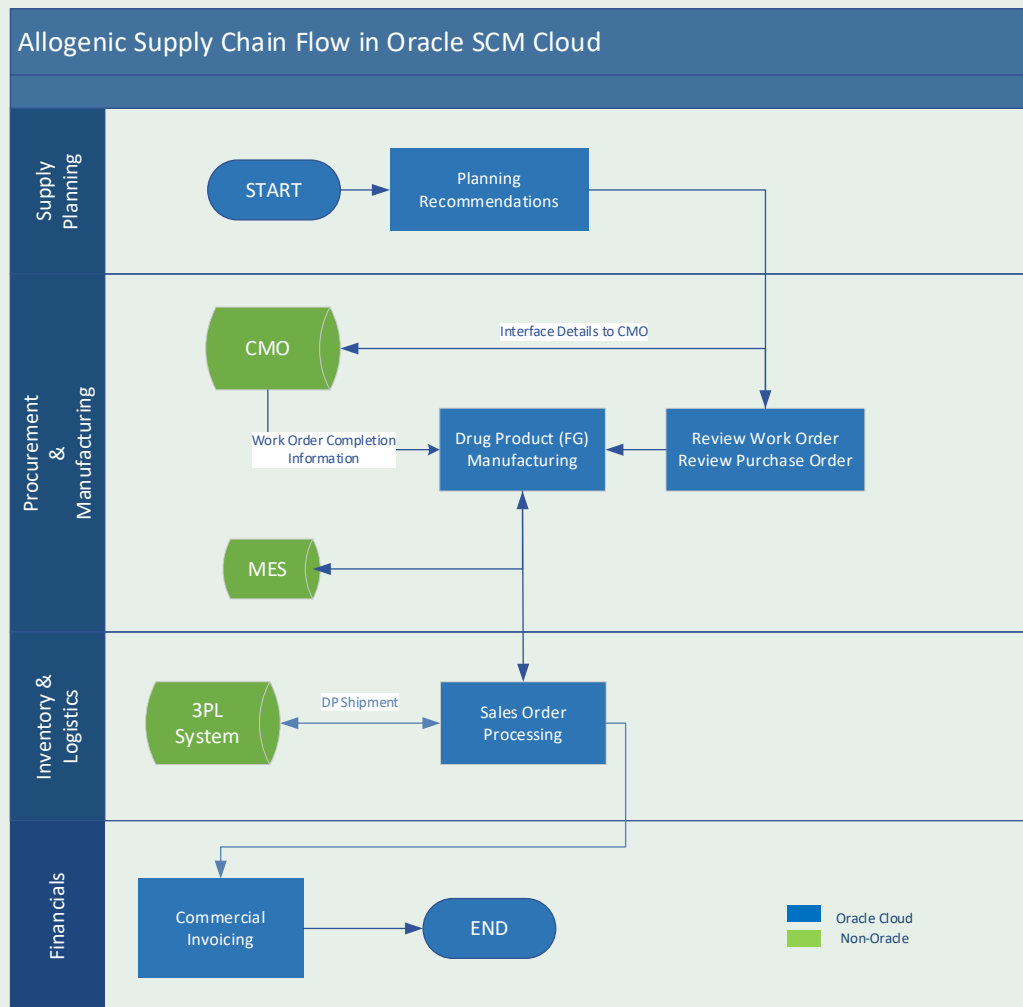


Figure 2 – Allogenic supply chain flow in Oracle SCM Cloud

Several Oracle SCM cloud modules are leveraged to manage the entire supply chain process flow for allogenic therapy manufacturing on a single cloud platform.

- **Supply planning**
Planning recommendations based on loaded forecasts will auto-generate purchase requisitions for raw materials, transfer orders, or work orders for allogenic drugs
- **Product data hub**
All therapy structures, including sub-assemblies used in the allogenic process, are maintained in the product data hub (PDH) and used for creating work orders in manufacturing for production

Figure 3 illustrates a simple allogenic therapy structure with one sub-assembly in the manufacturing process.

Legend

ALGN-FG – Allogenic Finished Good

RW – Raw Material

BSRW – Blood Sample Raw Material

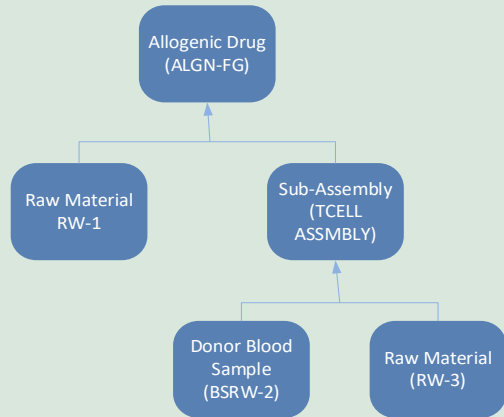


Figure 3 – Sample allogenic drug structure

Organizational structure

Figure 4 depicts how the warehouse structure looks in the Oracle cloud for a pharma company manufacturing allogenic therapies

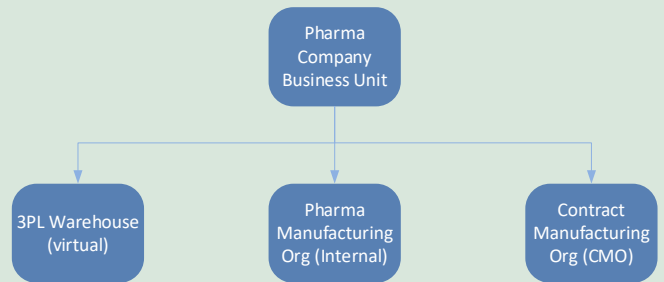


Figure 4 – A typical pharma company warehouse structure

Product genealogy is used to track allogenic drugs manufactured and shipped based on lots and serial numbers, donor purchase order, and the shipping document for the end dispatch to 3PL service providers.

Purchase

All requirements for raw materials to manufacture the product will flow into the purchase module and generate the necessary purchase requisitions

Manufacturing

All work definitions such as departments and resources to manufacture the allogenic drug are maintained as follows:

a. Order management

Distribution and order fulfillment is handled by creating sales orders for the final drug products

b. Receivables

Billing is handled by generating sales invoices for commercial customers of the manufactured drug

Supply chain architecture for allogenic drug manufacture

Figure 5 depicts the supply chain architecture with Oracle cloud ERP modules integrated with non-Oracle systems such as patient hub services, couriers, MES, and 3PL. The integration can be scaled easily using Oracle SOA/MFT or Oracle Integration Cloud (OIC) as the integration layer.

Requirements such as tracking COI will require Oracle PaaS extensions or enhancements to existing functionalities leveraging technologies such as Intelligent Track and Trace.

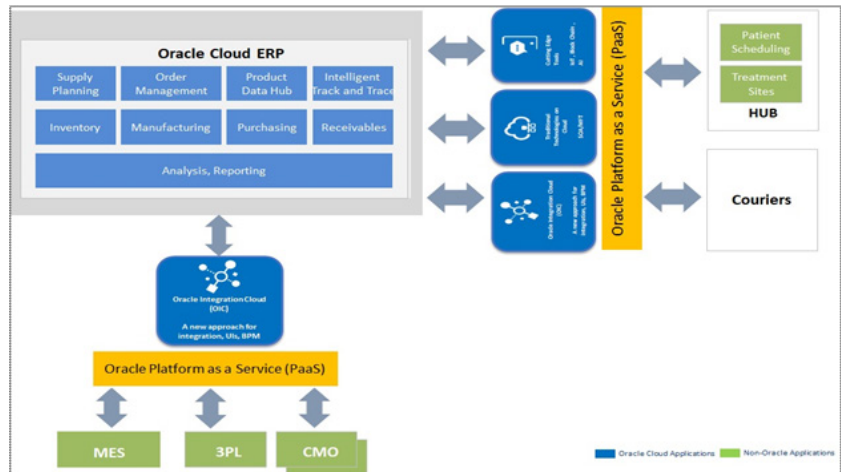


Figure 5 – System architecture for allogenic supply chain process in Oracle SCM cloud

Material flow in an allogenic supply chain process

Figure 6 shows a high-level material flow in an allogenic supply chain process in Oracle SCM cloud.

The example considers an indicative organization structure spanning all modules, talking to each other through on-hand transfers, purchase orders, or work orders. Data is also shared with non-Oracle systems such as CMO, MES, 3PL, and couriers.

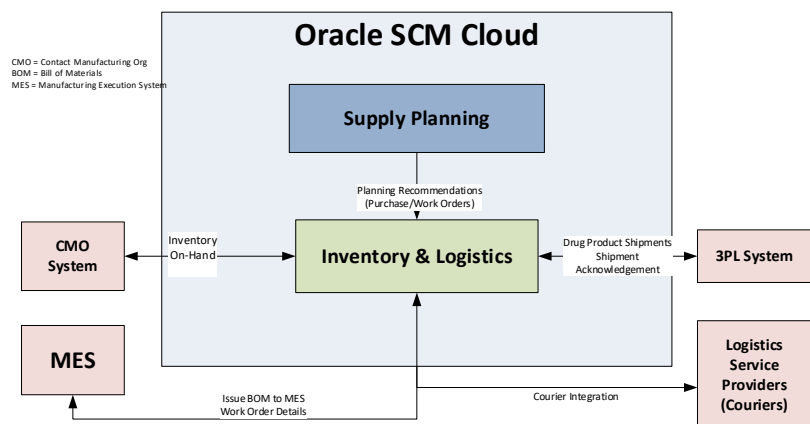


Figure 6 – Material flow for allogenic product manufacture using Oracle SCM cloud

Benefits of Oracle SCM Cloud

Given the sensitive and time-bound nature of allogenic therapy manufacture, having trackable systems in place is key to meeting all requirements of the process. An Oracle SCM cloud-based solution provides several critical benefits such as:

- Ability to complete therapy production and patient administration at the right time by generating work orders using recommendations based on historical consumption and forecasts. Reduces manual intervention
- A modular and extensible solution for configuration and integration with other non-Oracle pharma application systems for real-time tracking to keep the COI unbroken
- Adherence to patient treatment and safety, which are the core values in the pharma industry
- Ability to track and trace through ITT

Challenges in Cell and Gene Therapy

Cell and gene therapies show enormous promise as effective treatments, but there are some barriers and challenges that need to be overcome. The supply chain and logistics for these advanced therapies are critical to ensure that a patient gets the right treatment at the right time. Collaboration is the key to solving challenges such as data management and

process variability, as stakeholders work towards a common goal — getting life-saving treatments to the people who need them.

Key challenges include:

- Managing regulatory requirements of customs and border control as applicable. Additional regulations can come into play in the future in this space
- Handling personal data exchange related restrictions
- Tracking trans-shipment points across the chain of custody
- Dealing with changes in modes of transportation
- Being prepared to handle inclement weather hazards such as differences in weather between shipment and receipt locations, and the resultant impact on the supply chain
- Availability of resources such as personnel and material handling at the receiving facility

Infosys Oracle Services Vision: Exceptional Delivery, Promised Value

Our vision is to be the most trusted partner to transform our clients into resilient live enterprises, enabling them to achieve their business goals with holistic experiences and responsive value chains across their ecosystem, leveraging Oracle cloud practice and Infosys Cobalt.



Infosys Cobalt with its pre-configured solutions and innovation assets acts as an accelerator in the cloud transformation journeys of our global clientele. With Infosys Cobalt, enterprises can quickly develop prototypes and solutions to cater to dynamic trends and market demands while adhering to industry best practices.

Conclusion

Cell and gene therapies represent a breakthrough in medicine for the treatment of conditions such as cancer and life-threatening other diseases. Several therapies have been approved and many more are in final stages of research. These herald exciting times in terms of enhanced disease management and better health outcomes.

However, there are challenges in terms of making sure the drugs reach the right patients at the right time. Shipping and logistics, tracking and tracing, and regulatory requirements are major areas that need rapid response through seamless solutions.

Infosys Oracle Cloud Services along with Infosys Cobalt offers a robust end-to-end solution for the entire allogenic process using Oracle SCM cloud. This ensures that the chain of identity (COI) remains unbroken and intelligent track and trace mechanisms are in place throughout the entire process from raw material to treatment of the patient with the finished therapy.



About the author



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Debdatta is a Principal Consultant with the Oracle Life Sciences practice at Infosys. She has over 18 years of experience in Oracle applications. Her expertise includes implementing and leading Oracle E-Business Suite and Oracle Cloud engagements in procurement and supply chain management areas for clients across industries in North America, Asia, and Europe.



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