

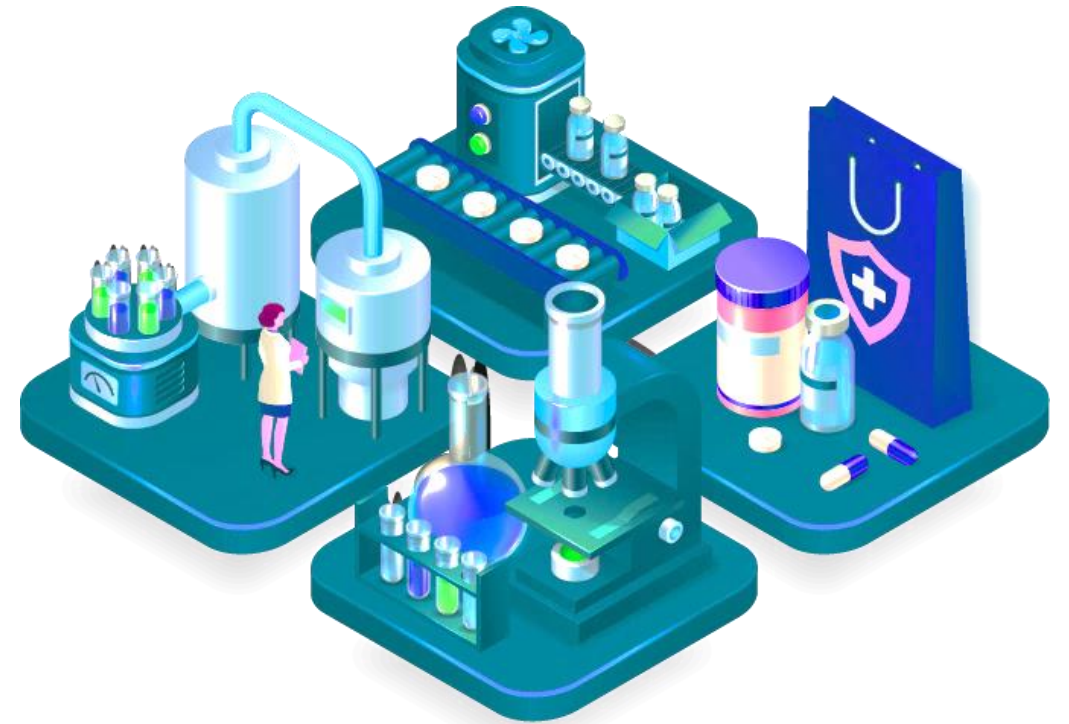
Cold Chain Management:

Time Out of Refrigeration (TOR)
For Life Sciences Leveraging SAP BTP



Agenda

- 01 Context and background
- 02 Industry challenges and imperatives
- 03 Solution features



Context & Background

01

Pharma APIs and finished products are often sensitive to **ambient parameters** like temperature, light, vibration, humidity as well as Time out of Refrigeration (TOR)

02

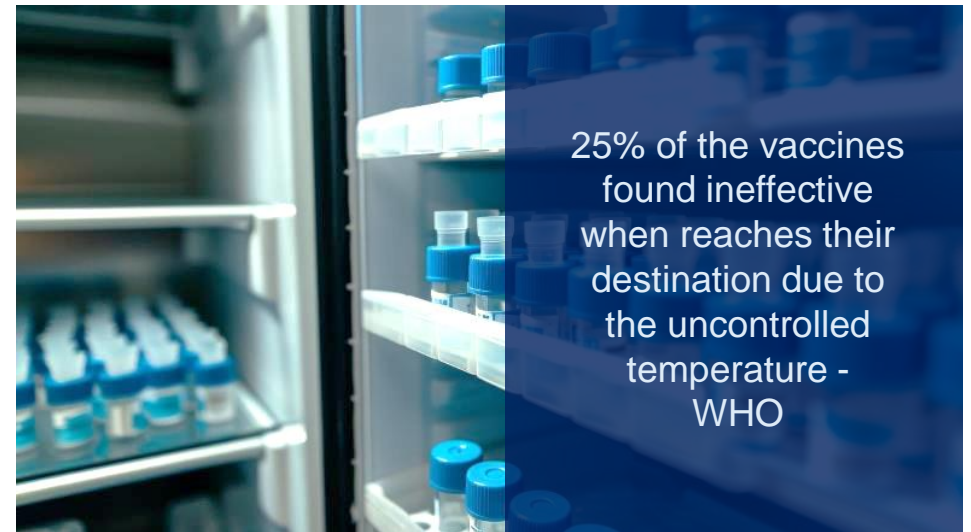
To maintain the **efficacy** of the drug it is imperative that the products must be maintained at the **prescribed ambient conditions**.

03

While it is relatively easier to control these parameters within the warehouses, it is equally important to establish **end to end visibility** of **APIs and finished drugs** through the supply chain.





04

Real time visibility of these parameters is needed to take **timely action** and hence prevent **product losses**.



Industry Challenges & Imperatives

Life sciences industry has been facing following challenges in cold chain management domain

Parameter	Challenges	Imperatives
 Visibility	<ul style="list-style-type: none"> No end-to-end visibility of APIs and finished drugs (especially temp controlled) Integration and tracking with CMOs 	<ul style="list-style-type: none"> Develop solution for E2E Temp Mgmt. / cold chain monitoring Integration with CMOs / external parties
 Data Model	<ul style="list-style-type: none"> Different data definitions and terms used across supply chain Different data models based on site specific applications 	<ul style="list-style-type: none"> Define global data model across value chain Stronger Data governance through global MDG setup
 Processes	<ul style="list-style-type: none"> No harmonized and standardized processes of cold chain across various Mfg. sites Paper based processes, loss of information 	<ul style="list-style-type: none"> MVP approach to build core enterprise processes, followed by site enablement and full fledge device integration
 Tracking & Reporting	<ul style="list-style-type: none"> No possibility to track batch / vessels during transit / with CMOs End to end ToR reporting No single / global reporting (site specific reporting) 	<ul style="list-style-type: none"> Establish global processes and cloud-based reporting solution

E2E Temperature Management Solution Benefits

- Reduction of process lead time (Leaner Process)
- Accuracy of TOR data and monitoring
- TOR based priority picking. Batches nearing max TOR limit could be picked first.
- Better compliance for regulatory audit support.
- Added support for stability and reserve samples.

Solution Features



Master Data Set up

- Define global and local manufacturing and supply chain nodes
- Define and set up stability matrix and workflows for approval at global and local level



Reporting

- Graphical reporting of sensor data for individual thing



TOR Management

- TOR Management: Calculation of Time out of Refrigeration (TOR) for rule-based actions.
- Trigger notifications or returns based on TOR level breach



Device Set-up

- Device master management, for temperature and humidity sensors using Infosys custom app
- Automation of device creation in BTP IoT device management cockpit.



Thing Management

- Create 'Things' of 3 types namely 'Handling Unit', 'Delivery with Handling Unit', 'Delivery without Handling unit'.
- Automation to create thing in BTP IoT – things modeler.
- ODATA based integration to connect to backend S/4HANA system to fetch details of handling units and delivery.
- Status based Sensor Assignment.



Thank you

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