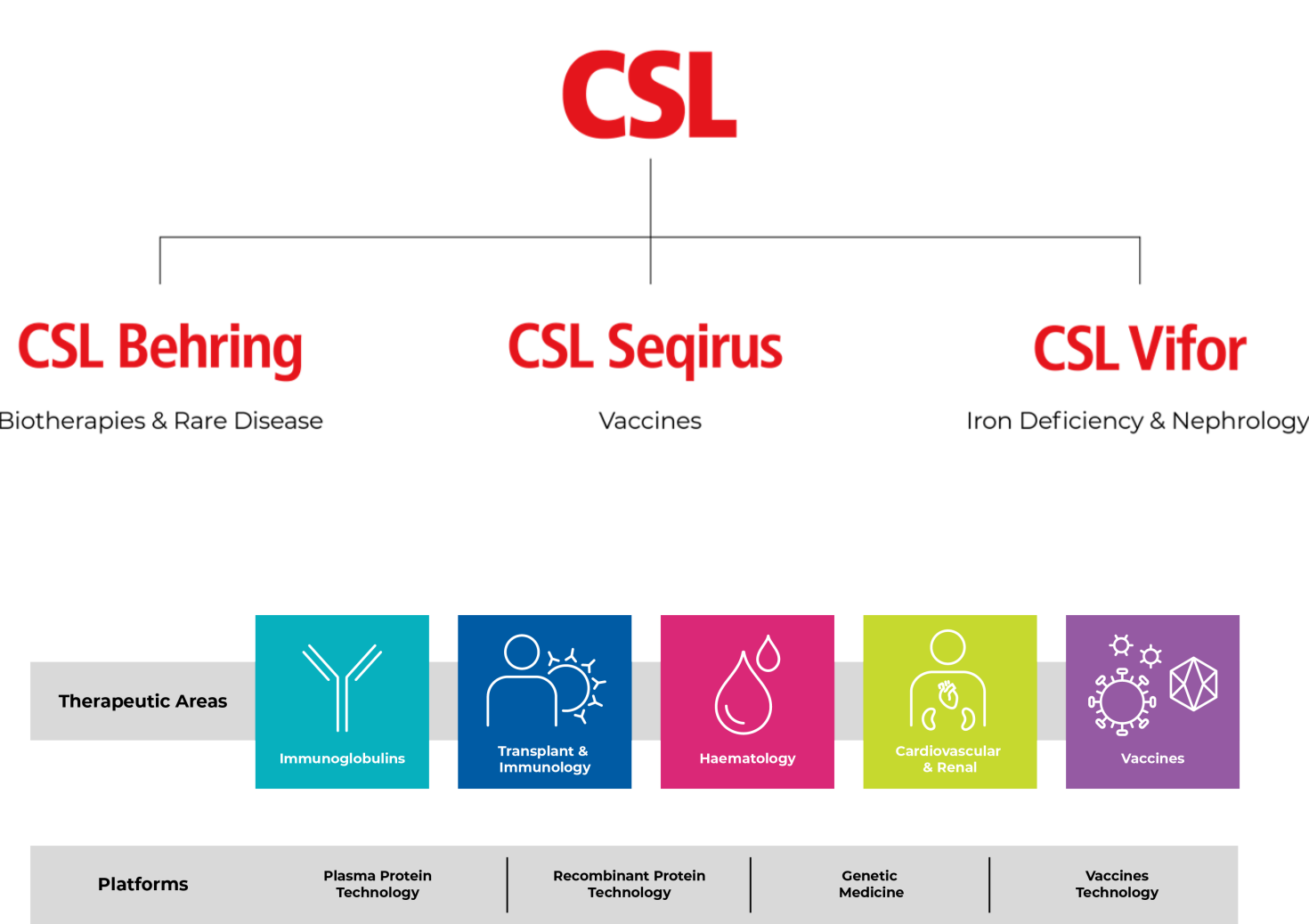


# Navigating internal company transition and change while ensuring temperature related operations remain intact


Temperature Controlled Logistics in  
Biopharmaceuticals Europe



# CSL at a Glance



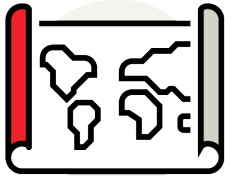
32,000+  
employees  
worldwide



serving patients  
and people in  
100+  
countries



operations in  
40+  
countries



2,500+  
R&D employees  
worldwide



- Assessing how pharma and biotech companies are handling structural changes amid high quantities of Mergers & Acquisitions
- Integrating temperature control and monitoring systems without compromising data quality
- Ensuring quality and compliance processes remain robust and able to meet requirements for regulatory inspections
- Mitigating the impact of staff turnover on supply chain logistics to avoid delays or quality issues

# Focused versus holistic approach

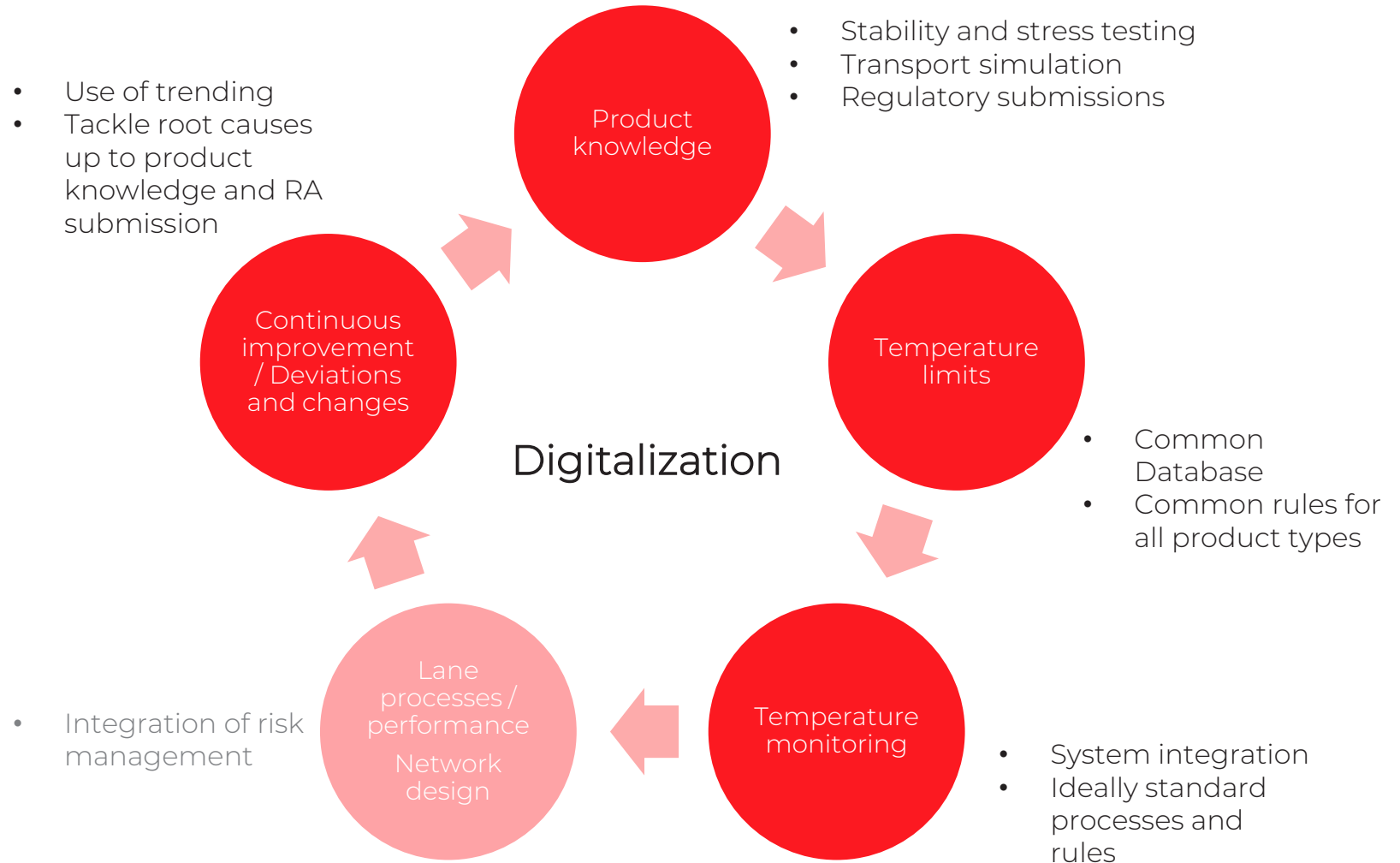
Temperature monitoring



Deviation management

*Implies case by case handling of deviations due to the low standardization level*

\* RA Regulatory Affairs



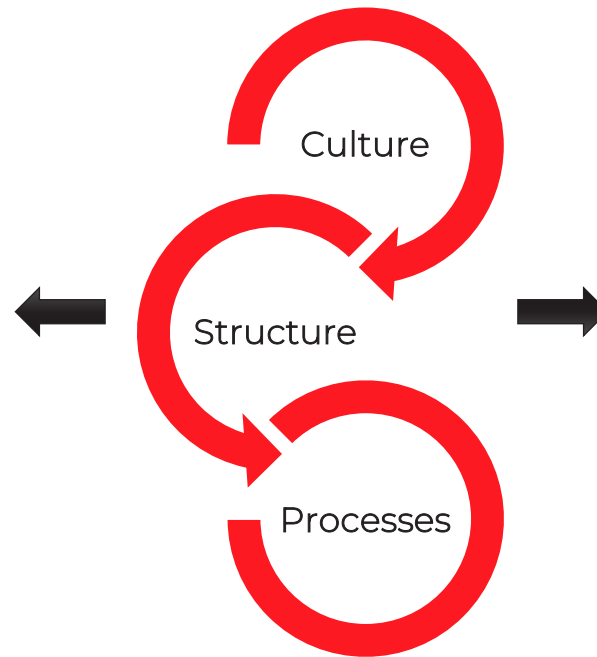
# Change Management

Onboarding stakeholders:  
Dev, Ops, CMO's, sites

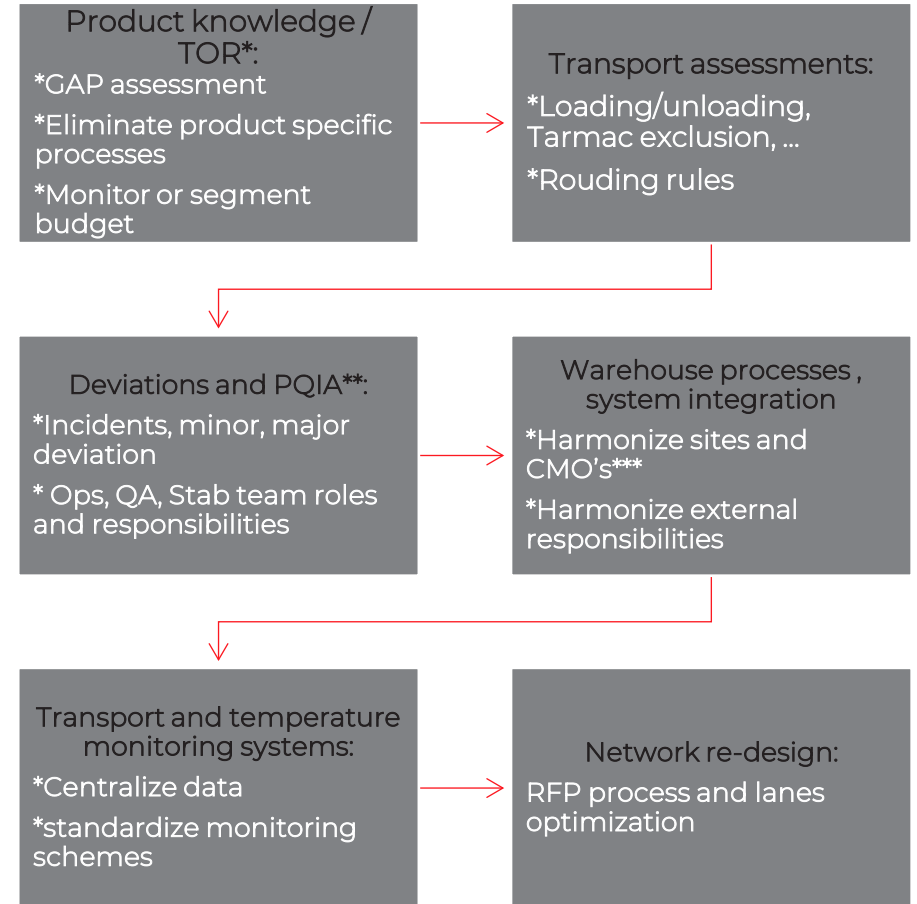
Adapting to the culture:  
Industries, regionality,  
company structure

Motivating through vision:  
Long term vision and  
quick wins

Project management:  
Clarifying, planning,  
enabling, communicating



## Systems and processes



\* TOR: Time Out of Refrigeration

\*\* PQIA: Product Quality Impact Assessment

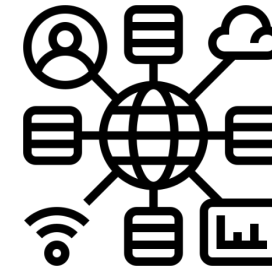
\*\*\* CMO: Contract Manufacturing Organization

**CSL Vifor**



# Digitalization

Efficiency, compliance, resilience and scalability



- Capturing the temperature data into systems
- Interfaces between temperature monitoring system and ERP\* to link the temperature to the product



Paperwork elimination /  
Assessments and  
communication  
automation

- Providers selection: Devices, platforms, integrators, ...
- Definition of a final IT infrastructure

Base for operational  
flexibility and next  
developments

\*ERP: Enterprise Resource Planning

# Digital Innovation

## Product traceability / genealogy

- Automation of the retrospective review to eliminate the need for segmentation of the TOR/TOF\*/Stability budget

## On time, in full and damage free

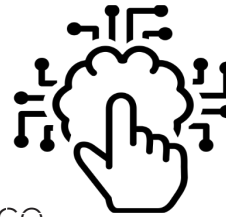
- Quality input back to ERP
- Continuous lanes validation and performance

## Deviation management

- Deviation entries creation automated through QMS\*\* interfaces

## Operational innovations

- Predictive risk identification for control towers
- Automated control towers
- Adaptable lanes (environmental risks and seasonnality)



AI services can be leveraged to support all the above purposes

\* TOF: Time Out of Freezer

\*\* QMS: Quality Management System

# Thank You / Questions



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