



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

Temperature Controlled Logistics in
Biopharmaceuticals Europe

CSL at a Glance

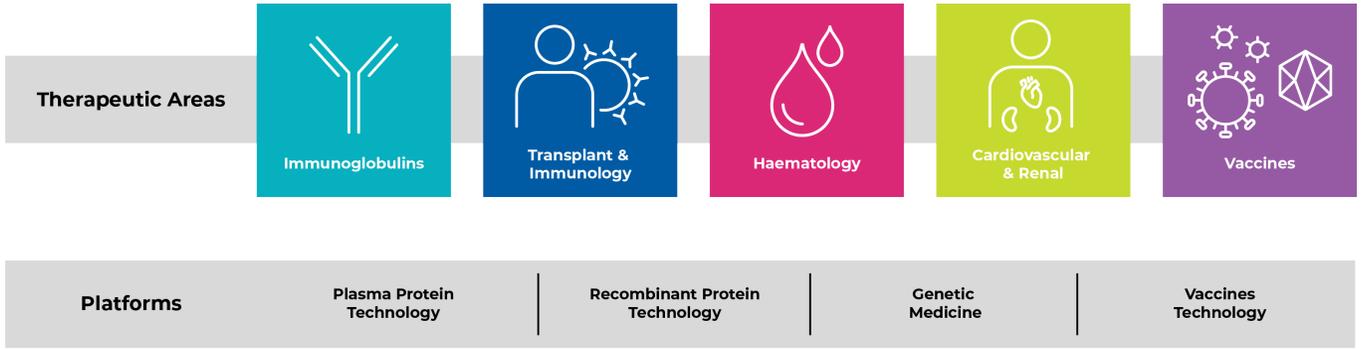


32,000+
employees
worldwide

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

- Use of trending
- Tackle root causes up to product knowledge and RA submission

Product knowledge

- Stability and stress testing
- Transport simulation
- Regulatory submissions

Continuous improvement / Deviations and changes

Digitalization

Temperature limits

- Common Database
- Common rules for all product types

Lane processes / performance
Network design

- Integration of risk management

Temperature monitoring

- System integration
- Ideally standard processes and rules

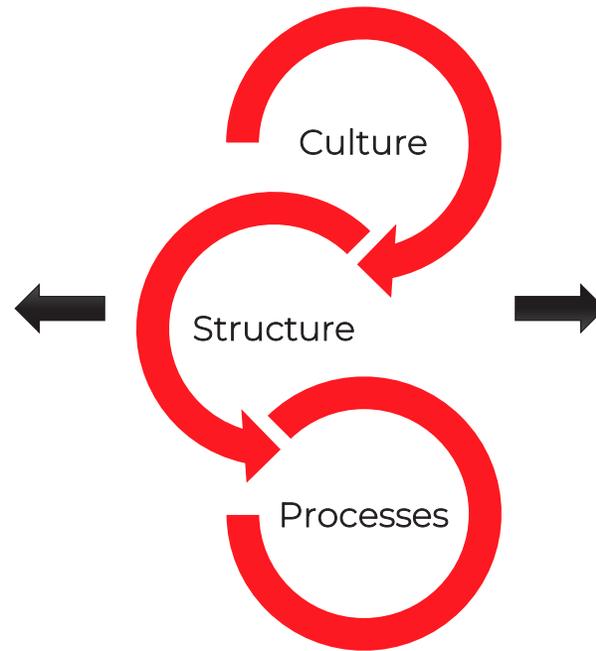
Change Management

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

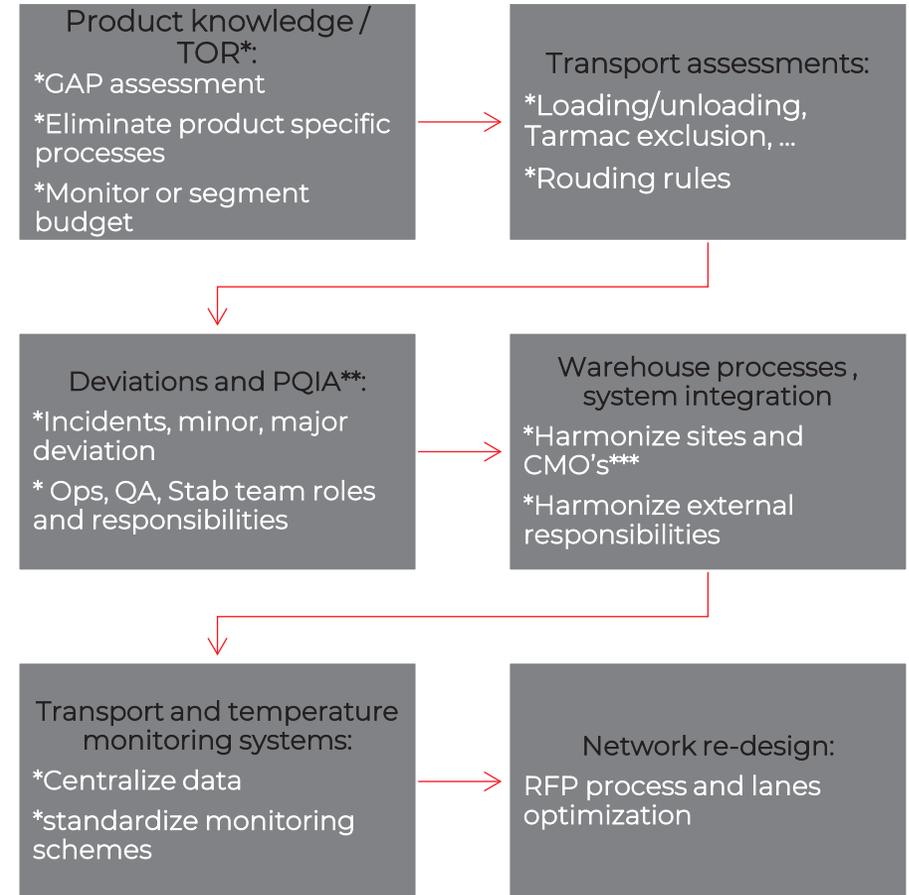
Adapting to the culture:
Industries, regionality, company structure

Motivating through vision:
Long term vision and quick wins

Project management:
Clarifying, planning, enabling, communicating



Systems and processes



* TOR: Time Out of Refrigeration

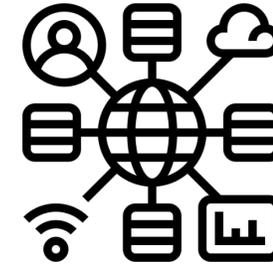
** PQIA: Product Quality Impact Assessment

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



Paperwork elimination /
Assessments and
communication
automation

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

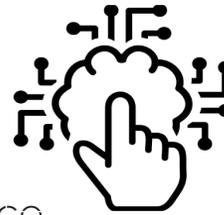
- Quality input back to ERP
- Continuous lanes validation and performance

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 seasonality)



AI services can be leveraged to support all the above purposes

* TOF: Time Out of Freezer

** QMS: Quality Management System

Thank You / Questions

Disclaimer

Certain statements, beliefs and opinions in this presentation are forward-looking, which reflect the Company's or, as appropriate, the Company's directors' current expectations and projections about future events. By their nature, forward-looking statements involve a number of risks, uncertainties and assumptions that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements. These risks, uncertainties and assumptions could adversely affect the outcome and financial effects of the plans and events described herein. A multitude of factors including, but not limited to, changes in demand, competition and technology, can cause actual events, performance or results to differ significantly from any anticipated development. Forward-looking statements contained in this presentation regarding past trends or activities should not be taken as a representation that such trends or activities will continue in the future. As a result, the Company expressly disclaims any obligation or undertaking to release any update or revisions to any forward-looking statements in this presentation as a result of any change in expectations or any change in events, conditions, assumptions or circumstances on which these forward-looking statements are based. Neither the Company nor its advisers or representatives nor any of its of their parent or subsidiary undertakings or any such person's officers or employees guarantees that the assumptions underlying such forward-looking statements are free from errors nor does either accept any responsibility for the future accuracy of the forward-looking statements contained in this presentation or the actual occurrence of the forecasted developments. You should not place undue reliance on forward-looking statements, which speak only as of the date of this presentation.