ZETA SYMPOSIUM

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Advantages of a Recipe Driven Execution Program – A future network of standardized Processes & Systems

Jens Laucht / CSL Behring

Execution Systems / Global Lead Architect

CSL (COMMONWEALTH SERUM LABORATORIES)

CSL Ltd

CSL Behring | **CSL Seqirus** | **CSL Vifor**

CSL is an Australian multinational specialty biotechnology company that researches, develops, manufactures, and markets products to treat and prevent serious human medical conditions.

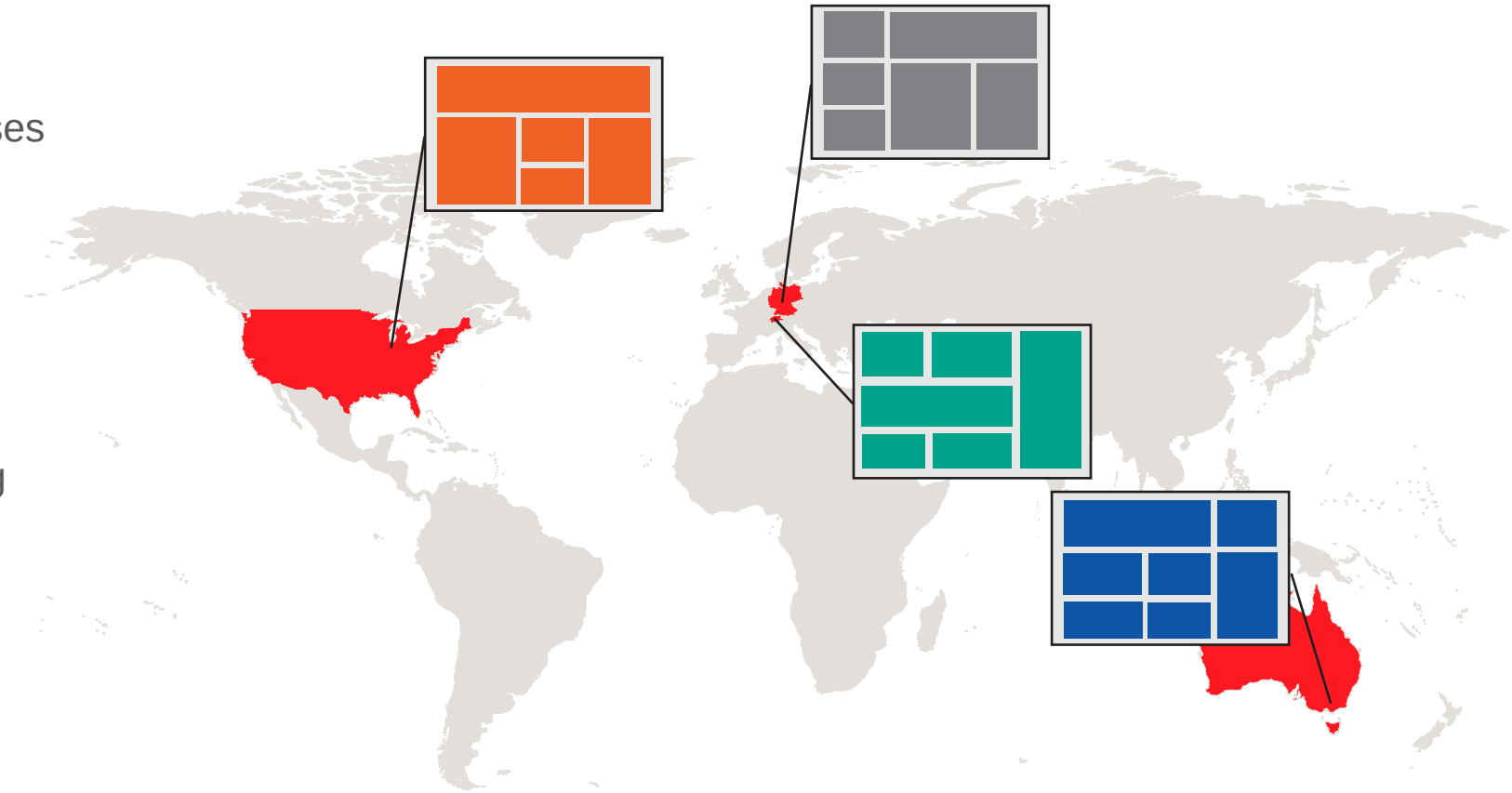
CSL has 32.000 employees and 9 manufacturing sites in US, EU and Australia.

PAST: A PATCHWORK OF DIVERSE SYSTEMS AND PROCESSES

Overall production network comprised of multiple and diverging site-based processes and execution systems

Negative Impacts to business:

- Unique applications + interfaces
- Multi-system user expertise
- Inconsistent business practices driving inconsistent systems
- Higher design and startup costs

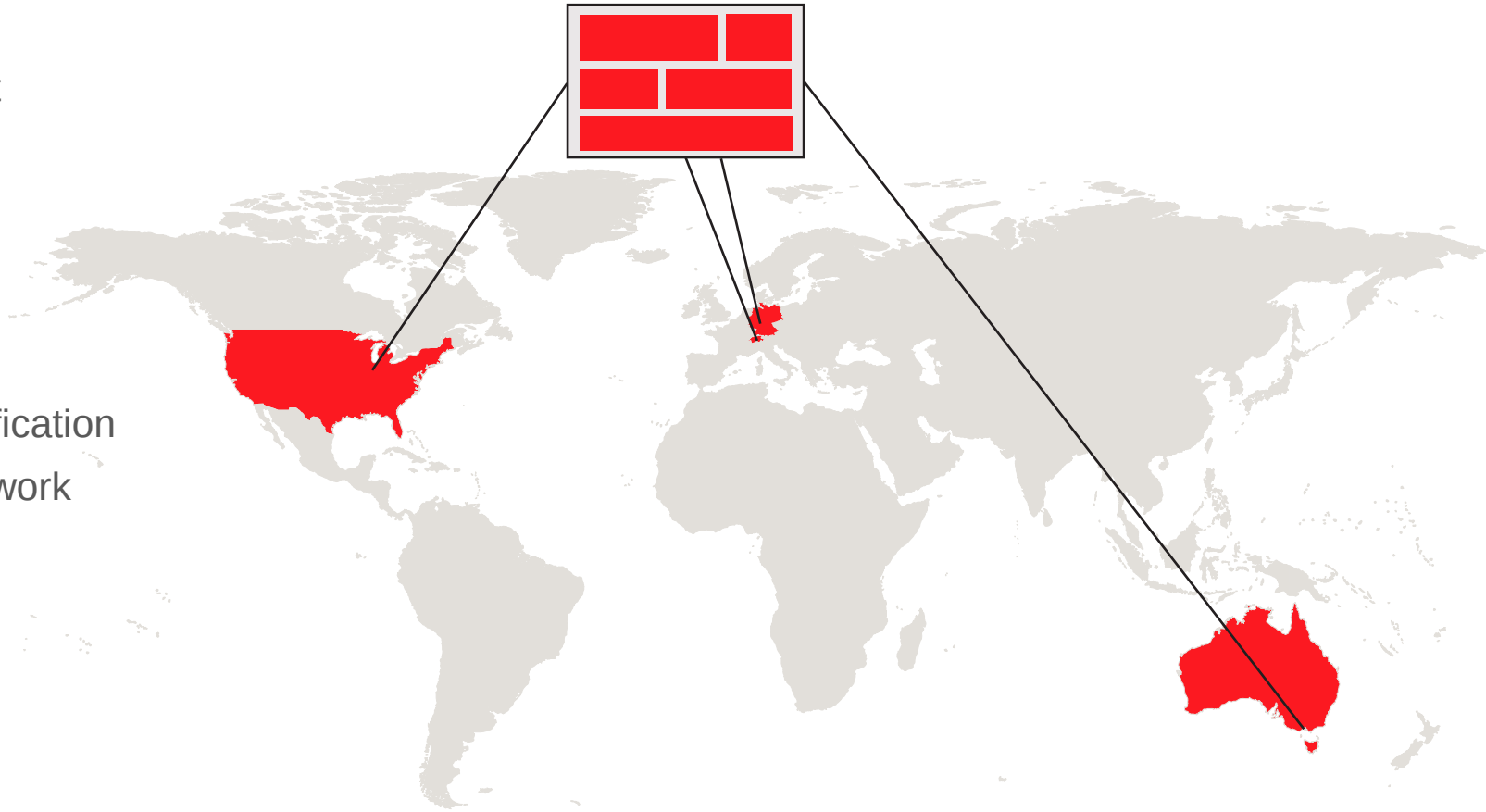


FUTURE: A NETWORK OF STANDARDIZED PROCESSES & SYSTEMS

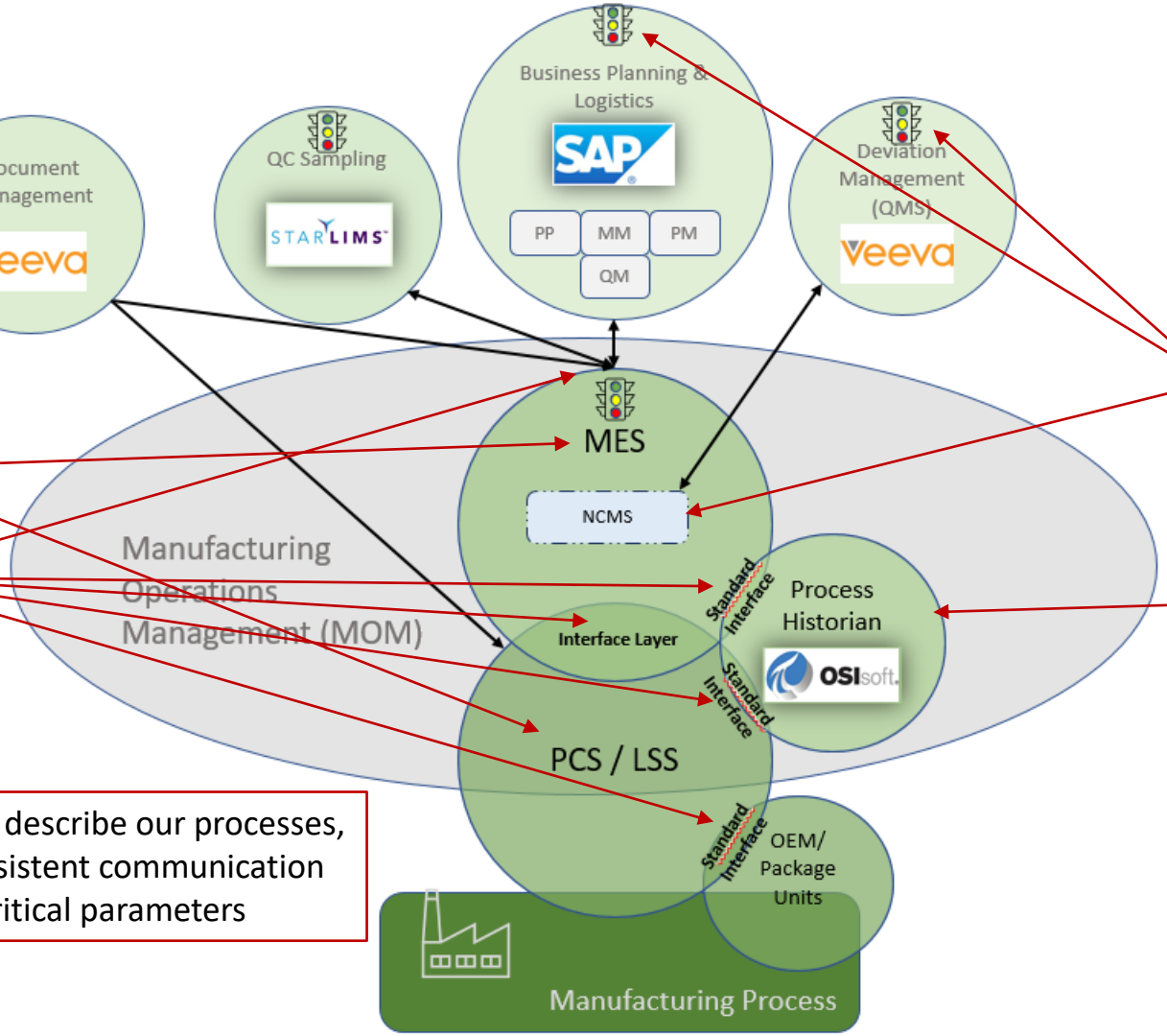
This concept aims to replace these different processes and systems with uniform standardization.

Key drivers are:

- Design once → Deploy everywhere
- Reduced cost of implementation & qualification
- Greater adaptivity and agility across network
- Centrally managed unified library
- Design should be fit-for-purpose on the business needs



WHAT IS RDE?



Standardized MES and PCS/LSS platform

Standard Interfaces

NCMS to support real-time batch review by exception

Process Data Historian Platform to enable a consistent approach to data analytics (S88 contextualization)

A common language for how we describe our processes, based on S88+S95, enabling consistent communication of the process description and critical parameters

NCMS

Non-Conformance Management System (NCMS)

- to support real-time batch review by exception
- simpler Batch Release process
- MES events will be triggered by PCS/LSS
- Manufacturing Function (MF) will be used to trigger NC events
- Non-Conformance events are critical alarms, critical parameter changes, or manual recipe deviations

PRIMARY VS. SECONDARY MANUFACTURING

Primary / Batch RDE Control

- MES Lite approach
  - eBR and NCMS within MES
  - S95 interfaces to EP
  - Standard interfaces to PCS and PI
  - MES acts as a service provider for PCS

- PCS is the leading system
  - PCS with S-88 structure (contextualized data)
  - Batch engine drives the process
  - Standard interface to MES and PI
  - Standardized interfaces to equipment
  - Create MF for MES incl. NC trigger for NCMS

- Historian as central point for all data incl. contextual

Secondary / Discrete RDE Control

- MES is the leading system
  - eBR and NCMS within MES
  - S95 interfaces to EP
  - Standard interfaces to PCS and PI

- Line Supervisory System Lite approach
  - Standard interface to MES and PI
  - Standardized interfaces to OEM/OEE/PU
  - Create NC trigger for NCMS

- Historian as central point for all data incl. contextual

BENEFITS OF RDE

- Reduced total cost of ownership through
  - standardized process automation design and interfaces
  - reduced qualification by using global library modules
- Error-Proof – Drive manufacturing consistency & repeatability through
  - standardized process automation design and interfaces
  - automate manual transactions and recipe management
- Decrease batch review and release time through
  - enabling real-time batch review by exception
  - enabling simpler batch release by exception
- Eliminate paper batch records and the need to manually transcribe data
  - 1 eBR from MES
- Create enhanced data analytics through
  - all process data incl. contextual in Historian
  - conduit for "big data" analytics tools

THANK YOU