Harmonizing Data & Applications
for a better *Manufacturing Process*

Accelerator Forum 2024

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Operations

Enabling a Healthier World

Harmonizing Data and Applications for a Better Manufacturing Process

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Alessia Carlaccini, November 2024

Company Overview

About Lonza

Lonza is one of the world's largest healthcare manufacturing organizations. Working across five continents, our global community of around 18,000 colleagues helps pharmaceutical, biotech and nutrition companies to bring their treatments to market.

United by our vision to bring any therapy to life, we support our customers with a combination of technological insight, world-class manufacturing, scientific expertise, process excellence and innovation. Our work enables our customers to develop and commercialize their therapeutic discoveries, allowing their patients to benefit from life-saving and life-enhancing treatments.

Our business is structured to meet our customers' complex needs across four divisions: Biologics, Small Molecules, Cell & Gene, and Capsules & Health Ingredients.

~18,000

Full-time employees

>125

Years of history

>30

Global sites

Our Divisions

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Our business is structured to meet our customers’ complex needs across four divisions:

Lonza
Biologics

In **Biologics**, we accelerate and de-risk the path from drug substance development to drug product supply for complex modalities including mammalian, microbial, mRNA and bioconjugates.

Lonza
Small Molecules

In **Small Molecules**, we support the journey from early development to commercial supply, with drug substance, drug product and particle engineering services.

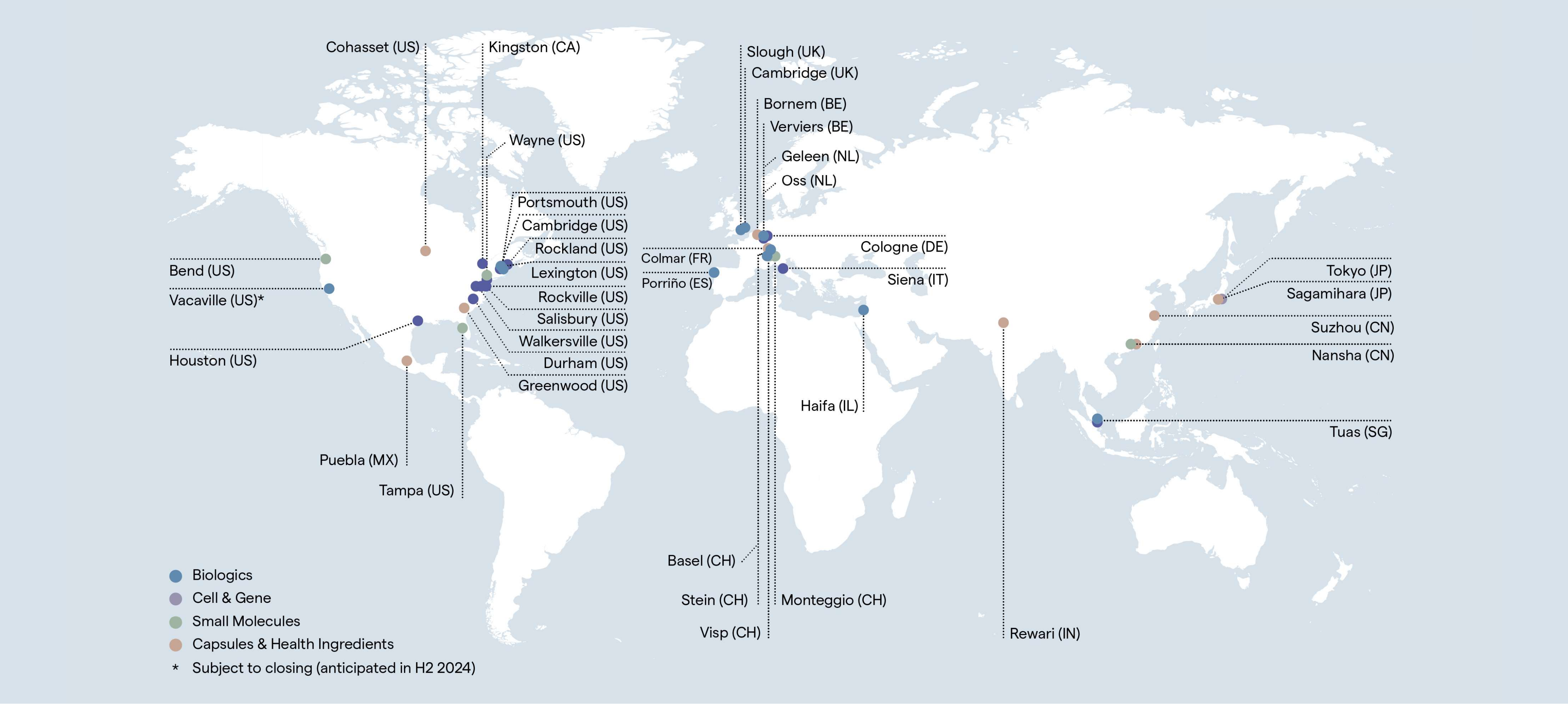
Lonza
Cell & Gene

In **Cell & Gene**, we support and equip our customers to develop, de-risk, commercialize and scale their emerging therapies.

Lonza
Capsules & Health Ingredients

In **Capsules & Health Ingredients**, we enable our customers with innovative and functional capsules, differentiated dosage form solutions and science-backed health ingredients.

Our Global Footprint



Recognized CDMO Expertise

>880 pre-clinical and clinical large[1] and small[2] molecules

>195 commercial large[1] and small[2] molecules

Biologics[1]

Small Molecules[2]

[1] As of December 2023, including mammalian, microbial, bioconjugates, drug product services and cell and gene therapy products (personalized medicines are included in pre-clinical and clinical molecules only, early development services are included for pre-clinical molecules only)
[2] As of December 2023, including active pharmaceutical ingredients (API), highly potent API (HPAPI), dosage form and delivery systems and particle engineering

R&D Investments and Innovative Partnerships

Investing to stay one step ahead of industry challenges

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Continuous Manufacturing

Approach to intensifying processes to support continuous manufacturing for improved delivery: N-1 perfusion, continuous protein capture and purification.

Small-scale capabilities in mRNA to complement commercial expertise

Bioavailability Enhancement

Innovative technology to allow spray drying for 'brick dust' molecules.

Solvent-free amorphous process and formulation.

Manufacturing capabilities of complex cytotoxins for Antibody Drug Conjugates.

Scalable Personalized Medicine

Integration of new analytical technologies within Cocoon® Platform through collaboration with companies like Agilent.

Possibility for real time adjustments to the manufacturing process, which may ultimately lead to a more potent and effective product.

Next Generation Enterics

Proprietary capsule with protection against stomach acid.

Opportunity for novel delivery of complex compounds: therapeutic proteins, antibodies, vaccines, etc.

The purpose of this presentation is to discuss **critical aspects and concrete steps** that can **improve processes, harmonize data and applications,** and ultimately, prepare companies for **digital/technology transformations in manufacturing at scale.**

The Journey

Harmonizing data and applications

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WHERE COMPANIES OFTEN START

ORGANIZATIONAL SET UP

PROCESS FRAMEWORK

E2E INTEGRATION

DATA HARMONIZATION

APPLICATION HARMONIZATION

WHERE TO START

Organization

Define and appoint Global Business Process Owners

Typical process ownership set up

Too many, too granular
Dedicated to an application or a project, perceived more a system custodian

Isolated
Isolated within a function or a department

Too theoretical
Perceived as administrative, detached from systems, data and applications

E2E Process Owners

Owner responsible for **E2E process** that includes a set of **related global processes**

Focuses across functions and process, looks at **end to end value stream optimization**, manages the interactions across departments

Part time roles

Global Business Process Owners

Owner responsible for **individual global process**, including future state development and performance management

Responsible for the entire process, **across applications and across technology stack**

Supported by a community of **local Owners/Stewarts**

Dedicated department, Full time roles ideally

Organization

Global Business Process Owner Scope

Continuous Process Improvement	**Process Design & Documentation**
Functional & Site Stakeholder Management	**Change Management**
Compliance, Governance & SOPs	**Data/ Applications/ Product Ownership**
Performance Monitoring	**Training & Communication**

Process Framework

Define process framework and overarching E2E processes

Typical framework

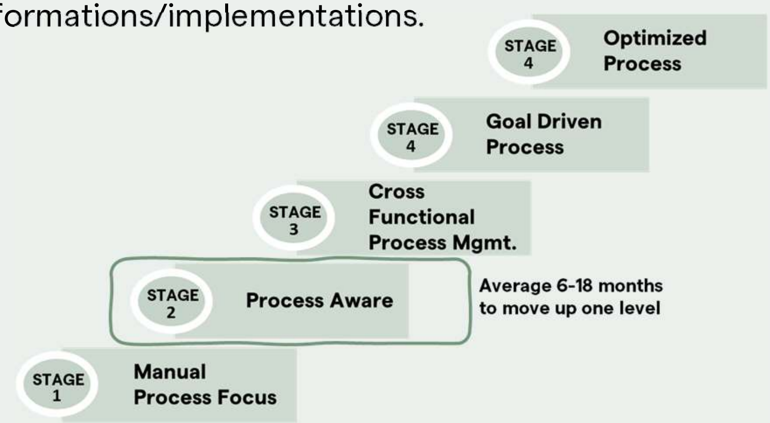
Not defined
No framework present in the company

Used outside Manufacturing
Variety of process frameworks used in other functions like Finance or Supply Chain

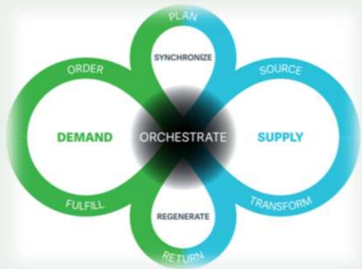
Too Many
Each project or department adopts a different process framework

Defining global process framework and standards is critical to enabling digital capabilities, and supporting data management and application management

Evaluate your **process maturity,** not just the digital maturity.
Lean and Continuous Improvement going ahead of digital transformations/implementations.



Define a **unified E2E process framework** across operations (manufacturing, supply chain, quality, etc.). e.g. SCOR



Leveragee **one framework across projects and programs**. Align S4HANA/ERP.

Integration

Focus on how roles, processes, systems and data integrate

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Typical integration approach

Case by case
System integrations, interfaces defined based on need.

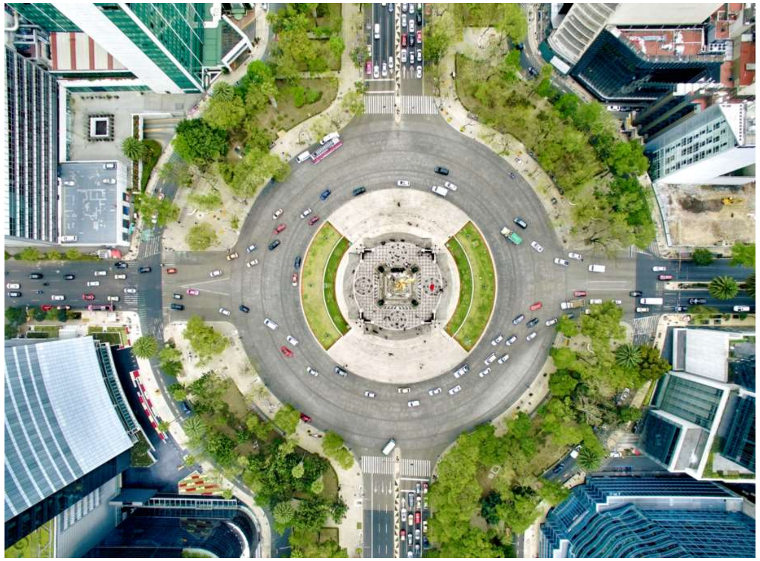
Governed within each project
Each project develop his own requirements for integration.

Lost in translation
Never-ending discovery and tribal knowledge dispersed across departments and technology stack

Track your E2E integration. Get a core design of how your process and platforms and data interacts as a basis of your integration strategy and technology roadmap

How **organizations** integrate

How **projects** integrate



How **systems** integrate with each other

How **data** integrate

Integration

How organizations integrate in manufacturing

How **organizations** integrate

- Build and boost **collaboration and trust across your core departments** impacting manufacturing (e.g. OpEx, MSAT, Production, Engineering and Automation, Quality, Supply Chain, Digital, IT).
- Develop **cross functional knowledge**
- Set **governance**
- **Empower team** to guide the transformation

How do I find the sponsorship and the funds?

Look into what you are already doing

You are already spending money and resources in

- Many ongoing parallel **process improvement, process mapping**
- Many **process and technology owners working on** projects and system lifecycle
- Many **third-party vendor frameworks recreated** in each major technology implementation program
- Attempt to **harmonize procedures**
- **Data cleaning, preparation, translation** every time you start a new project, over and over again
- Many more.....

Create your business case

The Journey

Harmonizing data and applications

ORGANIZATIONAL SET UP

Define and appoint "real" Global Business Process Owners

PROCESS FRAMEWORK

Define process framework and overarching E2E processes...and use it

E2E INTEGRATION

Focus on how roles, processes, systems, data and projects integrate... always

DATA HAMONIZATION

Start small, tackling your most important data assets for manufacturing...and start managing them

APPLICATION HARMONIZATION

Control the growth and harmonize the application landscape...where it brings value

Key Take Aways

Don’t try to get to the organizational end state in one go, **mature step by step.**

Technology progresses very fast, people and organization don’t.

Appoint **the critical process and data roles with your best people in operations and empower them**. Don’t put technology experts in charge of your processes but include them in all steps.

Build and boost **collaboration and trust across your core departments** impacting manufacturing process.

Put a process framework in place into the manufacturing and quality areas. Don’t expect that ERP/S4HANA transformation will fix your processes within the manufacturing plant.

Think in customer/product value stream, across departments, processes, applications and across technology stack.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