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Roche: Open-DCP.ai - Bridging Innovation and Compliance in Pharma 4.0

Advancing GxP with an Open-Sourced Data Computation Platform

Tobias Ladner, Digital Solutions Lead

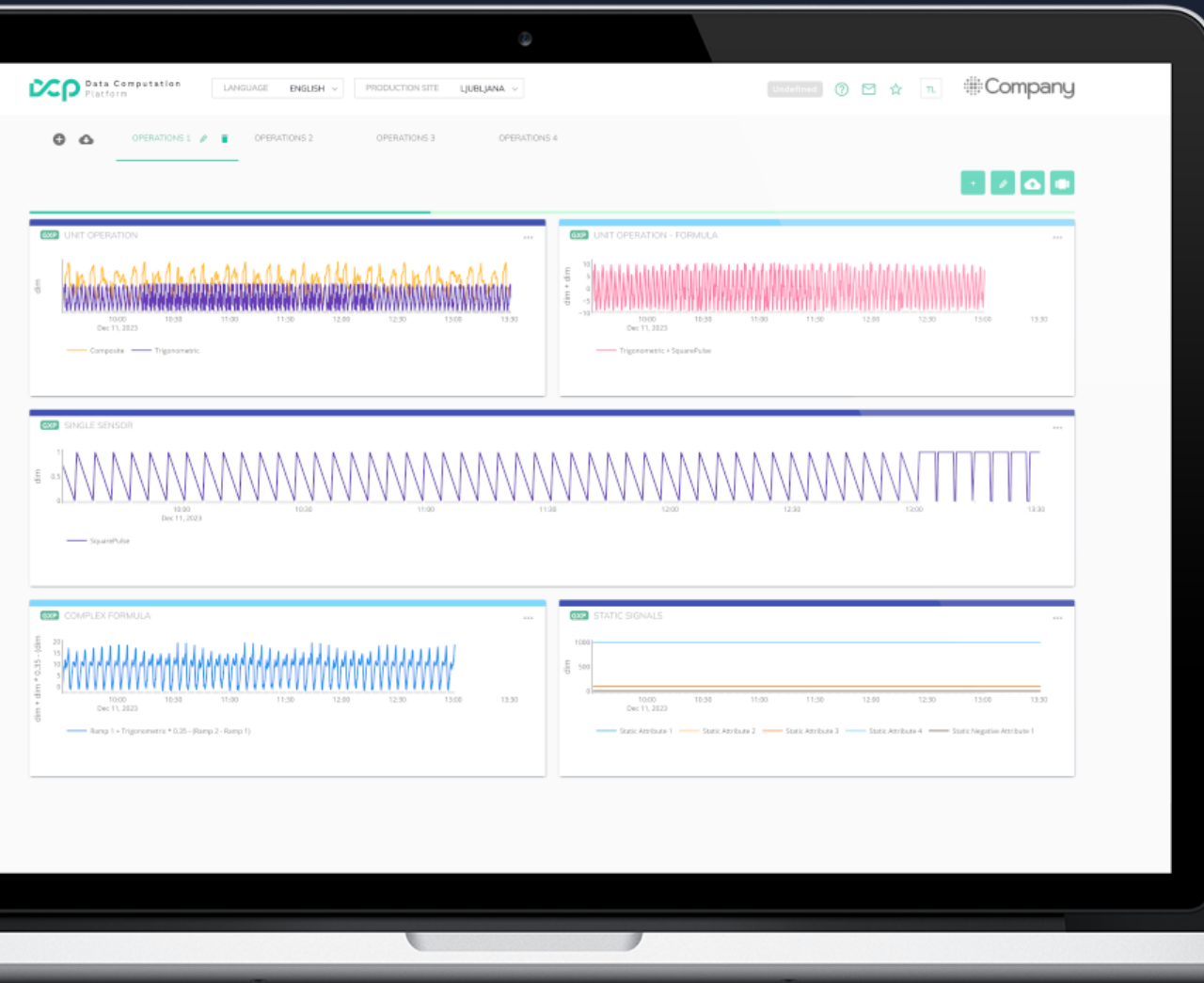
Bridging Innovation and Compliance in Pharma 4.0

Advancing GxP with an Open-Sourced Data Computation Platform

Tobias Ladner | AVEVA World Paris

October 2024

Learn more
open-dcp.ai



Roche at a glance



128 years

founded in Basel in 1896



A leader in healthcare

R&D

with CHF 13.2 billion invested in 2023



CHF 58.7 billion*

in Roche Group sales in 2023



>100,000

dedicated employees worldwide



**45 Roche medicines &
90 diagnostics****

on the WHO List of Essential Medicines
& Tests



>22 million people

treated with our medicines
in 2023





What is the Data Computation Platform (DCP)?

DCP is a modular global system for integrating various mathematical approaches to evaluate process data **following well-defined workflows.**

DCP will enable data-driven decision-making across the Roche network and accelerate future project implementation in **GxP environment.**

OpenGMP DevOps & Innovation



External Partners & Local Site Teams

Where is DCP available?



DEVELOPMENT

Penzberg
South San Francisco



DIAGNOSTICS

Penzberg



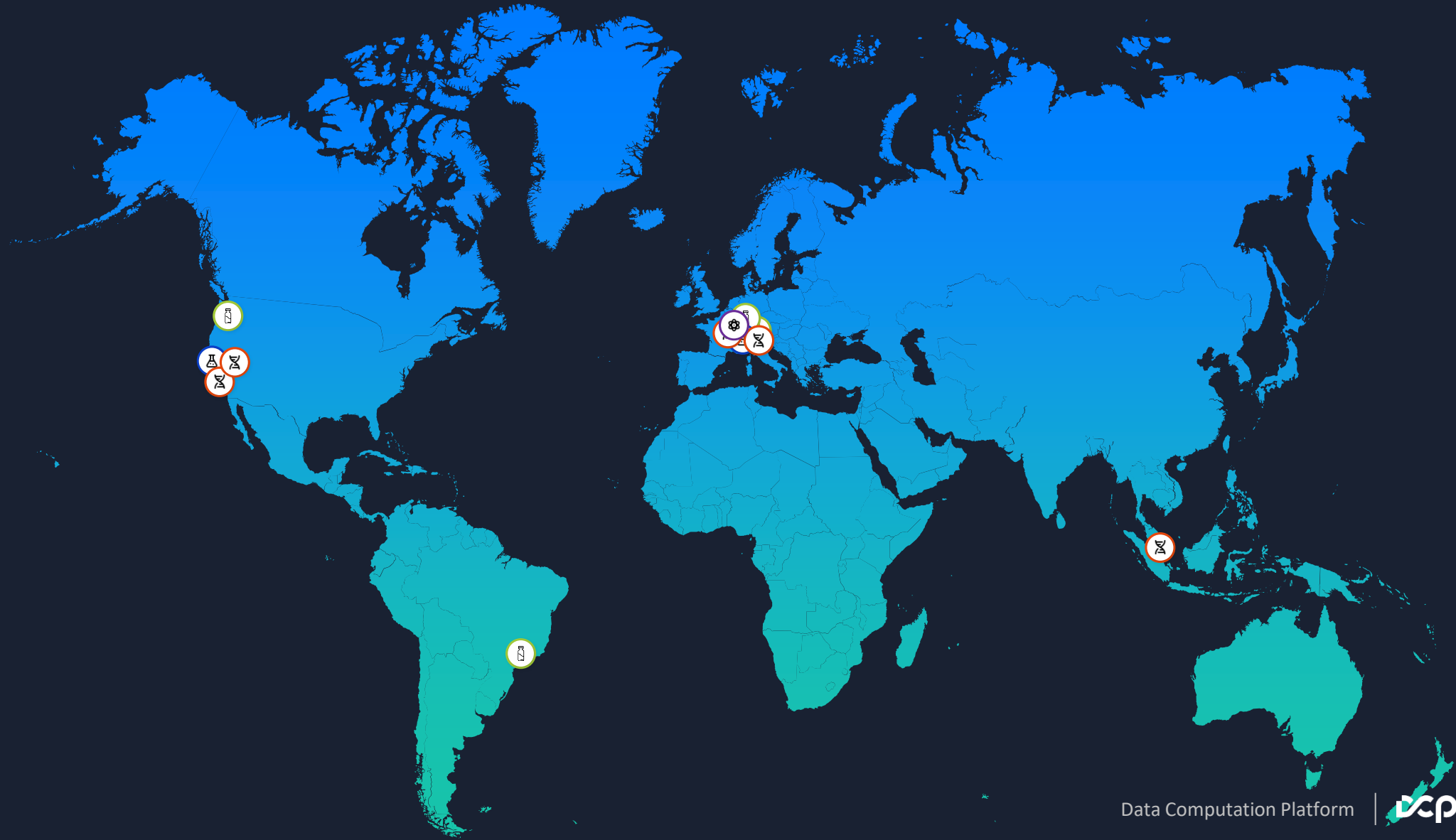
DRUG SUBSTANCE

Basel
Oceanside
Penzberg
Singapur
Vacaville



DRUG PRODUCT

Hillsboro
Kaiseraugst
Mannheim
Rio de Janeiro



Timeline

Over six years to forge innovative pathways within the manufacturing network.

- 2018**

Proof-of-Concept

Showcasing feasibility of multivariate data analytics (MVDA) for process health supervision in manufacturing network as browser based tool.
- 2019**

Pilot

Conduction pilots for MVDA at one Drug Substance and one Drug Product manufacturing site.
- 2020**

Transforming Software into Platform

Converting software developed during into scalable and expandable platform allowing to integrate modules.
- 2021**

Network Rollout & Additional Modules

Establishing DCP at 9 manufacturing sites, including business process and development of two new modules.
- 2022**

Validation of DCP Framework

Due to changed business requirements, the DCP Framework became validated and related business processes are defined.
- 2023**

Validation of first Module for GxP Usage

MVDA became essential part of the Real-Time-Release-Testing aspiration and, thus, required validation.

DCP API Service

DCP Modules

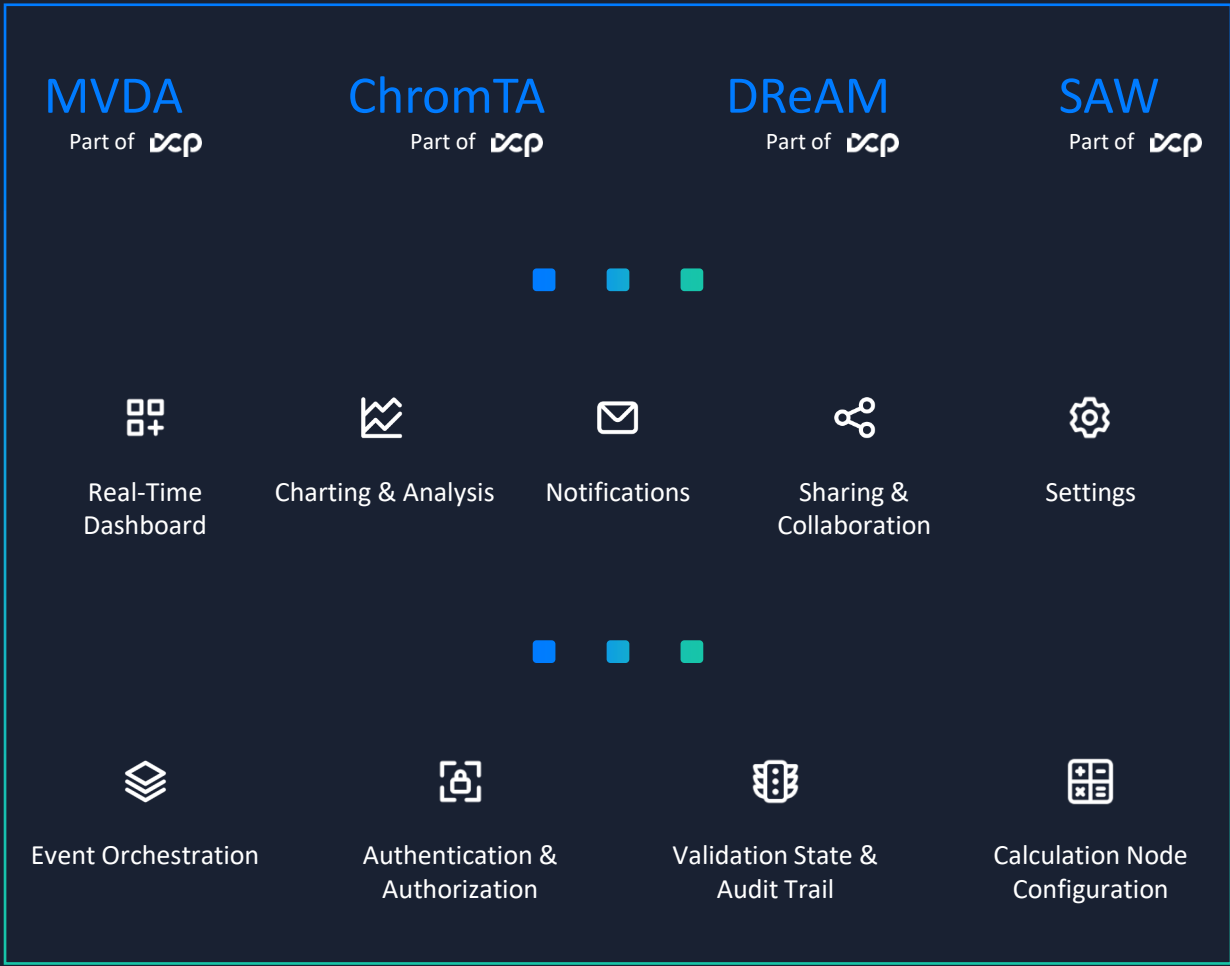
Enabling advanced analytics, visualizations and specific workflows.

DCP Basic

Providing fundamental tools to perform process monitoring and analysis.

DCP Core

Enabling GxP and non-GxP apps in the same platform while ensuring security and compliance.



Site specific
Each module can be activated individually per site.

Micro services
Development, deployment and validation individually per module.

Toolchain
CI/CD checking code quality, automated build and testing.

DCP Framework

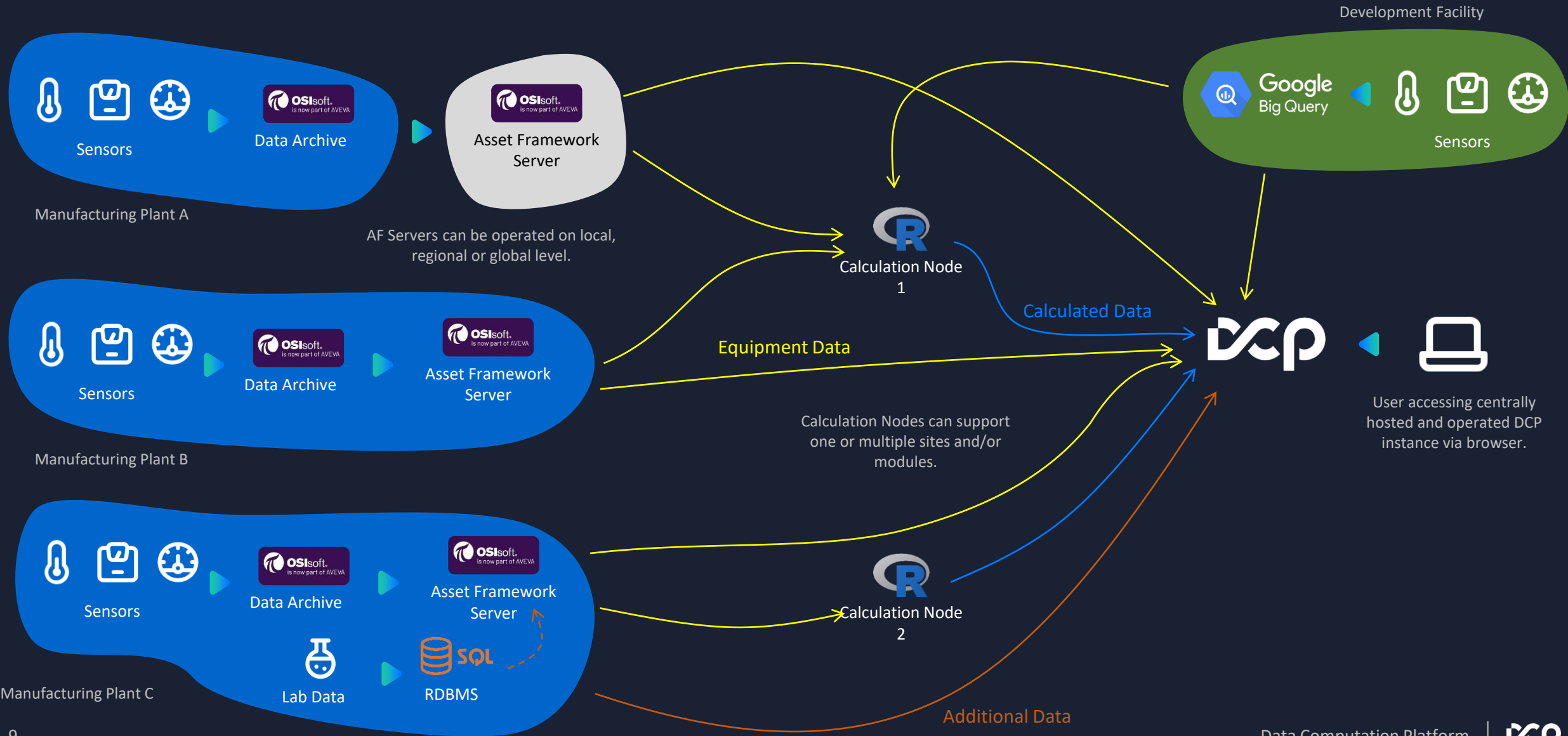
Reduction of development and operating costs through synergies in a platform rather than separate applications, with reduced validation effort for modules due to the reuse of numerous components.

Data Sources

To ensure a high level of data integrity, DCP consumes data directly from the various source avoiding data copies.



Data Processing Pipeline

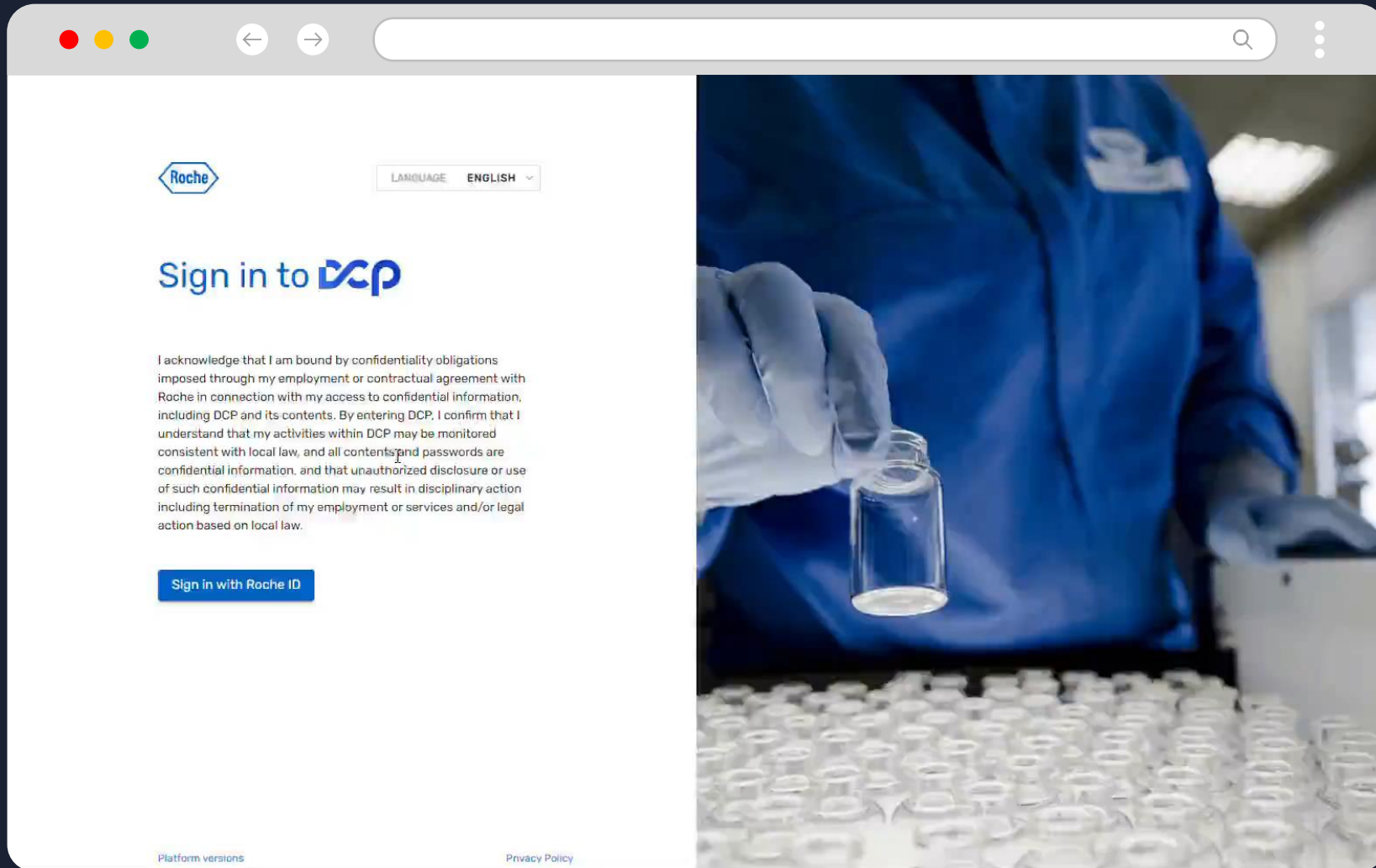




DCP Basic Enabling Process Data Visualization and Investigations

From instant data monitoring via the [Dashboard](#) and [Batch Data Overlays](#) that facilitate easy analysis and pattern discovery, to [automated email notifications](#) for anomaly detection — DCP Basic empowers swift decision-making with real-time insights and batch processing.

Overview of DCP Basic Capabilities



Core Capabilities

Collection of essential Tools for Effective Process Monitoring.

▶ Real-Time Dashboard

Create real-time widgets to simplify monitoring of processes and equipment.

▶ Time Series Data

Visualize sensor data streams alongside derived equations.

▶ Batch Contextualized Data

Sensor overlay for univariate comparison of historical and active batches.

▶ Email Notifications

Receive notifications if sensors or derived equations behave unexpectedly.

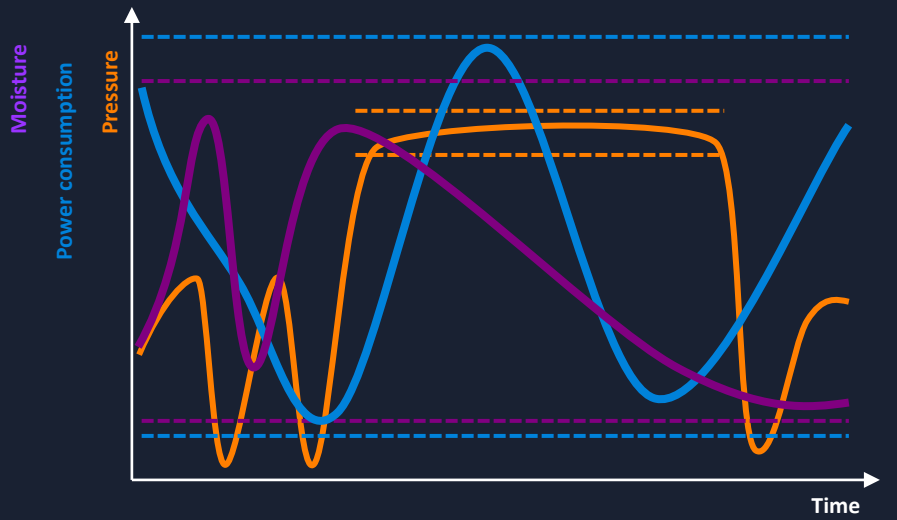
Use Case Leveraging DCP for GxP- Compliant Multivariate Data Analytics (MVDA) Process Monitoring

Real-time release testing (RTRT) is essential for [Instant Release](#), a key part of a global effort to reduce lead time. Parametric release, combining process control with analytical results and supported by tools like [MVDA](#), is a key implementation option for RTRT.

In the [Mannheim Drug Product plant](#), autoclaves serve as the pilot process for introducing the methodology.

Multivariate Data Analytics (MVDA)

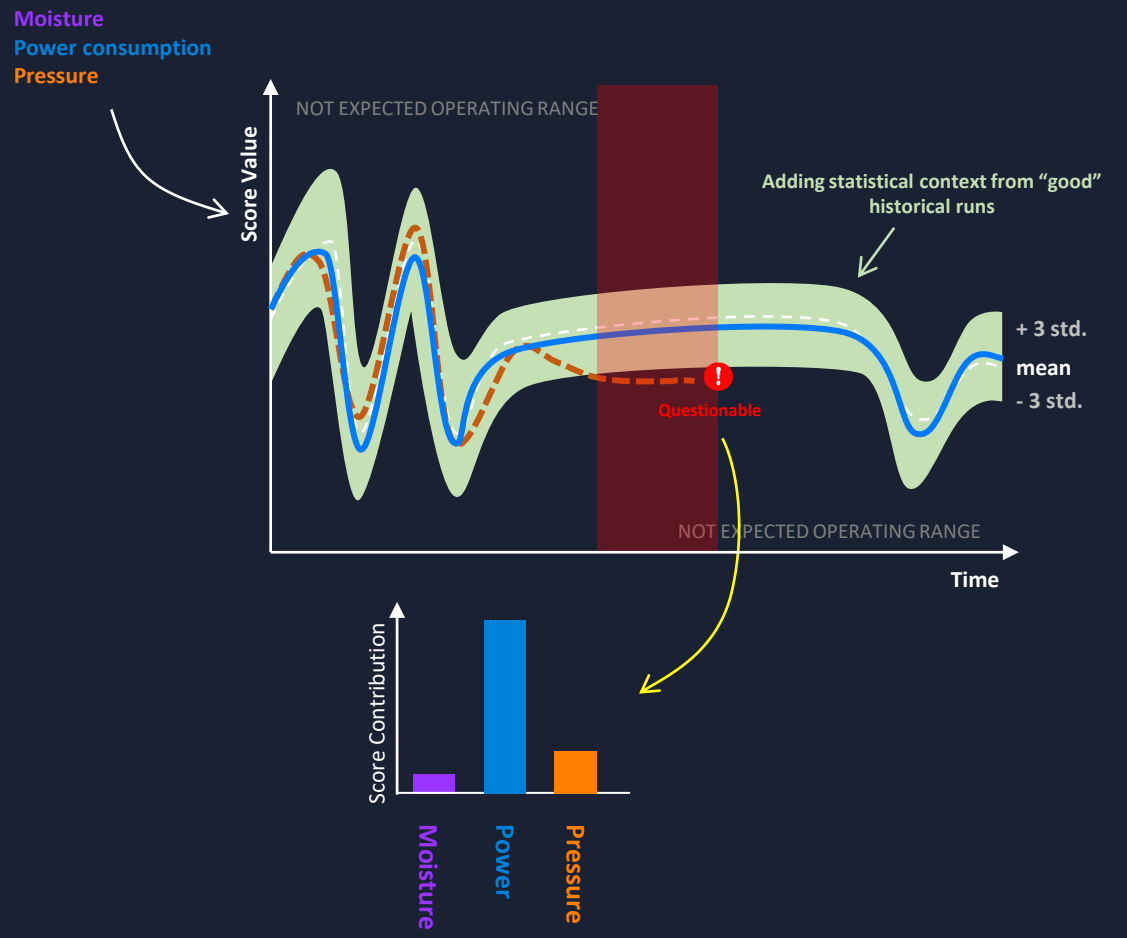
Univariate approach
(What we currently are doing)



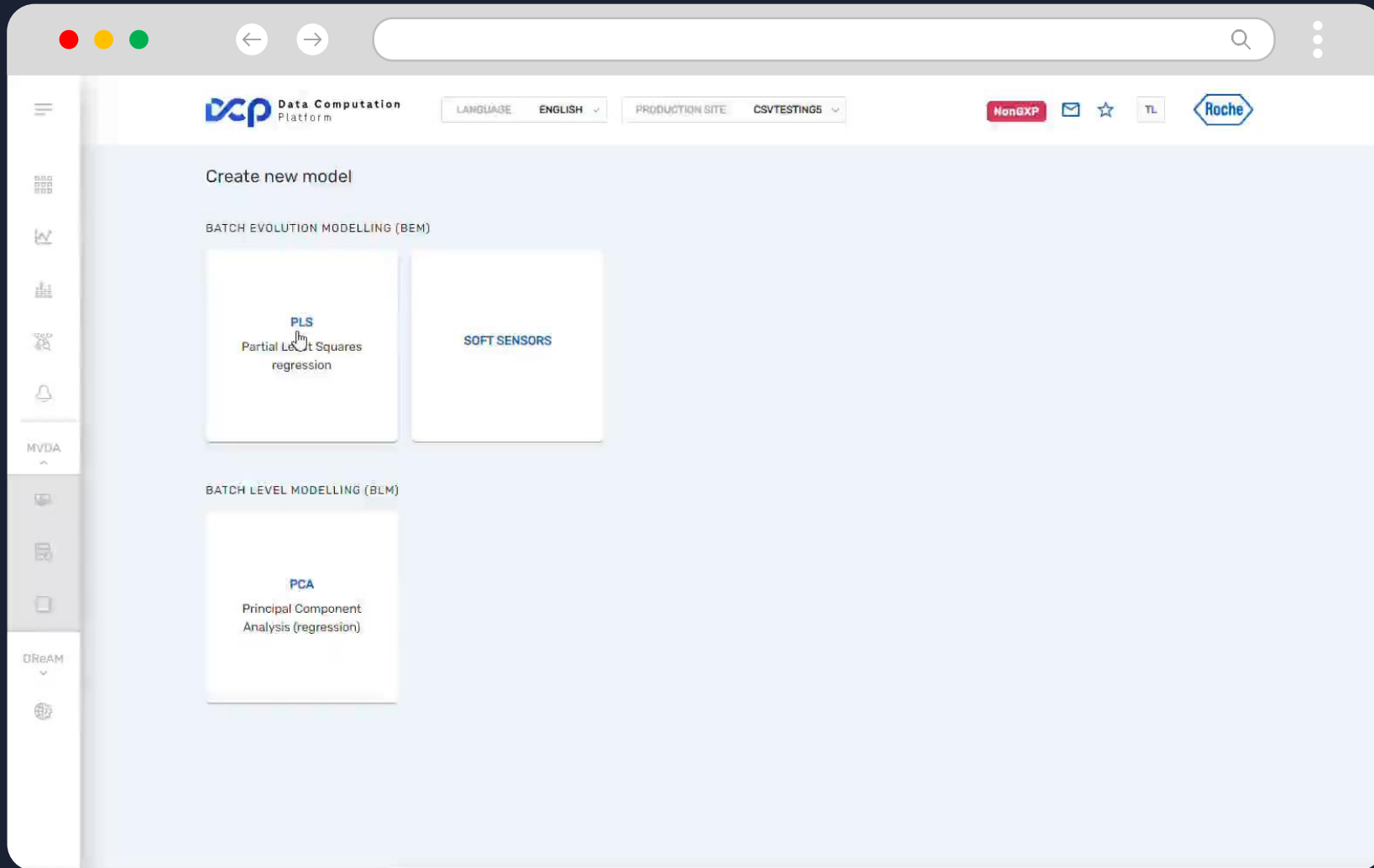
Univariate monitoring might get complex and confusing



Multivariate approach
(What we will do)



MVDA Model Development Wizard



Four-Step Wizard

User is guided through modelling workflow of different multivariate model types.

▶ Create Dataset

Select device related batches and sensors. Use filters to find specific batches.

▶ Model Configuration

Provide name for model. Additionally, advanced model settings can be applied.

▶ Model Diagnostics

Discover key statistics of the model and perform (optional) internal testing.

▶ Model Setup

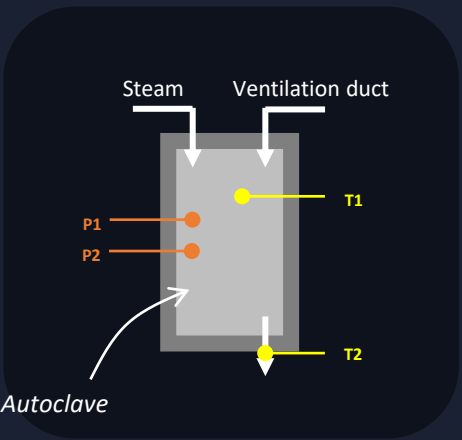
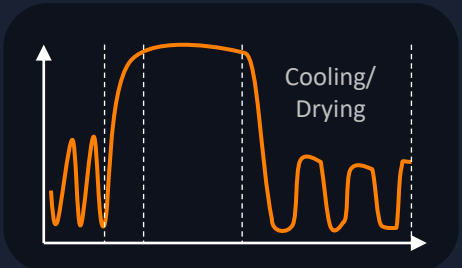
Provide modelling consideration details and define applicability of model.

PROBLEM STATEMENT

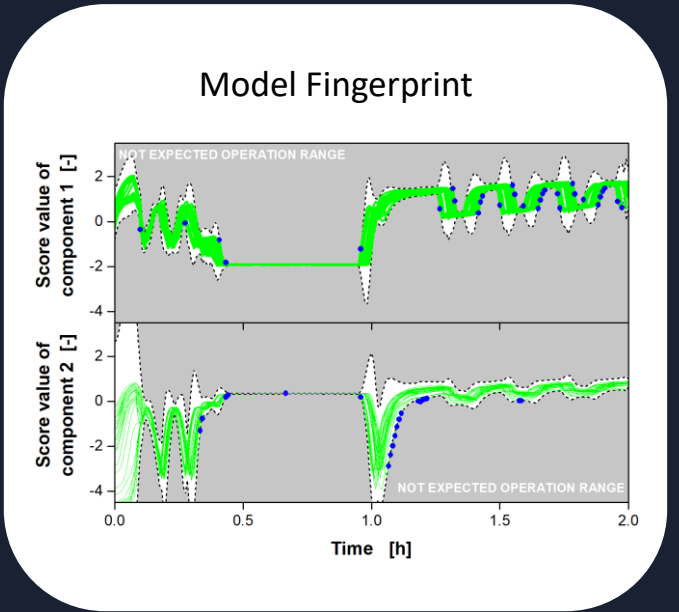
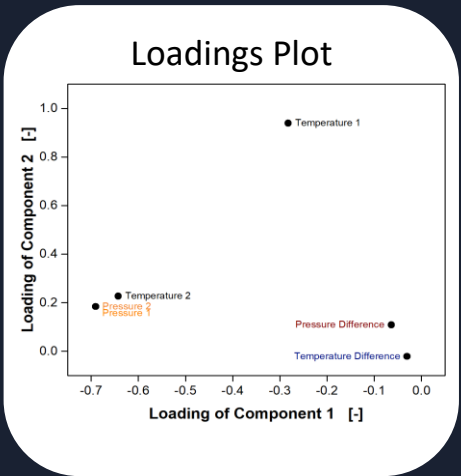
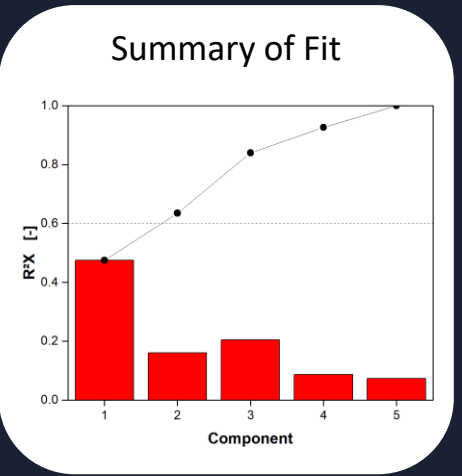
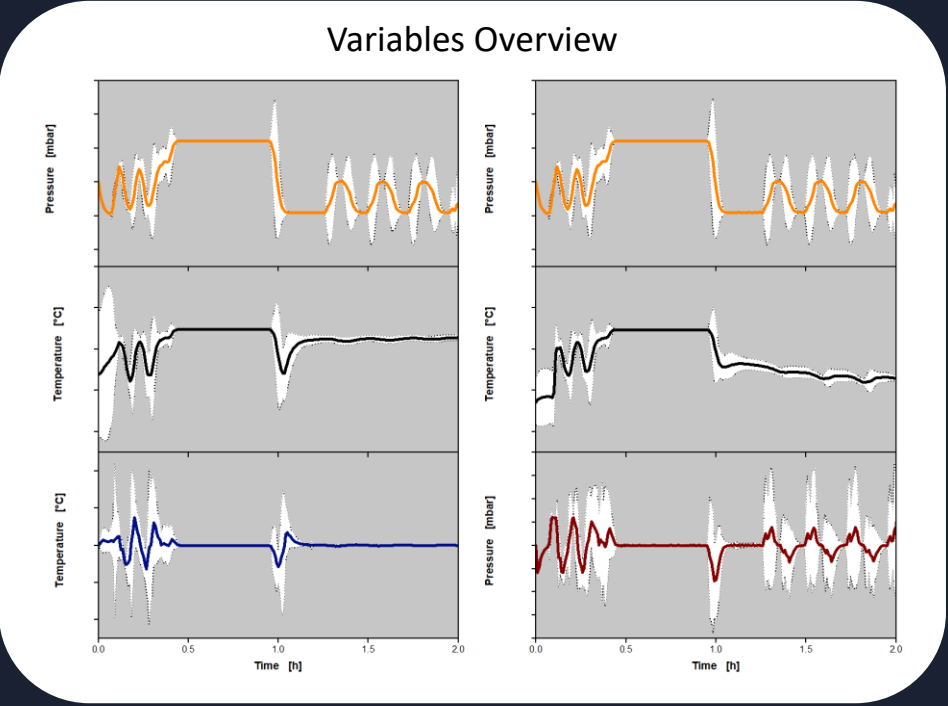
Timeline

✓ ⚙️ 🟡 !

After maintenance, floor staff observed autoclaved goods remaining wet, prompting a six-week investigation to identify the root cause.



MODEL FACT SHEET

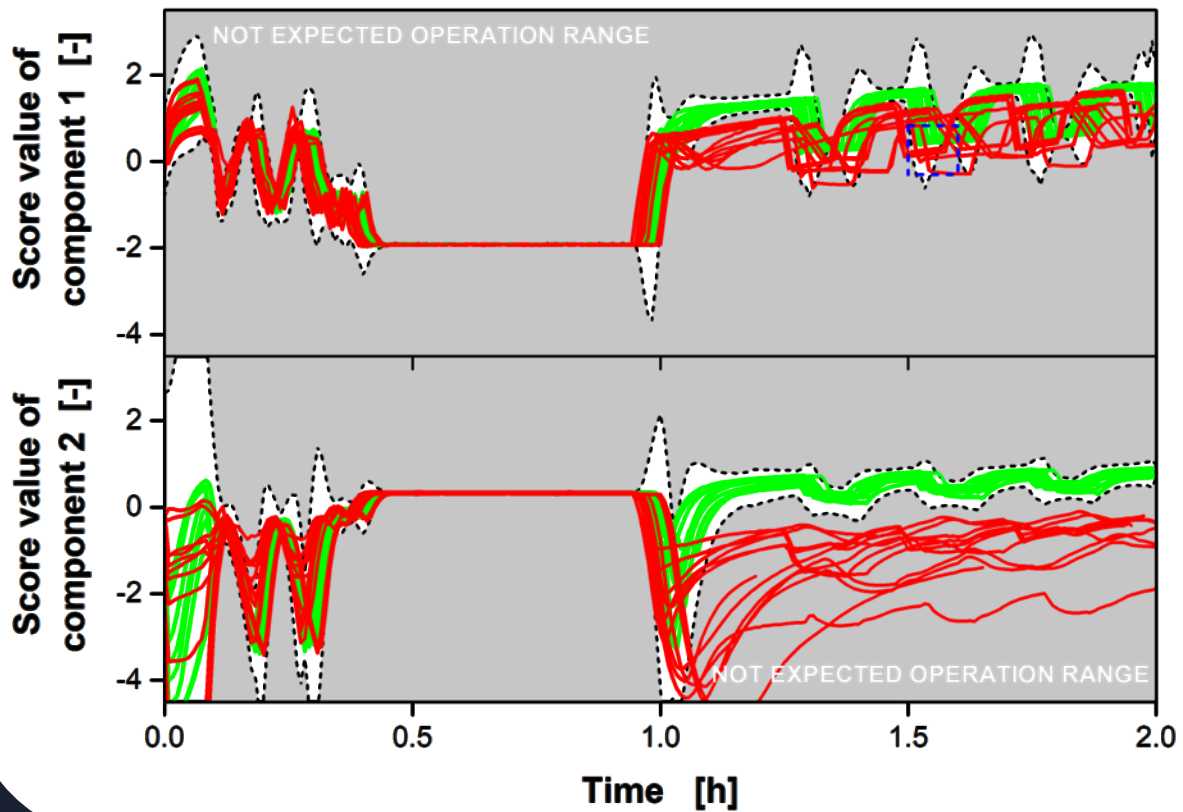


- 28 batches are included.
- Two components required.
- > 60 % process variance covered.

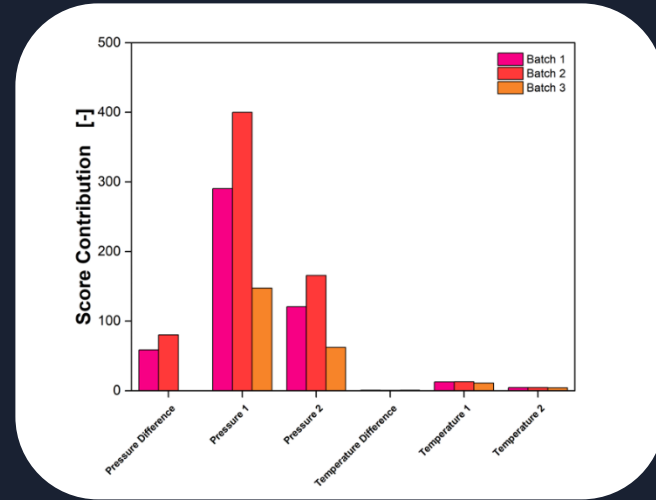
All variables are UV scaled, centered and equally weighted before adding to the model. Non of the variables are transformed or scale modified.

Pressure Difference: $P1(t_1) - P1(t_2)$
 Temperature Difference: $T1(t_1) - T1(t_2)$

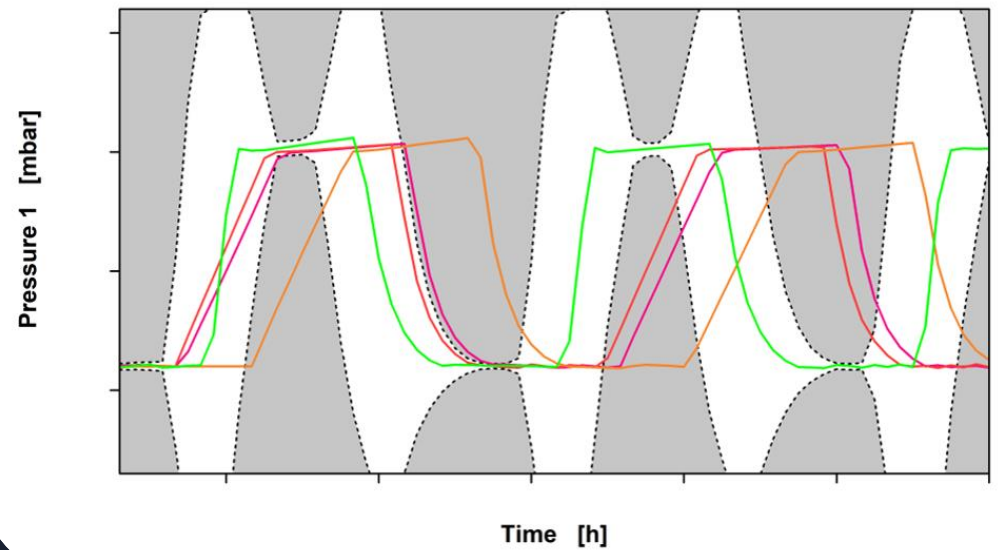
Multivariate Score Plot



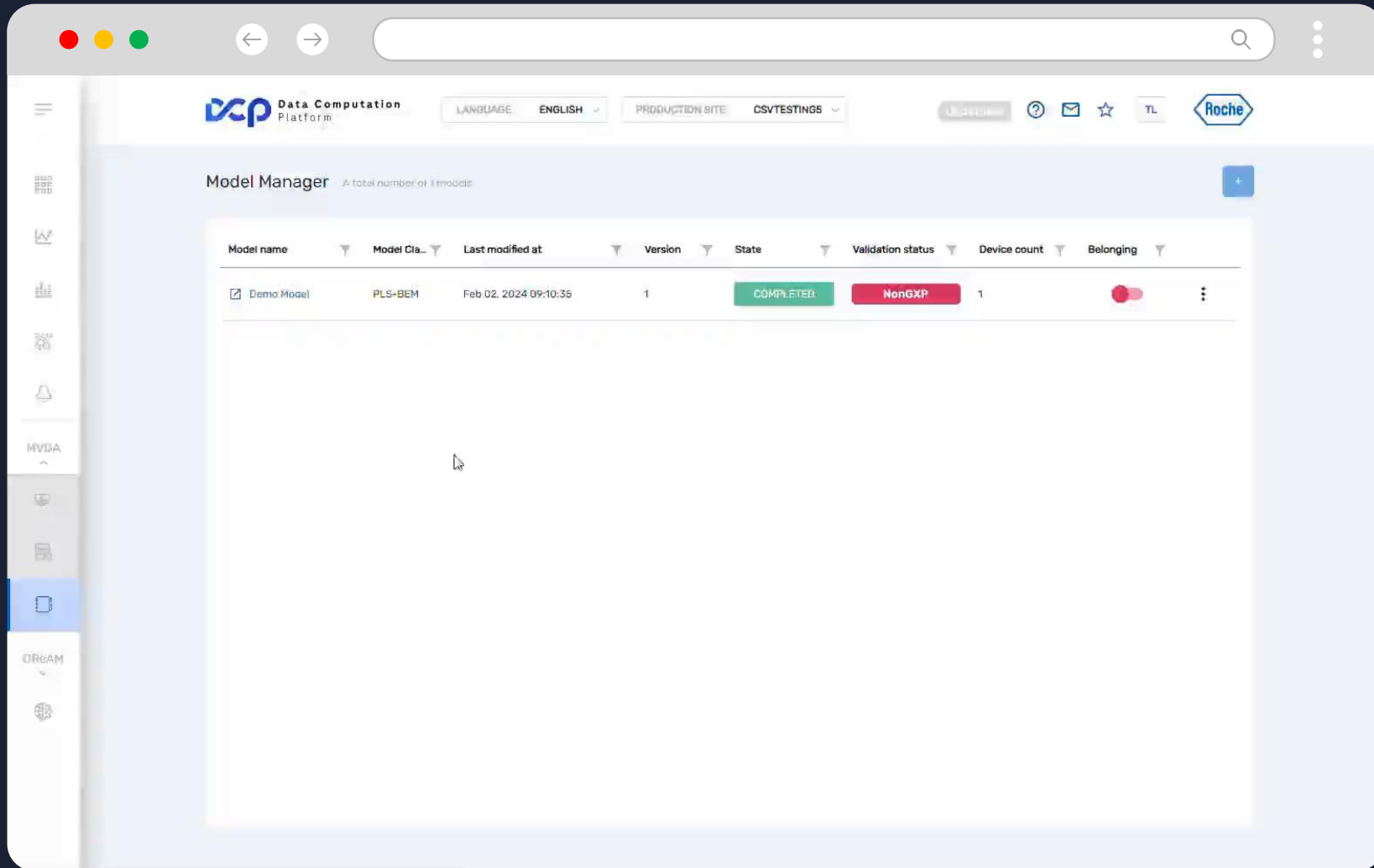
Contribution Plot



Univariate Sensor Signal



Model based Process Analytics



▶ Find the Model

Model can be opened via Model Manager or by following a hierarchical structure.

▶ Real-time & Historical


Multiple model types are supported per device to monitor in real-time or historical.

▶ Highlighting Outliers

Model excursions are highlighted with dots and violations are counted.

▶ Simple Data Drill-Down

Just by selecting data points, the data analytics can be started (e.g. Contribution Plot).

A photograph of a pharmaceutical manufacturing facility, showing several large, stainless steel fermentation tanks. The tanks are arranged in a row, with various pipes and valves connecting them. The lighting is bright and industrial, with a blueish tint. The tanks are the central focus of the image.

Use Case

An Operational Guidance App based on Titer prediction

Using data from various systems, this app employs advanced data manipulation techniques to [predict titer in fermentations](#). Its intuitive interface offers easy visualization tools, facilitating streamlined decision-making for operators in [Basel Drug Substance plant](#).

Empower Your Data Exploration

Simplified Analytics Workbench

SAW empowers manufacturing professionals with a GxP-ready solution, enabling effortless data connectivity, exploration, transformation, visualization, and collaborative decision-making while ensuring compliance and maintaining data integrity.



Connect



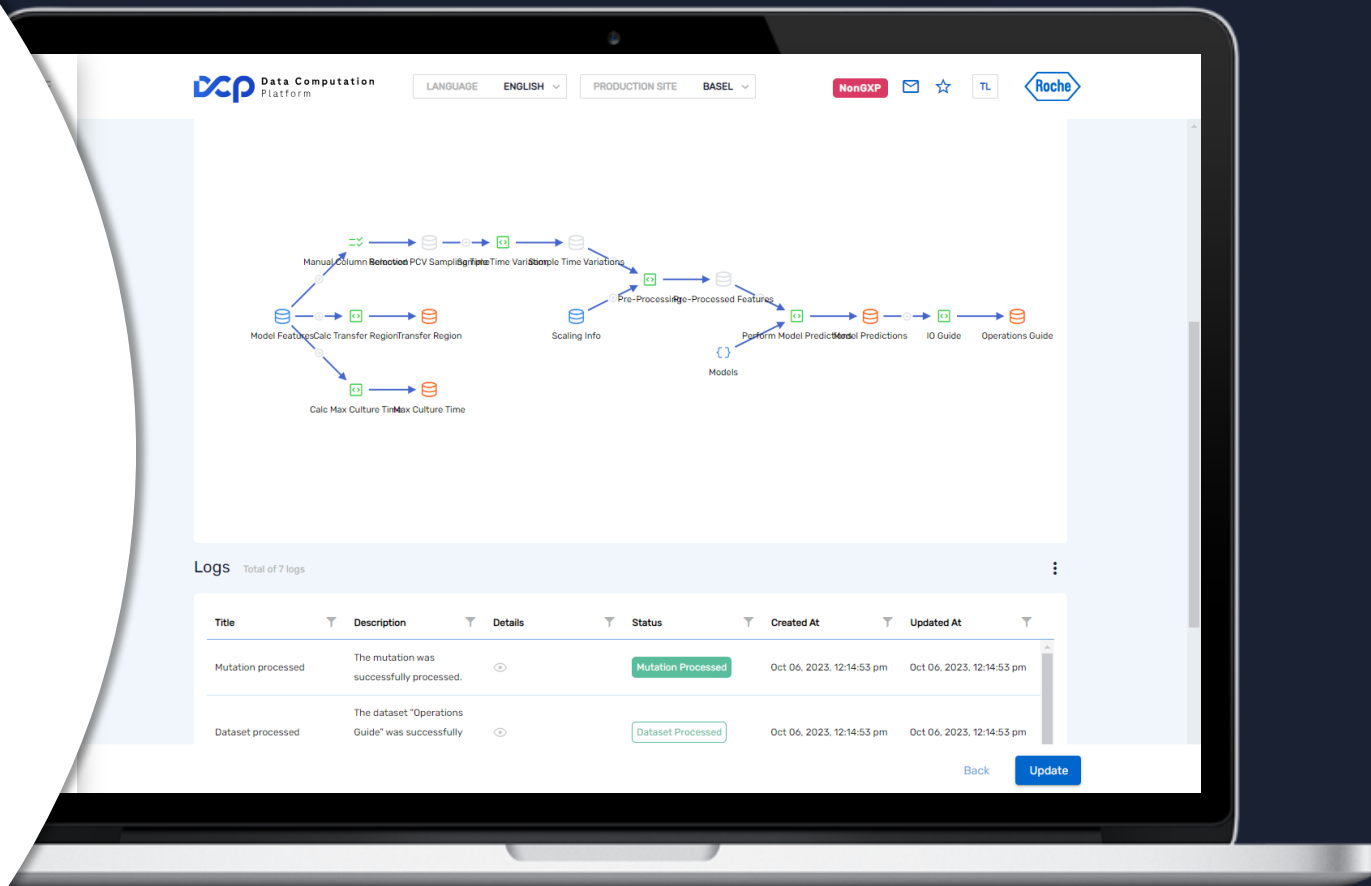
Explore



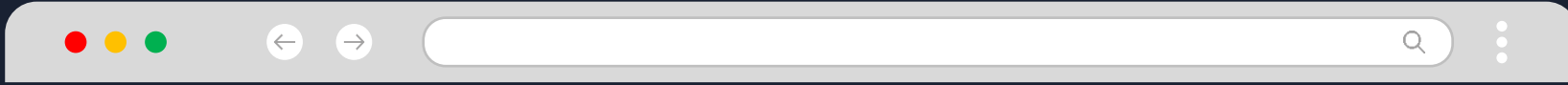
Transform



Visualize



Navigating the SAW Interface



▶ Connect Data Source

SQL Databases, AVEVA PI System, Snowflake, Google Sheets, ...

▶ Create Dataset

Effortless wizard for querying and importing data from source systems, with all manual edits meticulously tracked through an Audit Trail.

▶ Modify Data

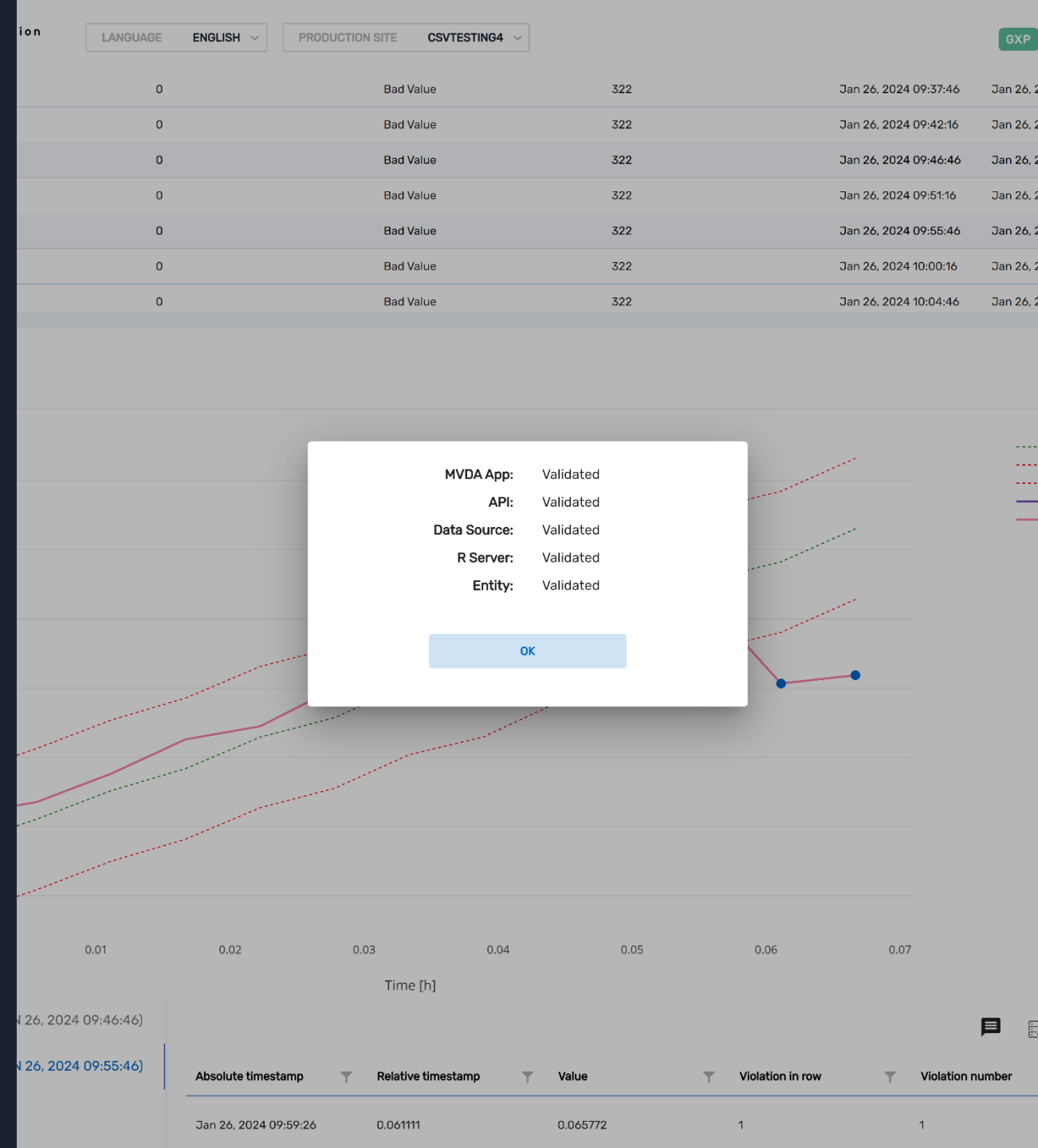
A user-friendly interface facilitates data transformation within a visual editor, complemented by scripting capabilities.

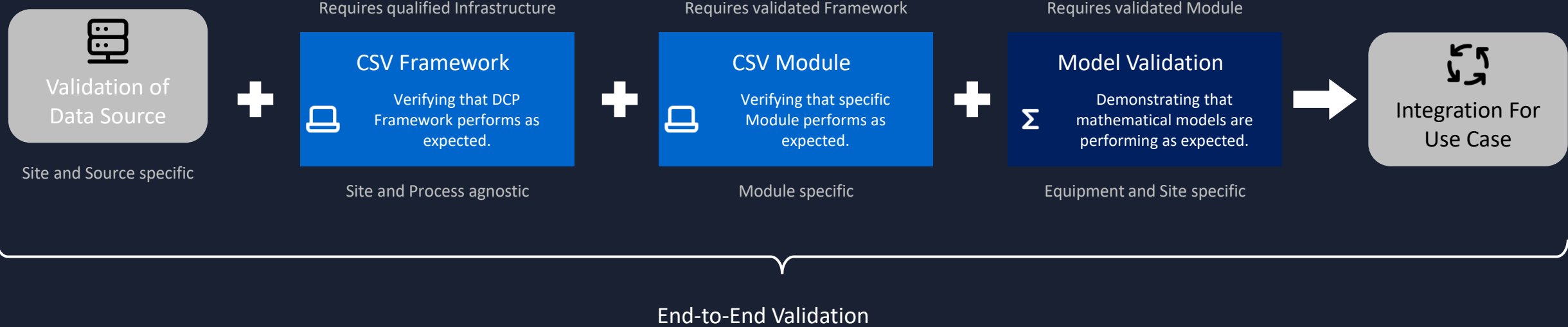
▶ Visualize and Ship

Diverse chart types and tables empower users to derive insights from the available data. Data filtering is facilitated through dropdown menus and range selections.

Validation Ensuring GxP Compliance and Reliability

Ensuring that a process, product, or solution is **consistently** capable of **meeting** the **requirements** of the end user in a compliant manner is crucial. This assurance is supported by **well-documented evidence and thorough testing**.



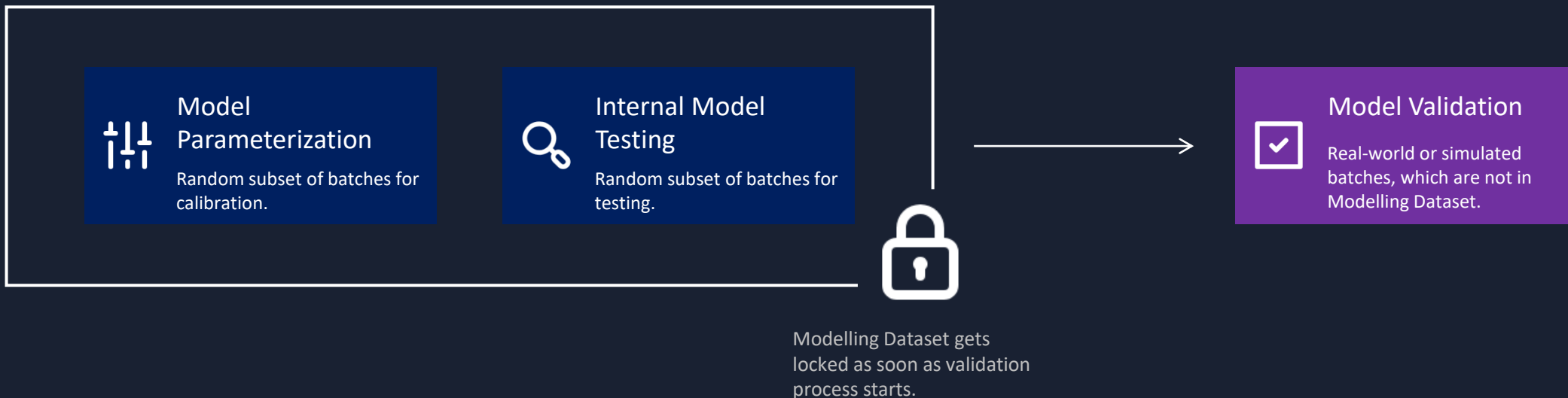


Validation Strategy

After successfully completing **validation** of the computerized system, including the module(s) and models where applicable, **integration** must occur to ensure accessibility for end users and to verify that the solution functions as intended, meeting all requirements. At this stage, **end-to-end validation** of the solution has been achieved.

Modelling Dataset

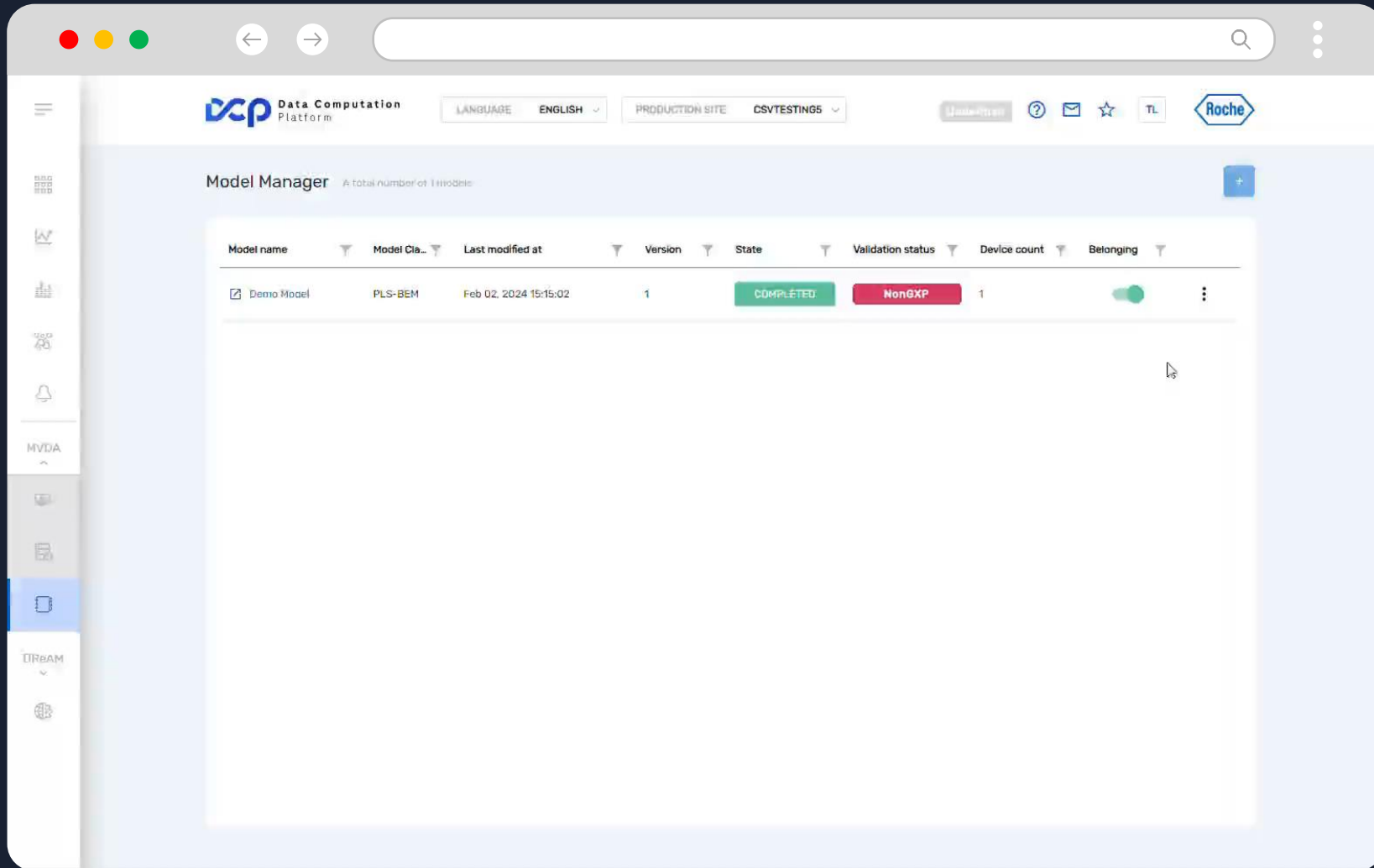
Batches expected to be representative for process.



Model Validation

Demonstrate that the mathematical models **deliver the expected performance** and adequately characterize the process under surveillance to ensure **meaningful** classification or differentiation between acceptable and unacceptable batches.

Model Validation Wizard



Four-Step Wizard

User is guided through validation workflow ensuring repeatable results across models & sites.

▶ Define Model Scope

Each validation requires general information and model acceptance criteria.

▶ Real-World Batches

Batches used for modelling cannot be used. Others can be used to challenge the model.

▶ Simulated Batches

In case that the real-world data is not sufficient, batches can be simulated with visualization aid.

▶ Complete Validation

Process automatically generated reports and link it with the EDMS.

Journey Towards Open-Sourcing Overcoming Challenges and Fostering Collective Progress

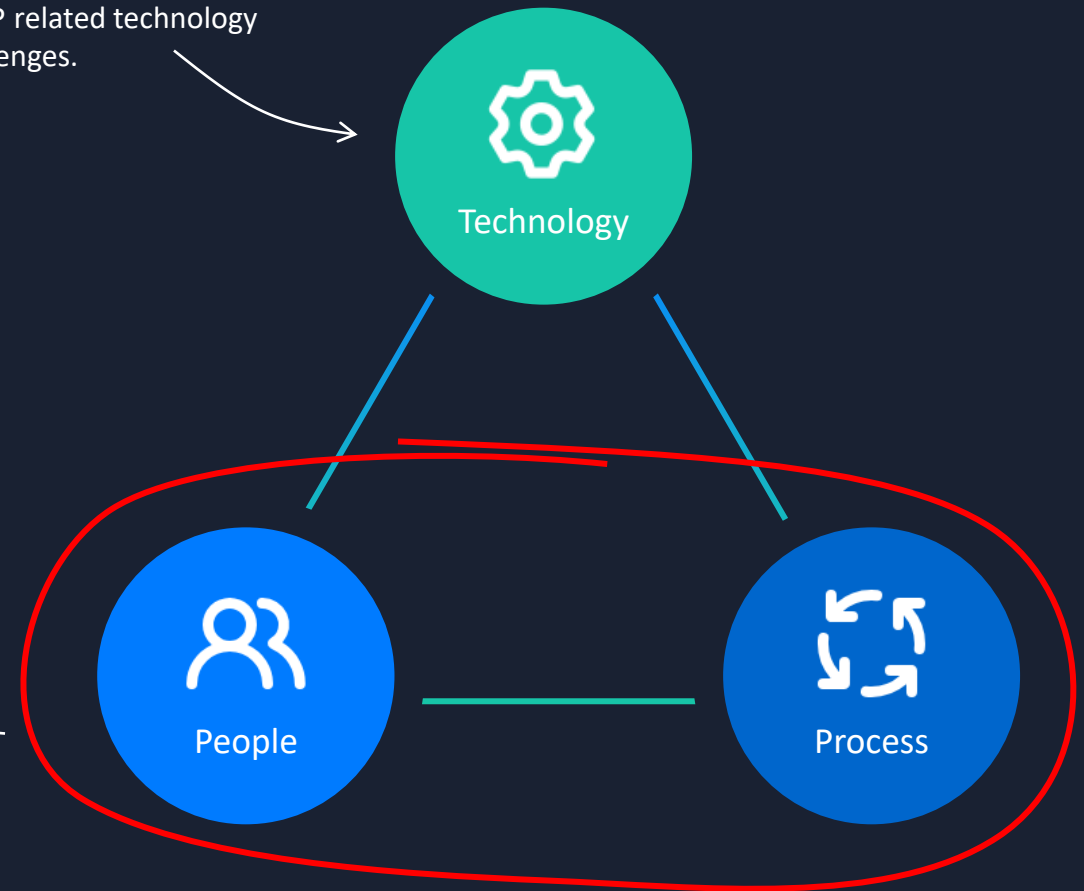
Embracing open-source principles, we are empowering the global community to [advance pharmaceutical analytics](#). Our journey towards open-sourcing DCP reflects our [commitment to innovation](#), transparency, and collective progress.



People, Process & Technology

Framework, designed to help companies build systems that effectively balance and coordinate how people, processes, and technology support each other.

DCP & Modules can help to solve some of the GxP related technology issues and challenges.

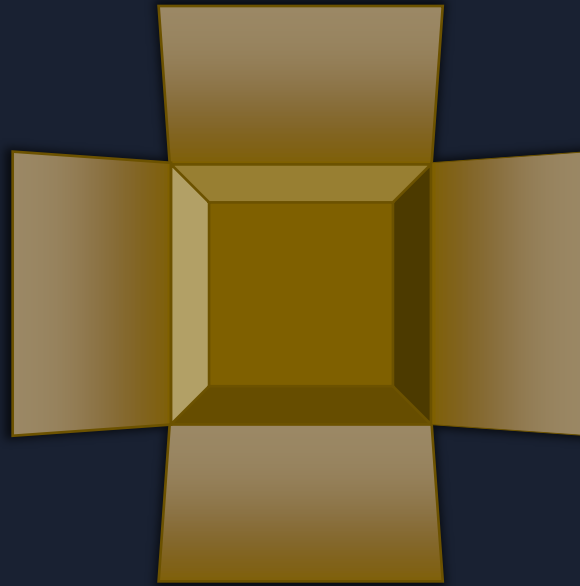


We can **learn** from the industry and drive **smarter** pharmaceutical manufacturing **together**.

Mindset, culture and end-to-end thinking remain as most crucial elements to ensure success in implementation and adoption.

Opening the Box

No established process for open-sourcing



▶ Intellectual Property Rights

Starting with the standard process for publishing papers, **more and more departments and roles became involved**: Intellectual Property (IP), Patent, Branding, Roche Medical Information Services, Inner-Source Department, and so forth.

▶ Confidentiality & Trade Secrets

The knowledge about our **manufacturing processes and operations** needs to be **protected**. Therefore, data models containing empirical operations data cannot be published.

▶ License Compatibility

DCP and its modules utilize multiple programming languages. Therefore, we had to evaluate over 30 repositories consisting of **3000+ packages** with various licenses.



open-dcp.ai

Business-oriented introduction to DCP includes visualizations and detailed explanations of the solution architecture, along with overviews of the capabilities offered by each published module.



Developer Docs

docs.open-dcp.ai

Comprehensive documentation covering the fundamental philosophy, core concepts, and detailed information about the testing framework and strategy for all DCP-related components.



Software Code

gitlab.com/roche/dcp

Backend, frontend, and mathematical scripts (R) for frameworks and modules are published in individual repositories on the Roche GitLab domain.



Compiled App

To ensure simplicity and rapid deployment, containerized compiled versions of DCP and its modules are made available on DockerHub. *(planned)*



Pioneering open-source GMP analytics for a more accessible,
enjoyable, and productive data-driven future.

Questions?

Please wait for the microphone.
State your name and company.



Please remember to...

Navigate to this session in the mobile app to complete the survey.



Thank you!