DataHow Symposium

AI-Driven Biomanufacturing: From Predictive Model to Adaptive Shop Floor Ecosystem

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Key paradigm shifts in the way we design & deploy AI

A holistic focus on business, technology and people enables transformative impact

Roche

BUSINESS

1. VALUE forward vs. Technology backward

2. Triple transformation requires blending of Digital (AI), IT & OE

3. Scale-up focused governance enabling move “from toys to tools”

TECHNOLOGY

4. Self-service data & digital products

5. Composable architecture vs monolithic

6. Rethink Validation 2.0

PEOPLE

7. Workforce of the future -

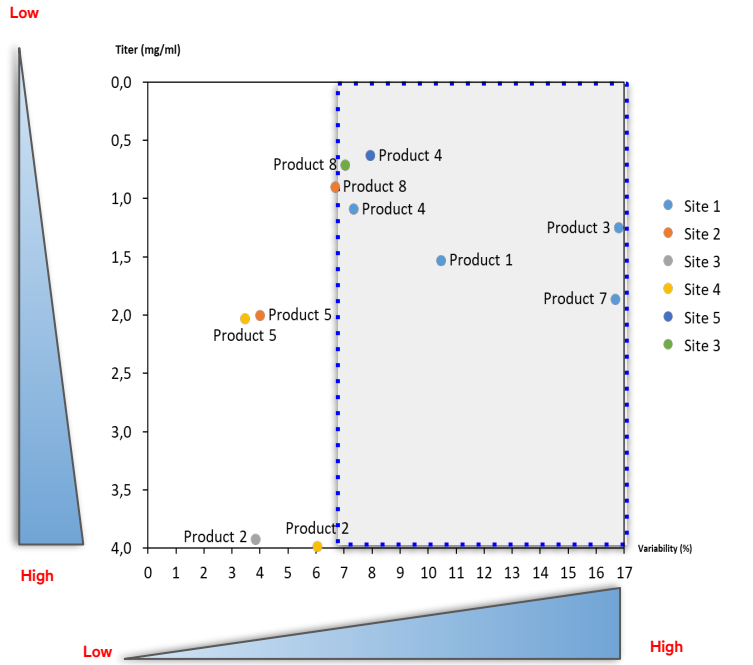
8. Digital Product owners vs Project Managers

The why?

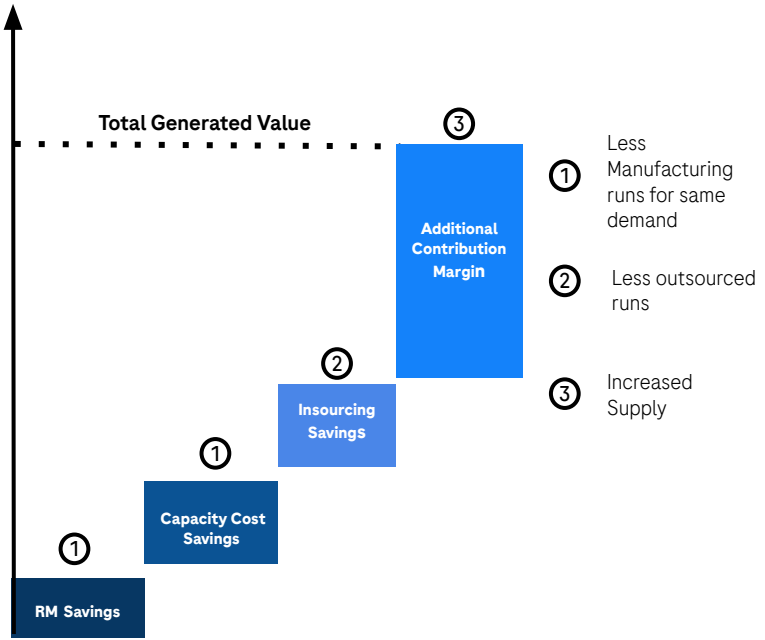
Setting the Context and Expected Outcomes

Titer Variability ranges from 5% to 30% leading to significant lost of API and potential value of 60+mCHF/Year at scale

Network Titer Variability Span

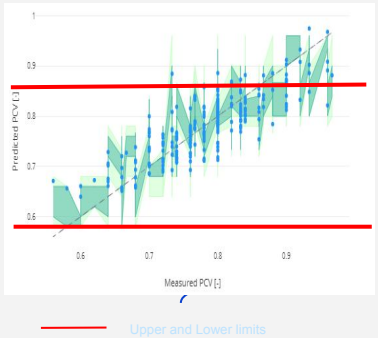


Cost Impact Drivers



Unexpected Critical Quality Attributes (CQAs) Deviations have tremendous business and financial impact

Challenges



CQAs deviations lead to batch write-off and are usually requiring intense and long effort for remediations

Business Opportunity

Right First Time

Optimised resource investment

Robust Supply to Patient

Financial / KPIs Opportunity

-30%
cost related to write-offs

-40%
resources related to recurring issues

> 97%
OTIF (On Time In Full)

The what?

From a fragmented data landscape to an adaptive shopfloor

We have developed an AI based Control of Product Health solution improving yield by +10% and managing multi-variate complexities

Complex biological manufacturing process

10 mfg steps over 30 -40 days

5-30% variability between batches

Multivariate influencing factors

Categories	Upstream	Downstream
Process Parameters	Temperature	Pressure
	Cell Density	Temperature
	Dissolved Oxygen	Flow Rate
	pH	Bed Height
	Stirring	Loading density
	Cultivation Duration	Conductivity
Processing	Cell age	Column Packing
	Media Hold Time	Pool Hold Time
	Bioreactor Hold Time	Number of Cycles
Raw / starting materials	Genetic Selection Marker	Buffer Conductivity
	Trace Element Impurities	Buffer Molarity
	Media Concentrations	Purity
	Cell Line	

300+ influencing factors

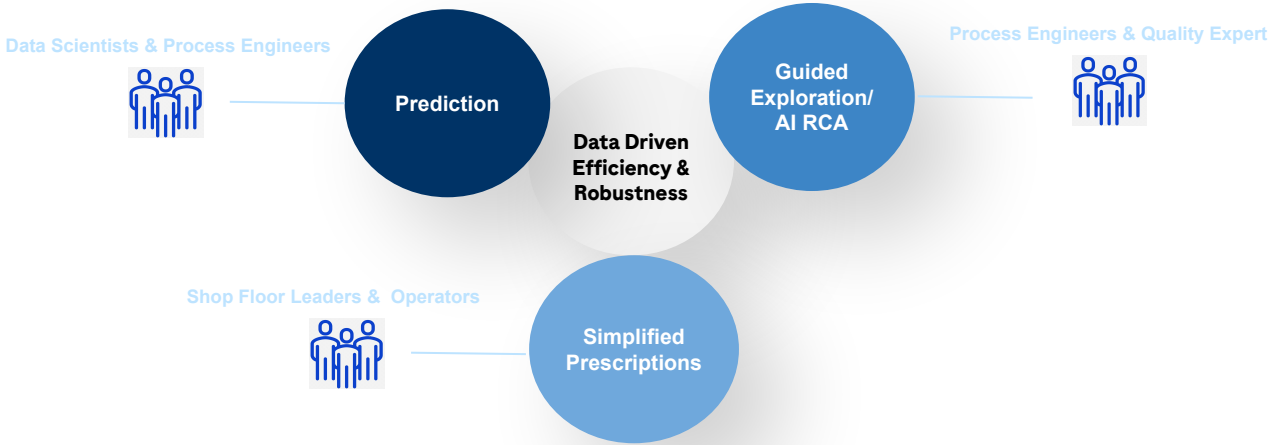
10 million data points

We create and sustain value with going through the entire AI value chain and creating a capability ecosystem

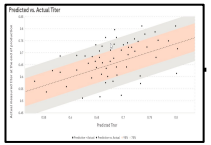
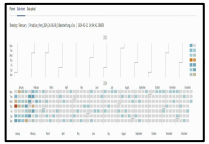
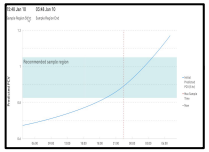
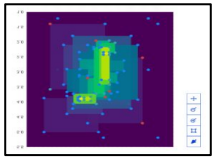
AI Value Chain deploying Manufacturing Digital Twins

Connection to Data System	Scalable and re-usable Data products	Advanced Features Catalog	Advanced Algorithm Catalog	Business & Decision Centric	Deployed Digital Way of Working & Capabilities

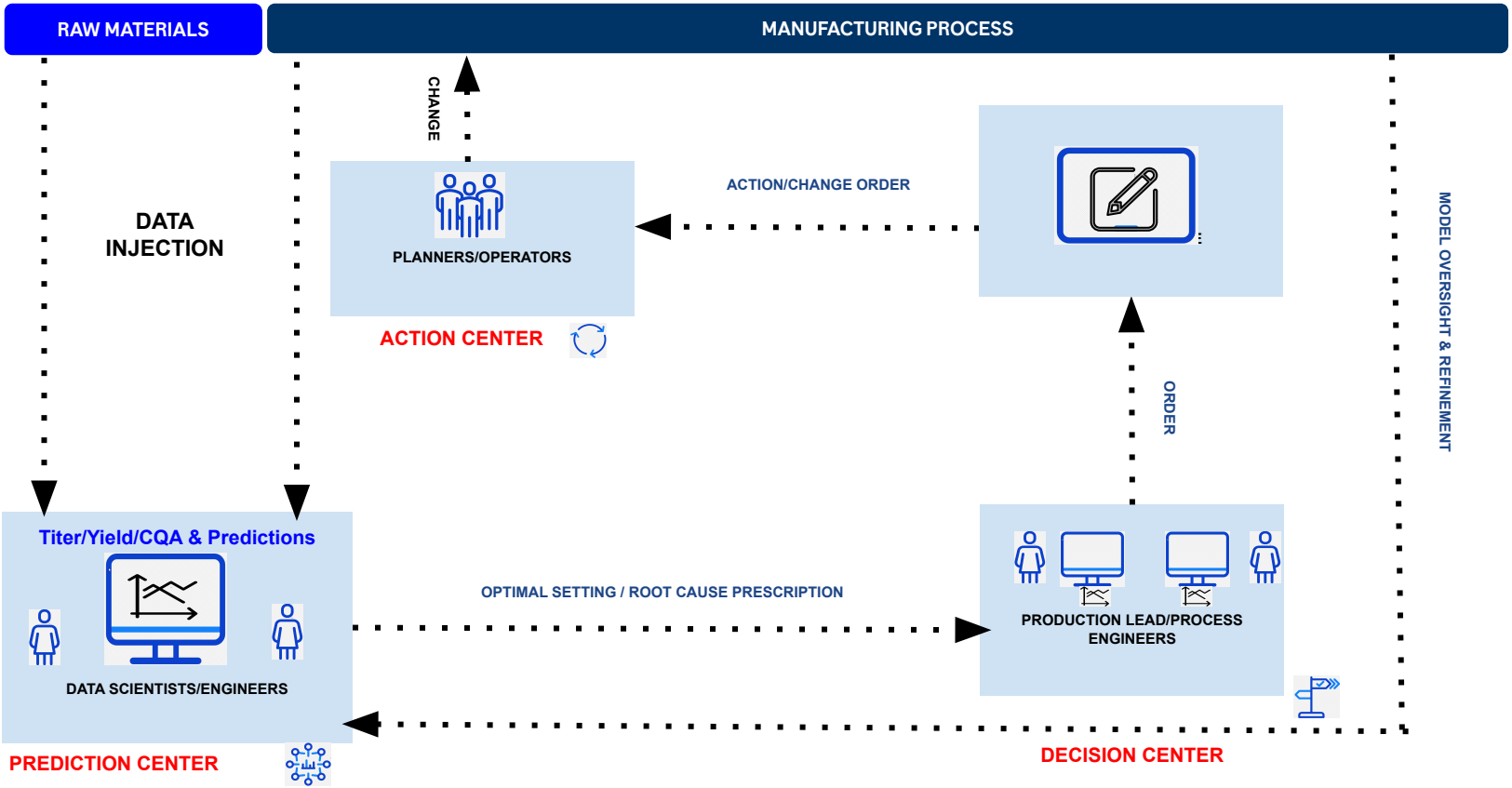
AI driven Manufacturing Site Capability Ecosystem



How does our digital App Suites look like?

App suites		Implemented Features	Users
1 Manufacture X		Predicted Titer, Cell age effect and cell growth Multivariate Process Dashboard for RCA	Data Scientists Proc,Eng
2 Plan X		Prescribe maximum batch to minimize cell age effect and prescribe associated planning	Production Planners
3 Operate X		Prescribe transfer time from one small bioreactor to a next bigger one + RCA Exploration guidance	Experts/ operators
4 Rm X		Prescribe optimal raw material concentration in media	Operators

AI driven Digital Ecosystem and Capabilities



The How?

Defining our Operating & Staffing Model

We developed a standard deployment process

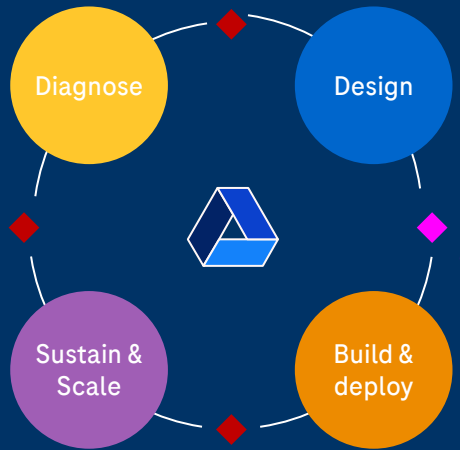
1 Diagnosis

Understand current status and quantify improvement opportunities

2 Design and Data Analytics

Define hypotheses,and analytics deployment priorisation

Generate Data Insights and prioritize remediation actions



Key Decisions Milestone on service or digital product options

4 Sustain & Scale

Track value generated complete analytics know-how catalog

Digital Product Maintenance and Scaling

3 Build & Deploy

Implement prioritised remediation actions

OR/AND

Build Digital Predictive and Adaptive Solutions

We developed Data Pipeline in a dispersed Data Landscape...

AVEVA OSIsoft.

PI System

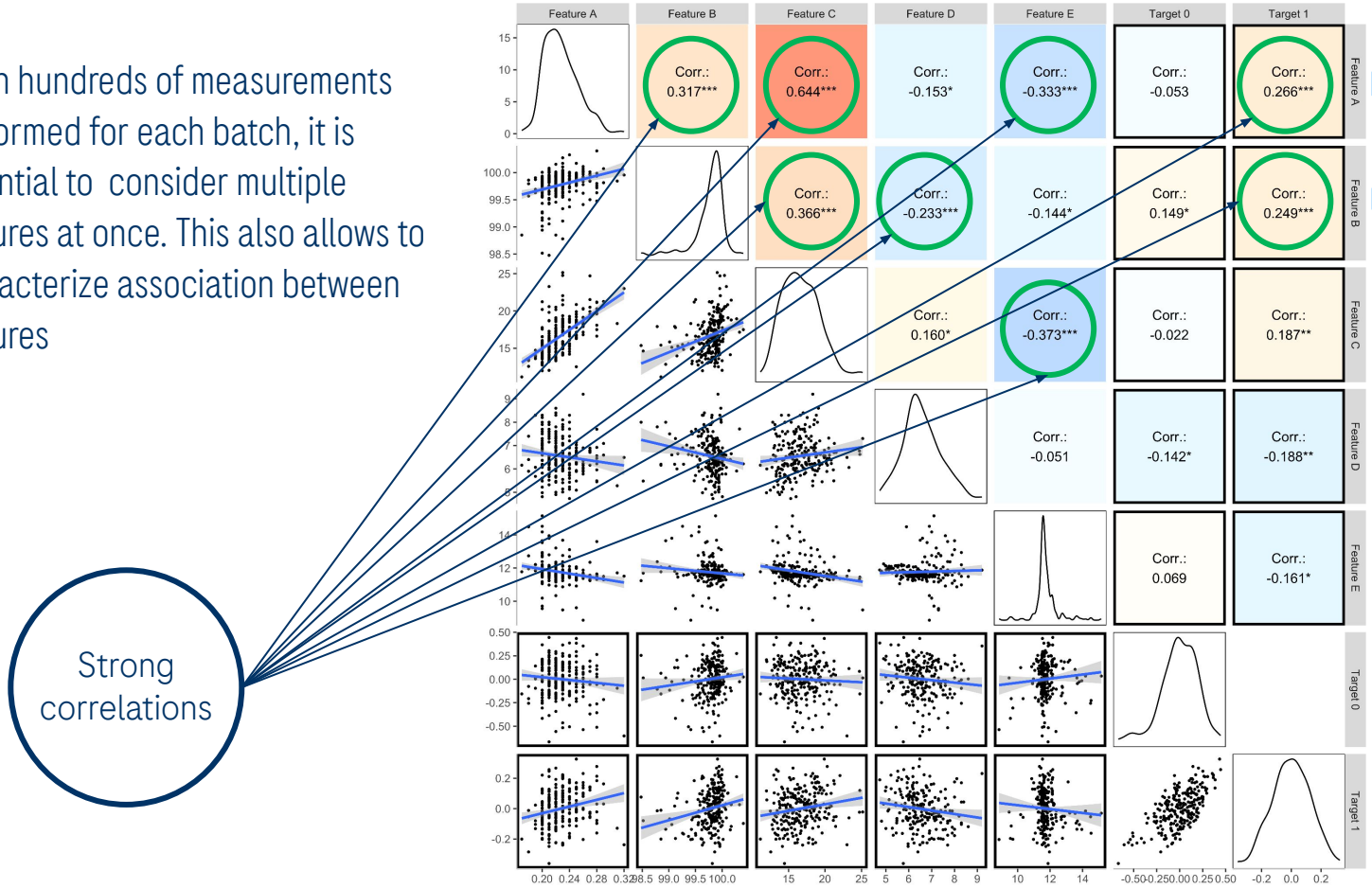
SAP

MES

(Manufacturing Execution System)

We built most relevant features with multiple parameters…

Given hundreds of measurements performed for each batch, it is essential to consider multiple features at once. This also allows to characterize association between features



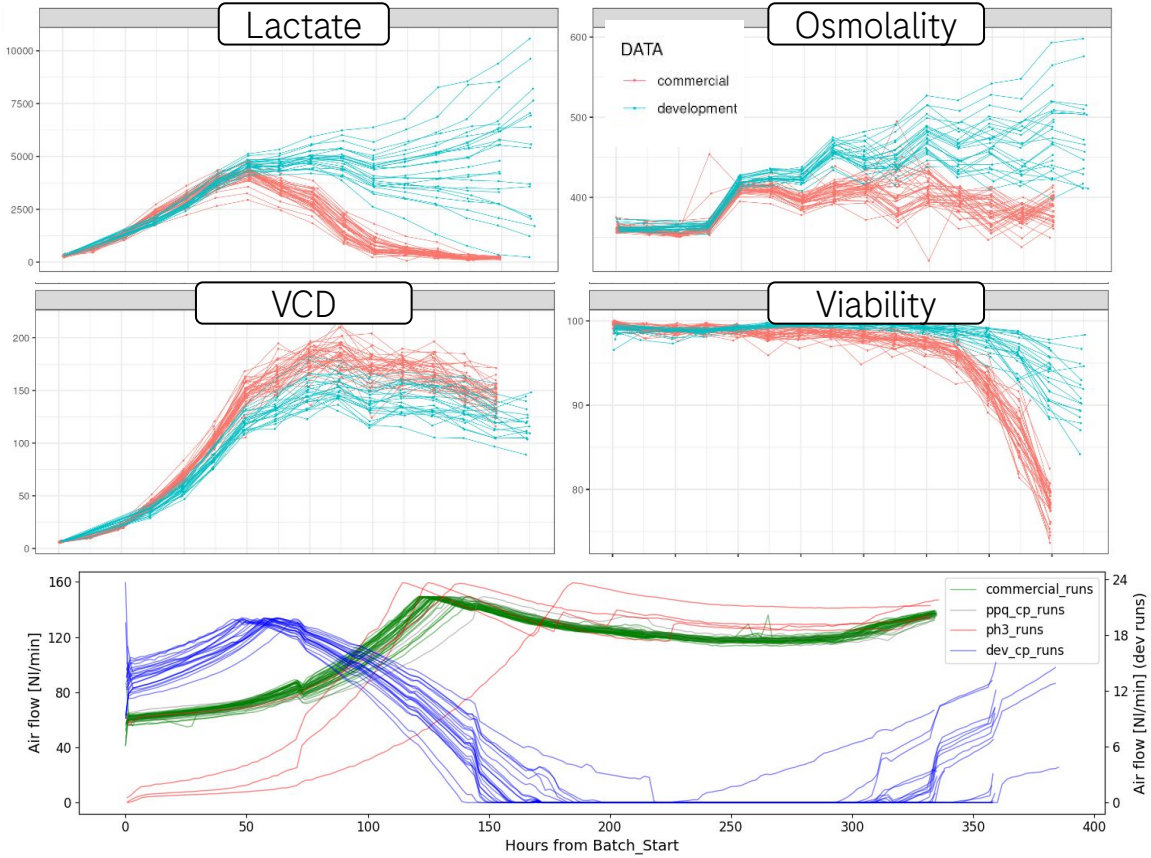
Strong correlations

Deep dive

Feature extraction

We had to deal process scale comparability...

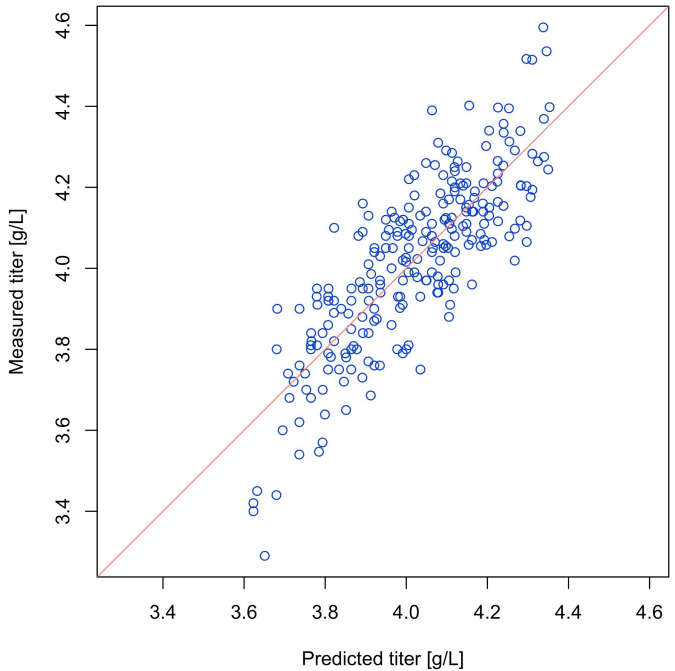
How well do the scales compare based on offline/online process data?



Comparable Scales enable leveraging and combining process development and commercial manufacturing data

We evaluate carefully our Model evaluation prediction strenght

Having the predicted titer closely match the measured titer should not be the (only) way of measuring model performance – it is more desirable to focus on impact of features and generalization



Ideally, one would like

Predicted titer ≅ *Measured titer*

in terms of similarity metrics (R^2, RMSE).

But one would also like to:

- ➔ Retain only impactful features
- ➔ Avoid overfitting
- ➔ Make sure the trained model is able to generalize to new batches

Scaling in regulated environment

From “toys” to GMP compliant tools

Scaling Readiness and Challenges to overcome

Today Scalability Readiness

Low High

Data Pipeline

AI Models

User Interface

DWoW*/OCM

*Digital Way of Working

Influencing Factors

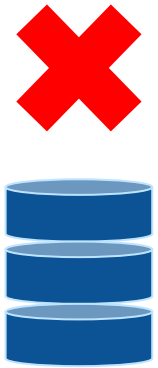
- Data Backbone readiness
- Data Connectivity
- Data Quality

- Key Process Data availability
- New Analytical Technologies
- Accuracy Oversight

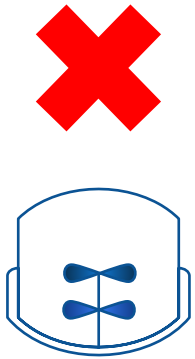
- End Users engagement and consideration during design

- Digital Maturity
- Transformation Standardisation
- Actions simplifications

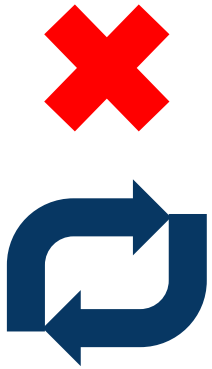
GMP Impact Core Considerations...



No Data Generation



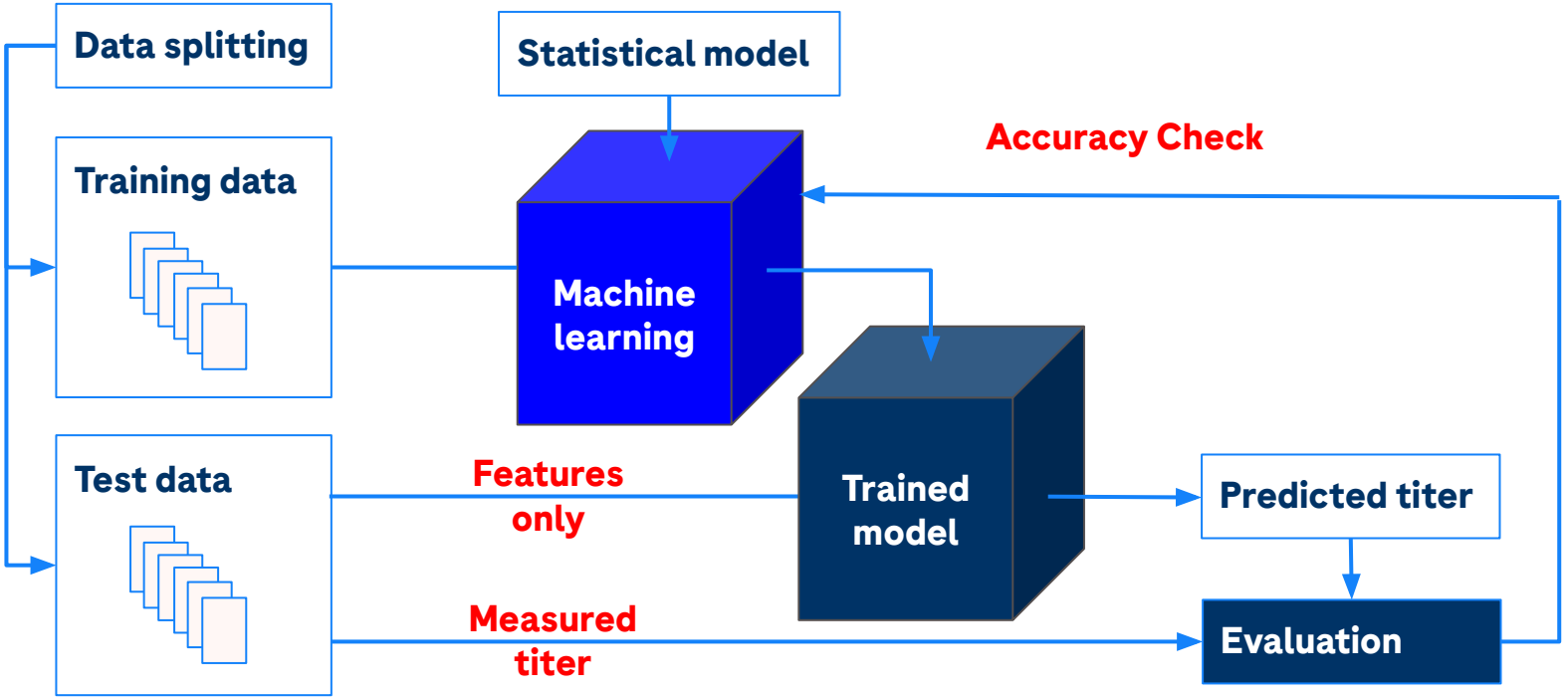
No alteration of manufacturing process (recommendation stays in validated ranges)



No automated (closed loop) decision

Continuous Model validation with continuous new testing data

By splitting the data into training and test data, we make sure that our model is able to generalize (predict) to an independent dataset coming from new batches



WEF announcement
Oct 8th, 2024

Roche Basel Drug Substance Manufacturing has been recognized as a “Global Digital Lighthouse Factory” by the World Economic Forum