

16-19 MAY 2022

Sartorius Membrane Digital Transformation Journey

Mark Egorov

AVEVA

Outline

- About Membrane Technologies at Sartorius
- Importance of Data to Membrane Production & Product Development
- Digitalization Journey
- Use Cases Solved & Challenges
- Future Roadmap
- Conclusions



Sartorius: Partner of life science research and the biopharmaceutical industry

Our mission

We empower scientists and engineers to simplify and accelerate progress in life science and bioprocessing, enabling the development of new and better therapies and more affordable medicine.



Our vision

We are a magnet and dynamic platform for pioneers and leading experts in our field. We bring creative minds together for a common goal: technological breakthroughs that lead to better health for more people.

Sartorius in brief



60+

Locations worldwide,
headquartered in Göttingen, Germany



~14,000

Employees¹



~€3.45bn

Sales revenue²



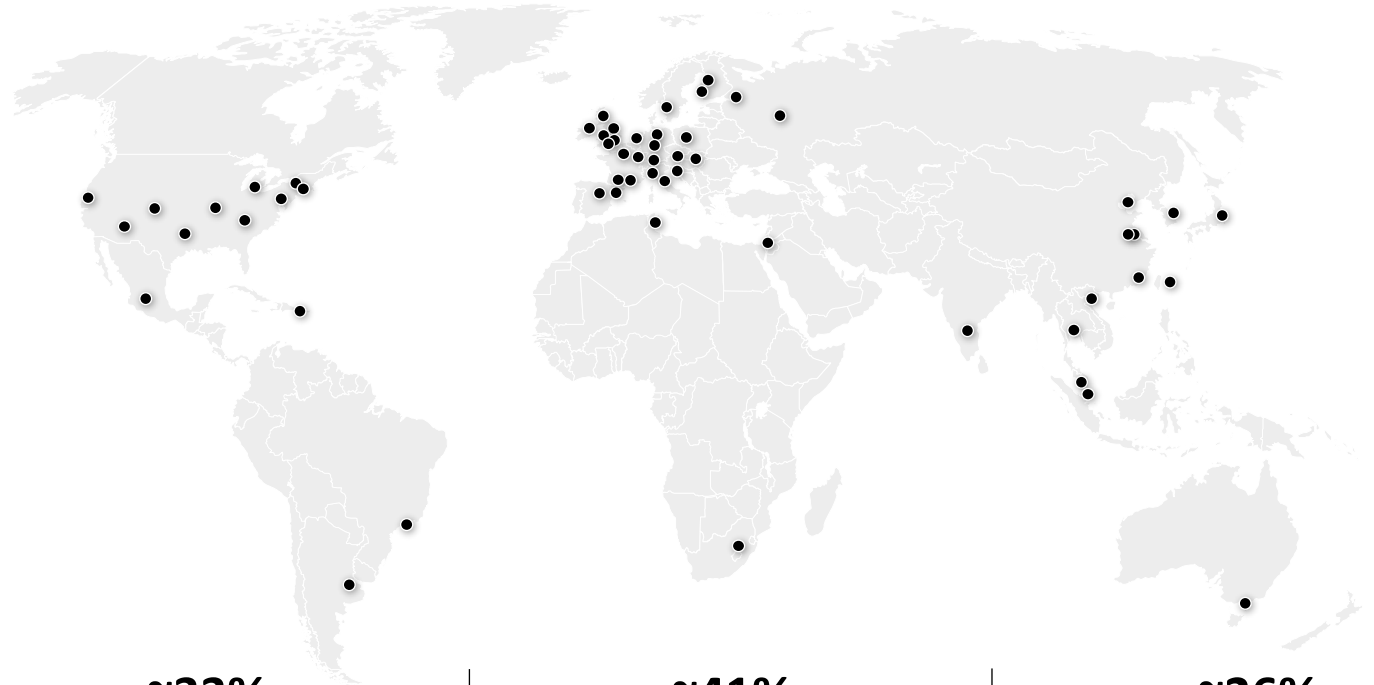
34.1%

EBITDA margin^{2,3}



~€37.4bn

Sartorius AG market capitalization¹;
listed on the DAX and TecDAX



~33%

Sales revenue
Americas

~41%

Sales revenue
EMEA

~26%

Sales revenue
Asia | Pacific

1 As of December 31, 2021, 2 FY 2021, 3 Underlying EBITDA

Sartorius – Our goal: Simplify manufacturing of biopharmaceuticals

Our technologies empower engineers in the biopharma industry to ...

- ... set up robust, flexible and safe processes for industrial production
 - ... reduce setup costs
 - ... enhance product yield
-



Sartorius – Our solution: Innovative technologies for all phases of drug production

Products

Scalable, easy-to-use technologies and products for the production of biopharmaceuticals, as well as digital tools for biopharma data analytics

Application areas

- Biopharmaceutical manufacturing (...)
- Quality control and testing (...)
- ...



Filtration



Cell culture technology & media



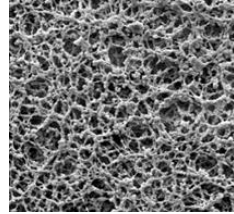
Fluid management



Purification

Sartorius Membrane Technologies

- **Membrane** – a thin polymer film with distinct porous structure – is a **key component in all filtration and purification consumables**



- There is a large variety of membrane types that differ in pore size and structure, surface properties and polymers to meet application requirements
- Membrane casting is a continuous (24/7) steady-state process, but each campaign (product changeover) can also be viewed as a batch process
- Produced membranes are cut into **rolls**, each batch consists of multiple membrane rolls, quality data is measured for each roll produced



Membrane Production Chain



Raw
Materials



Mixing



Casting



Modification



Half-finished
Products

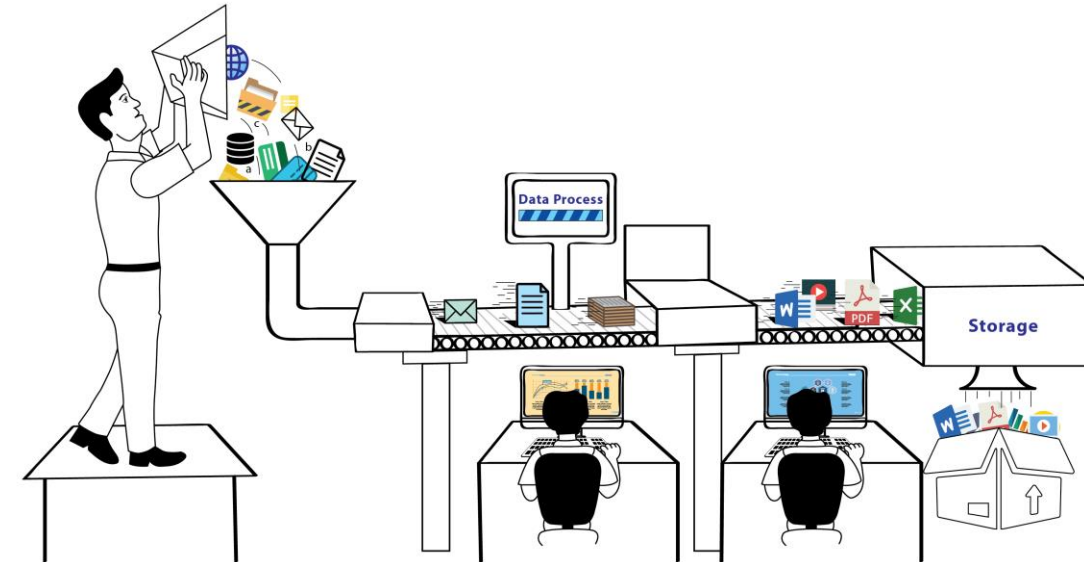
Quality: from raw materials to final product

Challenges: multiple membrane types from different raw materials, casting and post-processing steps, continuous 24/7 production

Importance of Data to Membrane Production & Product Development

Product quality and consistency are key customer requirements

- Membrane production is a complicated sequential process with many factors of influence:
 - Process parameters must be tightly controlled to ensure consistent quality
 - Product and process improvement require identifying critical process parameters and their correlation to quality attributes
- The availability of the right data at the right time
 - Has a direct impact on quality and production efficiency
 - Can speed up product development and reduce costs (in silico membrane development)
 - Enables efficient process monitoring and fast deviation detection



Structuring membrane process data – Enabling scale-up and evergreening

Challenges

- No centralized long term storage of process data at high resolution
- New equipment and information are not integrated fast enough
- Limited transferability of data models
- Limited scalability in the context of fast capacity increase

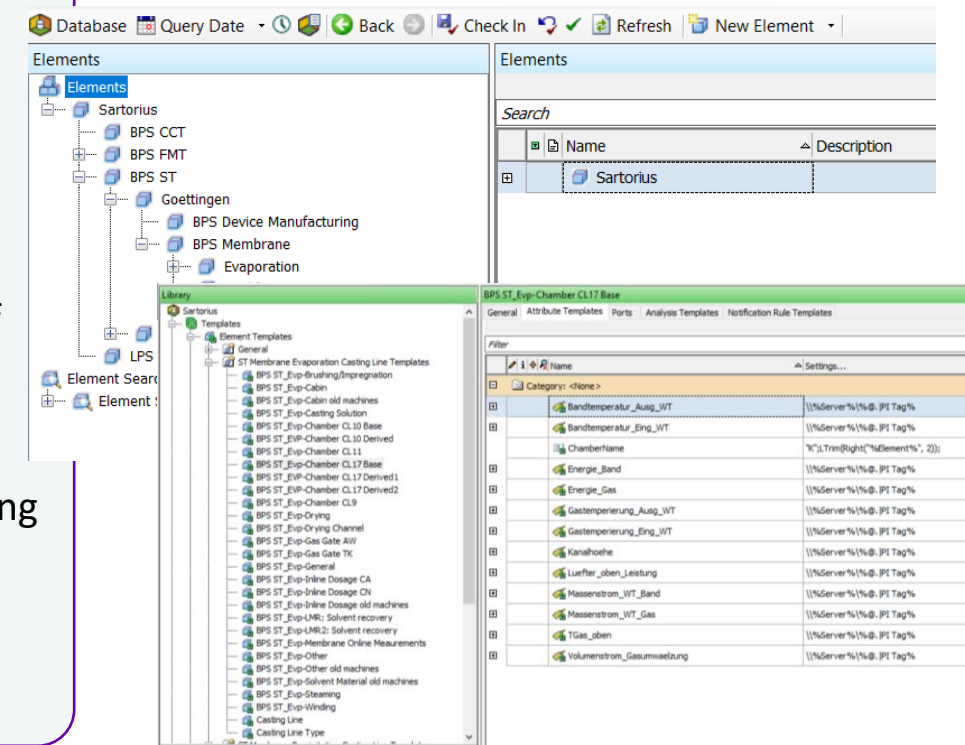
Solution

- PI System with integration to production data sources and monitoring tools
- Asset contextualization
- Equipment-specific performance calculations
- Equipment templates
- Self-service data access (PI Vision)

Benefits

- Agility in accessing data for modelling and process monitoring
- Centralized data integration
- Reduction of timeline in qualification and commissioning of new equipment

Ability to scale-up solutions promoting best practices

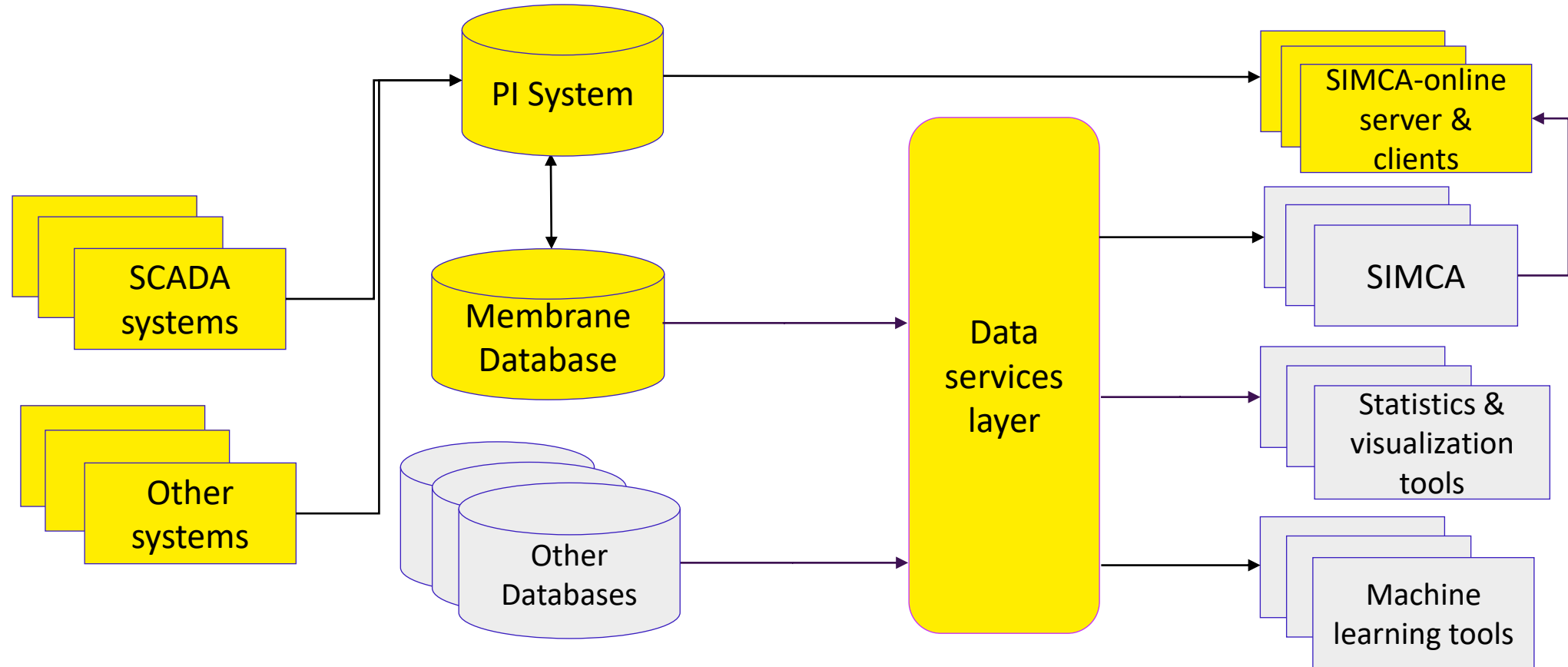


PI System as Integral Part of the New Data Infrastructure

Process and quality data

Data Integration

Monitoring / Analyse

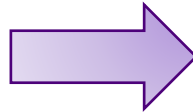


Use Case Solved # 1

Membrane roll statistics

Before integration with PI System:

- The Membrane database (connected to MES) is updated with process data captured from PCS in discrete manner at low time-resolution.
- There are limitations for intra roll statistical analysis
- Correlating roll quality data to process data is cumbersome.



Additional features after integration:

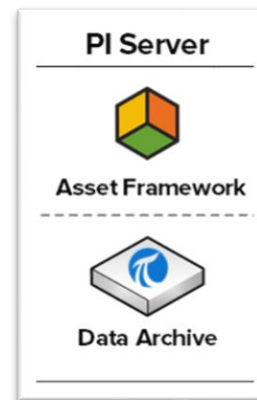
- The system gathers data from PI System and Membrane database and calculates additional statistics (stddev, max, min and mean value) for all process parameters for each membrane roll produced.
- The Membrane database is updated automatically and fed with the statistical data (done via a AF SDK application) to allow direct correlation of roll statistics data to roll quality data.

Use Case Solved # 2

Real-Time Data Analysis and Correlation Patterns

Before integration with PI System:

- Each production line had a different OPC Server, hence multiple SIMCA-Online connections (via OPC DA) had to be maintained.
- Direct use of tags prevented easy creation or modification of models for process monitoring.
- Real-time analysis could be disturbed by OPC server disconnection issues.
- Production could be disrupted due to direct connection of SIMCA to SCADA.



Additional features after integration:

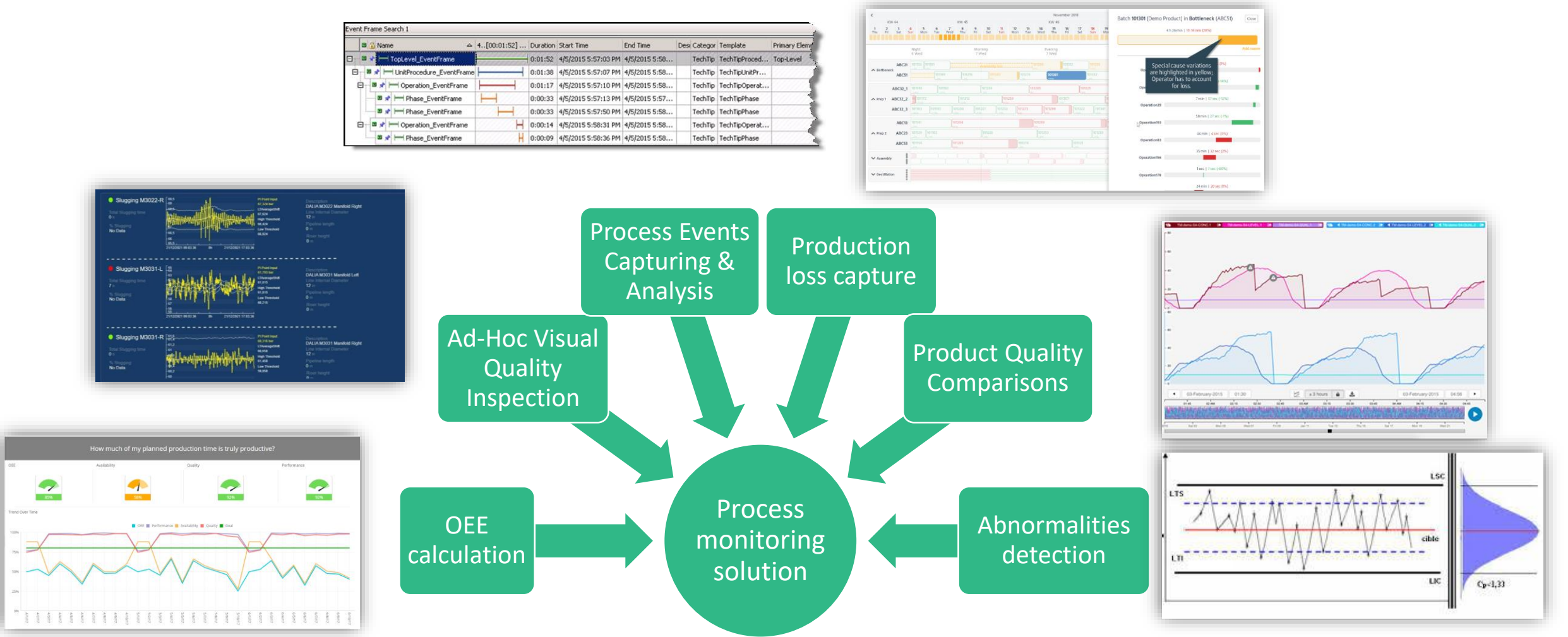
- One connection point to one PI System with buffering capabilities to prevent data loss.
- Ability to browse the AF assets for modelling the production line for easy drag and drop SIMCA model creations.
- Having all the history stored in PI System, the SIMCA models can be further fine-tuned and improved.

Economic Impact

Use of PI System in combination with other software tools such as SIMCA-online has direct economical benefits:

- Faster technology transfer & Integration of new equipment
 - Significant reduction of time and number of trials
- Timely detection of equipment failure or malfunction
 - Increasing overall equipment efficiency
- Root-cause analysis using combination of roll statistics and roll quality data
 - Process optimization leading to production increase
- Production changeover
 - Significant reduction of scrapped rolls
- Inline quality data control using PI Event Frames
 - Process optimization leading to production increase
 - Reduction of scrapped material

Future Road Map - Identify Process Events



Future Road Map - Identify Process Events

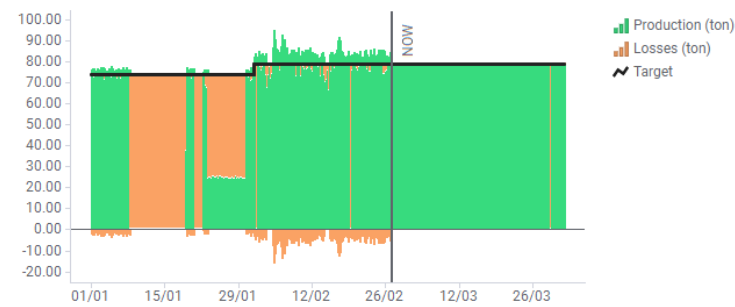
Sustainability – Product Consistency – Product Development

Online process monitoring (SIMCA-PI System)

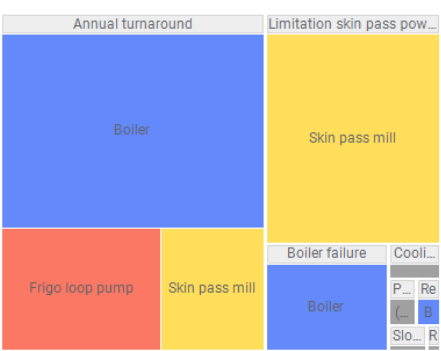


Automated loss classification and reporting

Production, target and losses (ton/h)

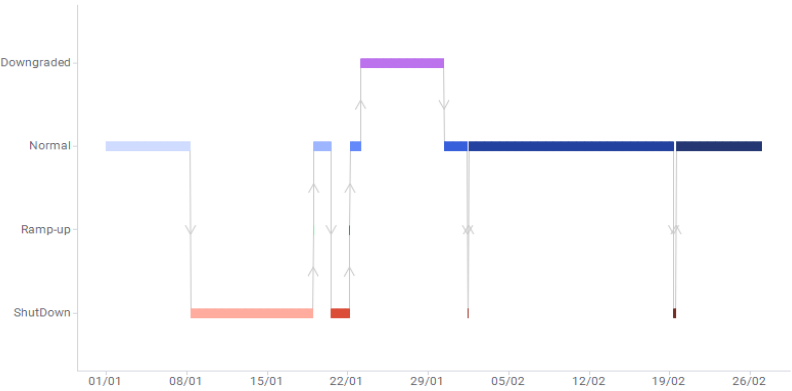


Loss root cause

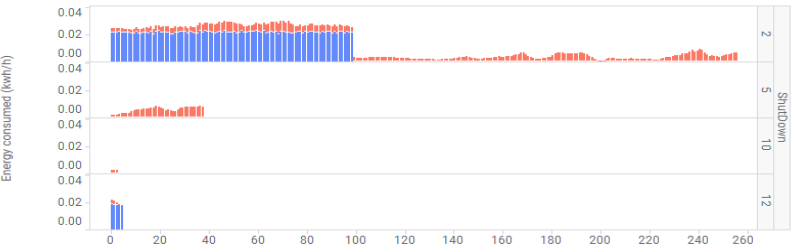


Plant energy management

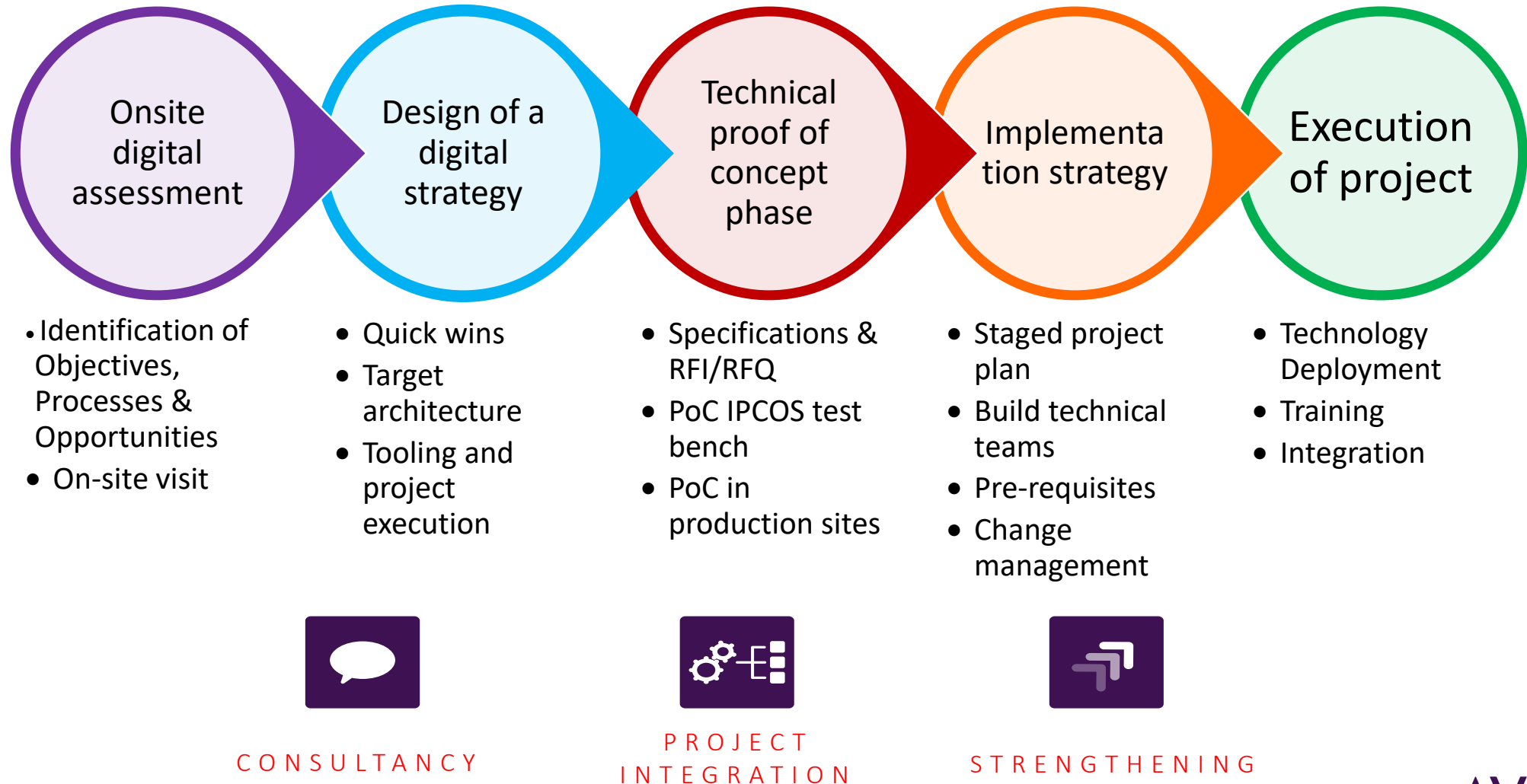
Operating modes overview



Energy consumption profile during Shut Down



IPCOS Digitalization Journey Involvement @ Sartorius



Simplifying Progress

The Sartorius logo is displayed in a bold, black, sans-serif font. It is centered within a bright yellow rectangular box that has a slight 3D effect with a darker yellow shadow on its right side.

Challenge

- For complex membrane production processes continuous real-time monitoring is required to ensure consistency and product quality.
- Development of new products / processes, technology transfer, process optimization heavily rely on the availability of process data and its use with quality and data from different production steps.

Solution

- Deployment of PI AF, PI Vision and PI EF in combination with Sartorius-own products such as SIMCA-online as a basis for real-time process monitoring and control.
- PI AF provide standardization and integration of process data with quality data to allow the use of advanced data analytics for process optimization and product development.

Benefits

- Timely detection of any equipment malfunction or help in preventing future incidents
- Identifying new critical process parameters and new process and machine improvements
- Accelerating the development of new products / processes
- Faster technology transfer and integration of new equipment

Special thanks

To my Sartorius colleagues:

- Sascha Vogt (Sartorius IT)
- Matthias Gröschel (PD SCT, Engineers)
- Isabelle Masselin (PD SCT, Data Analytics)
- Robabeh Moosavi (PD SCT, Data Analytics)
- Oscar Ruiz (Sartorius IT)

And to the IPCOS team:

- Filip Stroobant
- Mohamad Shamseddine
- Louay Aouad



Mark Egorov

Manager of Process Data Analytics

- Sartorius
- Mark.Egorov@sartorius.com