

MAY 18<sup>TH</sup>, 2022

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# Leveraging the combination of on-prem PI server and AVEVA Data Hub, to feed data analytics and ML applications on aseptic fill-finish lines

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**AVEVA**

# IMA LIFE

Operating through six production sites, **IMA Life** (*Aseptic Processing & Freeze Drying Solutions*) is one of the three pharmaceutical divisions of the **IMA Group**, world leader in the design and manufacture of automatic machines, highly specialised in the production of complete aseptic lines for parenteral products including:

- Vial washing & depyrogenation
  - Filling, stoppering & capping of liquid and powder drugs
  - Isolation technology
  - Freeze dryers & relevant automated vial loading/unloading systems
  - Decontamination technology
  - Secondary packaging
- **High speed lines, with performance from 400 up to 600 units per minute;**

**Consolidated technologies** acquired not only through experience spanning over **60 years** but also with **ongoing partnerships and large-scale projects** developed and managed **with leading pharmaceutical companies worldwide, such as**



patheon  
by Thermo Fisher Scientific

Catalent. AstraZeneca



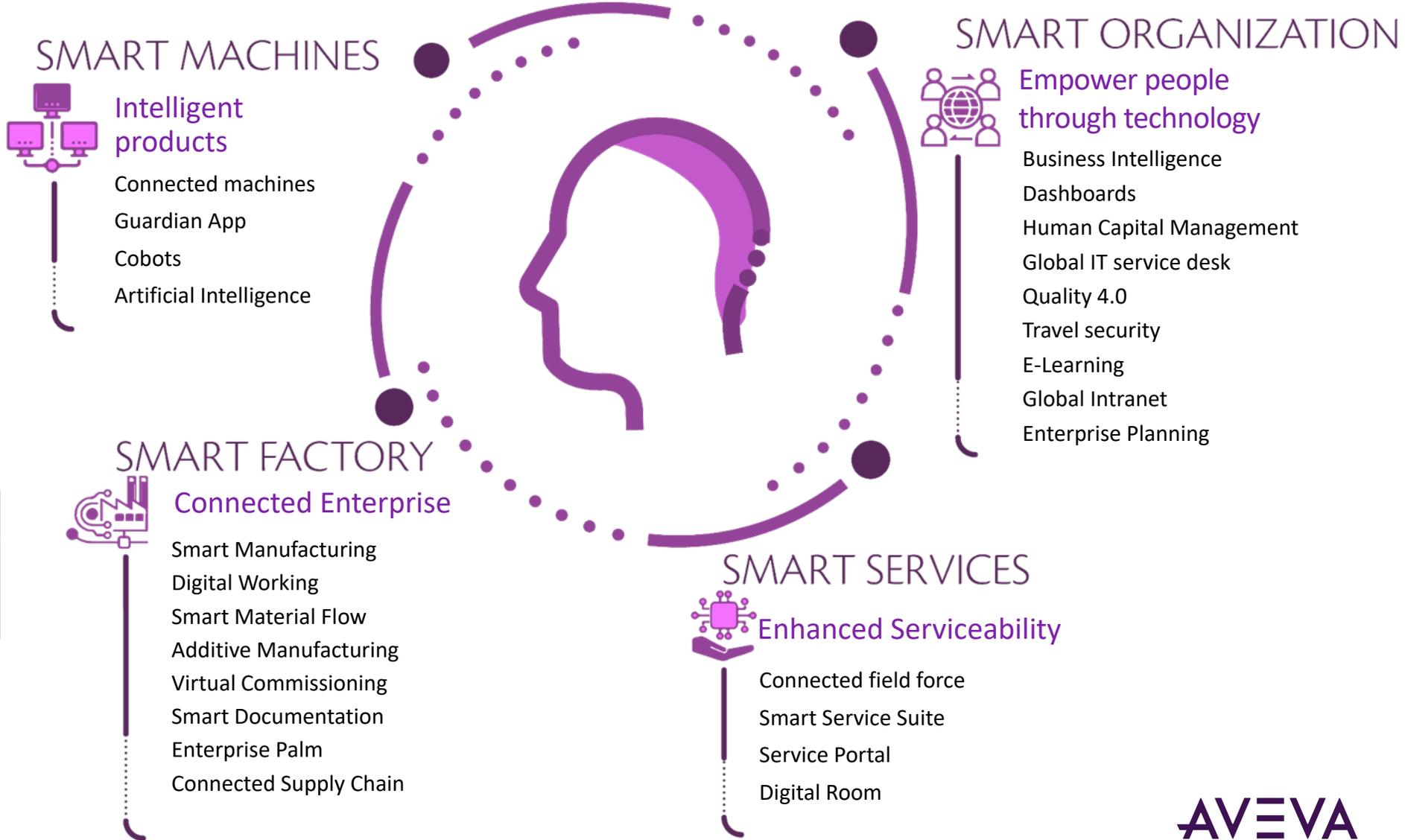
B|BRAUN MERCK



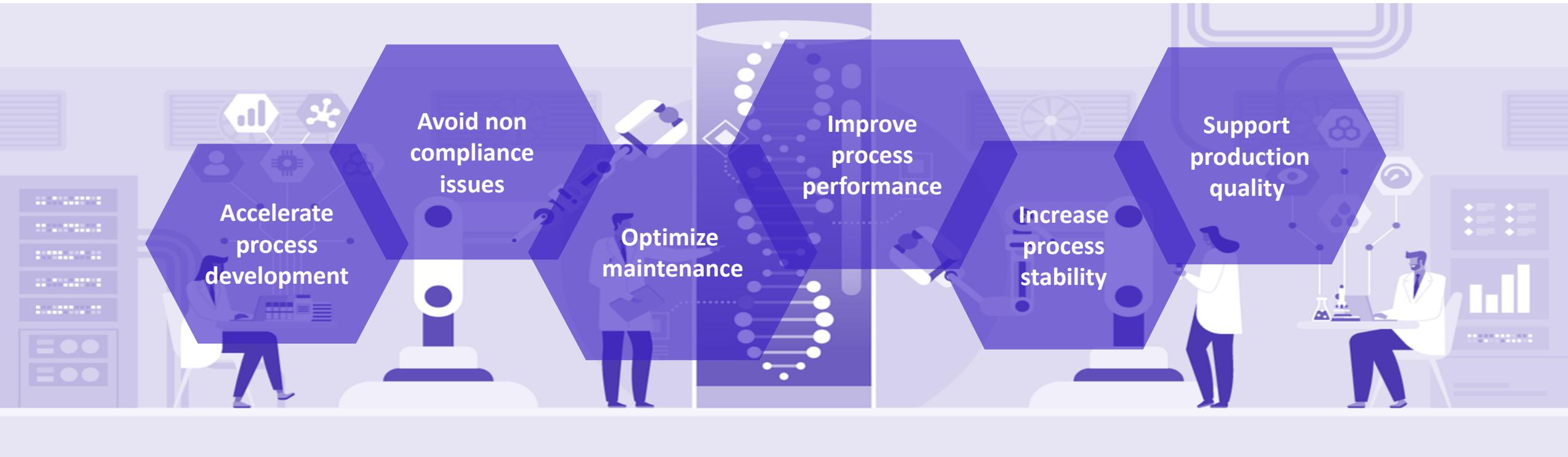
**AVEVA**

# IMA DIGITAL

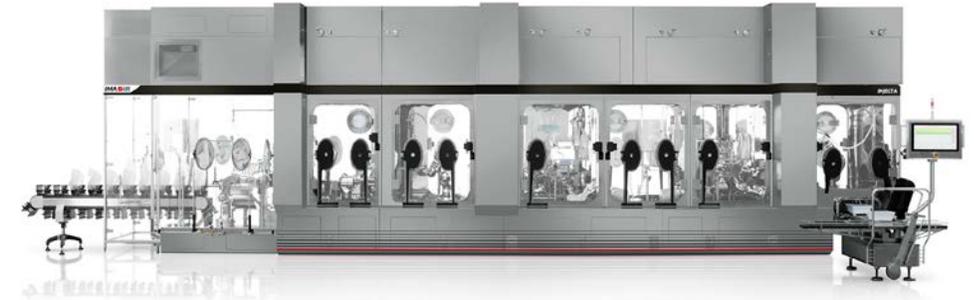
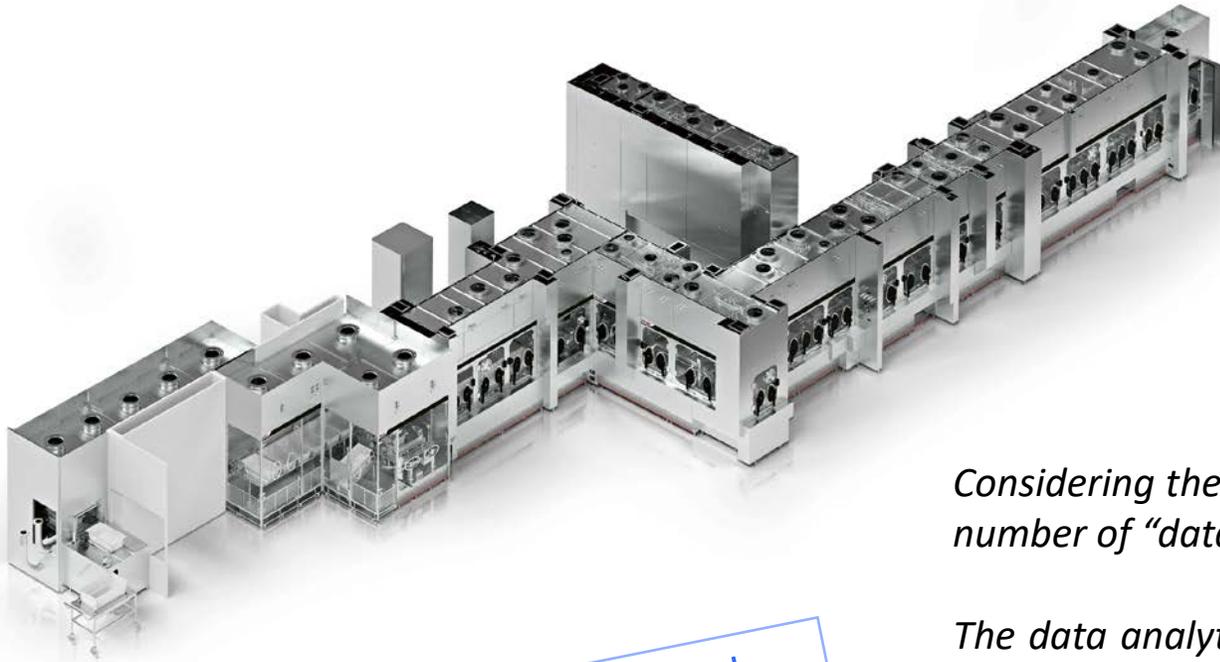
- 26 pilot projects
- 1 digital technology committee
- 14 IMA Project Managers
- 39 dedicated IMA Project Engineers
- 30% of total Research & Innovation man-hours dedicated to the IMA Digital Project
- 6 Partnerships with universities and research organizations
- 3 collaboration agreements with excellence partners
- 2 academic scholarships to Bologna University
- 5 international Projects



# PHARMA 4.0



# FILL-FINISH ASEPTIC LINES

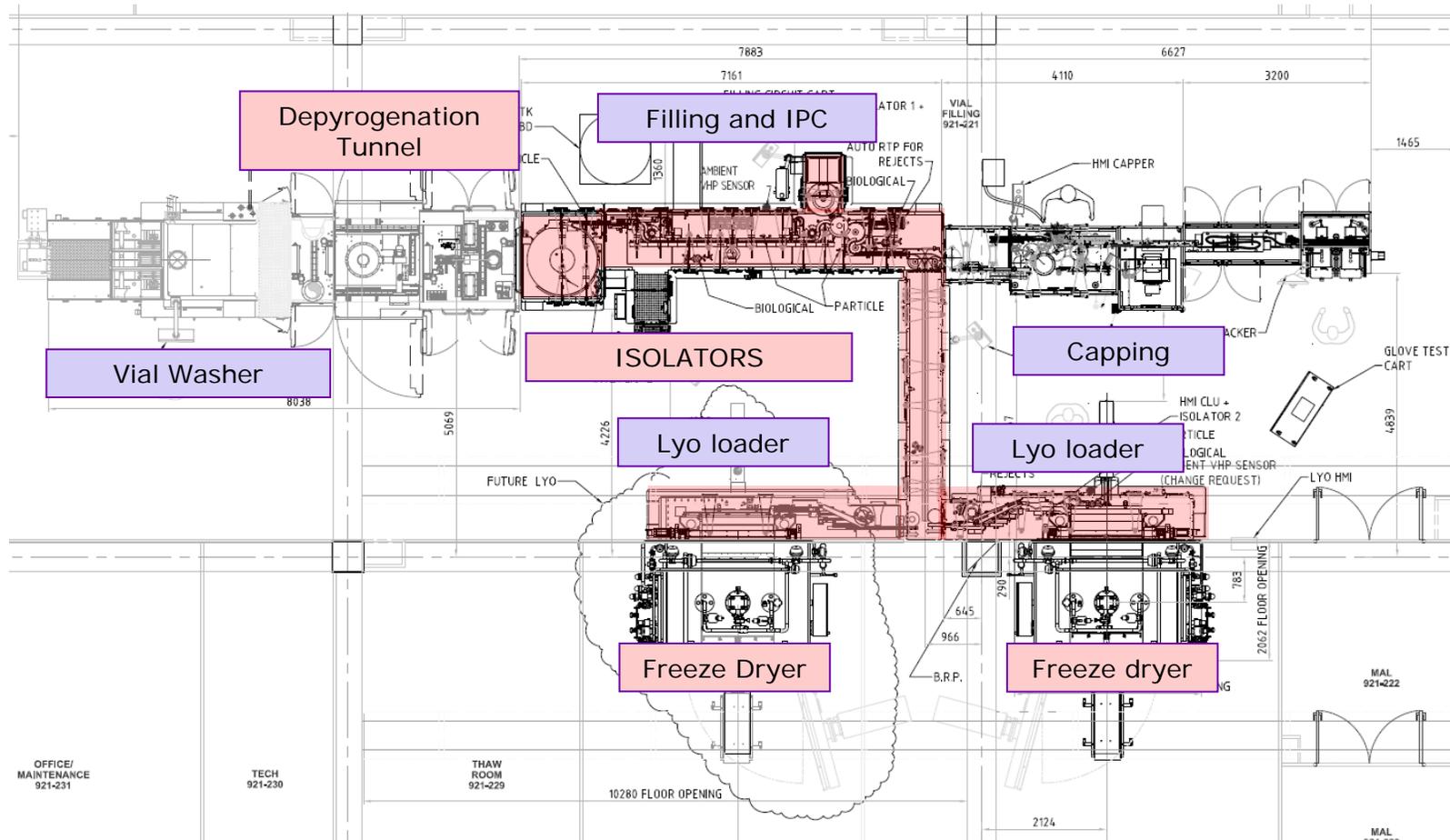


- How to manage, historicize and analyze the data, extracting the added value?

*Considering the number of machines present in a **fill-finish line**, the total number of “data points” or assets can reach easily **15000**.*

*The data analytics system, extended to the entire fill-finishing system, it could generate between 250 and 550GB / year.*

# FILL-FINISH PRODUCTION LINE EXAMPLE



Main “process” machines
  Main “production” machines

# PROCESS MACHINE INTEGRATION

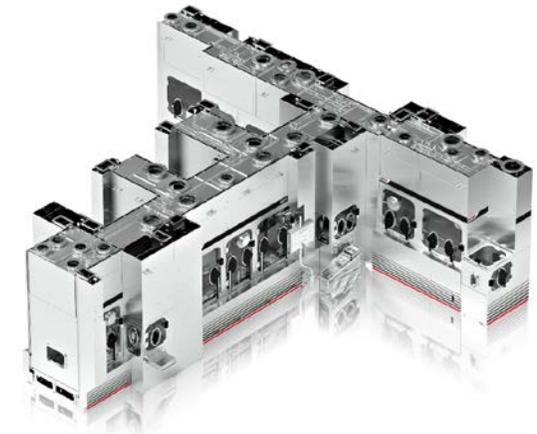
## Process analytics: why are process machines so different ?

- **The classic OEE-KPI extractions**, typical for production machines **is not exhaustive**. Rather, trends of variables compared and correlated over time, in the production campaigns/batches and in the different operating and environmental conditions become fundamental.
- **The number of monitored sensors and parameters are much higher than in a classical production machine**. A single isolator logical block or a freeze dryer can have up to 3000 monitored sensors and parameters necessary to guarantee and understanding of the dynamics of the machine and the operating conditions.
- **The correlations between sensors and parameters are often complex**, difficult to be evaluated except by expert engineers. It is important to show process information by graphs and tables so that even non-expert operators can obtain useful and easily usable data.
- **It is important to implement advanced analysis algorithms**. The analytics solutions should be able to integrate complex statistics and ML/AI algorithms.

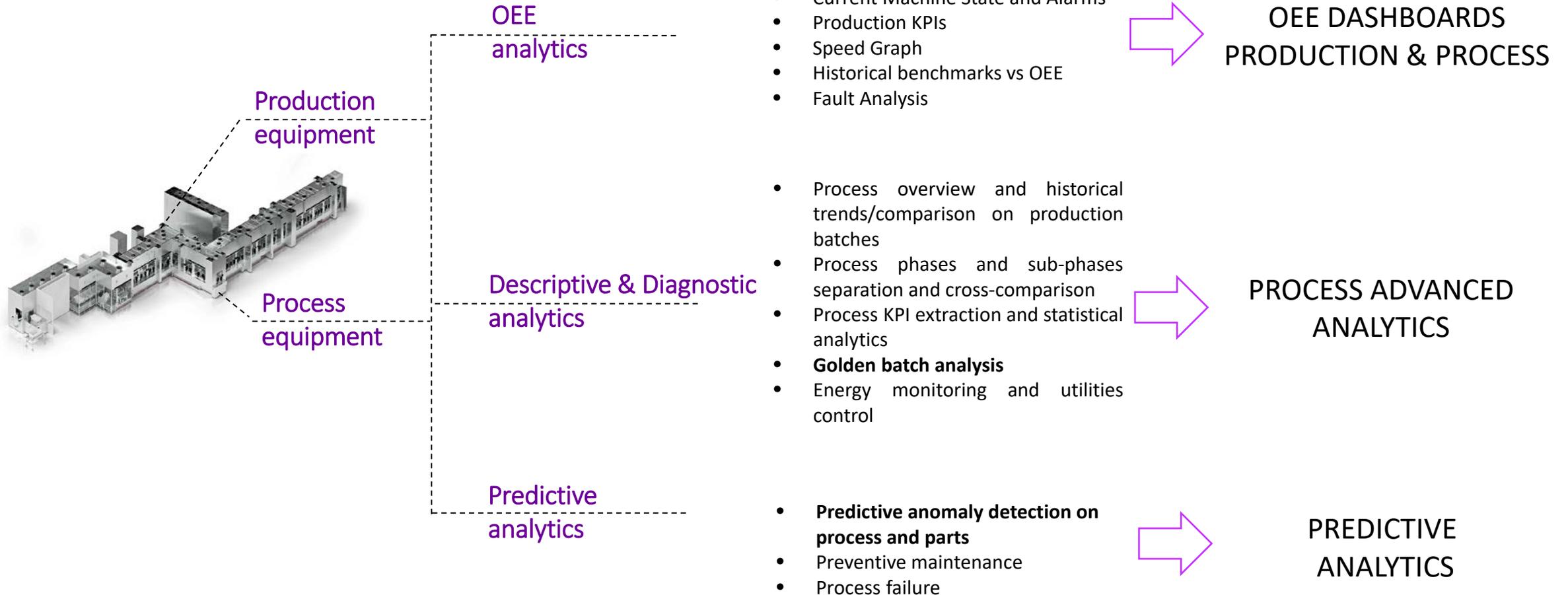
## FREEZE DRYERS



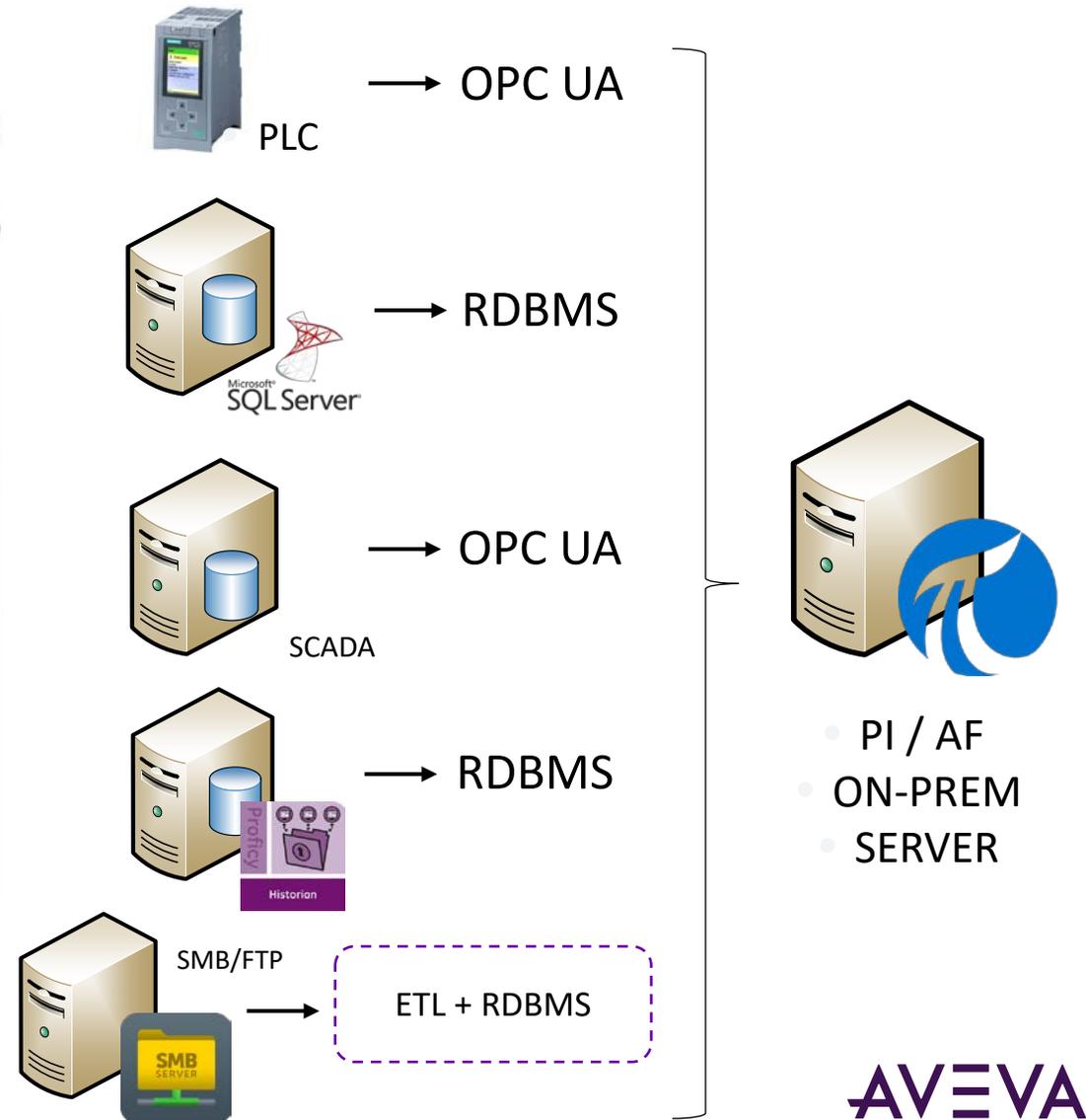
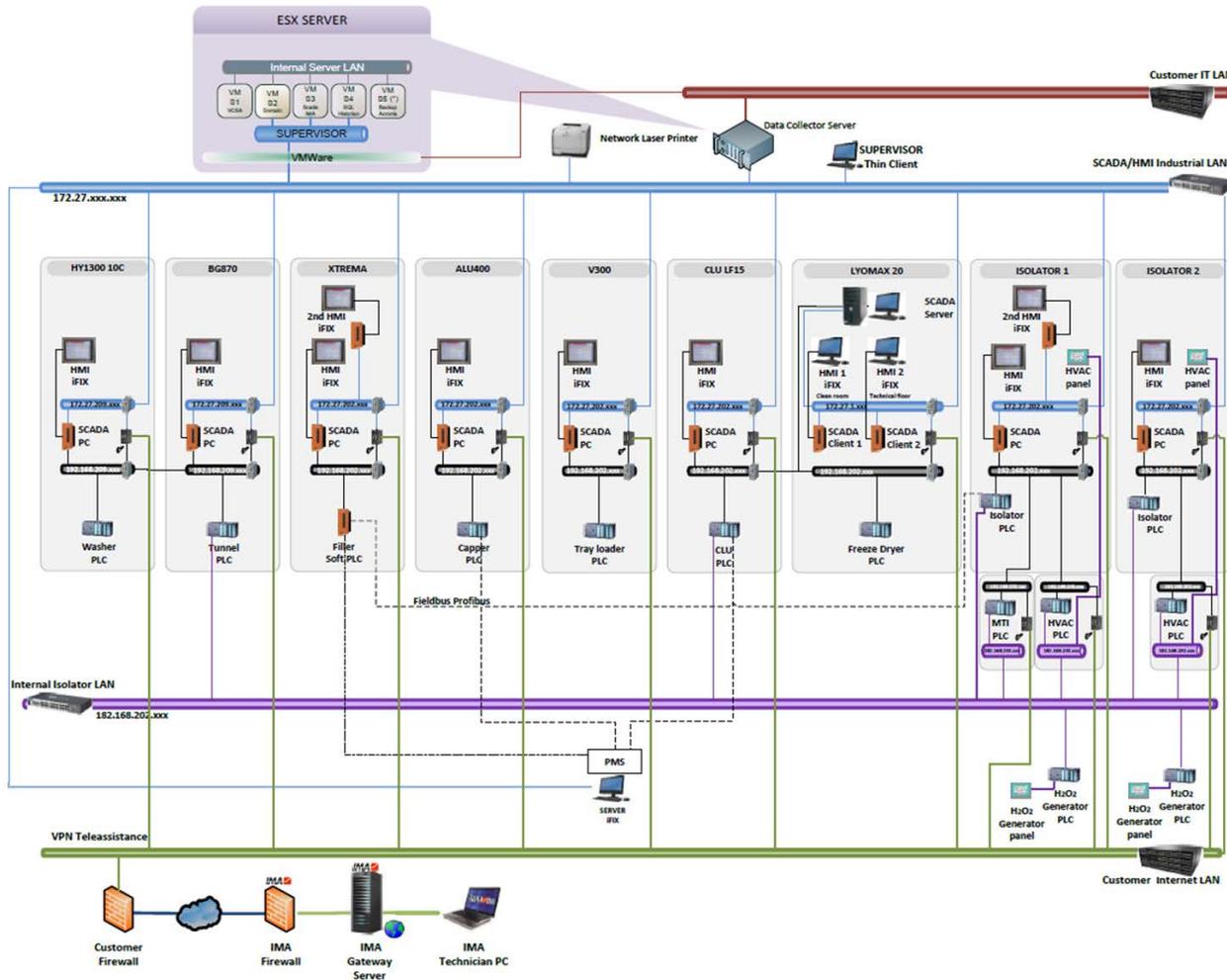
## ISOLATORS



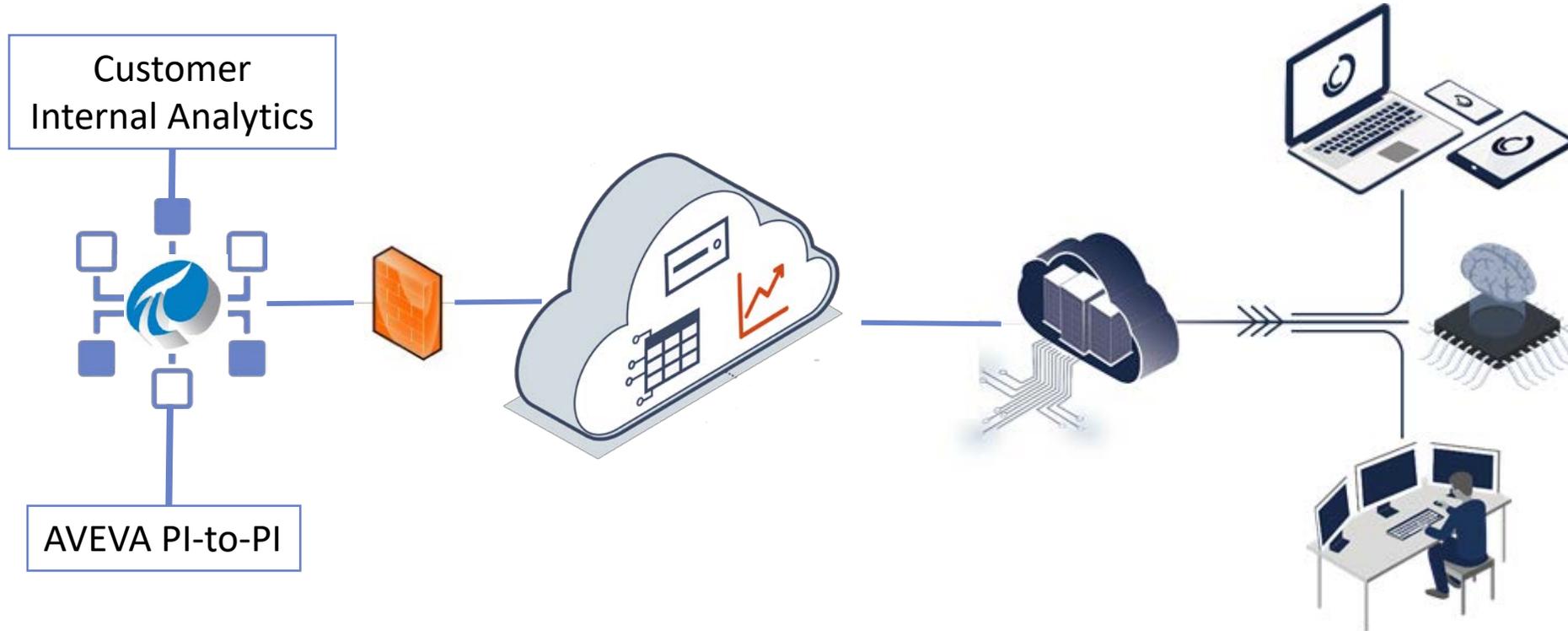
# IMA ANALYTICS FRAMEWORK



# DATA EXTRACTION USING PI



# FROM PI TO CLOUD



**CUSTOMER CONNECTED PLANT**  
Fill-finish IMA LIFE production plant concentrated using PI server

**CUSTOMER / IMA LIFE AVEVA DATA HUB CLOUD**  
Simplify the connection to complex lines and data architecture typical of big pharma customers

**IMA DATA ROOM**  
Virtual space in cloud where all information coming from the plants is collected and stored, and where the data analysis software programs reside.

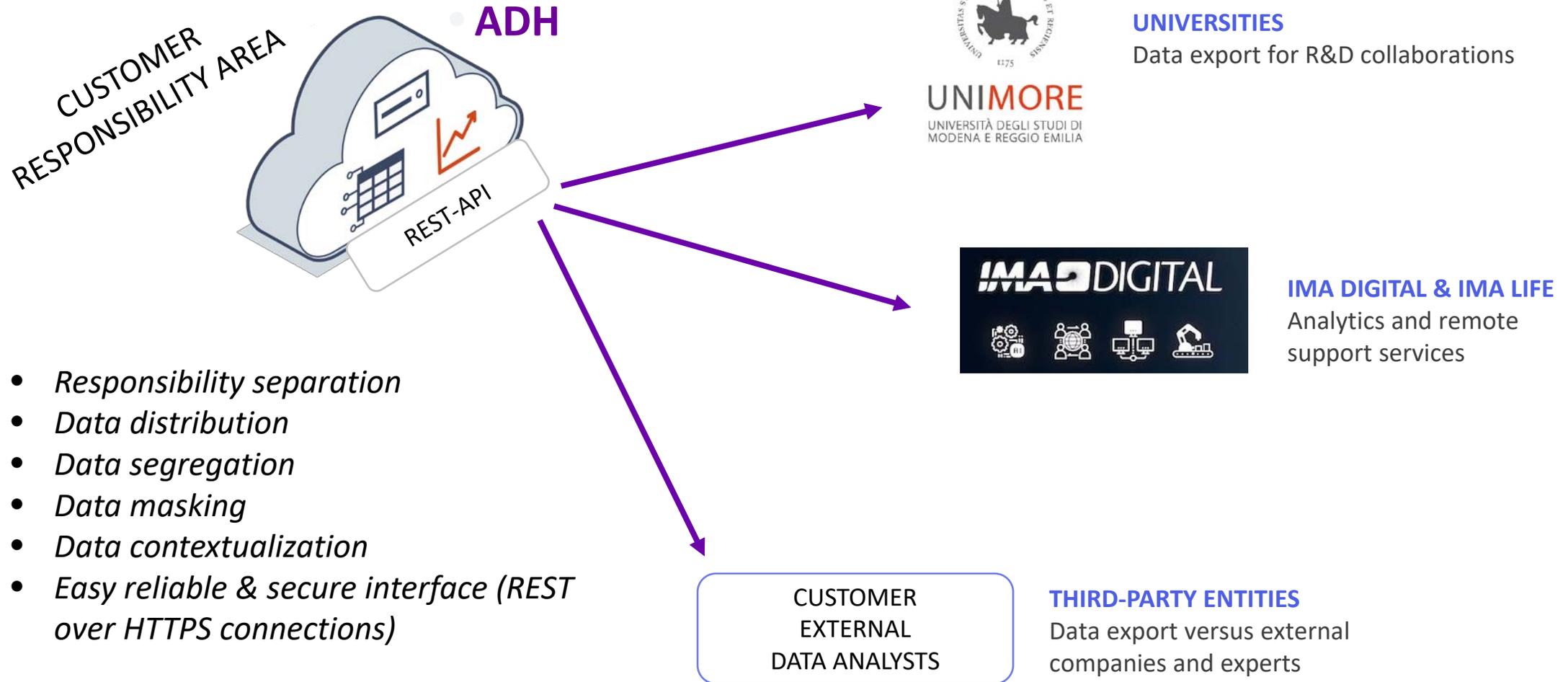
**IMA SENTINEL PORTAL**  
Monitoring of the system's performance

**IMA ARTIFICIAL INTELLIGENCE**  
AI based services using advanced algorithms and machine learning techniques to predict faults, detect anomalies, analyze trends and give deeper insights on production processes.

**IMA CONTROL ROOM**  
Set of services, to improve production, based on detailed reports, specific alerts and general support 24/7.

# CLOUD CONFIGURATION

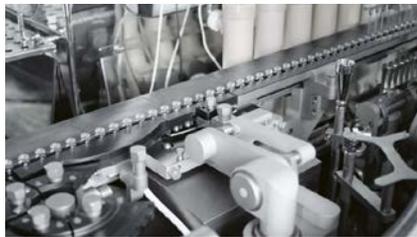
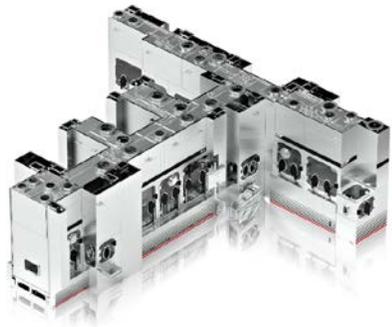
## Advantages using PI + AVEVA Data Hub



- *Responsibility separation*
- *Data distribution*
- *Data segregation*
- *Data masking*
- *Data contextualization*
- *Easy reliable & secure interface (REST over HTTPS connections)*

# DATA INTEGRATION

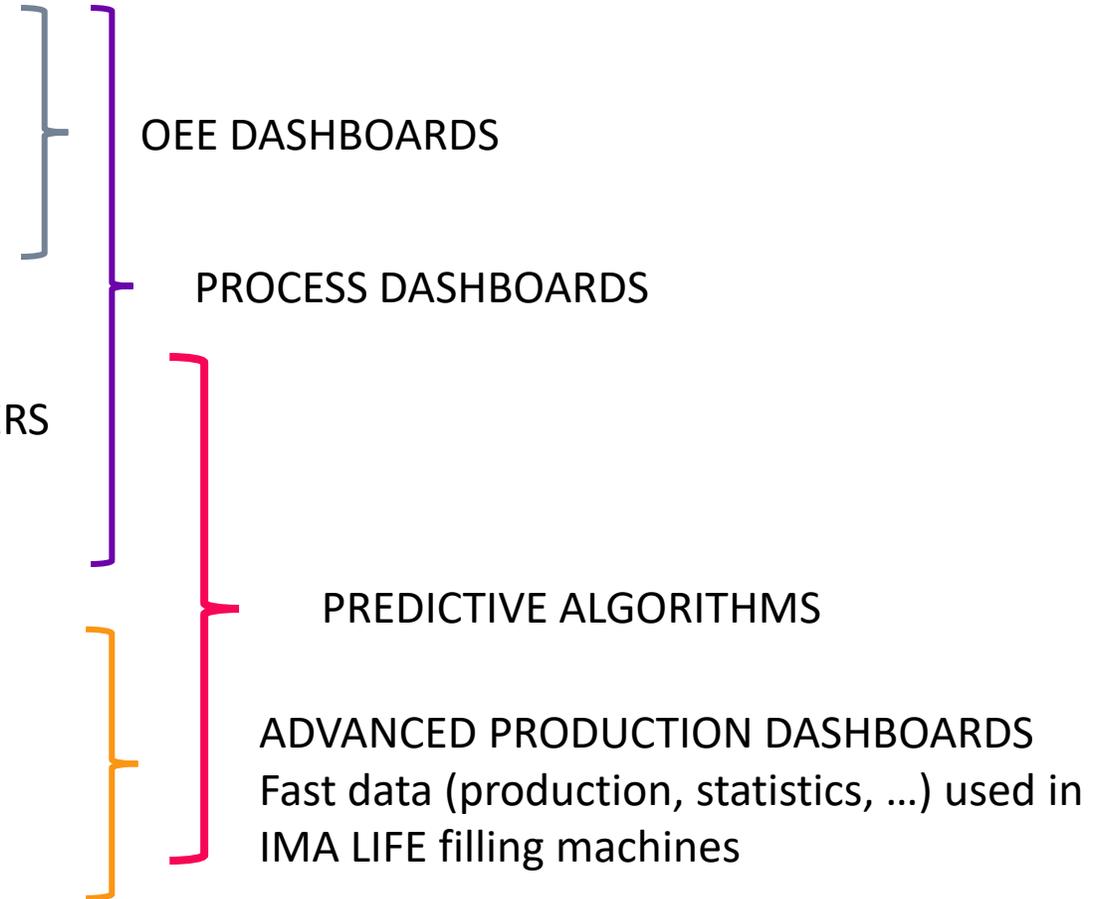
Raw assets and data streams



- MACHINE STATE
- SIGNALING (ALARMS)
- BATCH DATA
- LOGICAL STATE

- SENSORS AND PARAMETERS
- **ADDITIONAL SENSORS**
- PRE-PRECESSED DATA

- HIGH SPEED DATA  
BUFFERS  
(WEIGHT STATISTICS AND  
ACCELEROMETERS)



# OEE INTEGRATION

## Xtrema filler integration

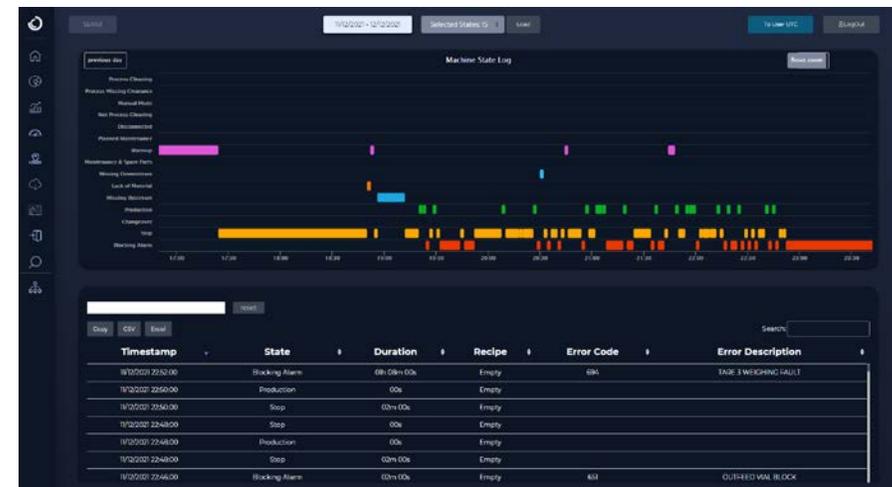
Machine: Xtrema series



MACHINE STATE  
SIGNALING  
BATCH DATA  
LOGICAL STATE

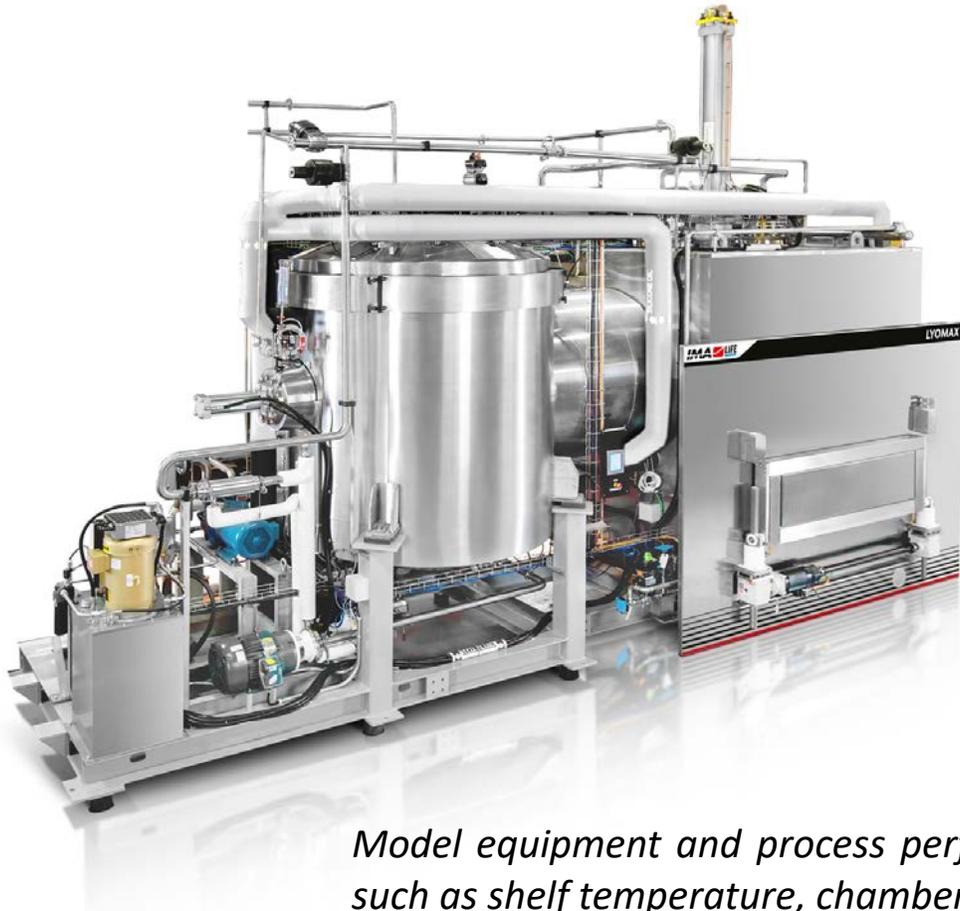


*OEE analytics  
generated inside IMA  
Sentinel using PI as  
data source*

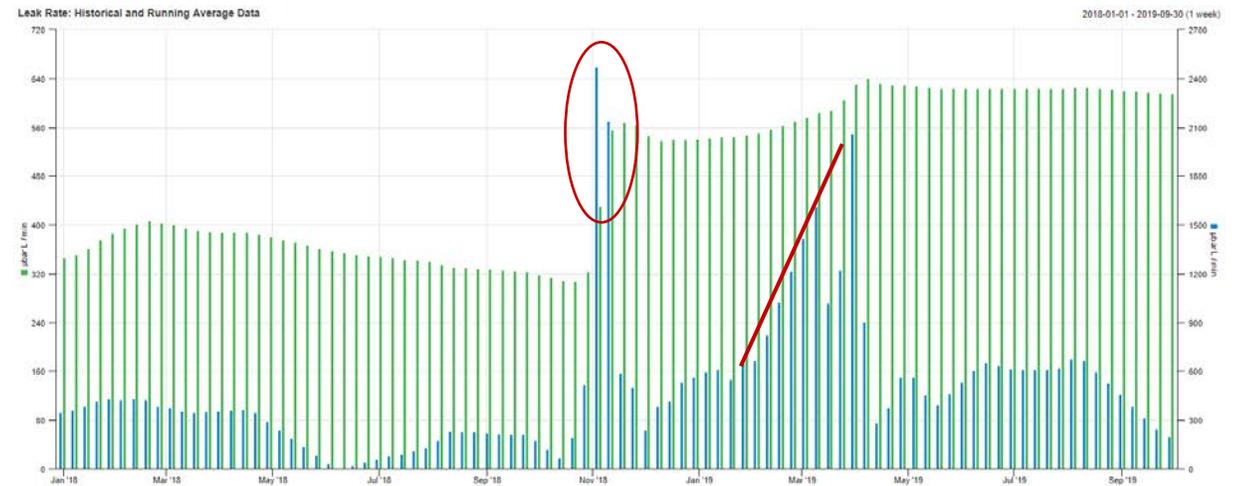


# FREEZE DRYERS

Descriptive and diagnostic analytics



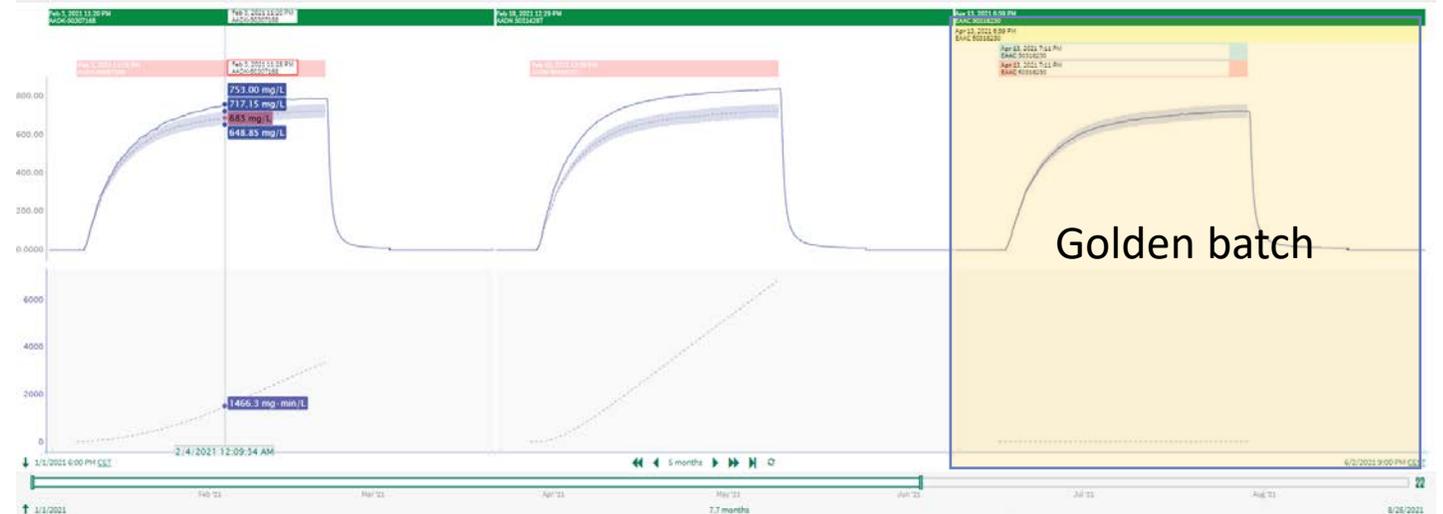
*Rolling average and real time leak rate comparison*



*Model equipment and process performance for detecting / predicting deviation, based on process metrics such as shelf temperature, chamber pressure, condenser temperature and pressure*

# ISOLATORS

Descriptive and diagnostic analytics



*Analytics example: VHP H2O2 concentration during isolator decontamination with golden batch comparison and KPI. It can be used to quickly understand the distance between a “reference batch” and the batch under investigation*

# ISOLATORS

Cross-correlation analytics between production and process machines



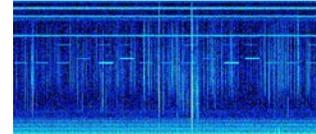
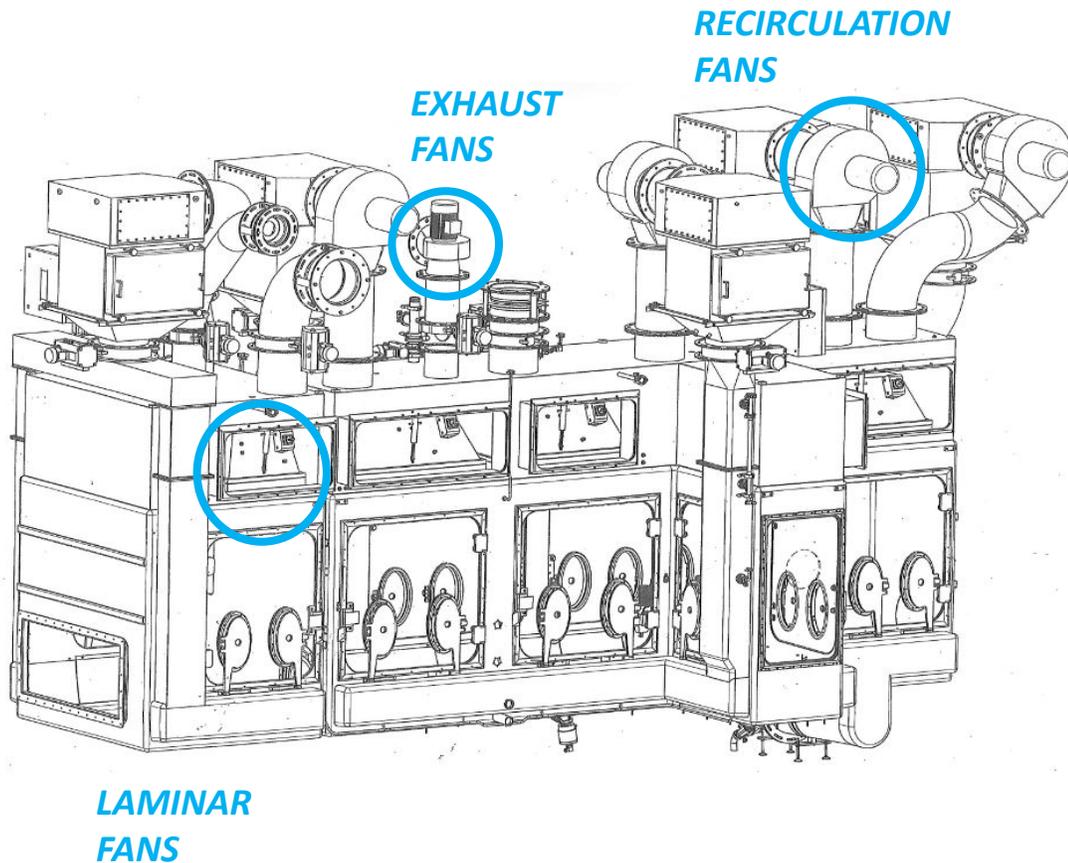
*Production control  
(Xtrema filling accuracy)*



*Process control  
(Isolator env. sensors)*

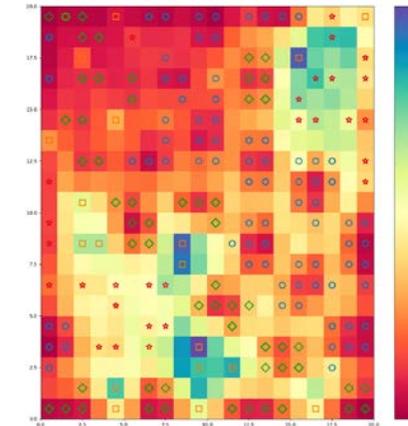
# PREDICTIVE ANALYTICS APPLICATION

Predictive analytics to detect fans failures

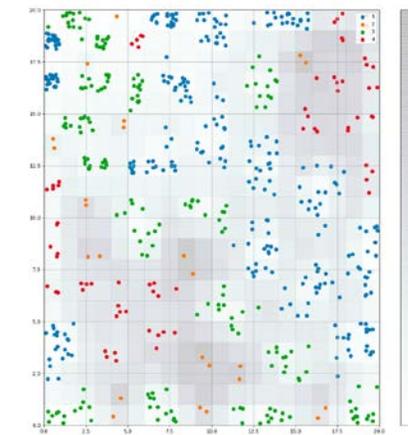


Predictive algorithm using accelerometers large band spectra

Supported by automatic-training generated during the routine use of the line



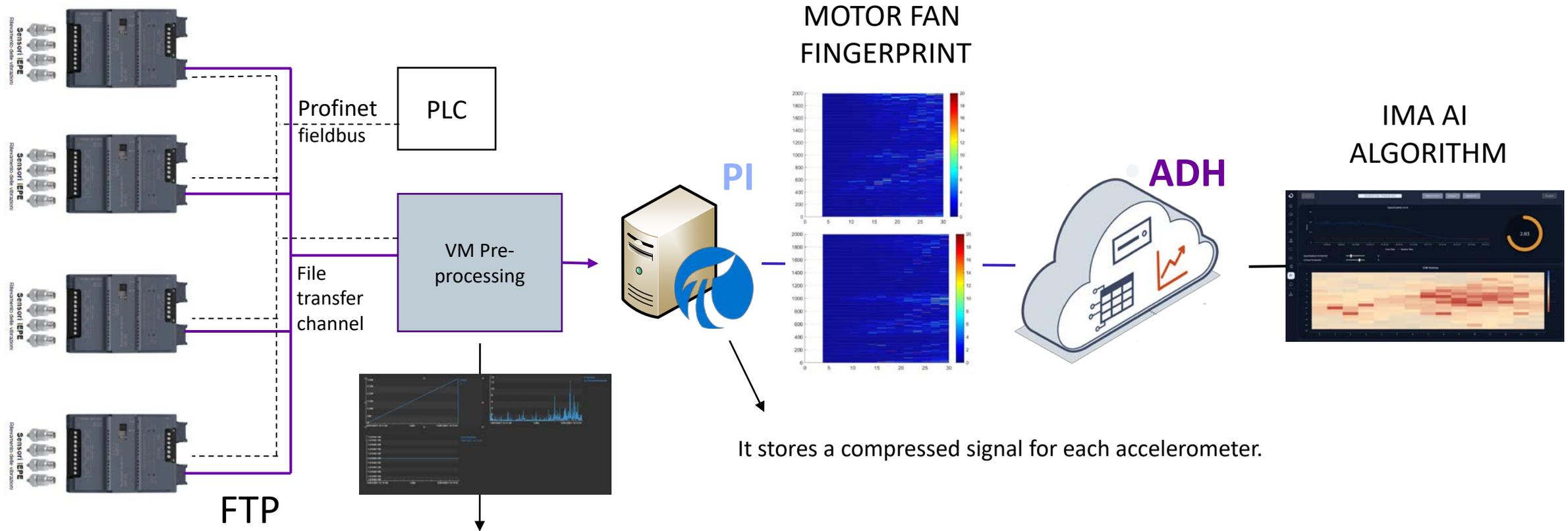
Application of "SOM" Self-Organizing Maps to detect motor anomalies



- 1 <-> M3410
- 2 <-> M3420
- 3 <-> M3430
- 4 <-> M3440

# PREDICTIVE ANALYTICS APPLICATION

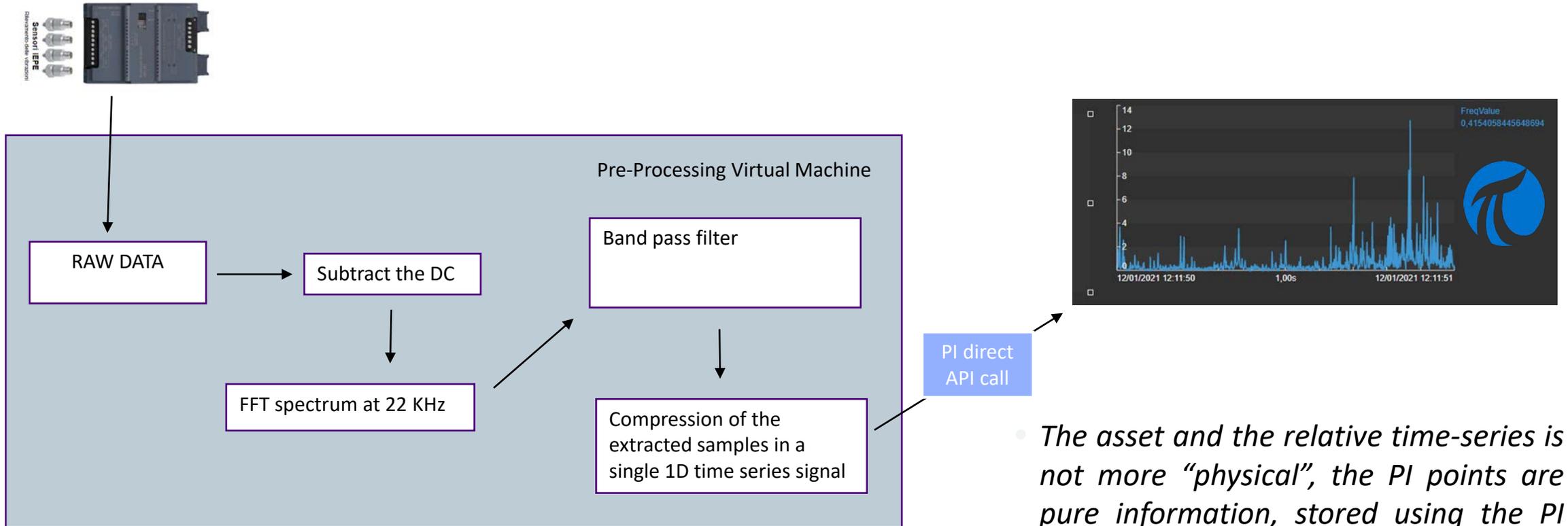
## Accelerometers add-on package



It executes the script that collects the WAV files via FTP protocol from all the control units, with a "polling" approach. It executes the pre-processing algorithm

# DATA CONVERSION USING PI FLEXIBILITY

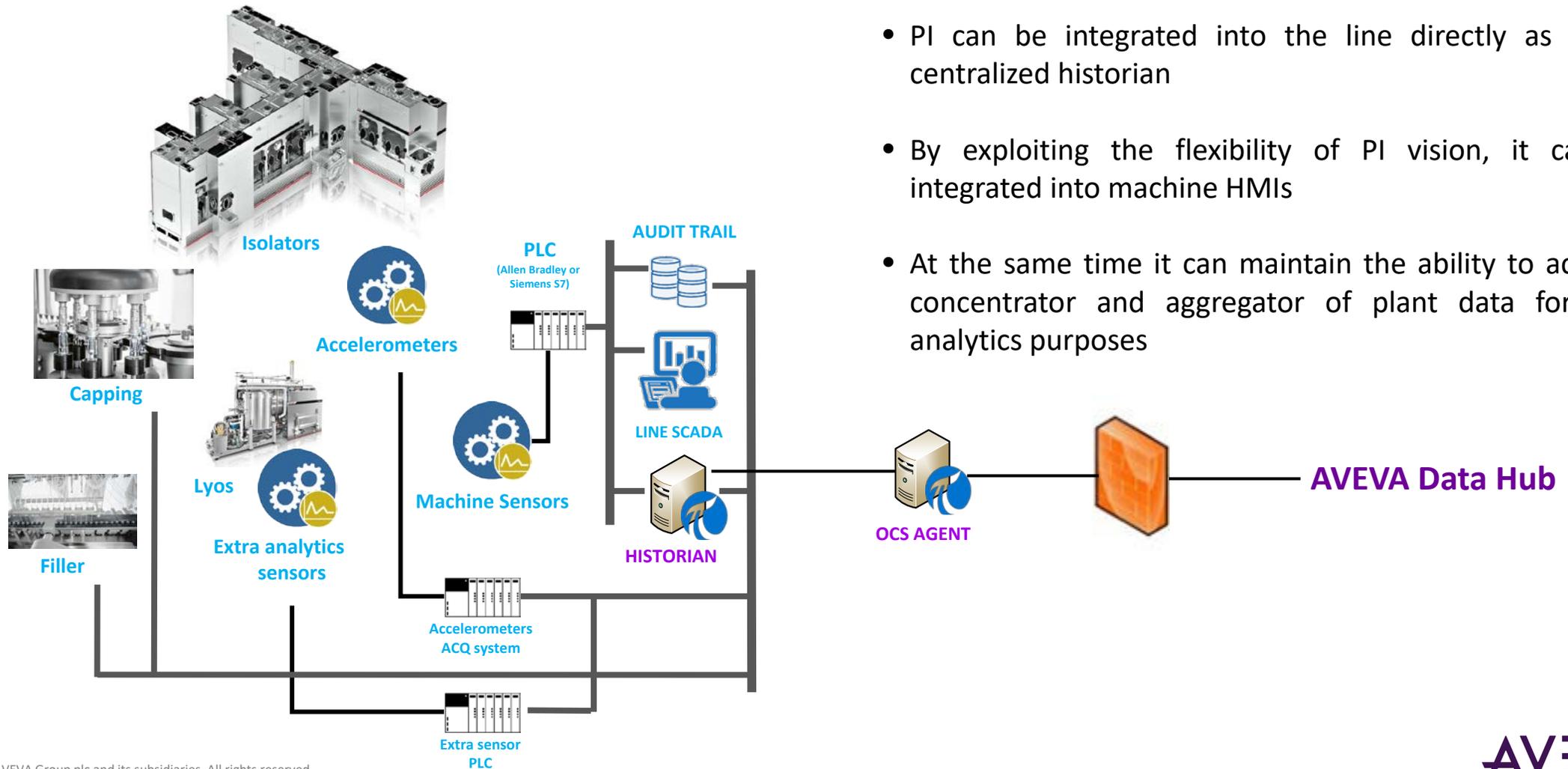
Sensor data stream can be elaborated to become non-physical compressed time series



- *The asset and the relative time-series is not more “physical”, the PI points are pure information, stored using the PI capabilities to manage compressed streams*

# PI INTEGRATION: ANALYTICS AND LINE HISTORIAN

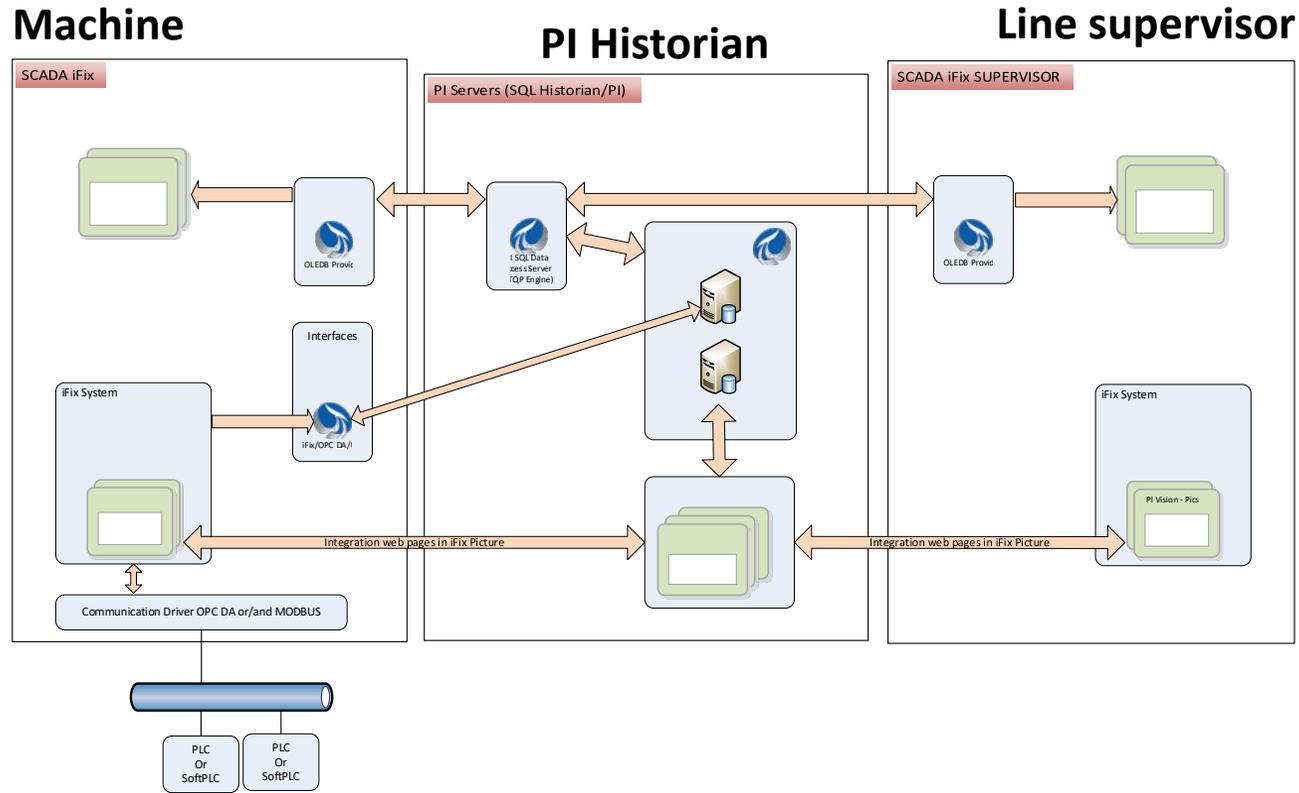
PI used as historian and PI Vision HMI integration



- PI can be integrated into the line directly as a line centralized historian
- By exploiting the flexibility of PI vision, it can be integrated into machine HMIs
- At the same time it can maintain the ability to act as a concentrator and aggregator of plant data for data analytics purposes

# PI INTEGRATION: ANALYTICS AND LINE HISTORIAN

## PI used as historian and PI Vision HMI integration



HMI with PI Vision integration

# CONCLUSIONS

- The challenges posed by the Pharma 4.0 requirements is radically transforming manufacturing facilities for injectable products
- The evolution towards digital architectures and analytical solutions requires the integration of on-premise and on-cloud components
- By exploiting an architecture based on PI server and AVEVA Data Hub, it was possible to support data analytics solutions able to integrate efficiency (OEE), diagnostic analytics and predictive maintenance
- Through the flexibility of the PI, it is possible to converge and contextualize extremely different data streams to support analytics and machine learning algorithms
- In modern plants, PI can be integrated not only as an on-premise data concentrator, but also as a line historian fully validated as part of the production line

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#### ABOUT AVEVA

AVEVA is a global leader in industrial software, driving digital transformation and sustainability. By connecting the power of information and artificial intelligence with human insight, AVEVA enables teams to use their data to unlock new value. We call this Performance Intelligence. AVEVA's comprehensive portfolio enables more than 20,000 industrial enterprises to engineer smarter, operate better and drive sustainable efficiency. AVEVA supports customers through a trusted ecosystem that includes 5,500 partners and 5,700 certified developers around the world. The company is headquartered in Cambridge, UK, with over 6,500 employees and 90 offices in over 40 countries.

Learn more at [www.aveva.com](https://www.aveva.com)