The Case for TEVA Pharmaceutical

Presented by **László Simon**

Agenda

- About TEVA
- Challenges
- Meeting with PI System
- Solution and Application examples
  - PI DataLink (Excel Add-Ins)
  - PI Batch Generator (PIBaGen)
  - PI ProcessBook
- Benefit
- Future Opportunities
- Conclusion

TEVA – TAPI Worldwide: 20 Sites

US:
TAPI-Missouri

Puerto Rico:
TAPI PR (Guayama)
TAPI PR (Humacao)
Theramex

Monaco

Italy:
Sicor
Santhia
Rho

PFC
Caronno
Bulciago
Settimo
Villanterio

Mexico:
TAPI-Mexico

TPW:
Debrecen
Sajobabony

Czech:
TAPI
Galena

Croatia:
Pliva (Zagreb – SM)

China:
TAPI China
TPC

Israel:
Plantex
Abic
Teva Tech

Antibiotics   **HP & Others**   **Fermentation**   **Synthetics**

TEVA Hungary

Debrecen

Area: 230 000 m²

Main activities: solid dosage form & API production, R&D activities

Sajóbábony

Area: 35 000 m²

Main activity: API production

Gödöllő

Area: 207 000 m²

Main activities: sterile production, R&D activities

Challenges – Regulated Industry
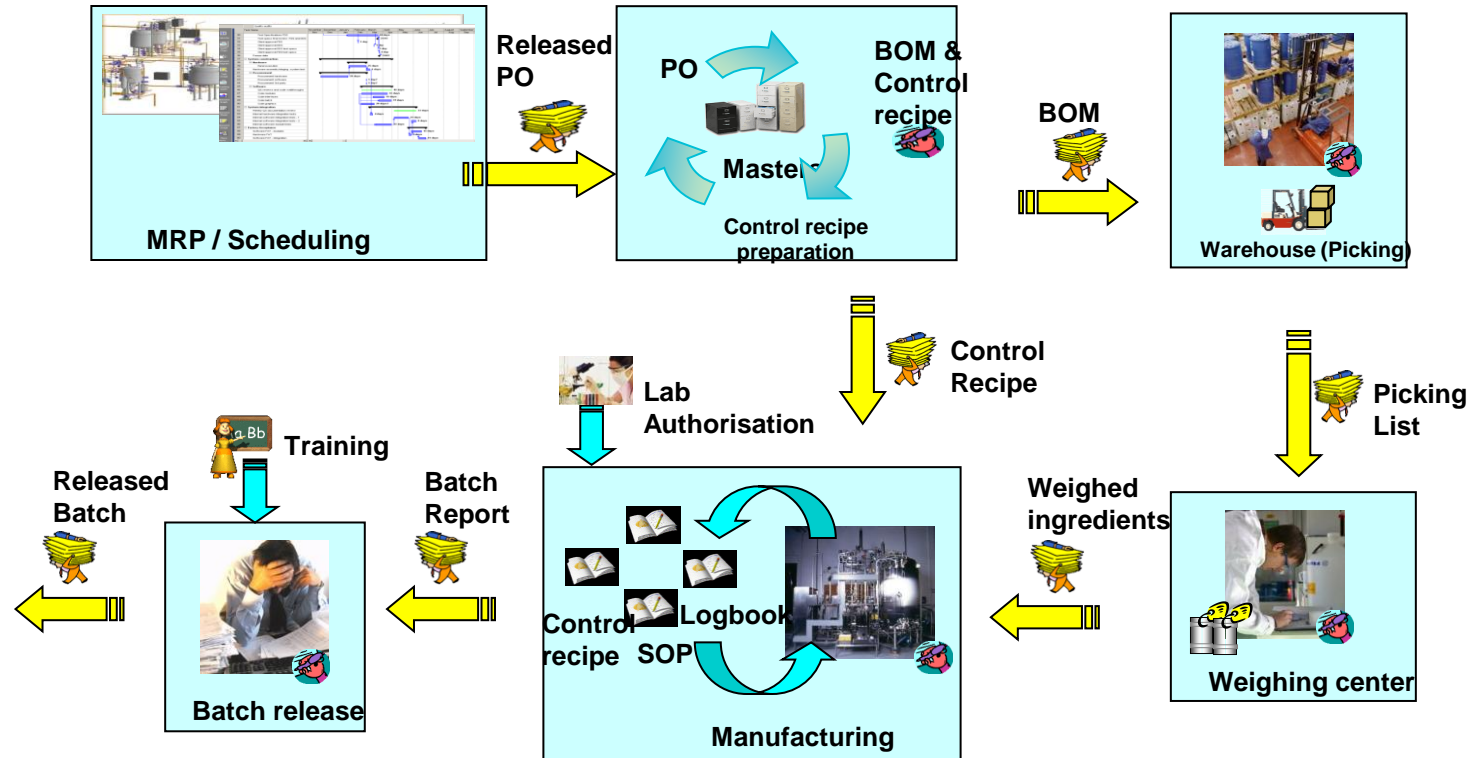
Challenges

- Very strong validation requirements

  → Stability even lack of flexibility

- Today, subject to high economic pressures

  → Improve industrial performance

✓ **Paper** is the major challenge for better performance

« Typical » Manufacturing process

Feel familiar?
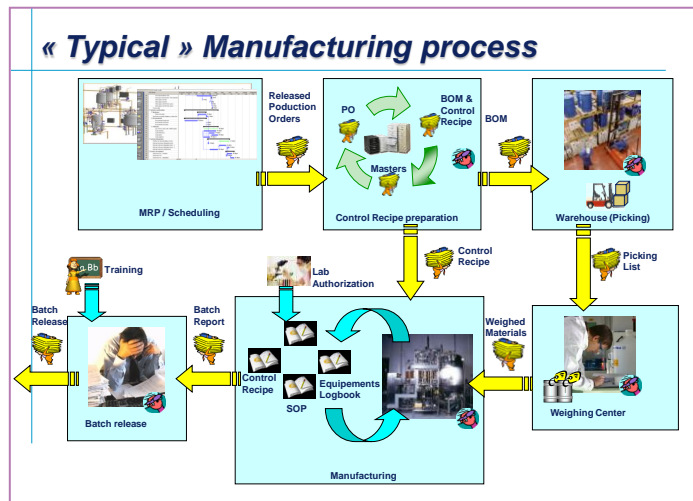
Challenges - DATA

- The fermentation cycle takes a few weeks, we have to make a judgment according to the process values with a goal of ensuring final product quality.

- DATA – > It's better to have it and not need it, than need it and not have it.
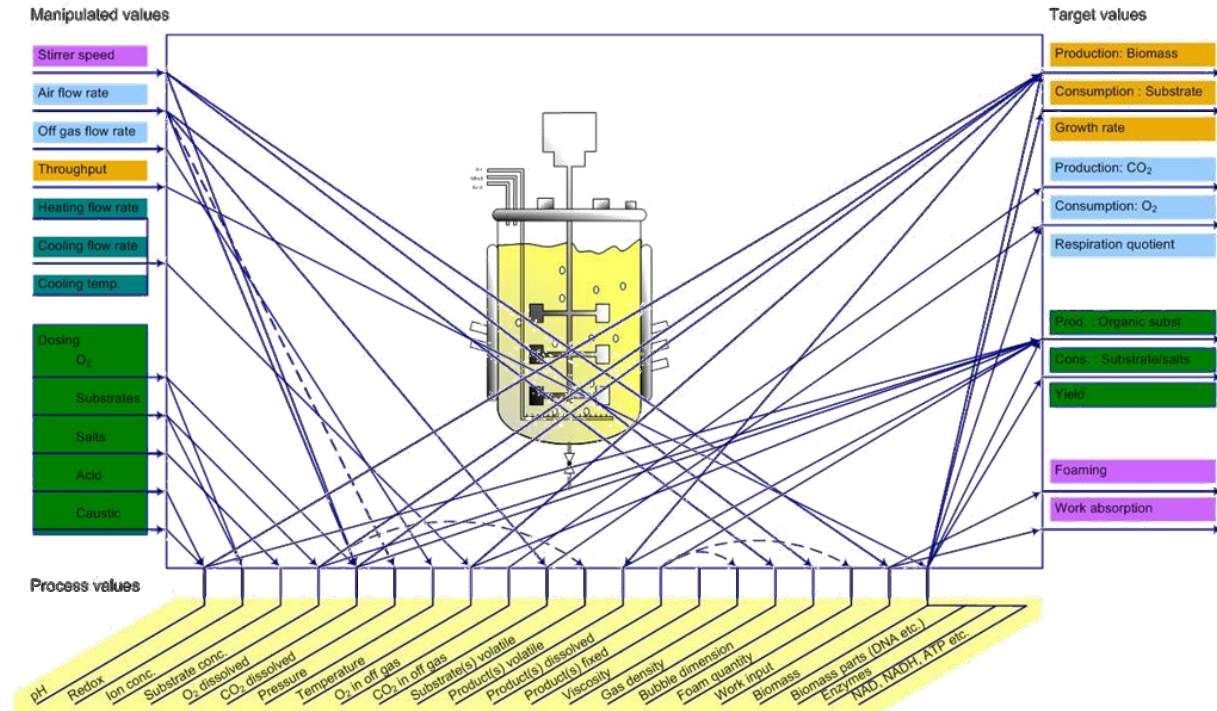
Meeting the PI System
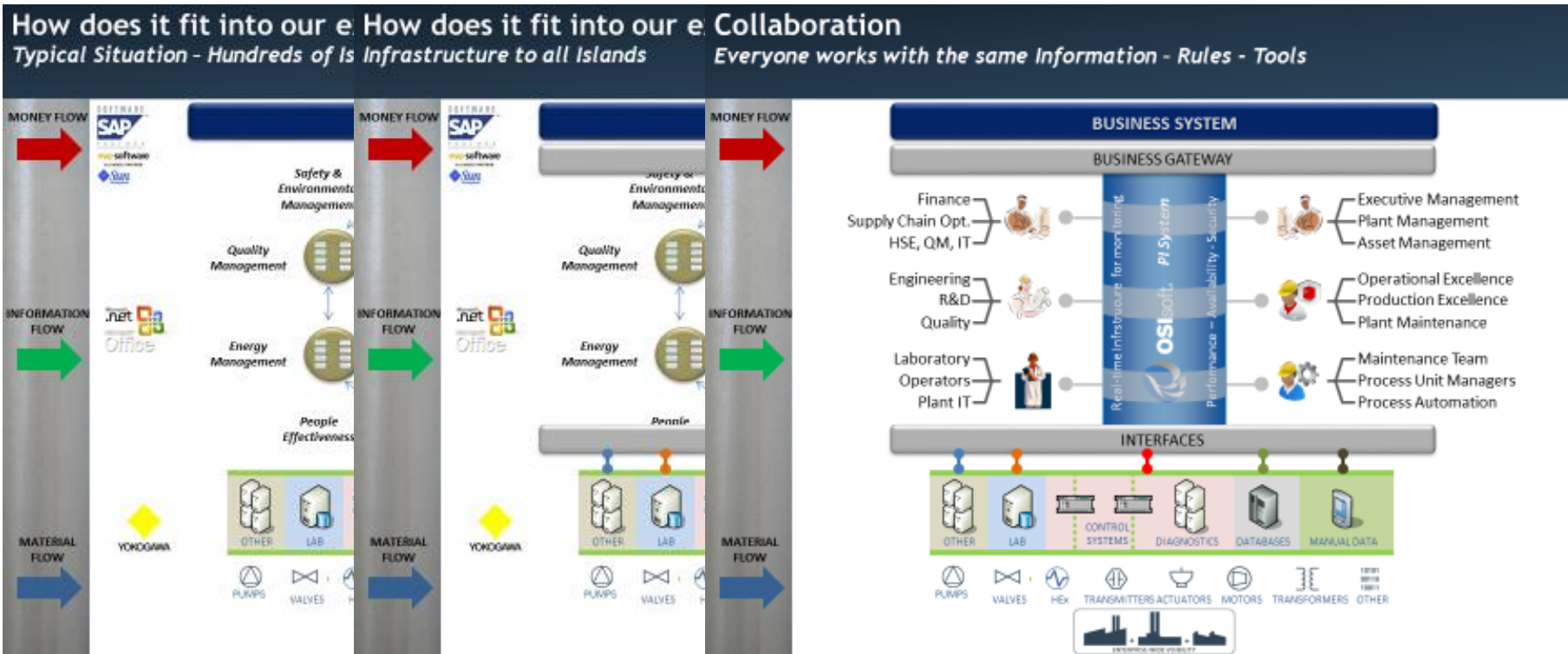
Application: PI System and PAT(= Understanding + controlling the manufacturing process)

PAT

Advanced Control

Quality build in by design
Right first time

monitoring product quality

Real-time release

MVDA

Classic control

Closed loop control

Temp., pH, pO2, pressure, …

monitoring process data

Lab

LIMS

Process feed

Stirrer motor

Process Analyzer

Hold / release

Sample

Process output
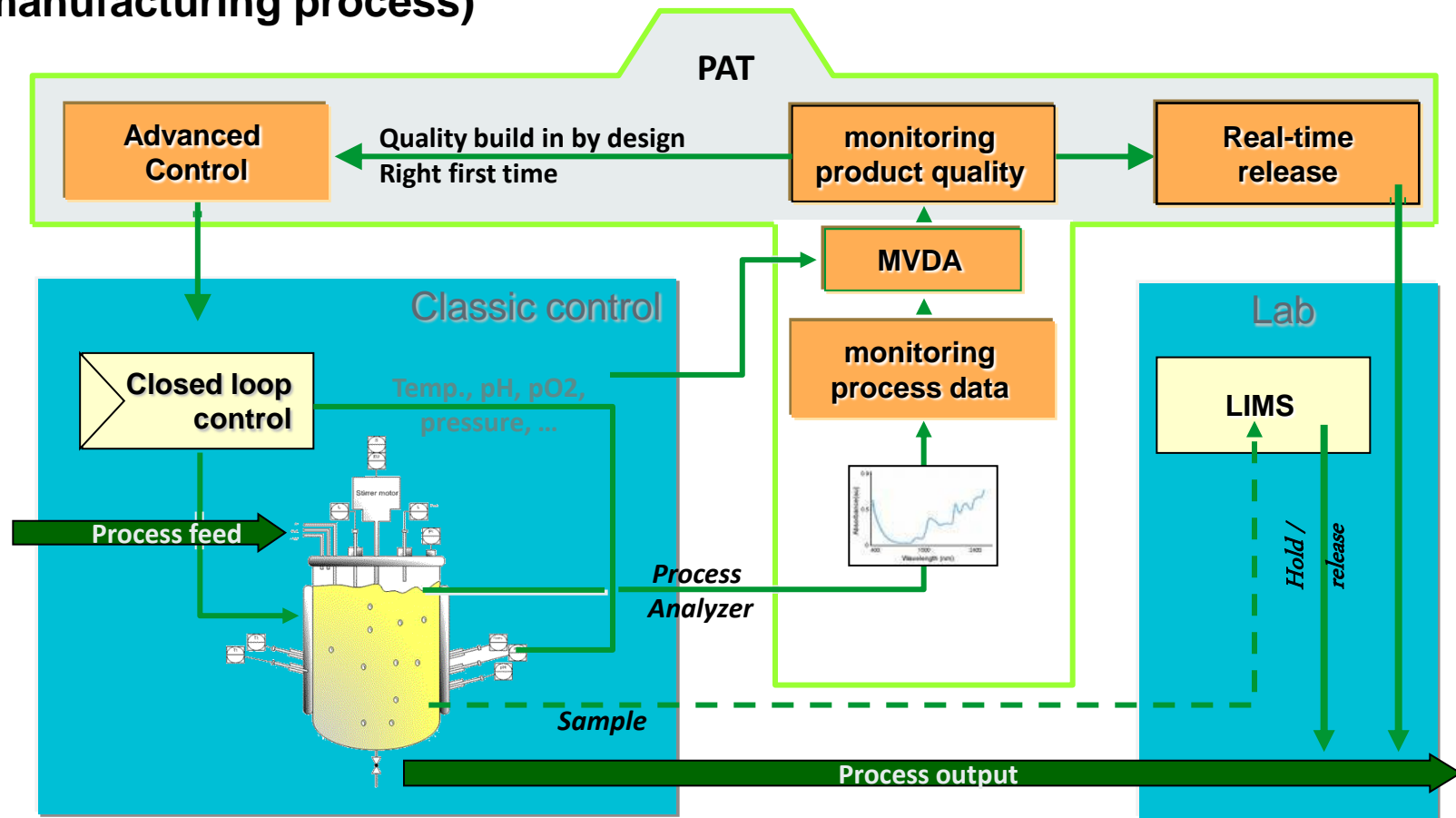
Application: PI System and PAT(= Understanding + controlling the manufacturing process)
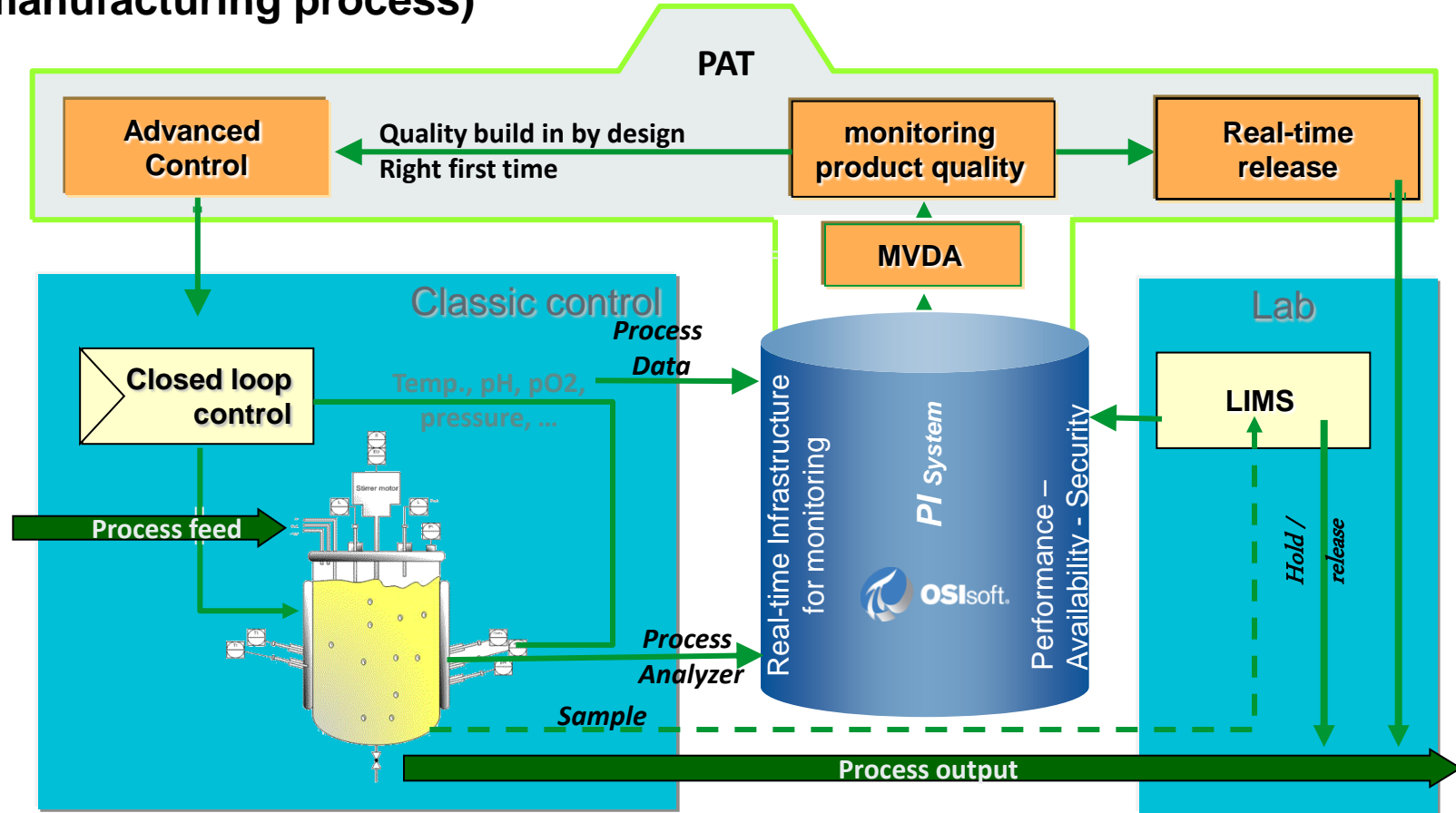
PI System Architecture
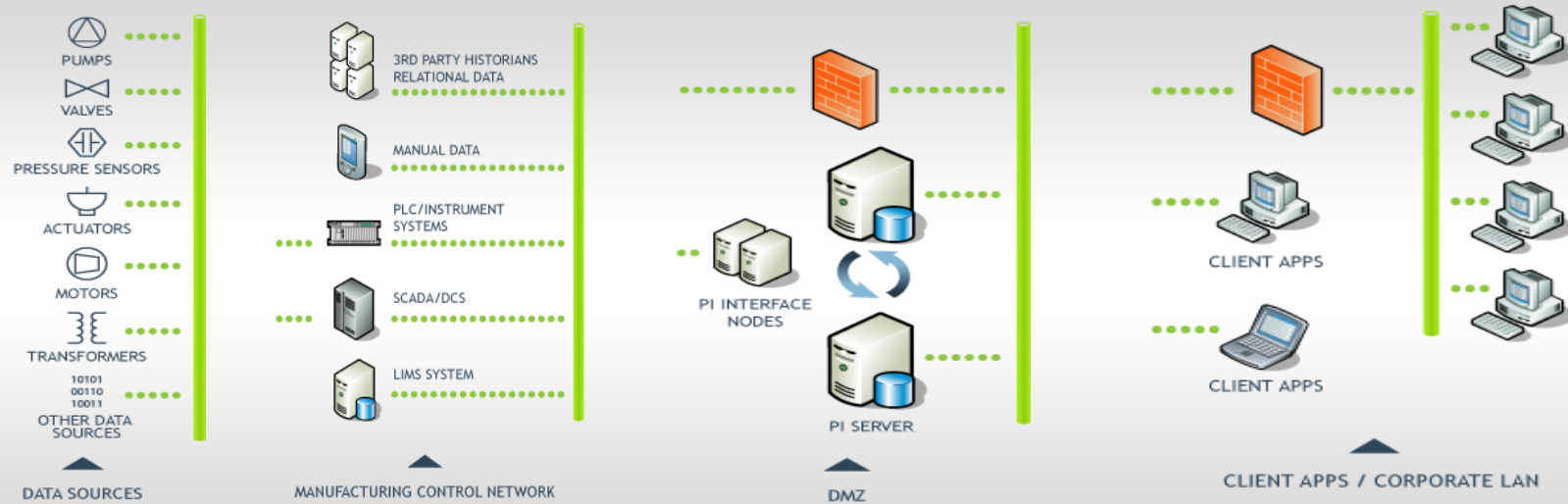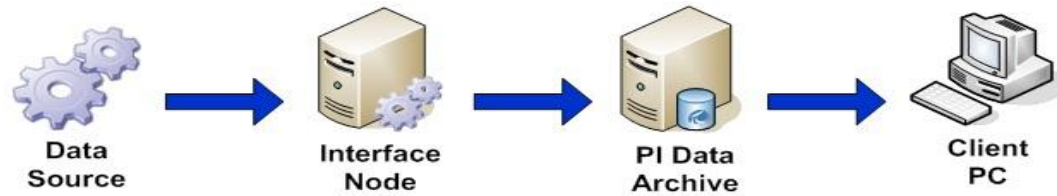
PI System Architecture

- 2000 tags
- PI Interface for OPC DA (2 pcs)
- PI Batch Generator (PIBaGen)
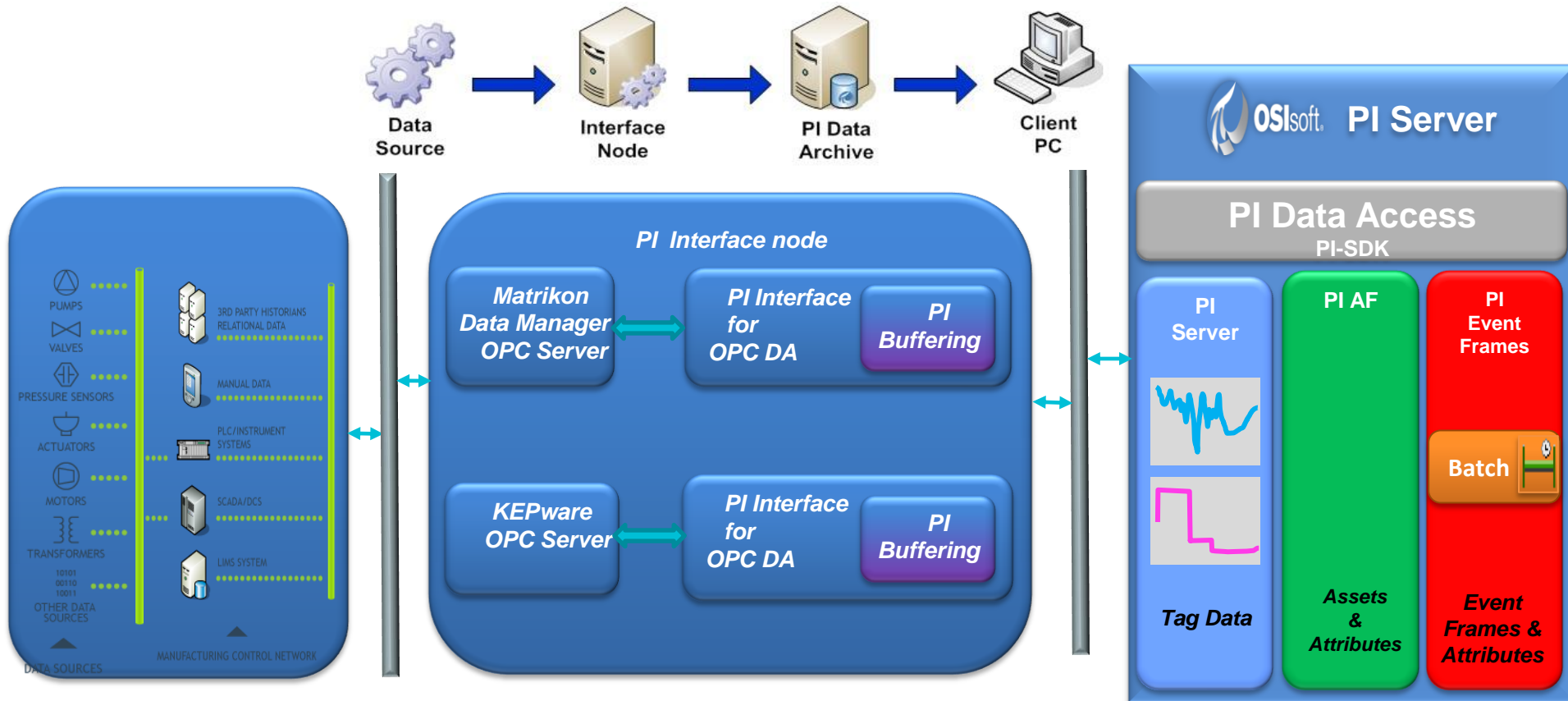
The PI System in Virtual Environment

PI System Management Tools (PI SMT)

PI SMT - Point Configuration and the Excel Add-Ins

PI Batch Generator example

PI Batch Generator example

PI Batch Generator example

PI BatchView with PI ProcessBook

PI BatchView with PI ProcessBook

PI DataLink – Excel application example (simple reporting)

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PI DataLink – Excel application example (simple reporting)

Benefit

- Less paperwork
- Site-wide process visibility
- Batch tracking, investigations
- Users can get the data what they need

Future opportunities

- Batch Reporting based on RtReports
- More data source - PI Server extension
- More eyes on PI System – new clients
- MES integration
- Technology transfer from "Glass lab" to full scale manufacturing

Conclusion

| Business Challenge	Solution	Results / Benefits
• Automate the manufacturing workflow • Provide an easy tool for comparing and analyzing batches • Provide a standard rapid an cost effective approach to capturing key process data	• PI System with Batch functionality	• Less paperwork • More focus on process less time with data mining • Optimized batch cycle time • Better equipment utilization

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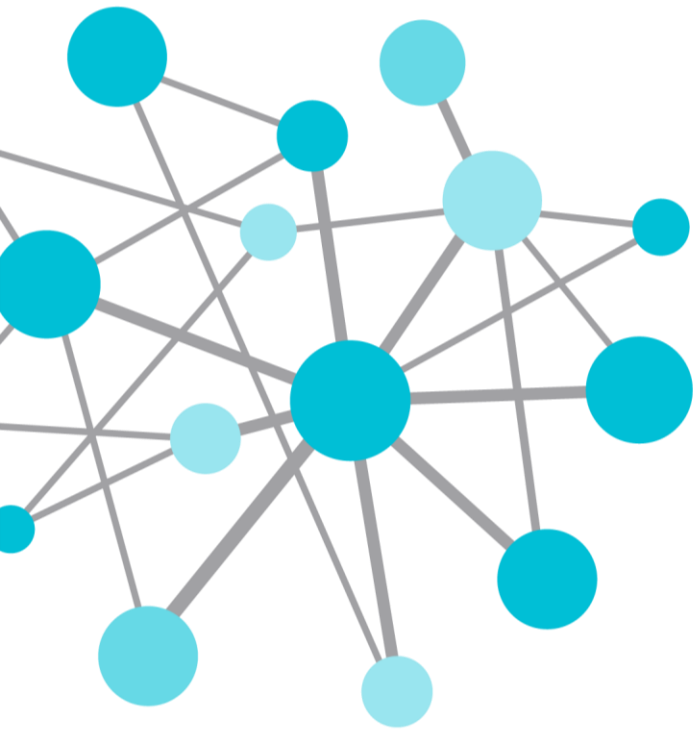- Head of Automation
- TEVA Hungary
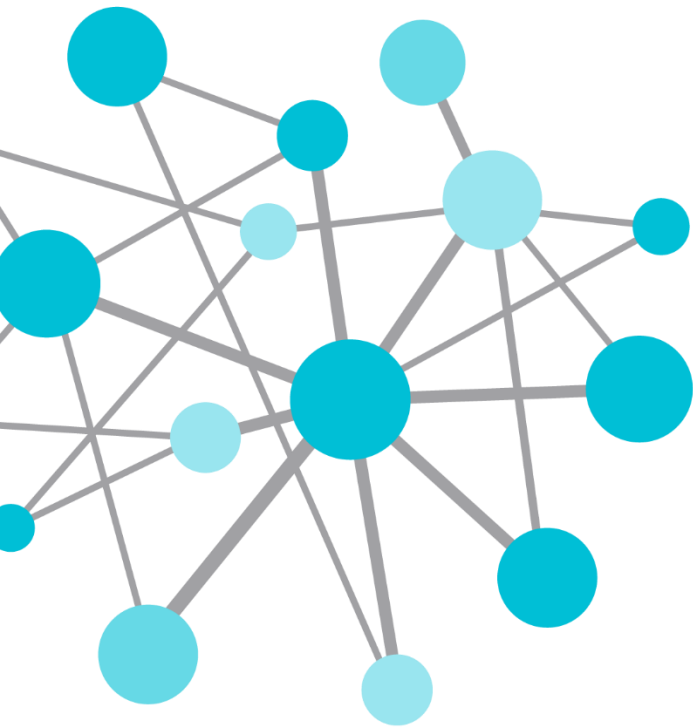
Questions

Please wait for the **microphone** before asking your questions

State your **name & company**

THANK YOU

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