

### Vial Size

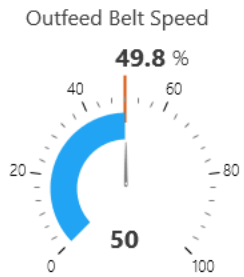
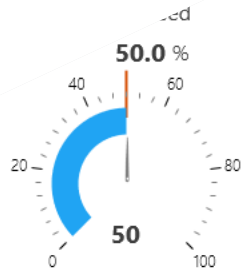
Disk 1 Height



Diameter

Disk 2 Height

-  Audit Trail
-  Recipe Management
-  Reports
-  User List



### Vial Analysis

Good / Rejected Vials



Vials Quantity Target **100**

Good Vials

### Process Graphs

Disk 1

### Time Counters

Planned Production **45 s**

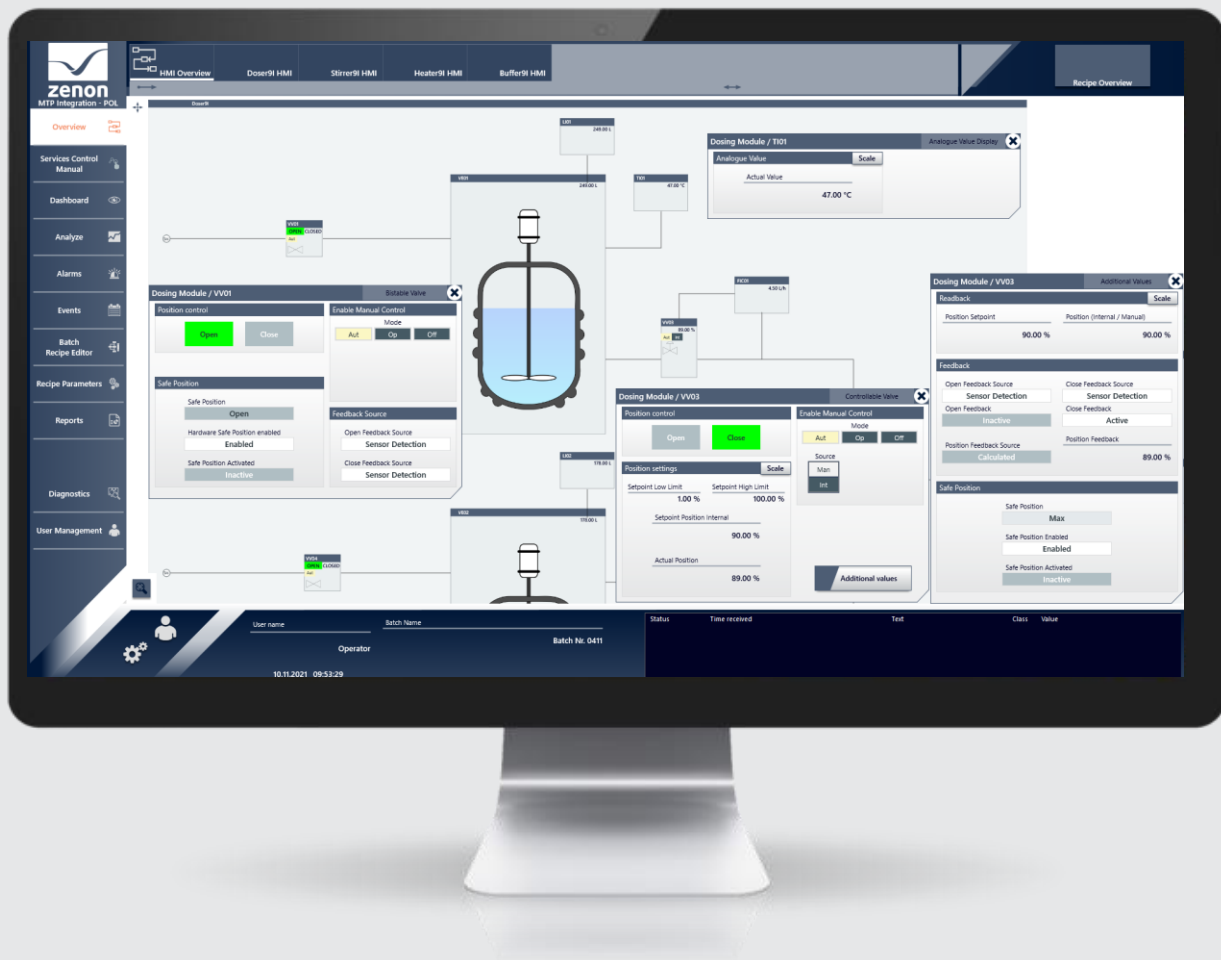
Gross C

# Plug & Produce nel Life Science

11.05.2022

Il webinar inizia tra pochi istanti...





# Benvenuti

*Plug and Produce nel Life Science – Webinar*

*10.00-10.45*

*Mercoledì, 11 Maggio 2022*

# I relatori di oggi



Noemi Torcasio  
Marketing Manager  
COPA-DATA Italia



Samuele Polito  
Sales Engineer  
COPA-DATA Italia



Giuseppe Menin  
Life Sciences & Process Industry Manager  
COPA-DATA HQ

# COPA-DATA in sintesi

**300+**  
dipendenti nel mondo

An icon showing five stylized human figures in a row, with a semi-circle of dots above them, representing a group of people.

**€64 M**

fatturato nel 2021

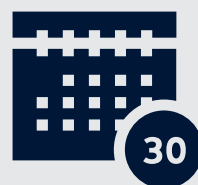


**5.000+**  
clienti soddisfatti



**100%**

indipendente  
azienda familiare



**1987**

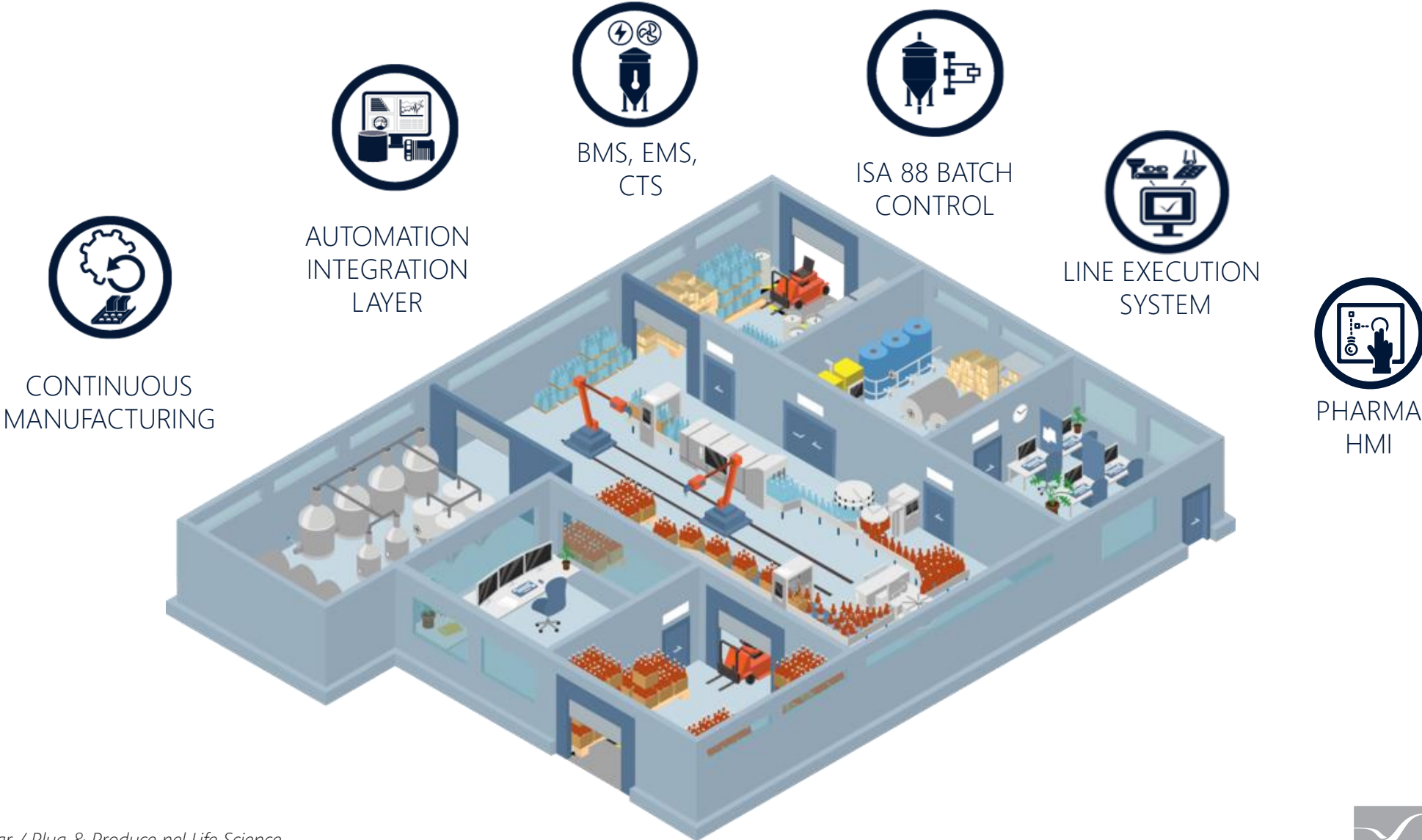
fondata in  
Austria



**200.000+**

sistemi zenon installati  
nel mondo

# zenon Software Platform



# Pharma HMI con zenon

*Facilità di gestione di bordo macchina, in conformità con le normative vigenti.*



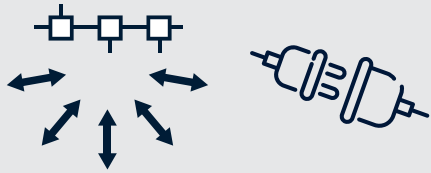
[▶ Video HMI](#)

# zenon Line Execution System - LES

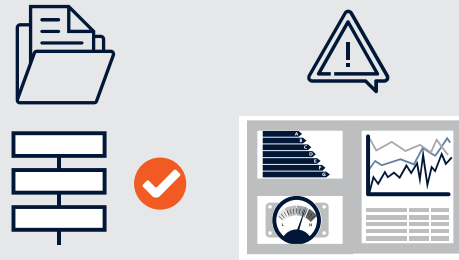
*Grandi vantaggi in un unico sistema*



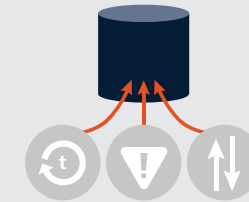
## CONNETTIVITA'



## GESTIONE DEL BATCH



## DATA STORAGE IN COMPLIANCE



## DOCUMENTAZIONE IN COMPLIANCE



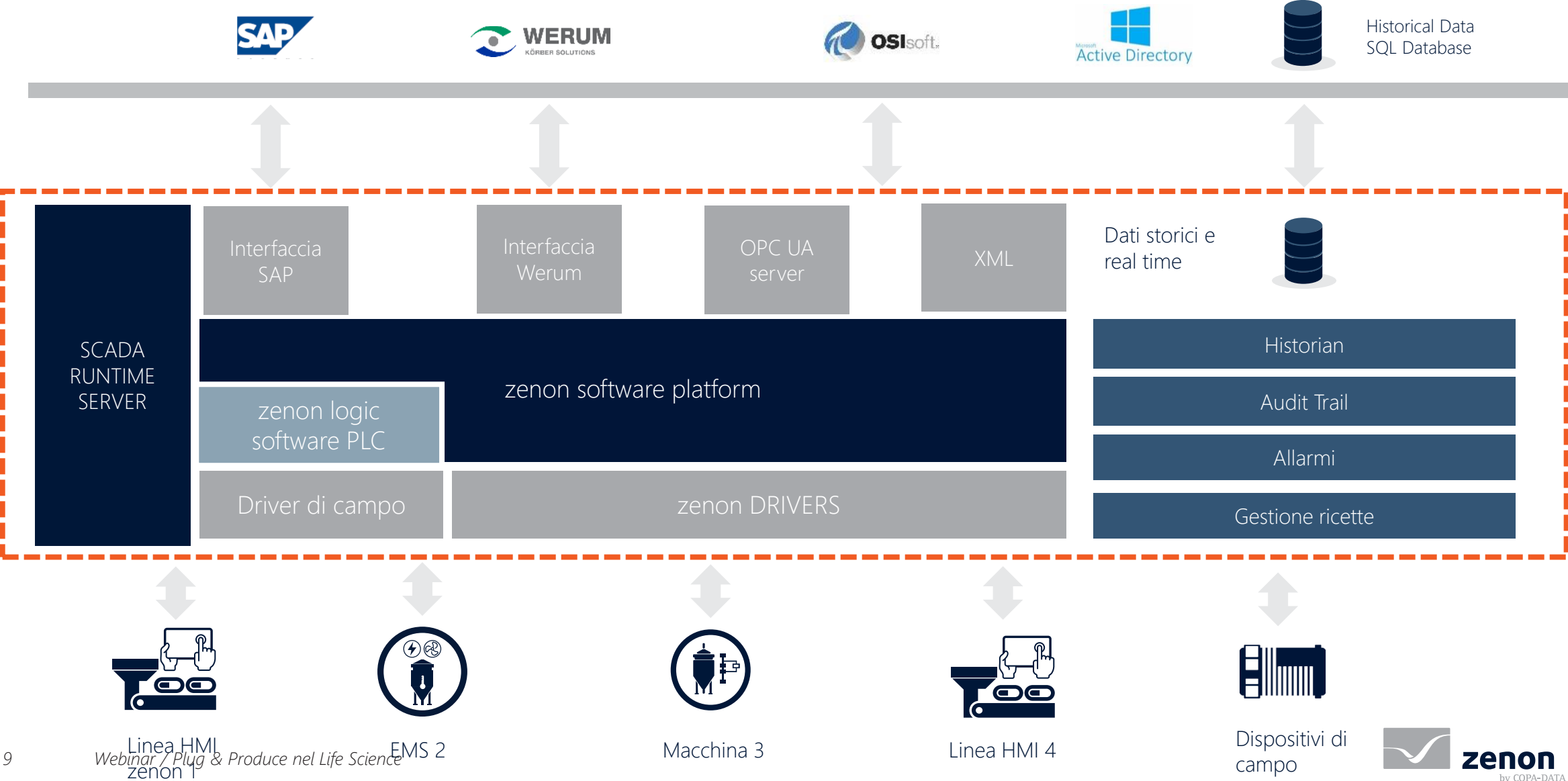
## INTEGRAZIONE NELL'INFRASTRUTTURA IT



## SEMPLICITA' DI INGEGNERIZZAZIONE FACILITA' DI VALIDAZIONE



# Automation Integration Layer





# Produzione a Batch secondo le normative ISA88

*Un sistema aperto e scalabile per la produzione a Batch*



# BMS, EMS, CTS

*Building Management System, Environmental Monitoring System, Centralized Technical Services*

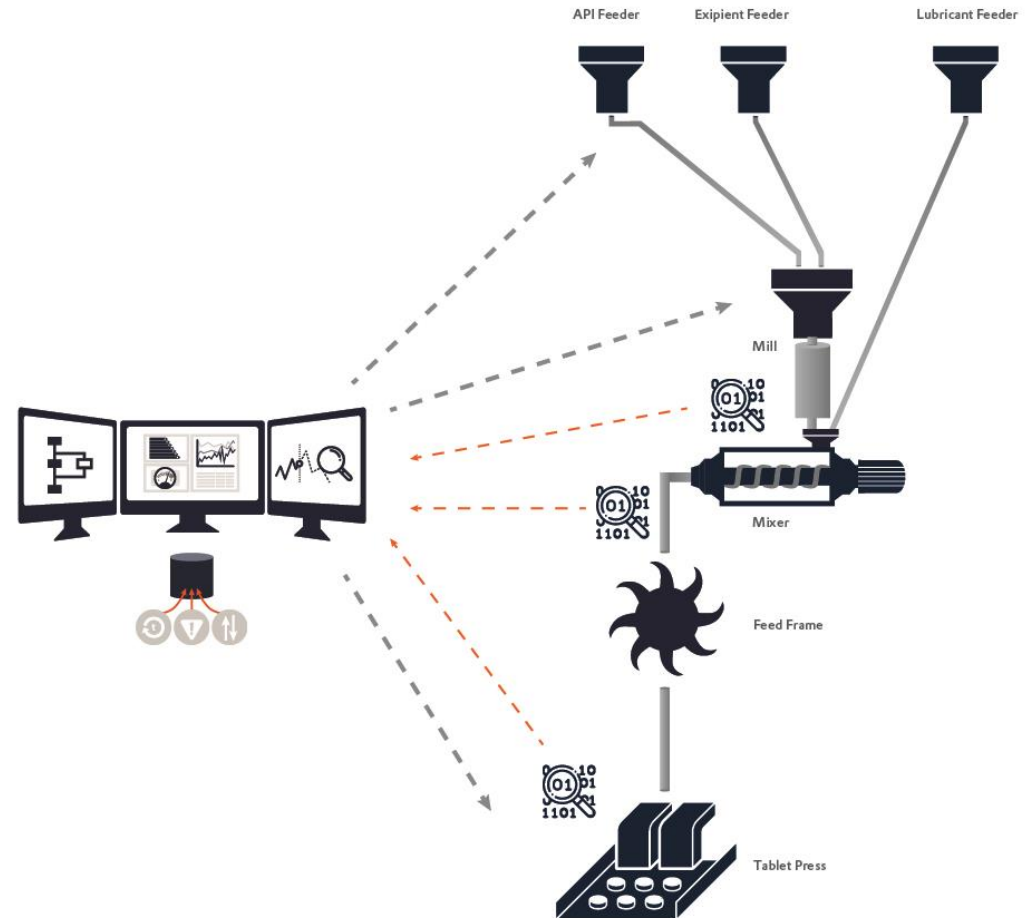


# Continuous Manufacturing

*Semplificazione dei sistemi complessi e gestione della qualità in linea*

Semplicità di utilizzo:

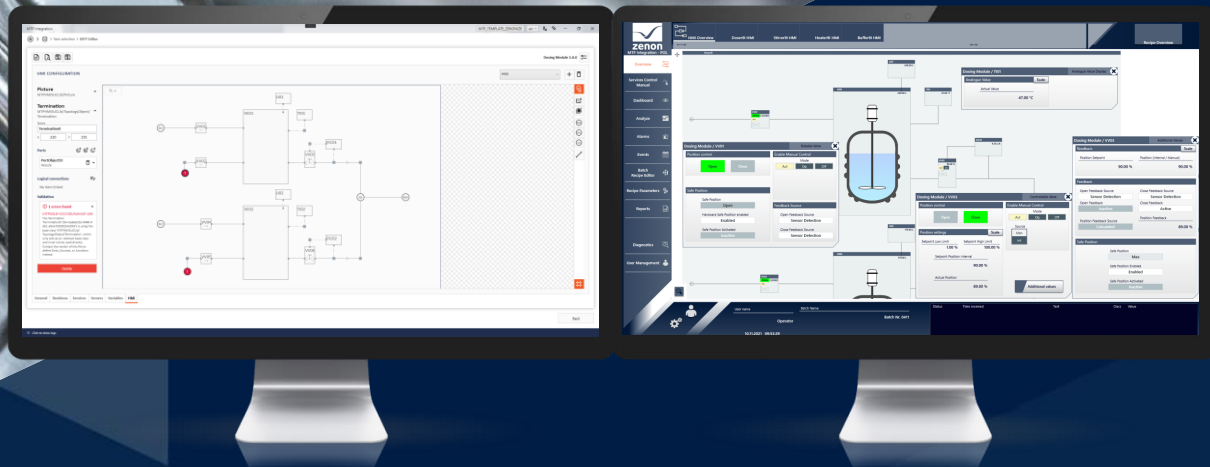
- ▶ Interfaccia semplificata
- ▶ Dati storici
- ▶ Gestione ricette
- ▶ Reportistica
- ▶ Parametri, set-point e trend



# zenon Software Platform per il settore Farmaceutico







# Plug & Produce con zenon e MTP

# VINTAGE OFFICE SETUP





**Configurazione moderna  
ossia un sistema modulare che  
supporta il plug & play**





# Il cambio di paradigma nell'automazione di processo

Classico impianto in acciaio inox



Produzione modulare nel settore biotech

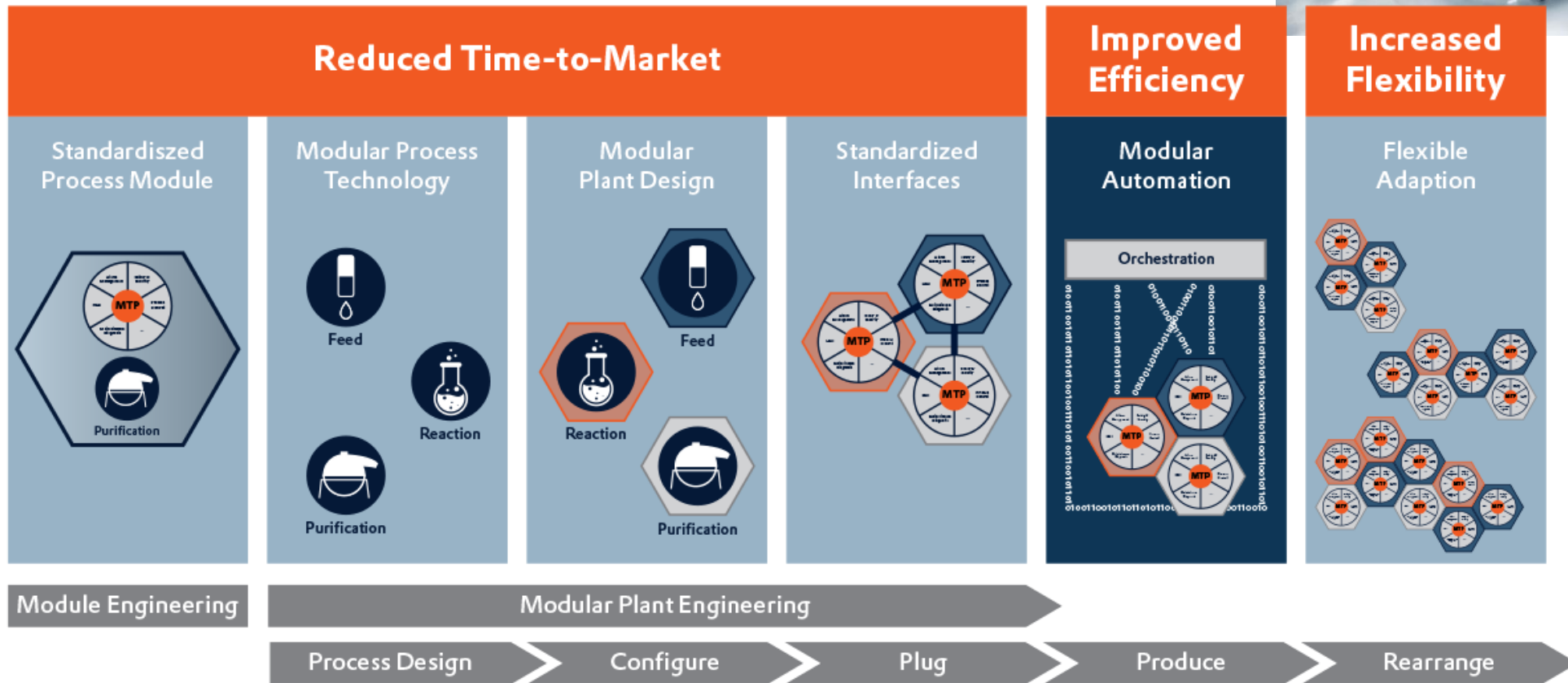




# Modular Plant Engineering



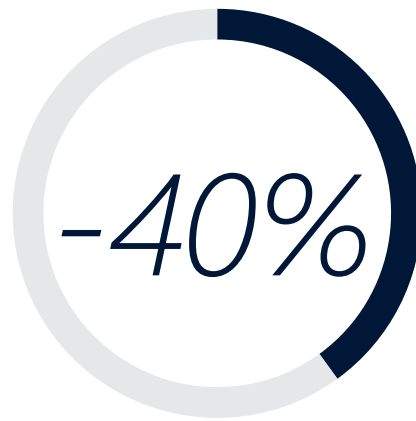
Source: Sartorius



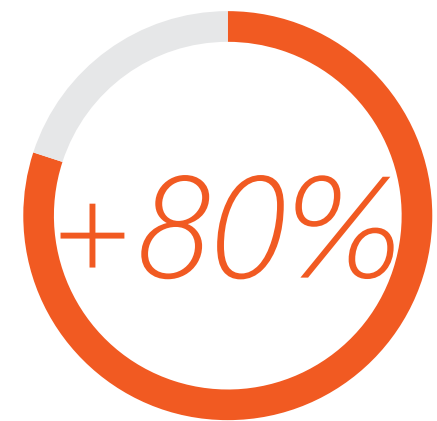
# I benefici della produzione modulare



TIME-TO-MARKET



COSTI DI PRODUZIONE



FLESSIBILITÀ

Source: Namur

# Alcune sfide ...

## INTEROPERABILITÀ

I moduli di produzione devono:

- ▶ Avere un linguaggio di comunicazione comune
- ▶ Offrire una descrizione delle proprie funzionalità comune.

## ORCHESTRAZIONE:

L'applicazione di controllo deve essere «orchestrata» da un ingegnere di processo.

## DATA INTEGRITY:

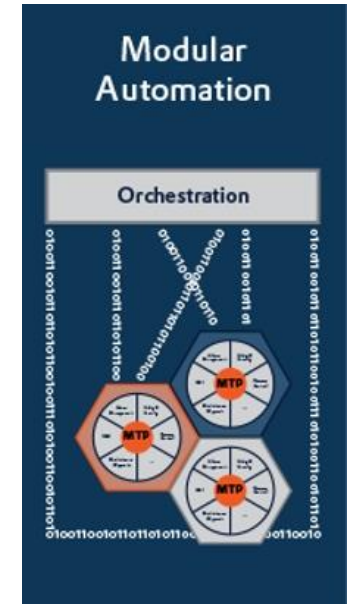
Electronic Records devono essere correttamente acquisiti e memorizzati.

## GMP COMPLIANCE:

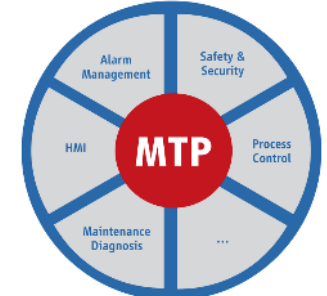
Gestire documentazione e convalida in un impianto che cambia configurazione da un lotto all'altro.

## BROWN FIELD:

Posso applicare la modula production ai miei skid / moduli di produzione che ho in azienda?

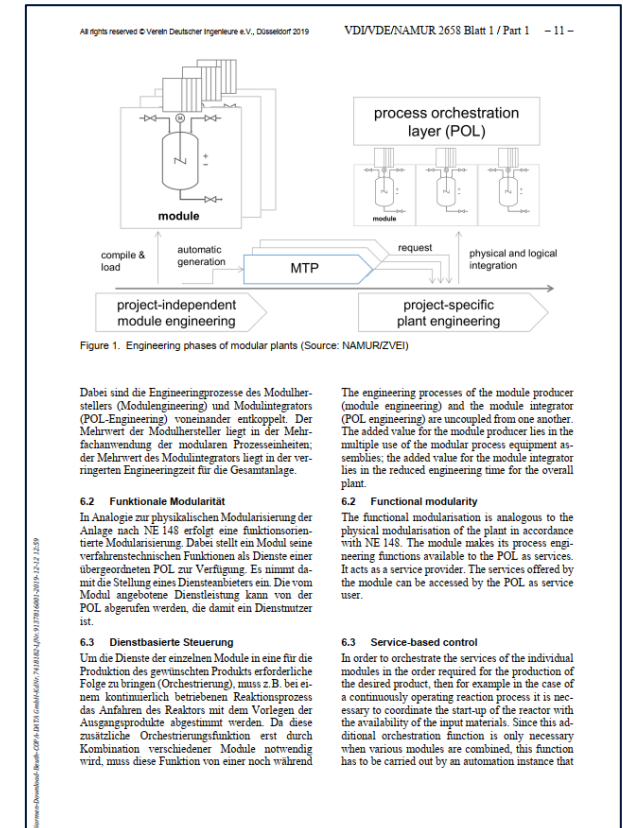


# MTP – Module Type Package

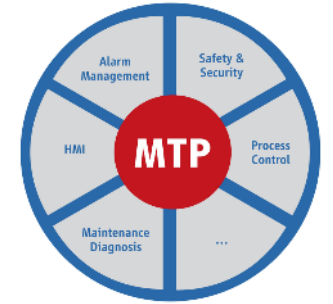


- ▶ MTP è una descrizione vendor-independent di moduli di produzione
- ▶ E' la base per progettare sistemi di controllo di impianti modulari in una modalità "Plug&Produce".
- ▶ E' un concetto ideato e promosso da NAMUR, un'associazione internazionale di aziende nel settore dell'industria di processo
- ▶ Normativa di riferimento: VDI/VDE/NAMUR\* 2658

ICS 35.240.50		VDI/VDE/NAMUR-RICHTLINIEN		Oktober 2019 October 2019	
VEREIN DEUTSCHER INGENIEURE VERBAND DER ELEKTROTECHNIK ELEKTRONIK INFORMATIONSTECHNIK INTERESSEN- GEMEINSCHAFT AUTOMATISIERUNGS- TECHNIK DER PROZESSINDUSTRIE		Automatisierungstechnisches Engineering modularer Anlagen in der Prozessindustrie Allgemeines Konzept und Schnittstellen Automation engineering of modular systems in the process industry General concept and interfaces		VDI/VDE/ NAMUR 2658 Blatt 1 / Part 1  Ausg. deutsch/englisch Issue German/English	
Die deutsche Version dieser Richtlinie ist verbindlich.		The German version of this standard shall be taken as authoritative. No guarantee can be given with respect to the English translation.			
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2 Begriffe	5	2 Terms and definitions	5		
3 Abkürzungen	6	3 Abbreviations	6		
4 MTP-Versionierung	6	4 MTP Version	6		
5 Module	6	5 Modules	6		
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5.2 Modultypen	7	5.2 Module types	7		
5.3 Transparenzstufen von Modulen	8	5.3 Transparency levels of modules	8		
6 Grundkonzepte der Automatisierung modularer Anlagen	9	6 Basic concepts of the automation of modular plants	9		
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6.3 Dienstbasierte Steuerung	11	6.3 Service-based control	11		
6.4 Bedienschnittstelle für modulare Anlagen	12	6.4 User interfaces for modular plants	12		
6.5 POL-Integration	13	6.5 POL integration	13		
6.6 Security modularer Anlagen	15	6.6 Security of modular plants	15		
6.7 Funktionale Sicherheit modularer Anlagen	15	6.7 Functional safety of modular plants	15		
7 Module Type Package	15	7 Module type package	15		
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7.2 Aufbau des Module Type Package	17	7.2 Structure of the module type package	17		
7.3 MTP-Packaging-Format	18	7.3 MTP packaging format	18		
7.4 Manifest	19	7.4 Manifest	19		
7.5 Modellierungsvorschriften	27	7.5 Modelling specifications	27		
7.6 Beispiel eines Manifests	30	7.6 Example of a manifest	30		
Schrifttum	31	Bibliography	31		
Anhang Beispiel eines Manifests in AutomationML mit zugehörigen Klassen MTPSUCLib, MTPDataObjectSUCLib, MTPCommunicationSUCLib, MTPCommunicationCLib	32	Annex Example of a manifest in AutomationML with the relevant classes: MTPSUCLib, MTPDataObjectSUCLib, MTPCommunicationSUCLib, MTPCommunicationCLib	32		
VDI/VDE-Gesellschaft Mess- und Automatisierungstechnik (GMA) Fachbereich Industrielle Informationstechnik					
VDI-Handbuch Informationstechnik, Band 1: Angewandte Informationstechnik VDI/VDE-Handbuch Automatisierungstechnik					

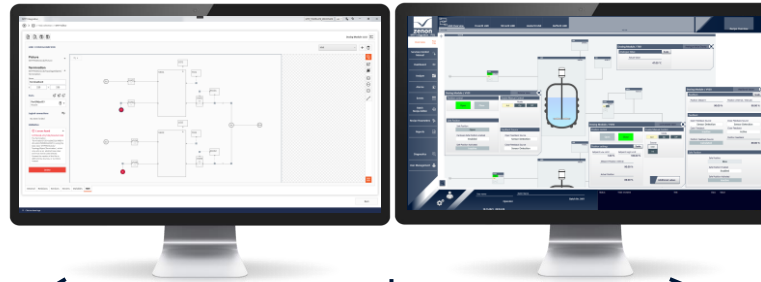


# Module Type Package: I componenti.

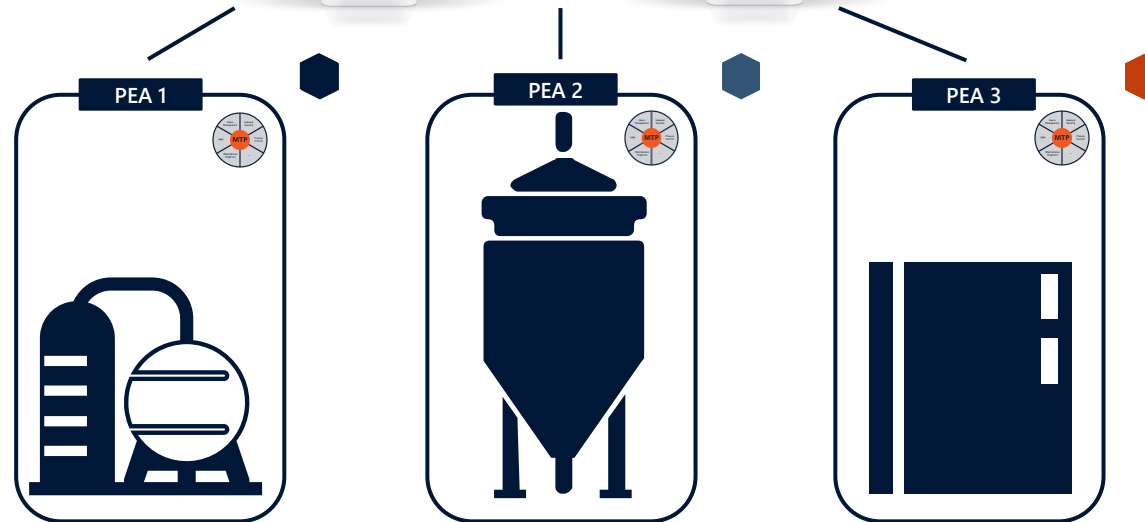


POL  
Process Orchestration Layer

POL – Process Orchestration Layer



PEA  
Process Equipment Assembly



Doser services:

- ▶ Filling
- ▶ Dosing
- ▶ Emptying

Reaction services:

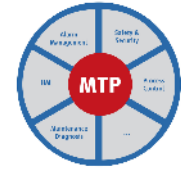
- ▶ Stirring
- ▶ Filling/Emptying
- ▶ Dosing
- ▶ Gassing

Temperature services:

- ▶ Tempering internal temp.
- ▶ Tempering external temp.

# MTP Manifest

La carta di identità del modulo PEA



E' un file **XML** (conforme a *AutomationML* - Automation Markup Language IEC62714)

Include informazioni come:

- ▶ Quali funzioni posso svolgere? (Services & Procedures)
- ▶ Quali dati di processo posso condividere? (Data Set)
- ▶ Come devo essere rappresentato? (P&ID)
- ▶ Alarms and Audit Trail
- ▶ .....

```
1 <?xml version="1.0" encoding="utf-8"?>
2 <CAEXfile xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns:xsd="http://www.w3.org/2001/XMLSchema" SchemaVersion="3.0" FileName="Buffer_MTP-1.00.mtp" xmlns="http://www.dke.de/CAEX">
3   <AdditionalInformation DocumentVersions="Recommendations">
4     <Document DocumentIdentifier="VDI/VDE/NAEUR 2658-1" Version="1.0.0" />
5   </AdditionalInformation>
6   <AdditionalInformation DocumentVersions="Recommendations">
7     <Document DocumentIdentifier="VDI/VDE/NAEUR 2658-2" Version="1.0.0" />
8   </AdditionalInformation>
9   <AdditionalInformation DocumentVersions="Recommendations">
10    <Document DocumentIdentifier="VDI/VDE/NAEUR 2658-3" Version="1.0.0" />
11  </AdditionalInformation>
12  <AdditionalInformation DocumentVersions="Recommendations">
13    <Document DocumentIdentifier="VDI/VDE/NAEUR 2658-4" Version="0.1.0" />
14  </AdditionalInformation>
15  <SuperiorStandardVersion AutomationML 2.10 /SuperiorStandardVersion>
16  <SourceDocumentInformation OriginName="John Doe" OriginID="COPA-DATA MTP Suite" OriginVendor="Ing. Punzenberger COPA-DATA GmbH" OriginVendorURL="https://www.copadata.com" OriginVersion="11.0">
17  <InstanceHierarchy Name="ModuleTypePackage">
18    <Version 0 />
19    <InternalElement ID="f7903713-8bf4-4f50-a7bf-62a989e7510c" Name="Buffer" RefBaseSystemUnitPath="MTPSUCLib/ModuleTypePackage">
20      <Description>SystemUnitClass who represents the entry point into an MTP Package</Description>
21      <Version 6.2.0 />
22      <Attribute Name="Version" AttributeDataType="xs:string">
23        <Description>Contains the Version of the MTP</Description>
24        <DefaultValue 1.0.0 />
25        <Value 6.2.0 />
26      </Attribute>
27      <InternalElement ID="617d2cc3-dcf3-40ae-b188-6fb839a82593" Name="CommunicationSet" RefBaseSystemUnitPath="MTPSUCLib/CommunicationSet">
28        <Description>Base class for the MTP Communication Aspect</Description>
29        <InternalElement ID="ea9e8364-ccd3-4219-a4f6-73d4c60f802" Name="InstanceList" RefBaseSystemUnitPath="MTPSUCLib/CommunicationSet/InstanceList">
30          <Description>SystemUnitClass for the List of DataAssemblies</Description>
31          <InternalElement ID="117618ec-3451-40ba-abc0-4b208ef2ae7c" Name="Temperature" RefBaseSystemUnitPath="MTPDataObjectSUCLib/DataAssembly/IndicatorElement/Anaview">
32            <Description>SystemUnitClass of the Anaview</Description>
33            <Attribute Name="RefID" Units="" AttributeDataType="xs:ID">
34              <Description>Reference ID - Relation of different data sets to a complete described Instance Object</Description>
35              <DefaultValue f818c6fe-479a-47a2-9dce-a61bb3859e91 />
36              <Value f818c6fe-479a-47a2-9dce-a61bb3859e91 />
37            </Attribute>
38            <Attribute Name="TagName" AttributeDataType="xs:string">
39              <Description>TagName Field</Description>
40              <DefaultValue Temperature Actual />
41              <Value Temperature Actual />
42            </Attribute>
43            <Attribute Name="TagDescription" AttributeDataType="xs:string">
44              <Description>TagDescription Field</Description>
45              <DefaultValue />
46              <Value />
47            </Attribute>
48            <Attribute Name="QC" Unit="" AttributeDataType="xs:IDREF">
49              <Description>Worst Quality Code variable</Description>
50            </Attribute>
51          </InternalElement>
52        </InternalElement>
53      </InternalElement>
54    </Version>
55  </InstanceHierarchy>
56 </SourceDocumentInformation>
57 </CAEXfile>
```

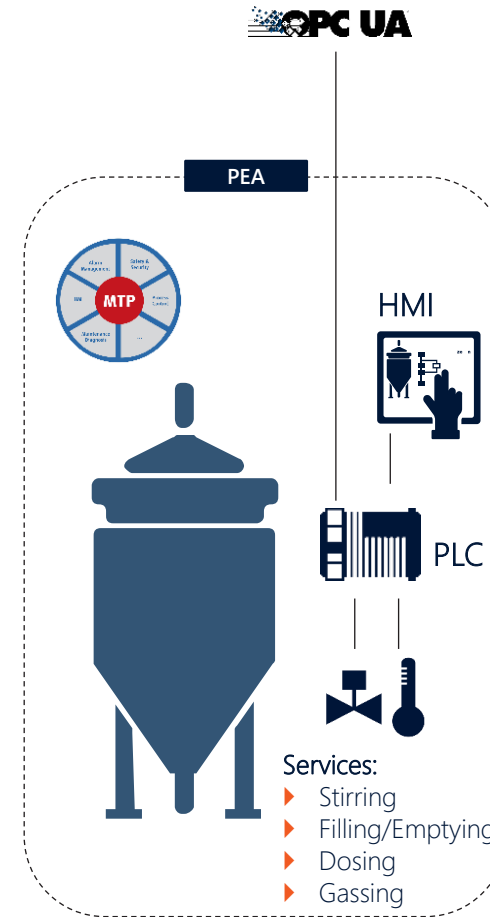
# PEA – Process Equipment Assembly

## CHE COS'È?

- ▶ Un modulo fisico in grado di realizzare un insieme di servizi
- ▶ Dispone di un Sistema di automazione locale (PLC)
- ▶ Può disporre di un HMI locale (optional)
- ▶ Le caratteristiche sono descritte nel file MTP (*Manifest*)
- ▶ Comunica con il POL via OPC UA

## PROGETTAZIONE, DOCUMENTAZIONE E CONVALIDA:

- ▶ La progettazione del PEA è indipendente dal POL
- ▶ Il progettista deve creare il file MTP.
- ▶ MTP Manifest è la base per generare la documentazione del modulo.
- ▶ PEA viene testato e validato indipendentemente dal POL.



Bioreactor as a PEA



A real Bioreactor



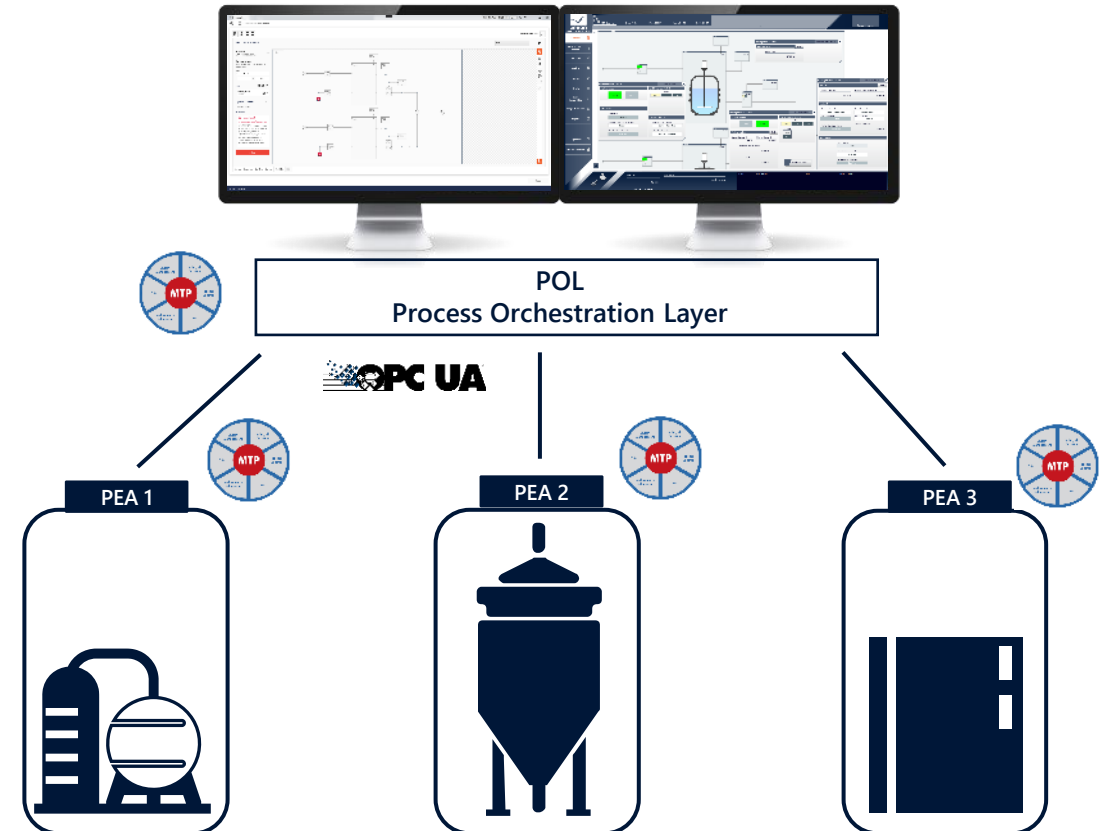
# POL – Process Orchestration Layer

## CHE COS'È?

- ▶ Una piattaforma software in grado di:
  - ▶ Importare e orchestrare i PEA
  - ▶ Monitorare e controllare il processo produttivo collegandosi ai vari PEA via OPC UA.
  - ▶ Produrre e memorizzare i record elettronici per assicurare la data integrity (Batch information, Process Values, Alarm, Audit Trail).

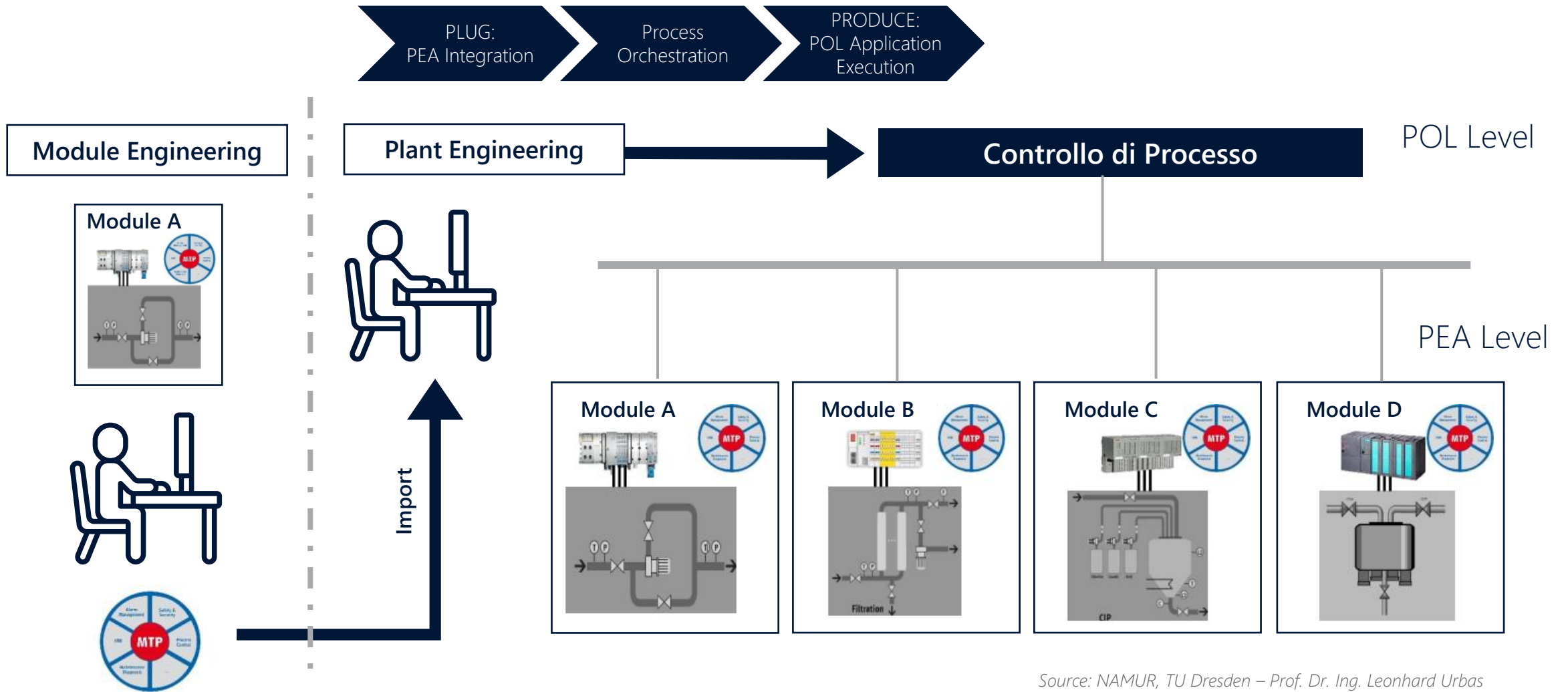
## PROGETTAZIONE, DOCUMENTAZIONE E CONVALIDA:

- ▶ L'importazione e l'orchestrazione deve essere effettuata da un ingegnere di processo guidato da un tool grafico.
- ▶ L'applicazione POL viene generata automaticamente
- ▶ La documentazione dell'applicazione POL può venire prodotta sfruttando le funzionalità del tool di orchestrazione.





# Le fasi di progettazione



Source: NAMUR, TU Dresden – Prof. Dr. Ing. Leonhard Urbas

# zenon MTP Suite

*Perform tasks covering the entire MTP life cycle*



# zenon MTP studio

MTP Studio - PREVIEW VERSION

MTP\_DEMO\_EMPTY en

Task selection > Manage SOTs > MTP import

Import an existing MTP file

Select a Module Type Package file below to preview it. Afterwards, it can be imported as a Smart Object Template into the connected zenon project.

C:\Users[Mathias.Lackner\Desktop]\Projects\MTP\Webinar\MTP Demo package\MTP files\Buffer v6.2.0.mtp

**MTP: Buffer (6.2.0)**

Display Name

Comment

Based on VDI/VDE/Namur standards:

- VDI/VDE/NAMUR 2658-1 (v1.0.0)
- VDI/VDE/NAMUR 2658-2 (v1.0.0)
- VDI/VDE/NAMUR 2658-3 (v1.0.0)
- VDI/VDE/NAMUR 2658-4 (v0.1.0)

Based on AML version:

AutomationML 2.10

Creators:

Vendor Ing. Punzenberger CO...  
 URL https://www.copedat...  
 Author John Doe  
 Tool ID COPA-DATA MTP Suite  
 Version 11.0.0.0  
 Release 11  
 Last written 2022-05-01T14:56:29...  
 Project ID -  
 Project title Demo Project

Revisions:

Author Bob Bahn

Overview  Server

DataAssemblies Services HMI

Click to show logs

MTP Studio - PREVIEW VERSION

MTP\_POL1

Task selection > Process orchestration > POL Project

Name POL1

Drag and drop a template or instance from the list to the drawing area to add an instance to the POL project.

Buffer v4.0.0  
 Ing. Punzenberger COPA-DATA GmbH  
 Buffer\_01 POL1

Buffer2 POL\_

Stirrer v3.0.0  
 Ing. Punzenberger COPA-DATA GmbH  
 Stirrer2 POL\_

Stirrer\_01 POL1

Logical view HMI view

Generate POL project

Previous Save

Click to show logs

HMI CONFIGURATION

Picture MTPHISUCLib/Picture

Visual Object MTPHISUCLib/VisualObject

Name

Fill Level Actual

Linked data assembly

Fill\_Level Analogue Display (AnaView)

Indirectly referenced entities No item linked.

Device image settings

eCI@ss

Version

IRDI

Appearance settings

X 500 Y 150  
 W 100 H 100  
 Z-index 0  
 Rotation 0

Ports

General Revisions Services Variables Servers **HMI**

Previous

Click to show logs

# POL – PI&D e controllo di processo

The screenshot displays the Zenon HMI interface for process control. The main window shows a process flow diagram with two vessels, 'Stirrer\_1' and 'Buffer\_1', connected by pipes and valves. The 'Stirrer\_1' vessel includes a motor and various control parameters like 'Fill Level Actual' (0.00 L), 'Speed Actual' (0.00 rpm), and 'Time Actual' (0 s). The 'Buffer\_1' vessel includes a 'Fill Level Stirrer' (0.00 L) and a 'Temperature' (65.00 °C). A 'Batch Recipe Overview' window is open, showing a recipe 'Demo' in 'Test in execution' status. The recipe steps include 'Recipe\_Fund... Initialisation', 'Stirring\_Dur... Stirring', and 'Heat\_Temp... Buffer\_1 Heating'. A table at the bottom right shows parameter values for the recipe.

Name	Wert	Istwert	Min.	Max.	Variable	CEL loggi...	Usage of TA...
P_Stirrer_1_Stirring_Time_Setpoi...	10 s	0 s	1	3600	P_Stirrer_1_Stirring_Time_Setpoi...	<input type="checkbox"/>	None
P_Stirrer_1_Speed_Setpoint_An...	50.00 rpm	0.00 rpm	0.00	1000.00	P_Stirrer_1_Speed_Setpoint_An...	<input type="checkbox"/>	None

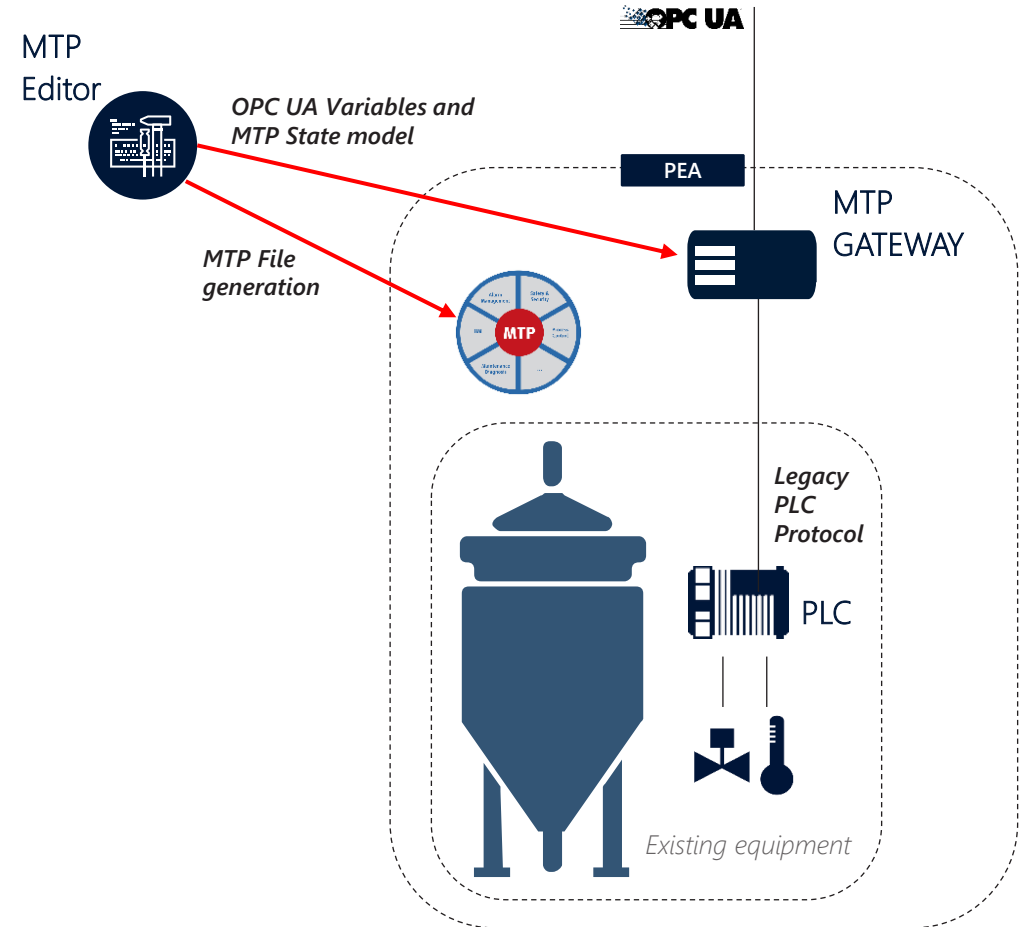
# POL – Historian e analisi dati

The screenshot displays the Zenon software interface for monitoring and analyzing process states. The main window shows a state transition diagram for 'PEA States' with three states: 'Idle/16', 'St... Exec... Co...C...Re...', and 'Execute/64'. The diagram shows transitions between these states over time, with specific timestamps like 14:02:00, 14:03:00, and 14:04:00. The right sidebar contains a list of curves with checkboxes for selection, including 'P\_Stirrer1\_Cleaning\_ServiceControl\_ProcedureCur', 'P\_Stirrer1\_Cleaning\_ServiceControl\_StateOffAct', 'P\_Stirrer1\_Cleaning\_ServiceControl\_StateAutAct', 'P\_Stirrer1\_Cleaning\_ServiceControl\_StateCur', and 'P\_Stirrer1\_Cleaning\_ServiceControl\_StateOpAct'. The bottom of the interface features a control panel with fields for 'User name', 'Batch Name', and 'Recipe Name', along with 'Start' and 'Comment' buttons, and a status bar showing the date and time '03/05/2022 14:07:02'.

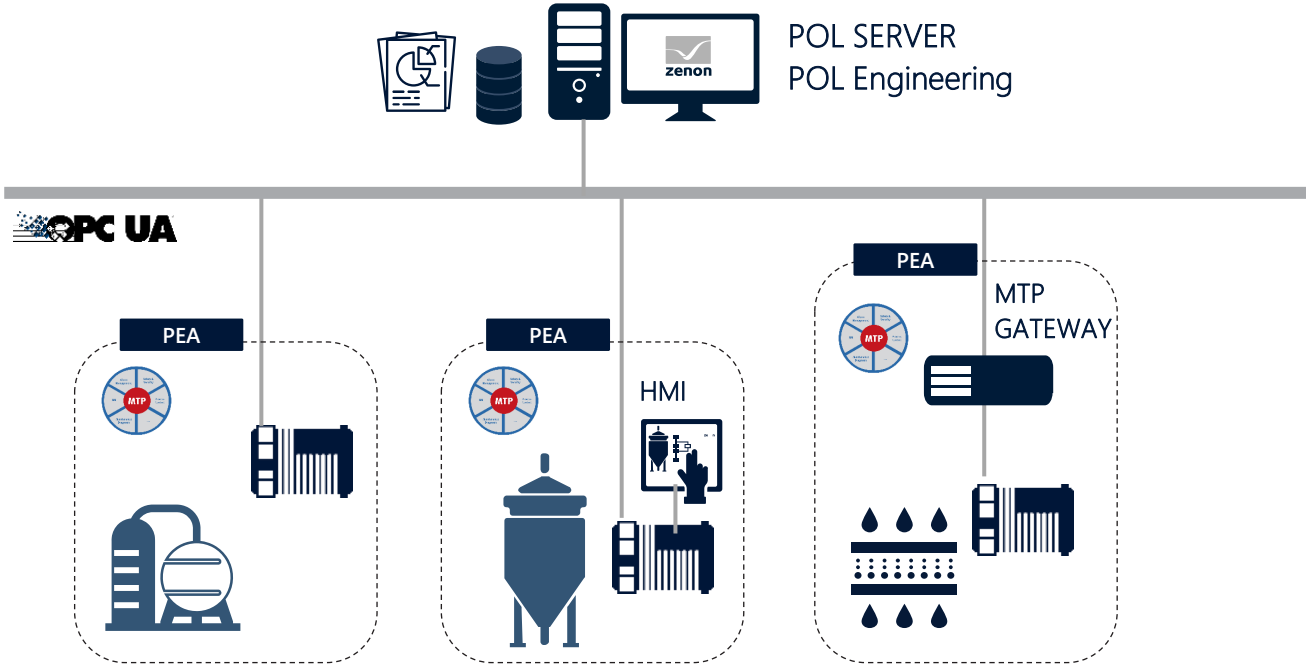
# Integrazione di moduli esistenti

zenon MTP Gateway

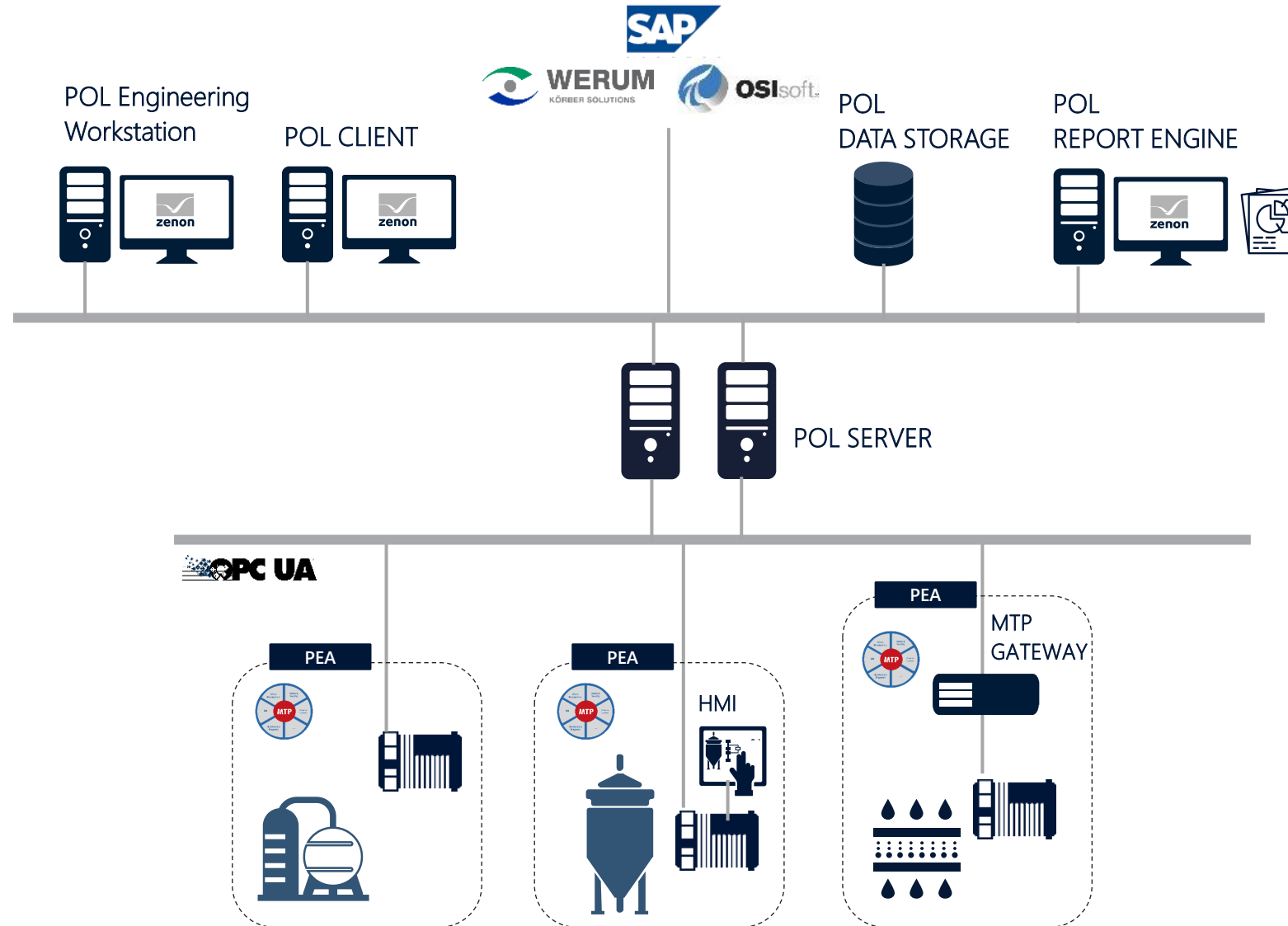
- ▶ MTP Gateway offre un'integrazione di moduli esistenti non "MTP ready".
- ▶ Prevede:
  - Connessione al PLC esistente del modulo
  - Comunicazione verso il livello MTP POL attraverso OPC UA (server)
  - SoftPLC IEC61131:
    - OPC UA Variables
    - MTP State Model
    - Logic for PLC variables conversion
  - Generazione file MTP attraverso MTP editor.



# Una semplice architettura MTP POL



# Un esempio di POL in area di produzione







*The zenon POL is one of the first POL's on the market with almost fully comprehensive POL functionalities.*

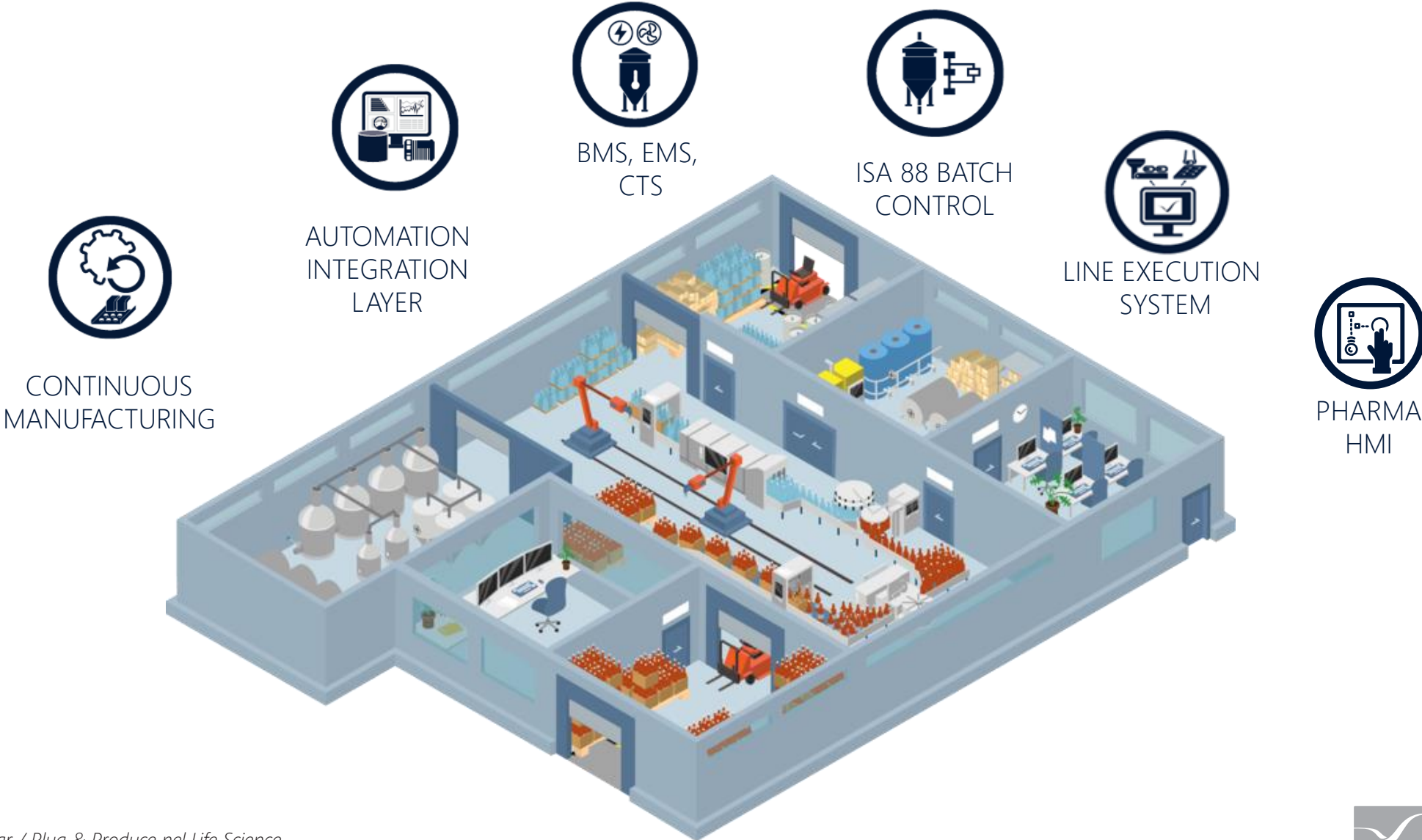
*Manfred Eckert, Associate Director Process Development at Merck*

# Q&A





# zenon Software Platform



# Vi aspettiamo a SPS: PAD. 5 STAND H055

MERCOLEDÌ 25 MAGGIO

APPUNTAMENTO:

CONVEGNO SCIENTIFICO  
AUTOMAZIONE AVANZATA

ORE 11.40

SPS ARENA

*"Plug & Produce in Life Science:  
modularità e interoperabilità  
nell'Automazione di processo grazie  
allo standard MTP (Module Type  
Package)"*

Giuseppe Menin – COPA-DATA

**SAVE THE DATE**

24-26 Maggio 2022, Fiere di Parma



**Visit us at the SPS Italia  
from 24-26 Maggio 2022  
Fiere di Parma**

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smart production solutions

 PAD. 5 Stand. 055

# Download utili

- ▶ Per saperne di più sulla nostra soluzione Pharma [clicca qui](#)
- ▶ Per scaricare il **Pharma HMI Application Set** ed avere una dimostrazione pratica di come funziona zenon [clicca qui](#)
- ▶ Per scoprire di più sulla produzione modulare (MTP) [clicca qui](#)

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# Questionario



**GRAZIE PER L'ATTENZIONE**

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