

Vial Size

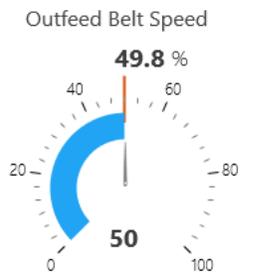
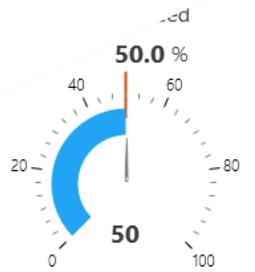
Disk 1 Height



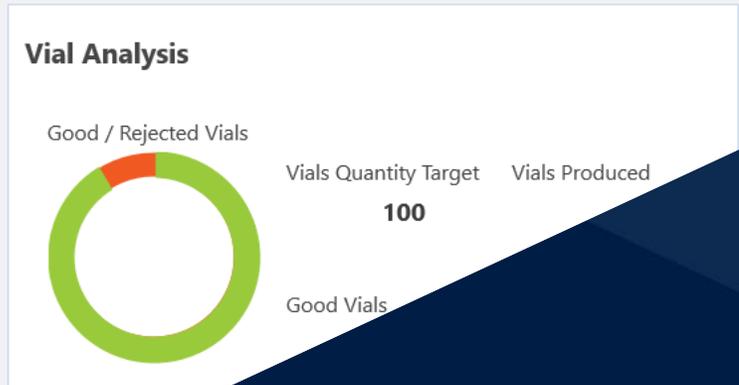
Diameter

Disk 2 Height

-  Audit Trail
-  Recipe Management
-  Reports
-  User List



- Weight
- Powder
- PackML
- Simulation

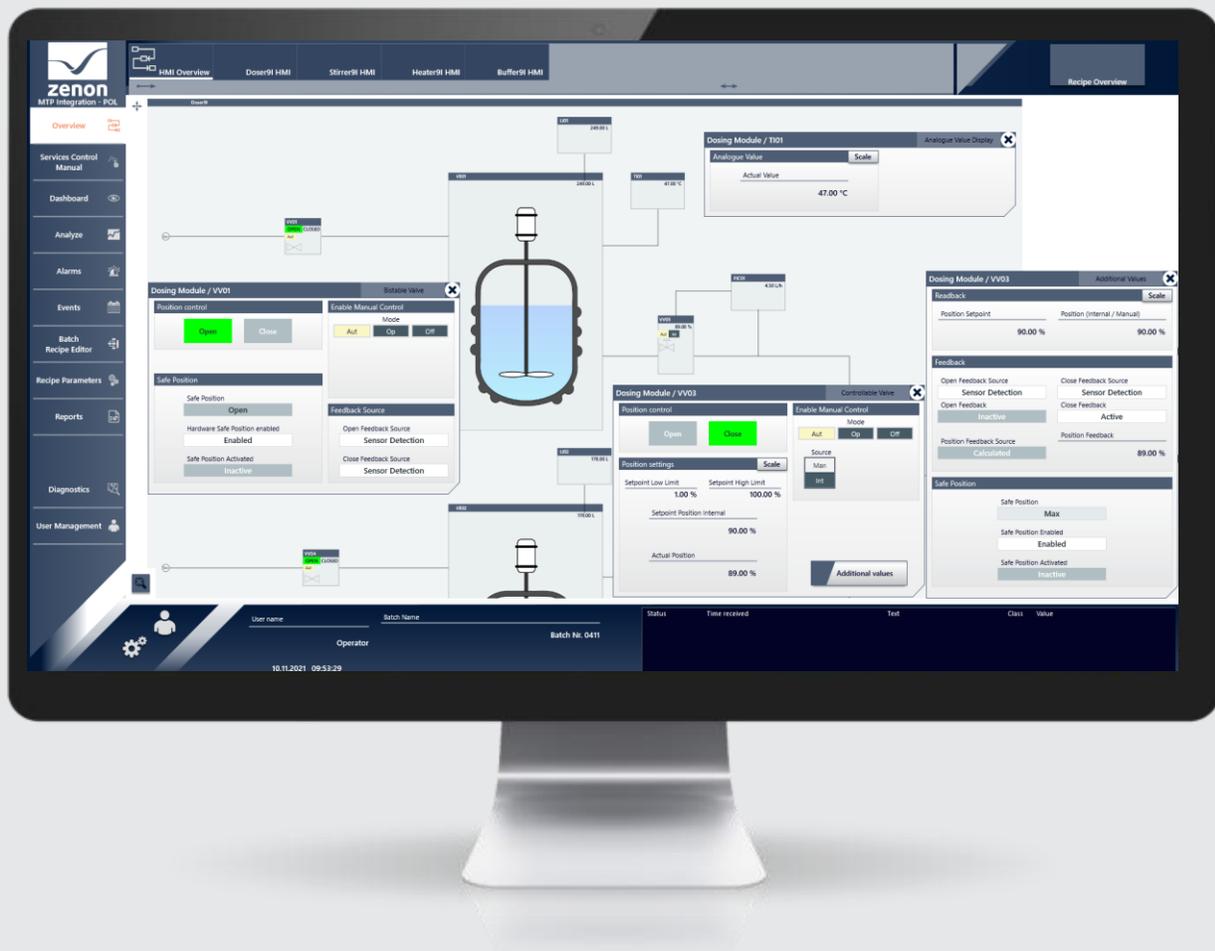


Plug & Produce nel Life Science

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

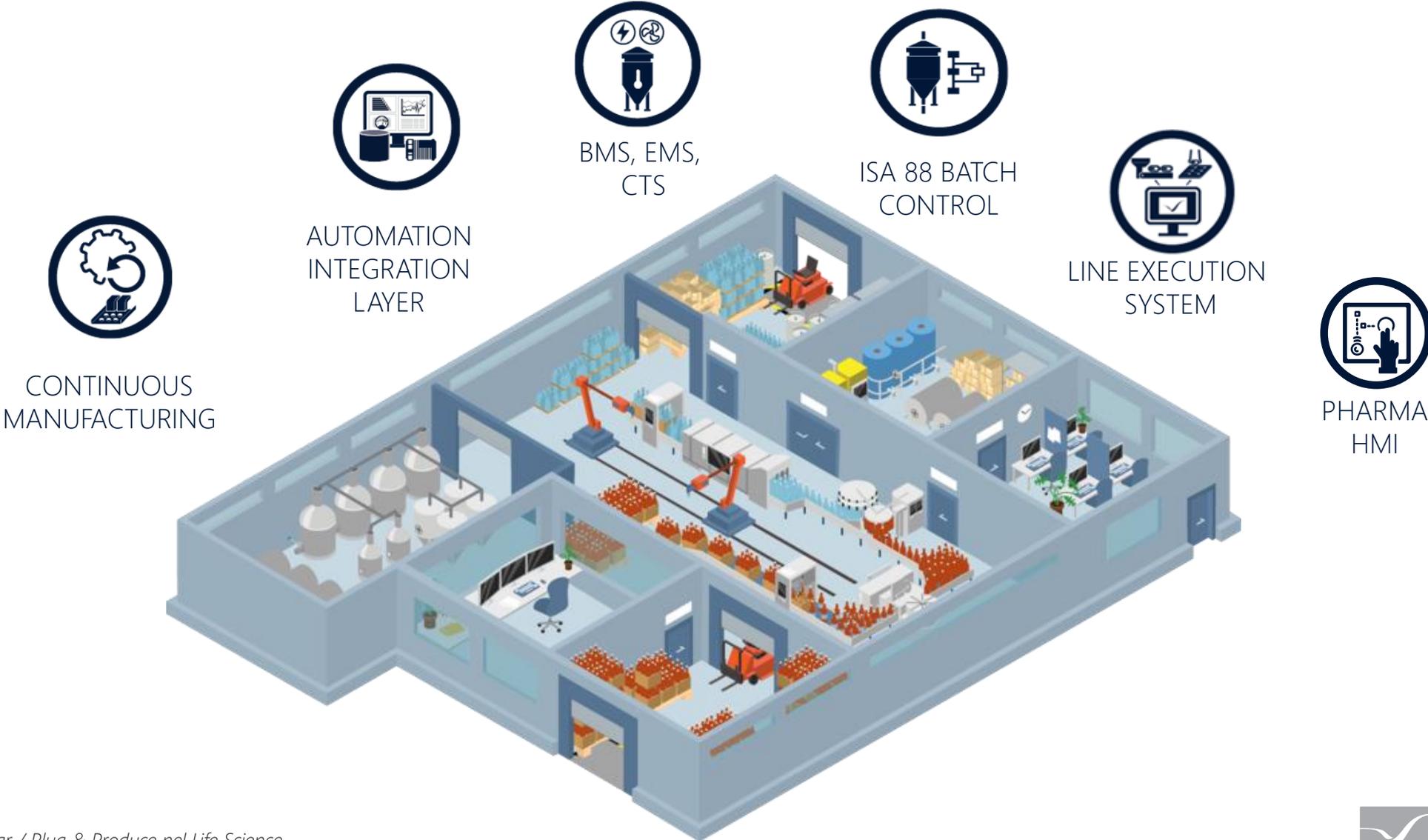
fondata in
Austria



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.



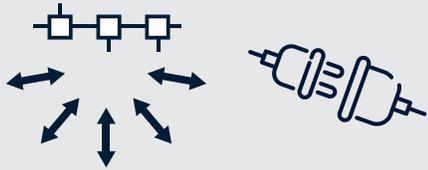
[▶ Video HMI](#)

zenon Line Execution System - LES

Grandi vantaggi in un unico sistema



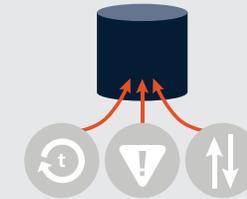
CONNETTIVITA'



GESTIONE DEL BATCH



DATA STORAGE IN COMPLIANCE



DOCUMENTAZIONE IN COMPLIANCE



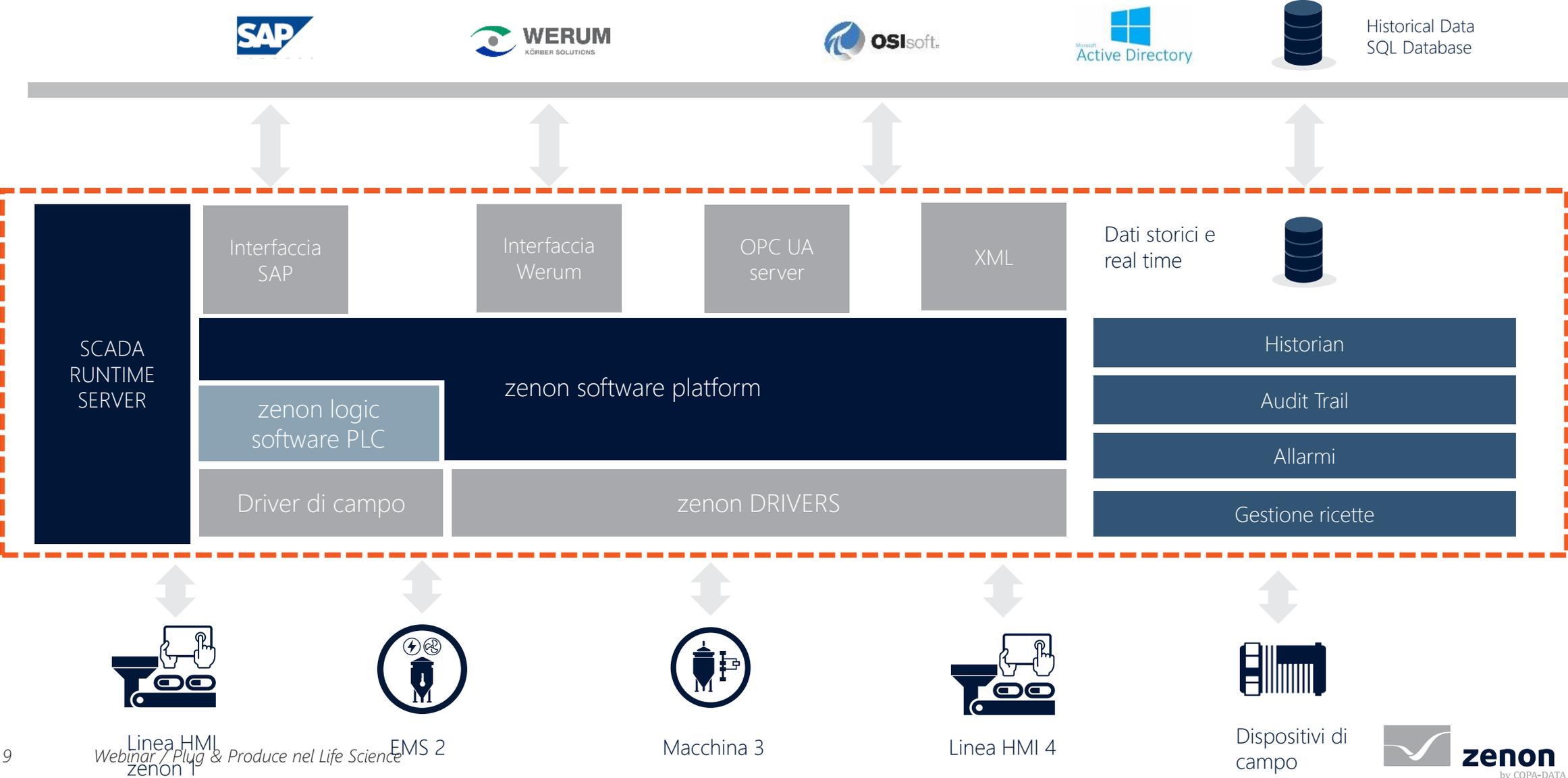
INTEGRAZIONE NELL'INFRASTRUTTURA IT



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

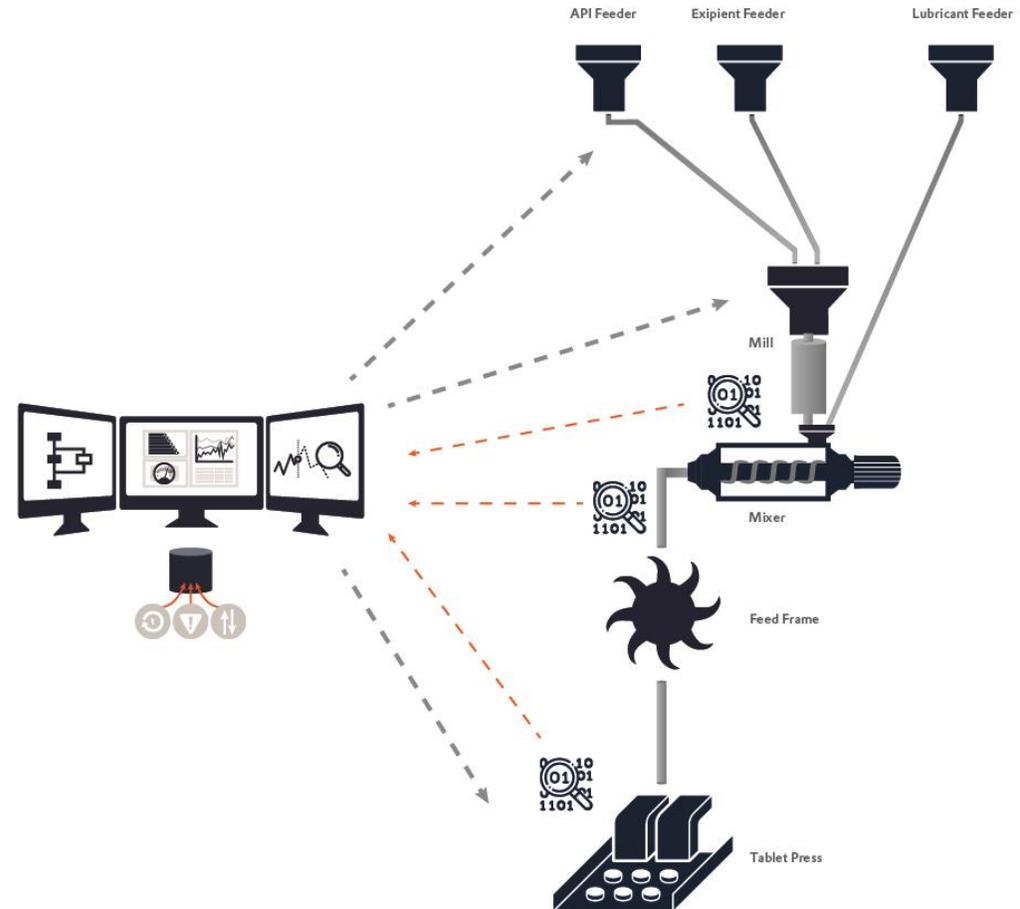


Continuous Manufacturing

Semplificazione dei sistemi complessi e gestione della qualità in linea

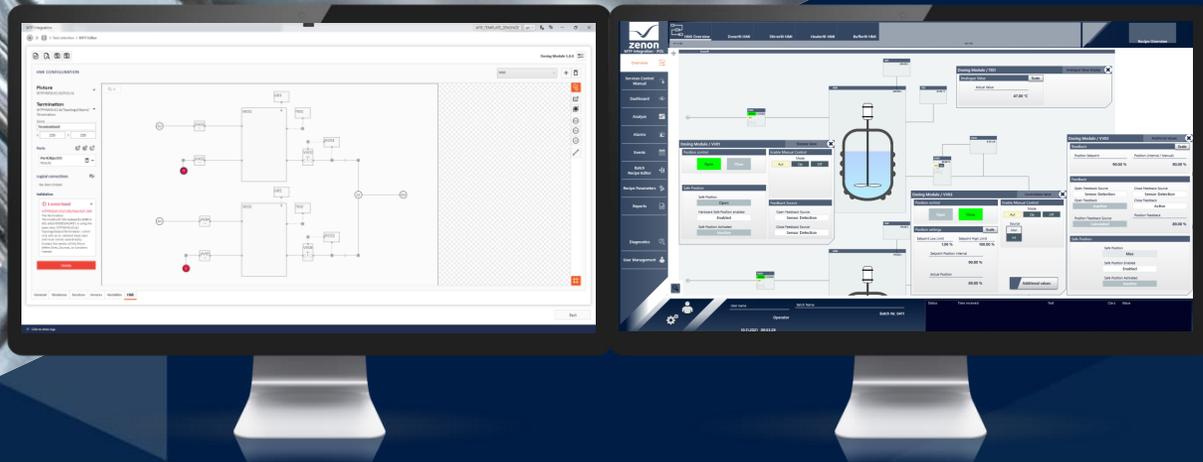
Semplicità di utilizzo:

- ▶ 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



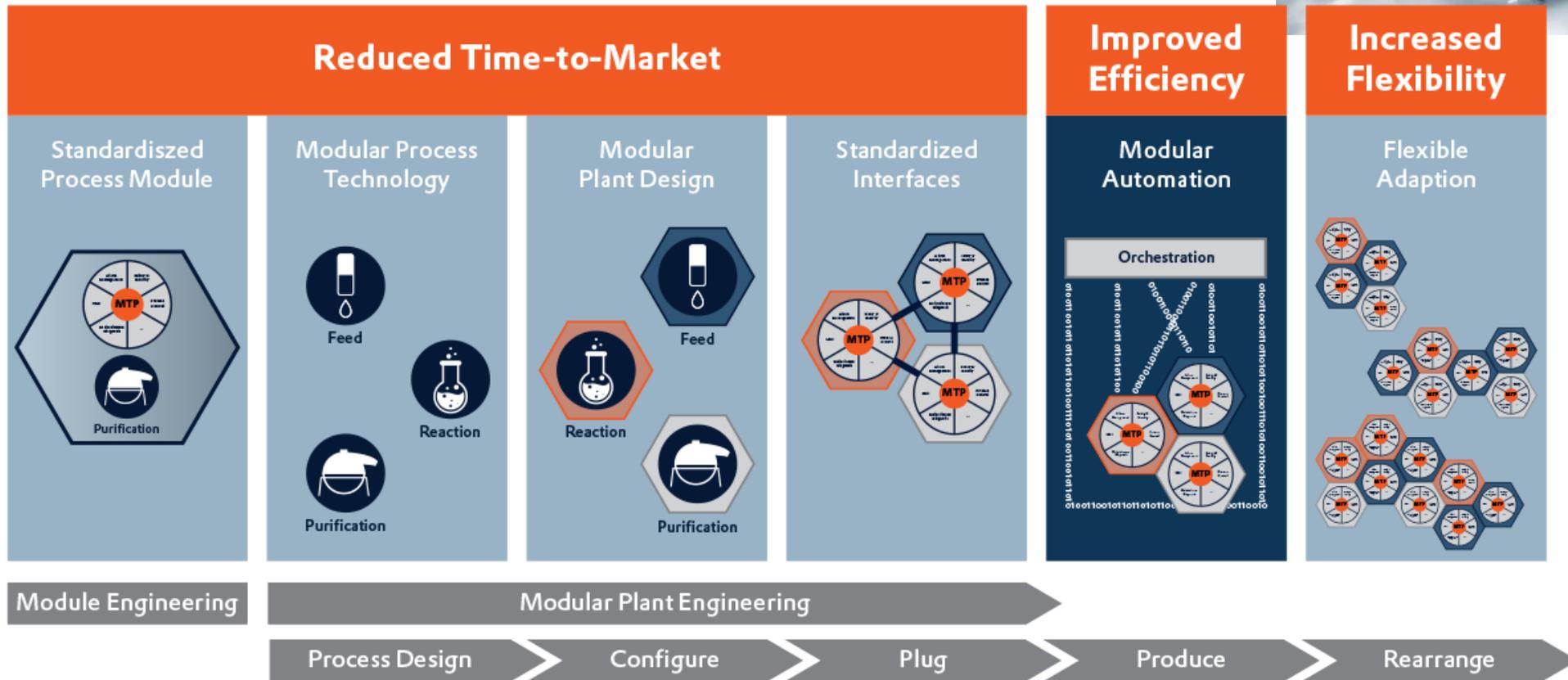
Produzione modulare nel settore biotech



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:

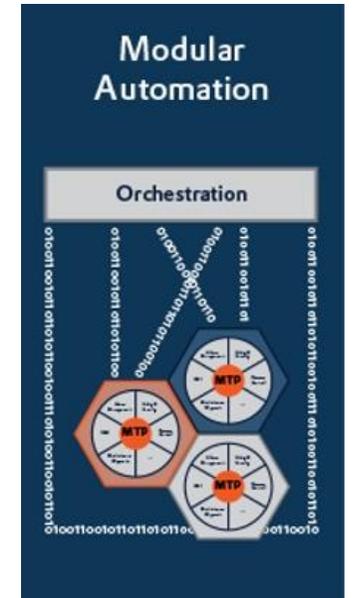
Electronic Records devono essere correttamente acquisiti e memorizzati.

GMP COMPLIANCE:

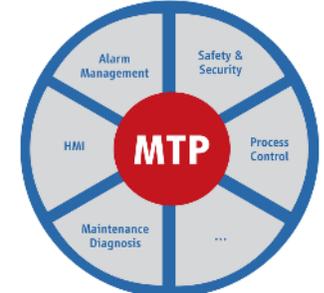
Gestire documentazione e convalida in un impianto che cambia configurazione da un lotto all'altro.

BROWN FIELD:

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

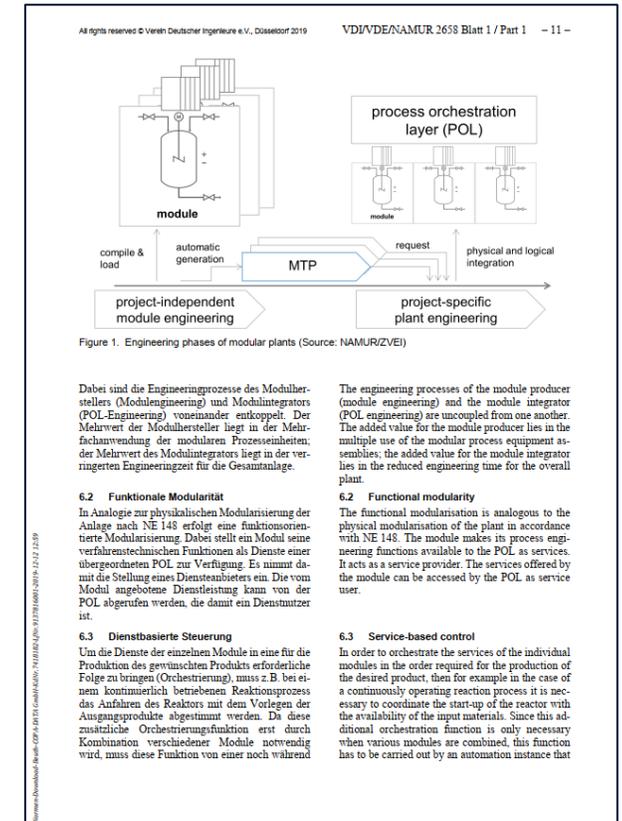


MTP – Module Type Package

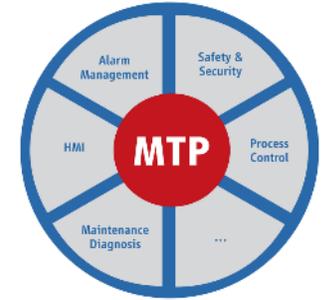


- ▶ MTP è una descrizione vendor-independent di moduli di produzione
- ▶ E' la base per progettare sistemi di controllo di impianti modulari in una modalità "Plug&Produce".
- ▶ E' un concetto ideato e promosso da NAMUR, un'associazione internazionale di aziende nel settore dell'industria di processo
- ▶ 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		
6.1 Engineering-Workflow	9	6.1 Engineering workflow	9		
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6.5 POL-Integration	13	6.5 POL integration	13		
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6.7 Funktionale Sicherheit modularer Anlagen	15	6.7 Functional safety of modular plants	15		
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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					

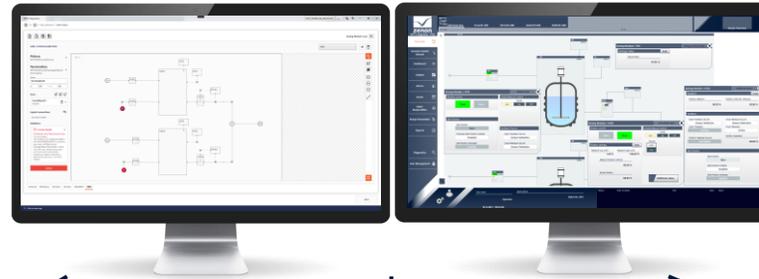


Module Type Package: I componenti.

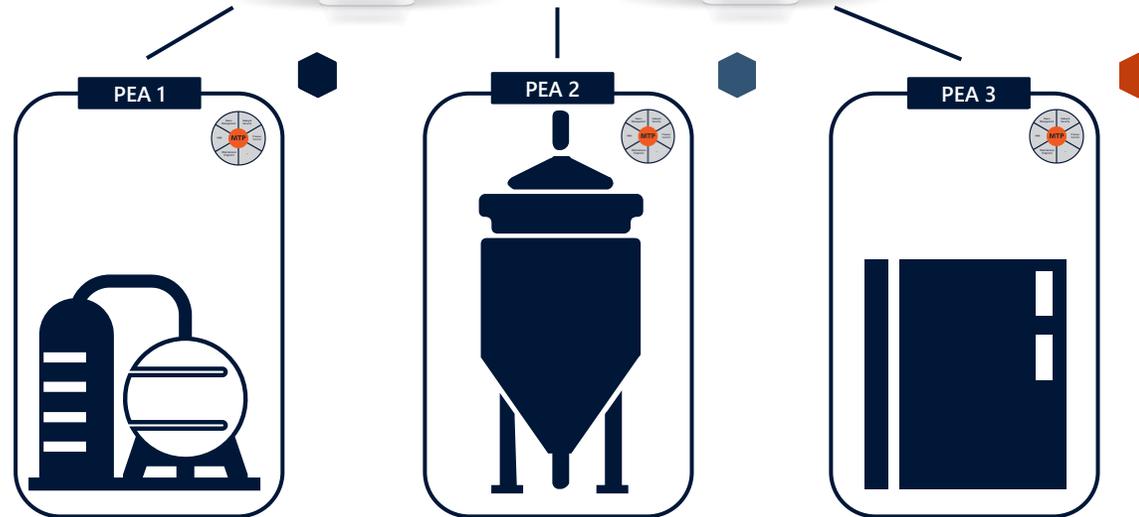


POL
Process Orchestration Layer

POL – Process Orchestration Layer



PEA
Process Equipment Assembly



Doser services:

- ▶ Filling
- ▶ Dosing
- ▶ Emptying

Reaction services:

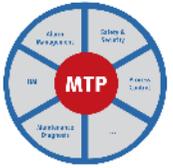
- ▶ Stirring
- ▶ Filling/Emptying
- ▶ Dosing
- ▶ Gassing

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/NAMUR 2658-1" Version="1.0.0" />
5   </AdditionalInformation>
6   <AdditionalInformation DocumentVersions="Recommendations">
7     <Document DocumentIdentifier="VDI/VDE/NAMUR 2658-2" Version="1.0.0" />
8   </AdditionalInformation>
9   <AdditionalInformation DocumentVersions="Recommendations">
10    <Document DocumentIdentifier="VDI/VDE/NAMUR 2658-3" Version="1.0.0" />
11  </AdditionalInformation>
12  <AdditionalInformation DocumentVersions="Recommendations">
13    <Document DocumentIdentifier="VDI/VDE/NAMUR 2658-4" Version="0.1.0" />
14  </AdditionalInformation>
15  <SuperiorStandardVersion AutomationML 2.10 />
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  </SourceDocumentInformation>
18  <InstanceHierarchy Name="ModuleTypePackage">
19    <Version 0 />
20    <InternalElement ID="f7903713-8bf4-f50-a7bf-62a989e7510c" Name="Buffer" RefBaseSystemUnitPath="MTPSUCLib/ModuleTypePackage">
21      <Description>SystemUnitClass who represents the entry point into an MTP Package</Description>
22      <Version 6.2.0 />
23      <Attribute Name="Version" AttributeDataType="xs:string">
24        <Description>Contains the Version of the MTP</Description>
25        <DefaultValue 1.0.0 />
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 </CAEXfile>
```

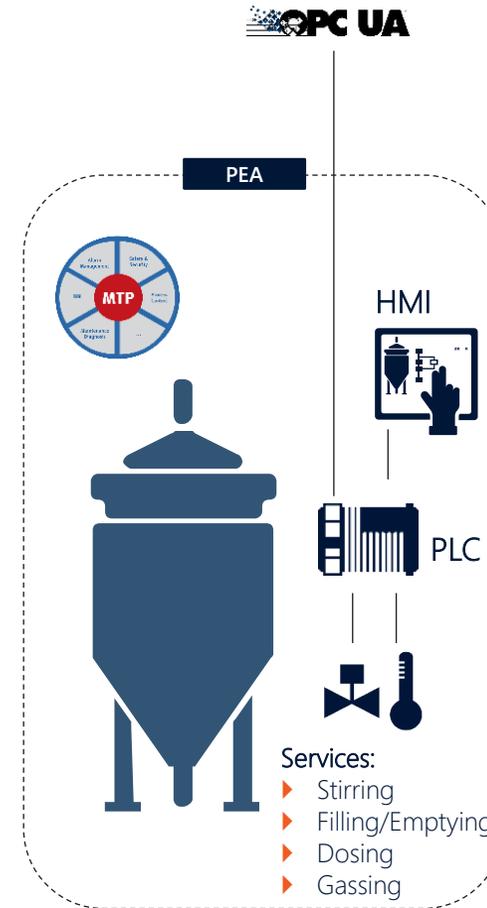
PEA – Process Equipment Assembly

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

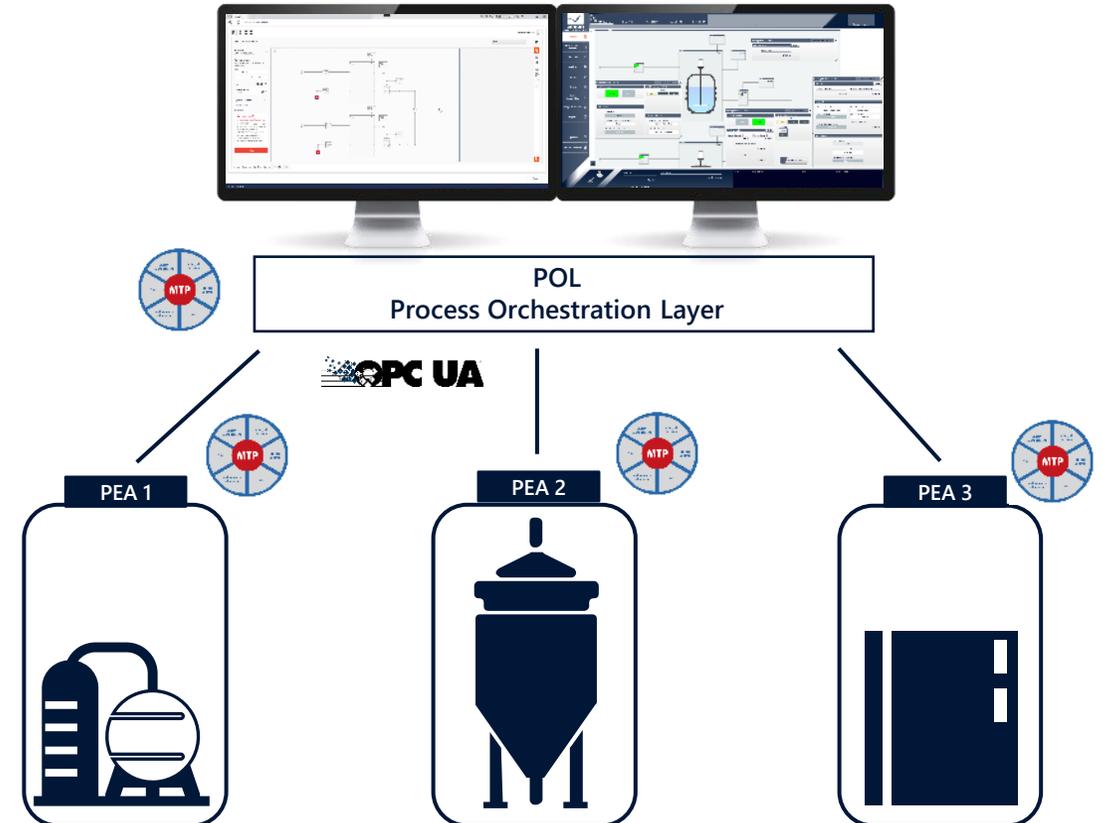
POL – Process Orchestration Layer

CHE COS'È?

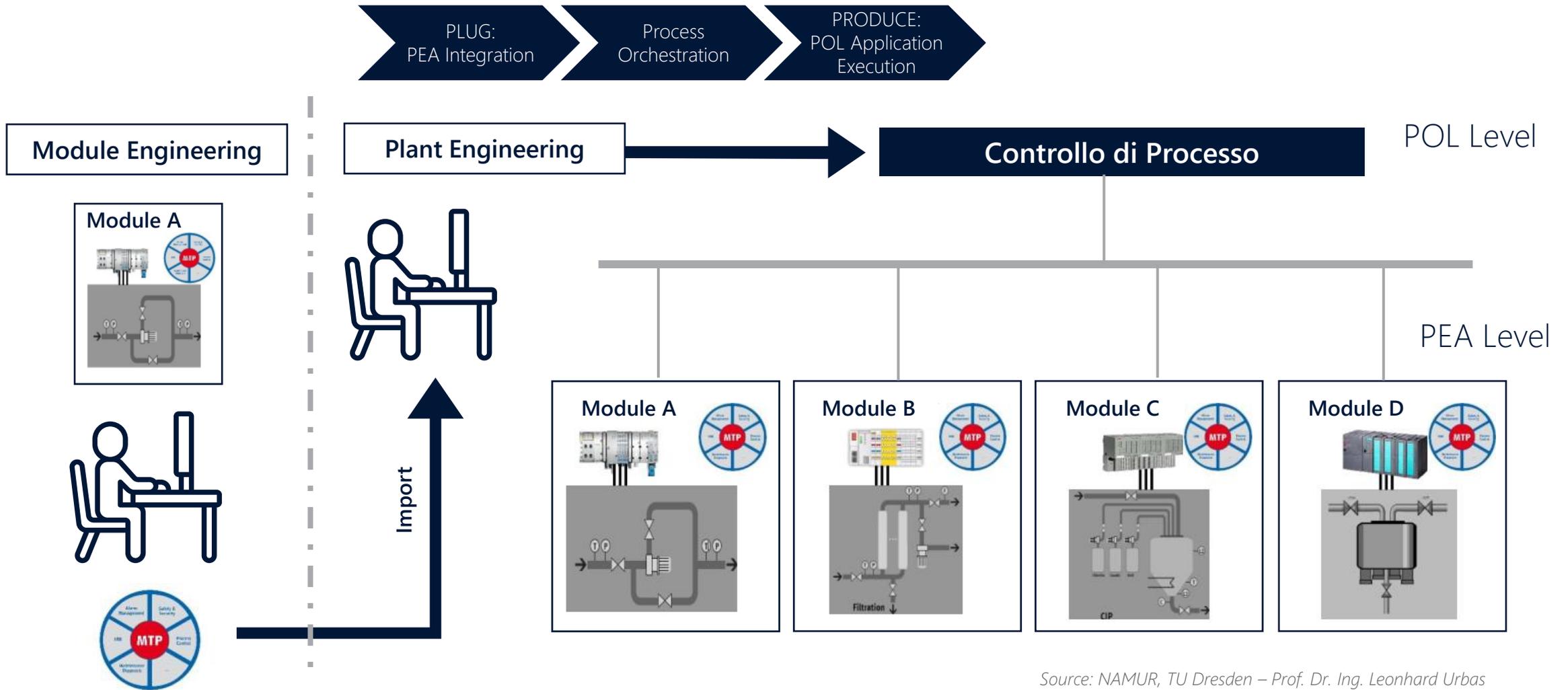
- ▶ Una piattaforma software in grado di:
 - ▶ Importare e orchestrare i PEA
 - ▶ Monitorare e controllare il processo produttivo collegandosi ai vari PEA via OPC UA.
 - ▶ Produrre e memorizzare i record elettronici per assicurare la data integrity (Batch information, Process Values, Alarm, Audit Trail).

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.



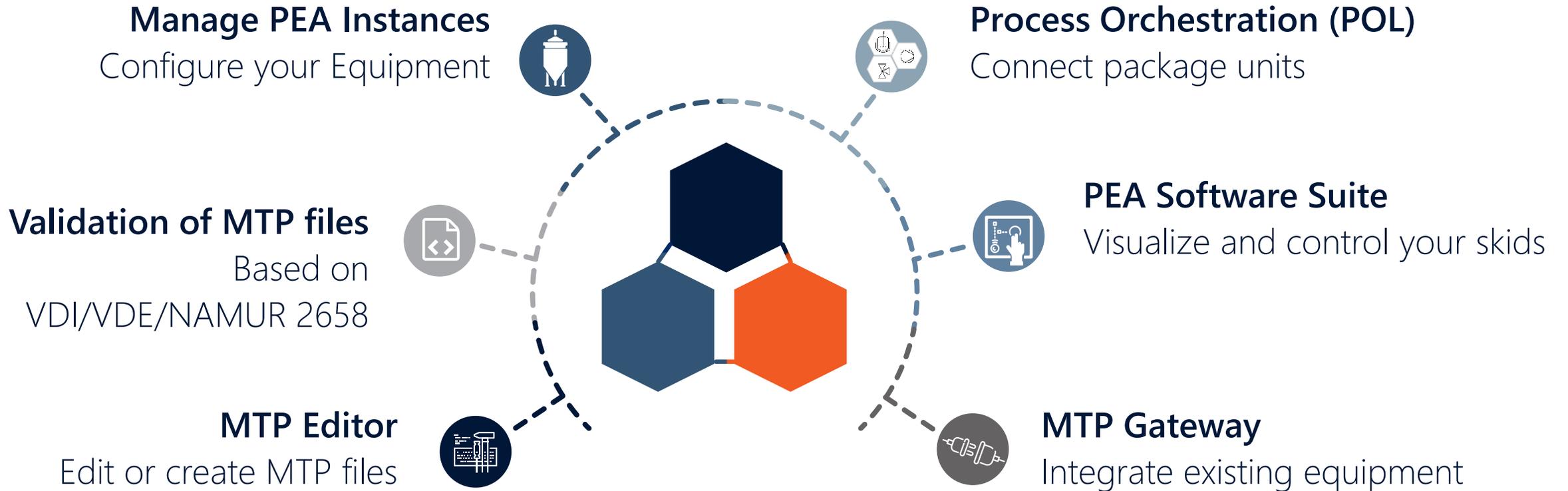
Le fasi di progettazione



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 MTPHMISUCLib/Picture

Visual Object MTPHMISUCLib/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 lists parameters like 'P_Stirrer_1_Stirring_Time_Setpoi...' and 'P_Stirrer_1_Speed_Setpoint_An...'. The interface includes a sidebar with navigation options like 'Overview', 'Dashboard', 'Alarms', and 'Recipe Parameters'.

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 'Idle/16'. The diagram shows transitions between these states over time, with specific actions like 'Execute/64' and 'Execute/64' labeled. The x-axis represents time from 14:02:00 to 14:04:00 on 03.05.

On the right side, there is a list of curves with checkboxes for selection. The active curves are:

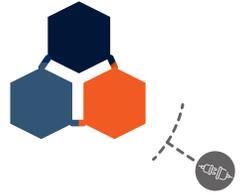
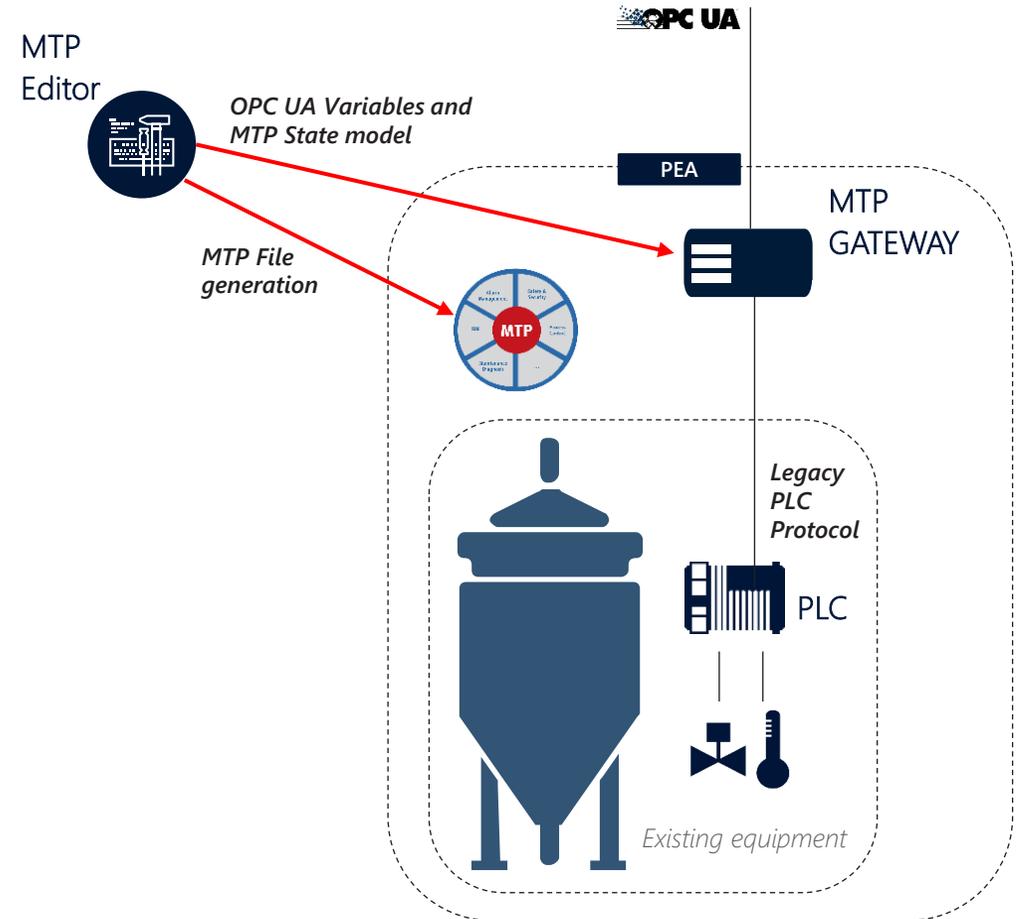
- P_Stirrer1_Cleaning_ServiceControl_StateCur
- P_Stirrer1_Stirring_ServiceControl_StateCur
- P_Buffer1_Heating_ServiceControl_StateCur

The interface also includes a sidebar with navigation options like Overview, Services Control Manual, Dashboard, Analyze, Alarms, Audit Trail, Batch Recipe Editor, Recipe Parameters, Reports, Diagnostics, and User Management. At the bottom, there is a control panel with fields for User name, Operator, Batch Name, and Recipe Name, along with Start and Comment buttons. The status bar shows 'Status' as 'Time received' and 'Text' as 'Archive "States" running'.

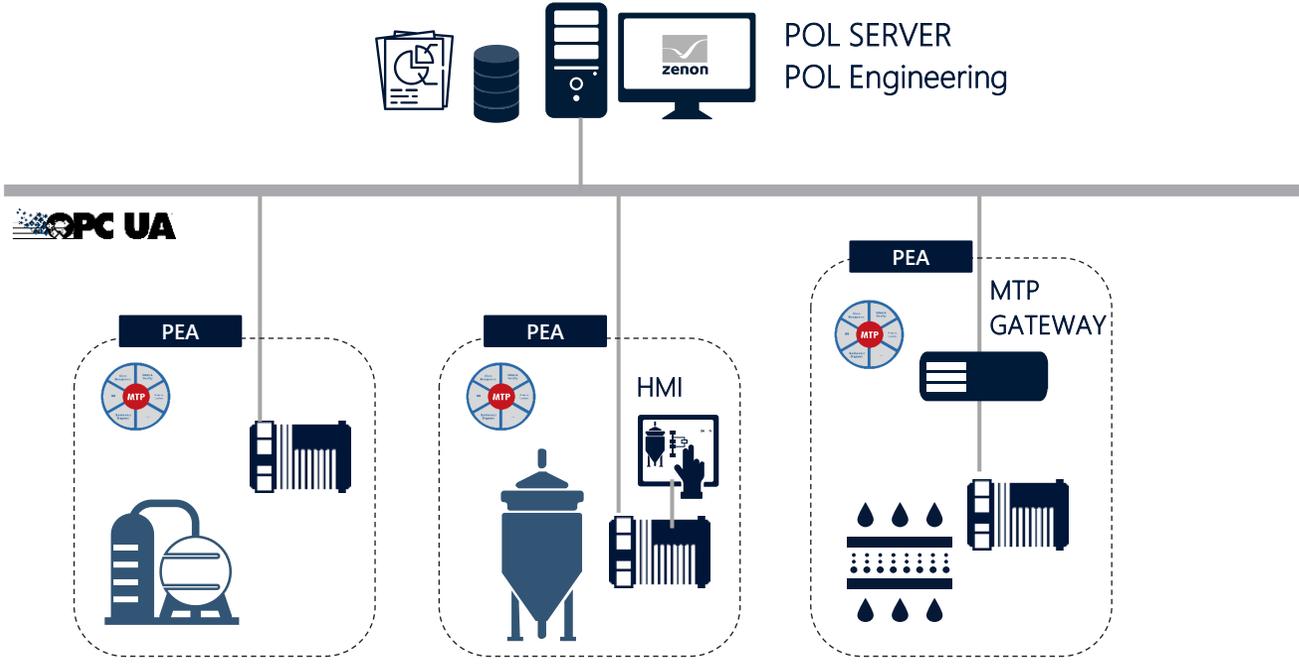
Integrazione di moduli esistenti

zenon MTP Gateway

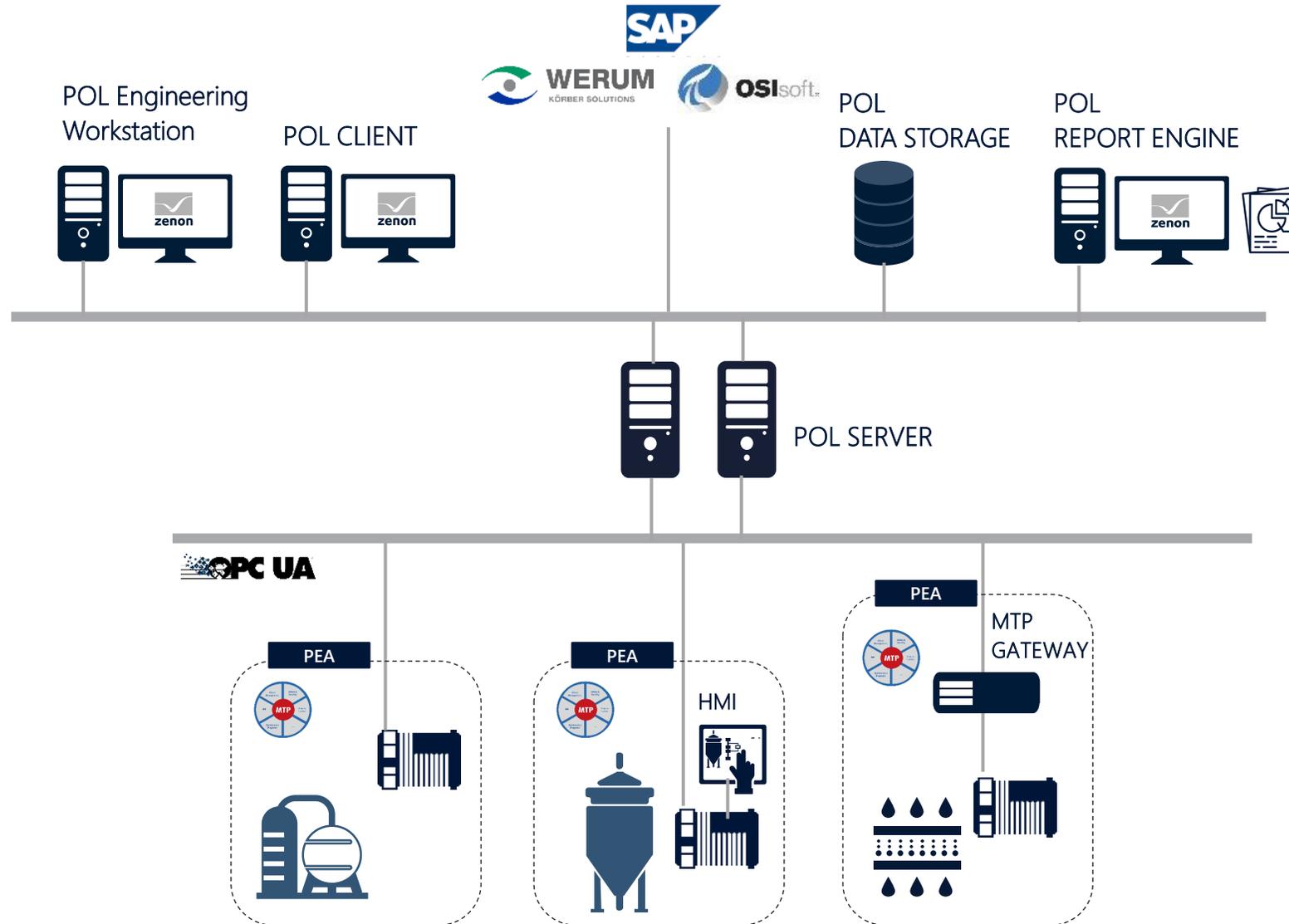
- ▶ MTP Gateway offre un'integrazione di moduli esistenti non "MTP ready".
- ▶ Prevede:
 - Connessione al PLC esistente del modulo
 - Comunicazione verso il livello MTP POL attraverso OPC UA (server)
 - SoftPLC IEC61131:
 - OPC UA Variables
 - MTP State Model
 - Logic for PLC variables conversion
 -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



Una semplice architettura MTP POL



Un esempio di POL in area di produzione





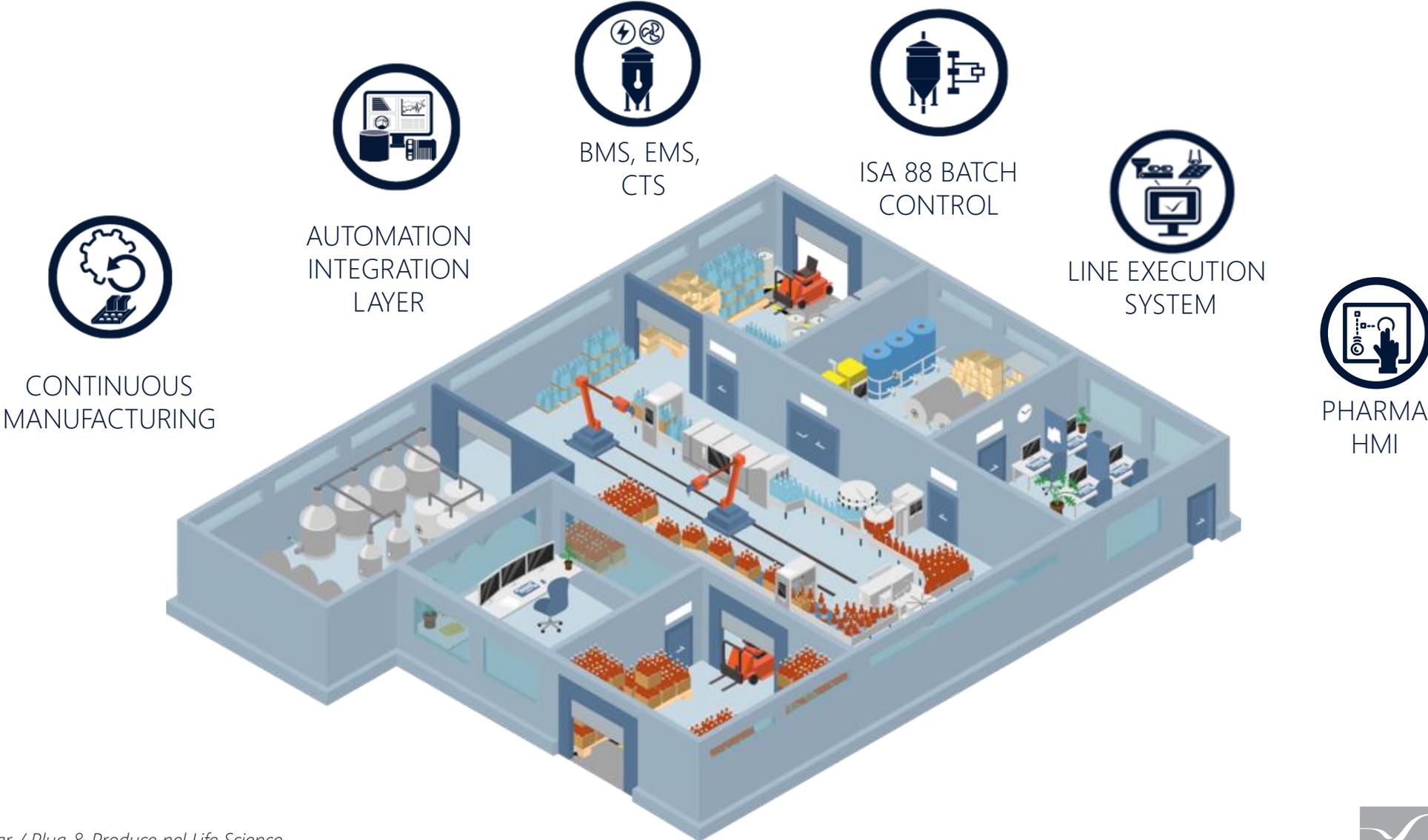
The zenon POL is one of the first POL's on the market with almost fully comprehensive POL functionalities.

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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ITALIA
smart production solutions

 PAD. 5 Stand. 055

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- ▶ Per scaricare il **Pharma HMI Application Set** ed avere una dimostrazione pratica di come funziona zenon [clicca qui](#)
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Questionario



GRAZIE PER L'ATTENZIONE

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