MTP and Modular Automation in the Biopharmaceutical Industry

NOCIA

Tomi Lahti Senior Product Manager MXIE industrial apps March 2025

Evolving solution to meet OT digitalization requirements

From industry first in Private Wireless towards an industrial digitalization platform

Industry first

private wireless deployment

Development of enterprise centric private wireless solution

Rio Tinto, Australia MPW

Industry first

private wireless as-a-service solution

Digital Automation Cloud (DAC)AC edge application

Industry first

private wireless solution integrated digitalization enabler platform

framework

Industry first

off the shelf mission critical edge designed for cross-OT industrial needs

MX Industrial Edge

Industry first

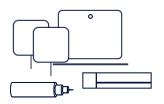
hyper interconnected OT edge & micro-Edge AI/ML platform as a service Gen ALLM OT assistant

MX Workmate + MX GRID

From 2011



2019



2020



2021



2024

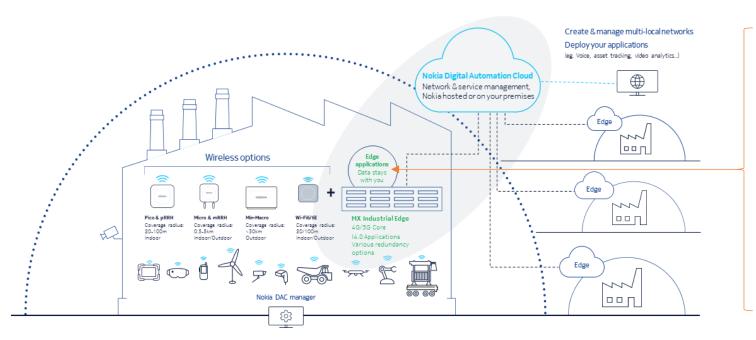






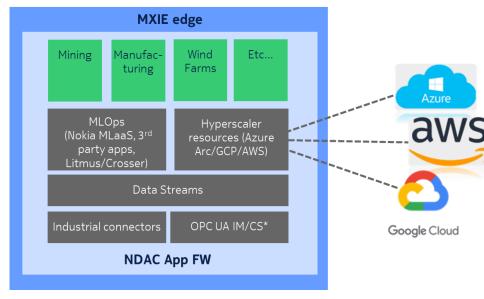
Nokia private 5G for communication with "Smart" enablement

Accelerate your digital transformation with a proven on-premise edge solution and industrial-grade private wireless connectivity



Industrial Edge capabilities for "Smart"

- Hybrid edge cloud continuum Centrally managed, distributed runtime
- Confidential data kept on site
- Local processing of data for critical applications
- Strong baseline for data-driven use case development with near-real time data steaming



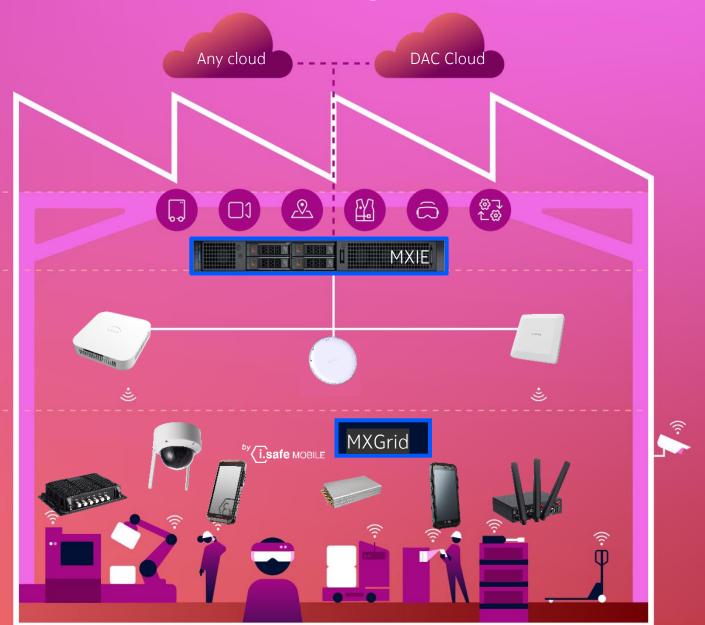


Nokia one platform for industrial digitalization

MX Industrial Edge + apps

4.9G / 5G / WiFi

Industrial devices



Cloud managed

Plug & play

Pay as you grow, subscription-based business model

Unified multi-site

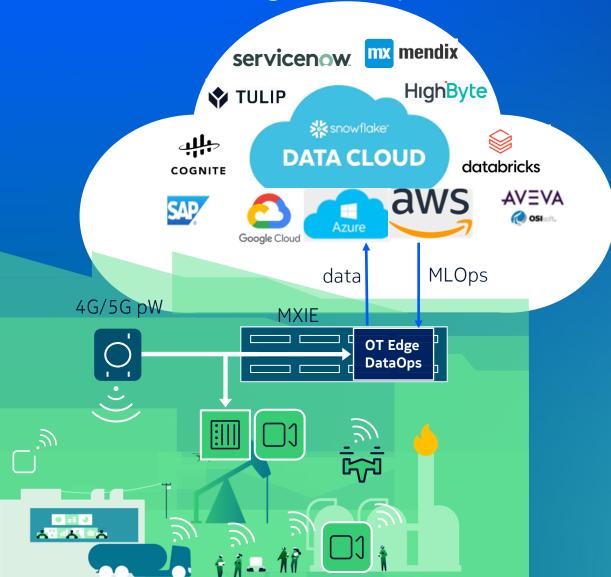
Expose APIs

Edge data lake and integrate with world's leading digital ecosystems and solution providers management



Edge DataOps – integral part of enterprise data architecture

Consumable edge data layer (UNS) enables extensible edge AI & data-driven use cases



Consumable edge data layer with Unified Namespace (UNS)

Abstract OT asset diversity and protocol complexity from readily actionable data layer Single-source-of-truth" for OT digitalization, systems & apps and cloud data ecosystems

Event-driven, real-time harmonized data provides runtime for edge inferencing with MLOps

Centrally managed, distributed execution to combine data fabric & mesh benefits

Seamless integration to hyperscalers (Azure, AWS, Google, Snowflake)

Harmonize data between sites/plants for scalability and flexibility

High cyber security and compliance with central governance and data security

Productivity gains throughout supply chain and data ecosystems

Harness Edge Al & Decision Intelligence for Operational Excellence

Support Intelligent Supply Networks for Smarter Manufacturing Address top challenges to scale edge AI and reduce tech debt across the enterprise





Read More: OT Edge DataOps

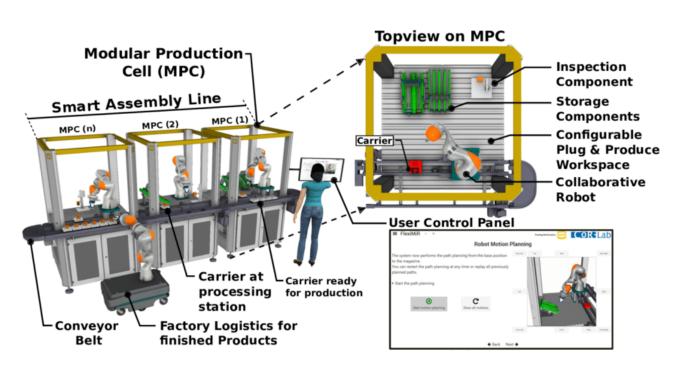


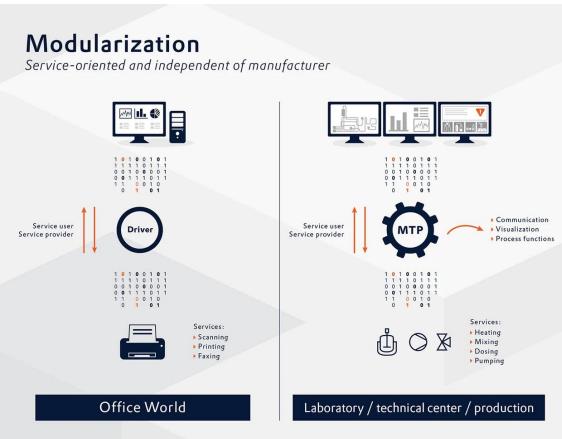
Modular Type Package



Modular Production Systems

Cost-efficient production of variants with the same system & standardized interfaces







Module Type Package



Module Type Package (MTP) means...



 Interface and capability description of intelligent equipment modules via standardized equipment data models and description language

















Goals of MTP are



- Time reduction of automation engineering and commissioning
- Manufacturer-independent connectivity of equipment modules

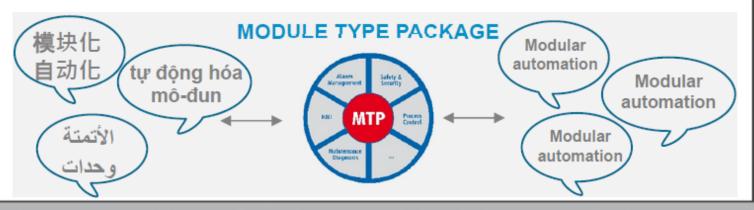
MODULE CONTROL



Benefits of MTP are



- Separation of automation engineering of plant and modules
- Easy integration via standardized, pre-tested an -qualified interfaces



MTP basics for life science manufacturing

Definition of profiles and the respective functions for bio pharma specific equipment

BioPhorum

- Bioreactor
- Chromatography
- Normal Flow Filtration

ISPE P&P

Bring in GMP requirements

- Data storage, Data integrity
- Time synchronization
- **User Management**

Module Type Package

Framework

- Data structures as interface
- State model
- Services to interact with modules

OPC UA

Transport of semantic data

Data Access, Alarms and Conditions, Historial Access ...

Secure transport due to certificates

Services

Ethernet, TCP/IP



Edge Intelligence start with semantic OT data

Smart "anything" at shop-floor requires AI and Networked Digital Twins, which requires structured, contextual data and semantic interoperability – and data automation

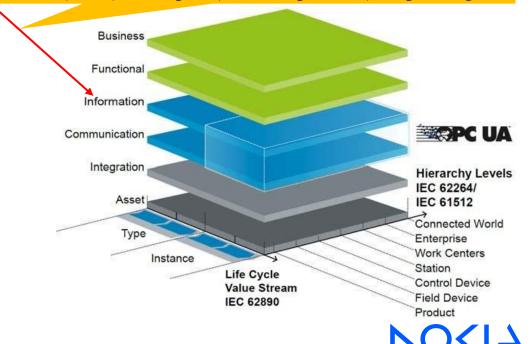
Industry 4.0 <u>Cyber-Physical systems</u> are backbone and core elements of Industry 5.0 (adds human and sustainability aspects) and Industrial Metaverse (adds remote operations and AR/VR interface to data and functions) too.

There Is No Industry 4.0 without OPC UA - RAMI 4.0

Industry 4.0-compliant Smart "anything" builds on few key concepts:

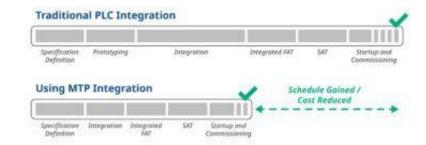
- Industrial (Cloud) DataOps (Cognite, Highbyte, Azure / AWS Data Fabric etc) efficient way to refine value from OT data for the various data-driven
 applications running at the edge, on-premise, and in the cloud. Together with
 Edge DataOps / Hub / Smart IIoT apps realizes RAMI 4.0 "Information layer"
 for semantic interoperability
- OPC UA vendor-agnostic interoperability with structured data, semantic information; ensure data value through data life-cycle and enterprise functions
- Networked Digital Twins semantically networked virtual elements of real assets in Industry 4.0 value networks, realizing cyber-physical interaction.
 Real-time data management with Edge DataOps is core enabler for any digital twin. To build effective digital twin solutions, the capability of integrating "Simulation, Optimization, Prediction, and Visualization models" is also crucial.
- MLOps data-based model's efficient deployment and management at scale, to enable replicable and efficient Edge AI solutions

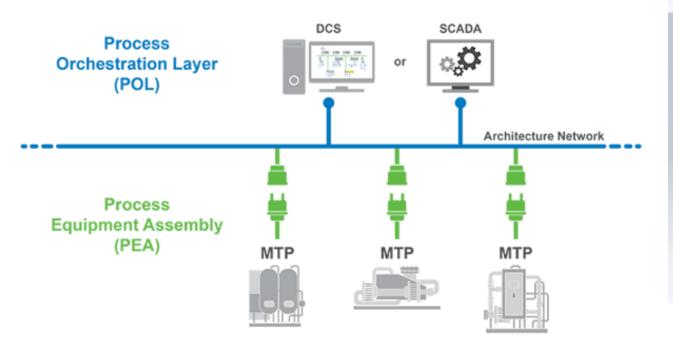
MXIE OT Edge DataOps abstracts diversified field assets and protocols from data plane, simplifying data operations through data lifecycle drastically, and producing composable edge data layer e.g. for edge Al

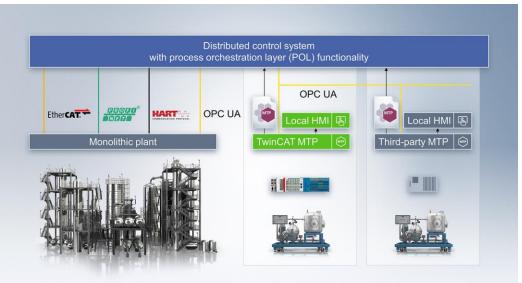


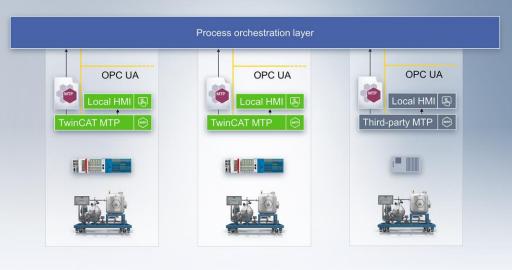
MTP in production

Suitable for both brownfield and greenfield











Experiences and benefits

open and standardized automation solutions

ZVEI the benefits from the first pilot projects can be summarized as follows:

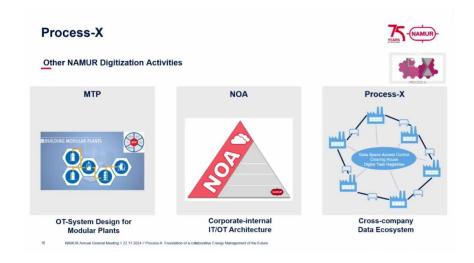
- -50% on reducing time-to-market
- -70% on reducing engineering effort
- +80% on increasing flexibility.

Skid and machine builder OEMs can use MTP to future-proof their offering

Controls engineers and systems integrators appreciate how MTP streamlines integration work, cutting integration time by half in many cases, while improving quality, reducing errors, and easing support

OPC Day Finland 2021: Module Type Package (MTP), VDI/VDE/NAMUR 2658, IEC 63280

OPC Day Finland 2024: MTP and Modular Automation in the Biopharmaceutical Industry

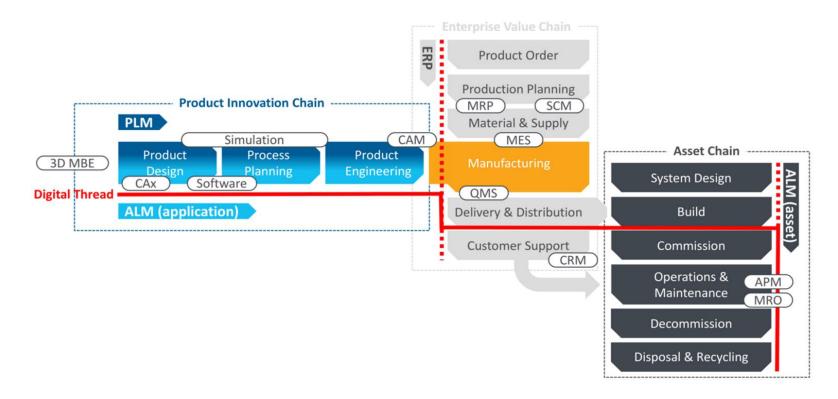


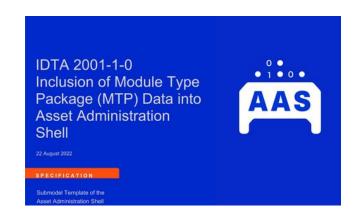


Digital twin and digital thread

Asset lifecycle Management – digital twin from engineering to operations

"The information modeling capabilities and the OT connectivity of OPC UA, coupled with the comprehensive asset representation and life-cycle focus of AAS, result in a powerful architecture not only for the Digital Product Passport (DPP) but for Industry 4.0 applications in general" - <u>source</u>

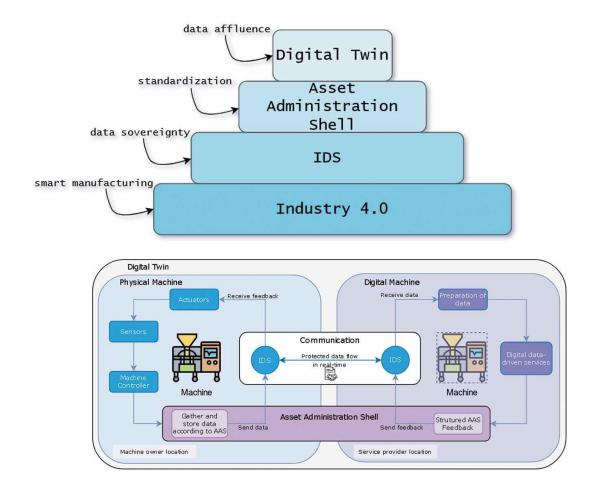


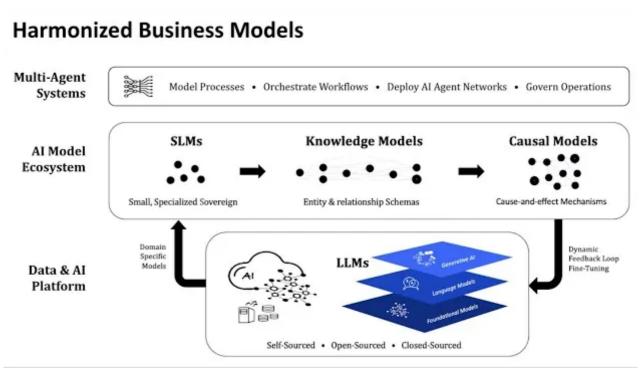




Standardized manufacturing – unexpected benefits!?

OPC UA, Asset Administration Shell, Industrial Data Spaces – food for advanced Al!







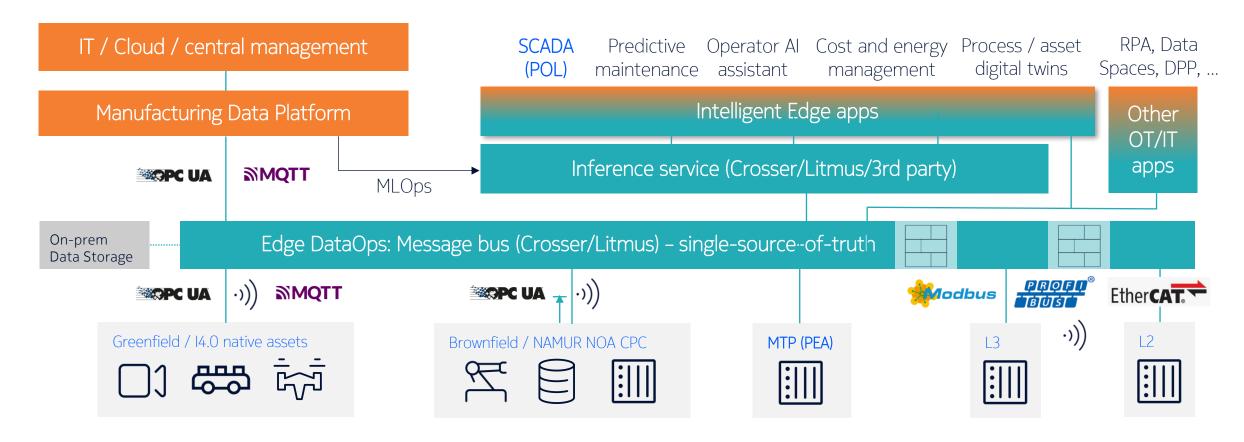
IT / Clouds

On-prem edge

Core Process Control / Assets

Edge DataOps produces consumable data

Edge supporting ISA-95, NAMUR NOA, O-PAS, future architectures - Data-driven decision-making support needs single-point of truth at edge!





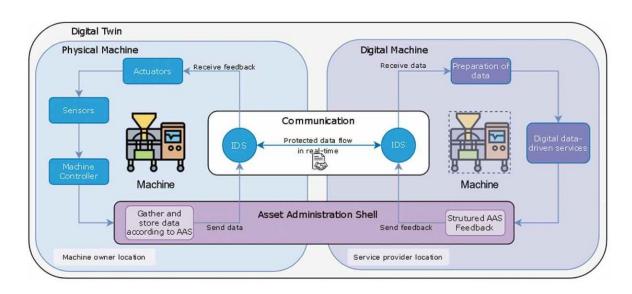
Edge DataOps for Industrial Digital Twins – forward-looking way

Benefits of standardized approach with consumable edge data layer

I4.0 asset digital twin "blueprint" for lifecycle mgmt

- Edge data practices (DataOps); decoupling data generation from data consumers, consumable data layer
- Asset Admin Shell (AAS) core role for asset lifecycle AND operational excellence (data models)
- IDS (data ownership and sharing contracts) + data connectors for data sharing

- AAS is "base digital twin" for I4 asset management
 - connects multiple data streams during asset lifecycle
- ALM by SAP (<u>BNAC</u>) is based on AAS, realizing 'digital thread'
- DPP (Battery Passport, Product Carbon Footprint etc) is required for electric vehicles, mandatory in Europe 2027
- Secure data sharing via
 IDS data spaces when
 ever needed in ecosystem
 (like for co-operation with
 3rd party ML/AI vendor)



Following the industry 4.0 paradigm, concepts have been presented to introduce innovative data-driven digital services that can now be introduced by Digital Twins, backed up by a secure and reliable communication infrastructure based on OPC UA and IDS technologies, and the standardization of information models based on the Asset Administration Shell.

Shop-floor decision-making - demands for Edge Platform

Operational intelligence sets clear demand for edge & smart IIoT app capabilities

1

Al and DT on-prem

Proliferation of artificial intelligence, machine learning and networked digital twins at scale - on-prem

2

Hybrid edge-cloud

Processing edge data needs to be performed at the edge and in the cloud or enterprise. 3

OPC UA (over MQTT)

IEC 62541, framework for industrial interoperability based on data models, context and metadata – data modelling is key for all intelligent operations!

4

Semantic interoperability

Interoperable API's (data products) which serve standardized information modelling are key for successful intelligent use cases

5

Open standards - tested

Supporting open Industry 4.0 standards enables interoperability and secure data sharing to partners – best served via collaboration like <u>Open</u> Industry 4.0 Alliance 6

OT Edge DataOps

Edge must support enterprise data governance and Industrial DataOps (semantics, knowledge databases)



Summary - Edge enables Modern Data Governance at any Industry

Modern data approach starts from edge and reach trough data lifecycle

Modern Edge Data Stack:

Smart IIoT at edge abstracts protocol and asset diversity and enables OT digitalization acceleration

Data Models: Smart IIoT at edge delivers structured OT data with metadata to IT tools to scale up OT digitalization, and fosters OT teams' data ownership

Refine IT/OT convergence:

Smart enterprise data governance understand OT data nature and specialty

Industrial DataOps definition (according to IoT Analytics)

The process of enhancing data quality by providing structure and context for accurate, logical data representation, ensuring usability by downstream applications



Related information

OPC Day Finland 2021, Keynote: ISPE Pharma 4.0 Plug & Produce, Josef Trapl, Takeda & Henrik Stellmann

The ISPE Baseline® Guide: Pharma 4.0™ is a valuable resource for any size company to begin, reinvigorate, or advance their transformation journey

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