

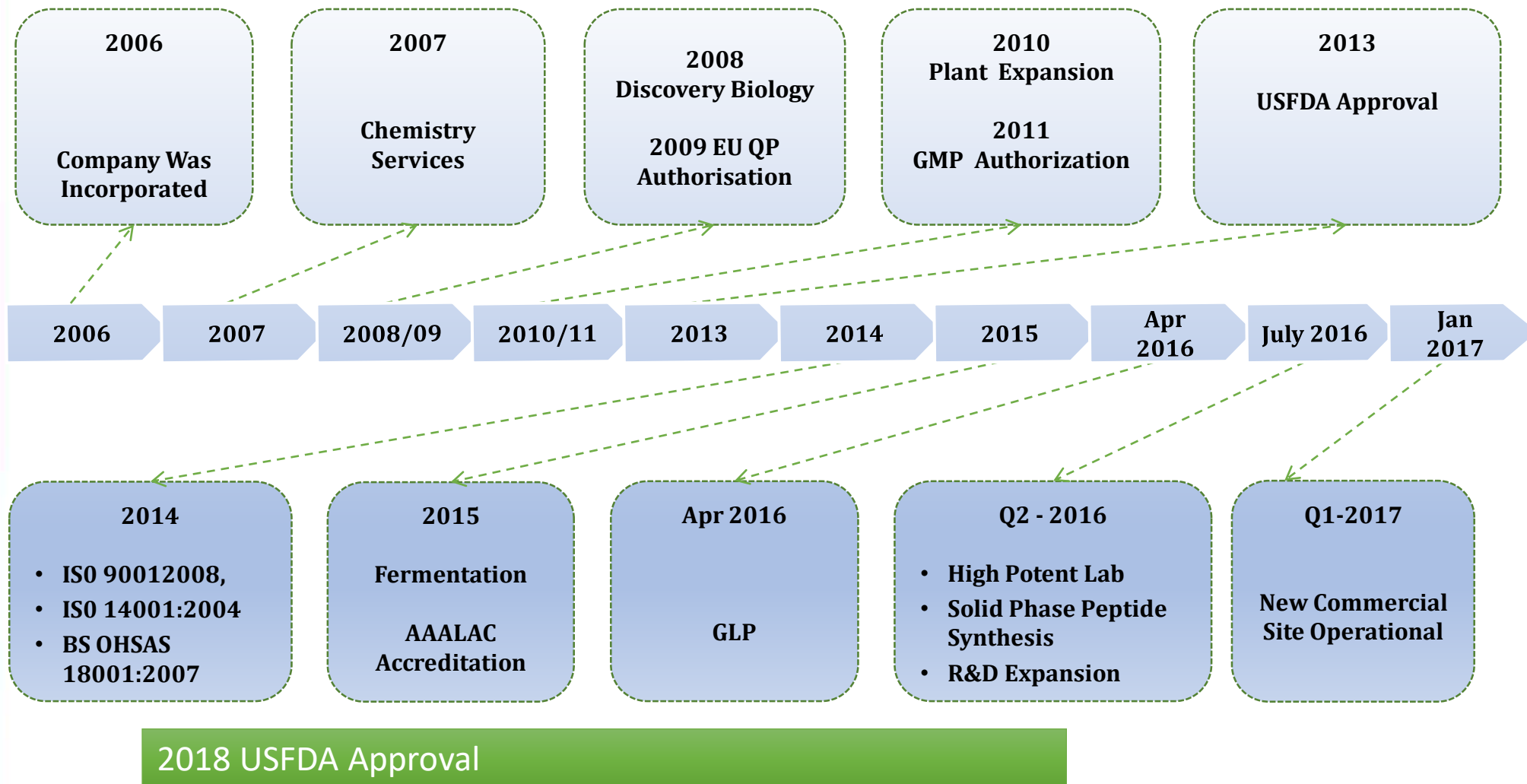
**Smart Factory, Integrated Approach
and Applications of Industry 4.0 in Pharma**

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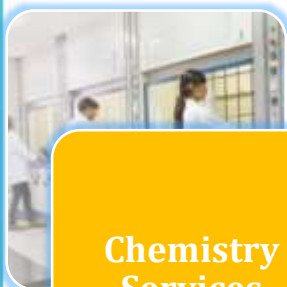
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24th Nov 2018



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Chemistry Services

Medicinal Chemistry

Library Synthesis

- Natural product inspired virtual compound libraries

Custom Synthesis

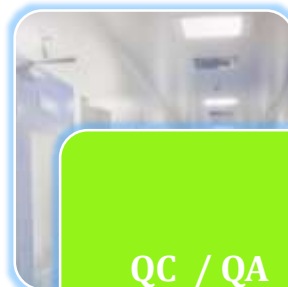
Process Chemistry

DoE, QbD concepts

GMP Manufacturing

HiPo suites

Peptides (Solid Phase)



QC / QA

Method Development

Method Validation

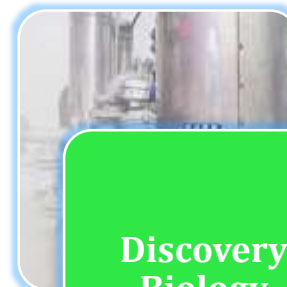
API release testing

Stability Studies

Separation Science

Regulatory Support

- e-CTD filing
- Open/closed part DMF
- IND filing



Discovery Biology

Platform technologies

Molecular Modeling

Preclinical Biology

Assay Biology

Microbiology

- In vitro studies
- In vivo Studies



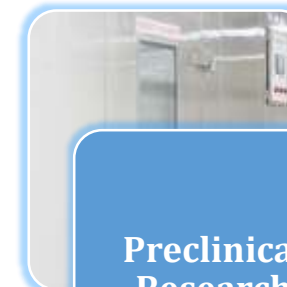
Fermentation & Cell Culture Services

High density cell cultivation

Low, Medium & High pressure chromatography

Microbial & mammalian cell lines (of fungi, yeast, bacteria, actinomycetes, and mammalian)

Process development & scale up



Preclinical Research

Preclinical Biology

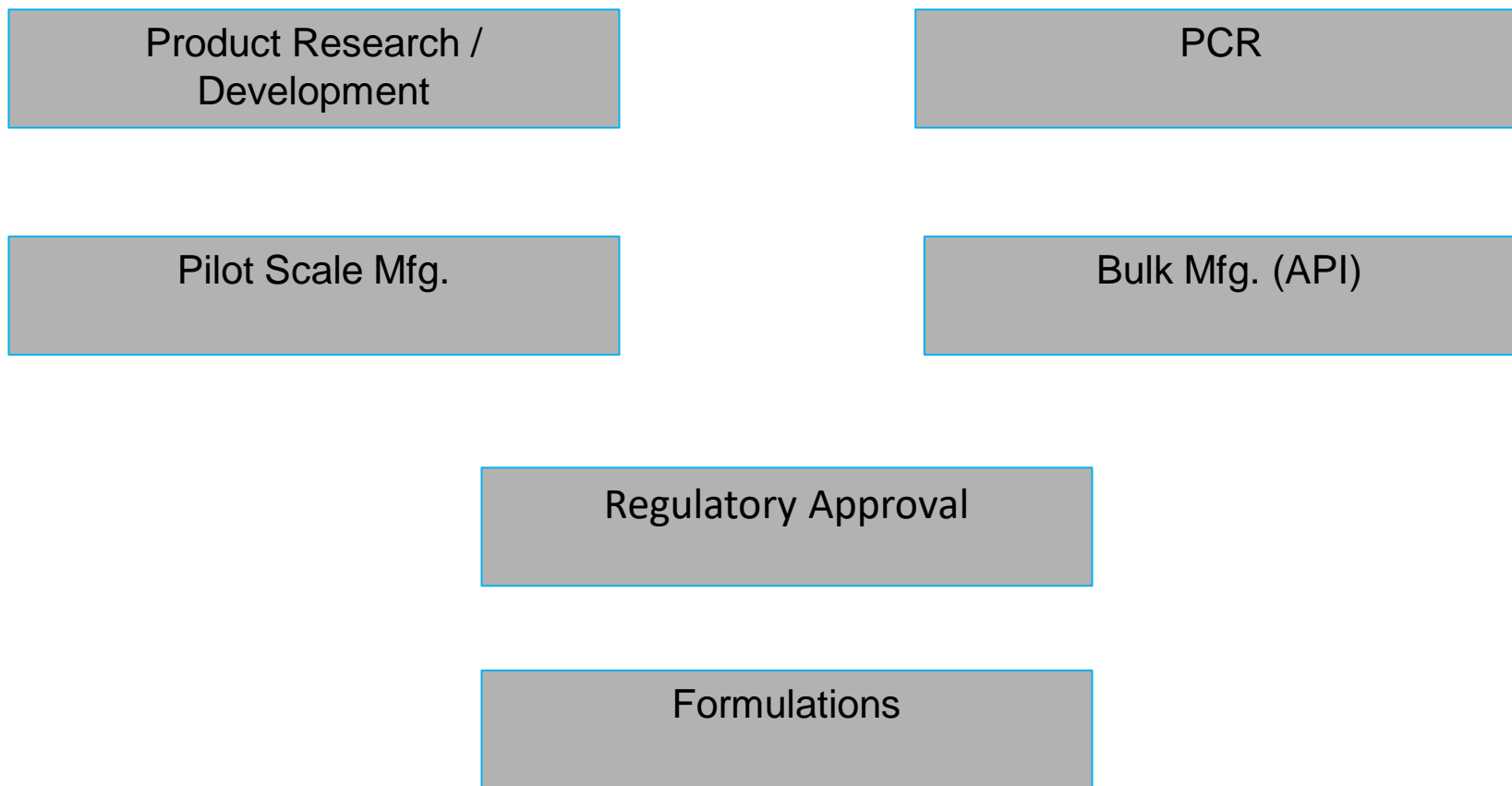
Efficacy Studies

ADME Studies

Toxicity Studies

In vivo Pharmacology

Pharma Product Cycle



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Gap between manufacturing and Enterprise systems

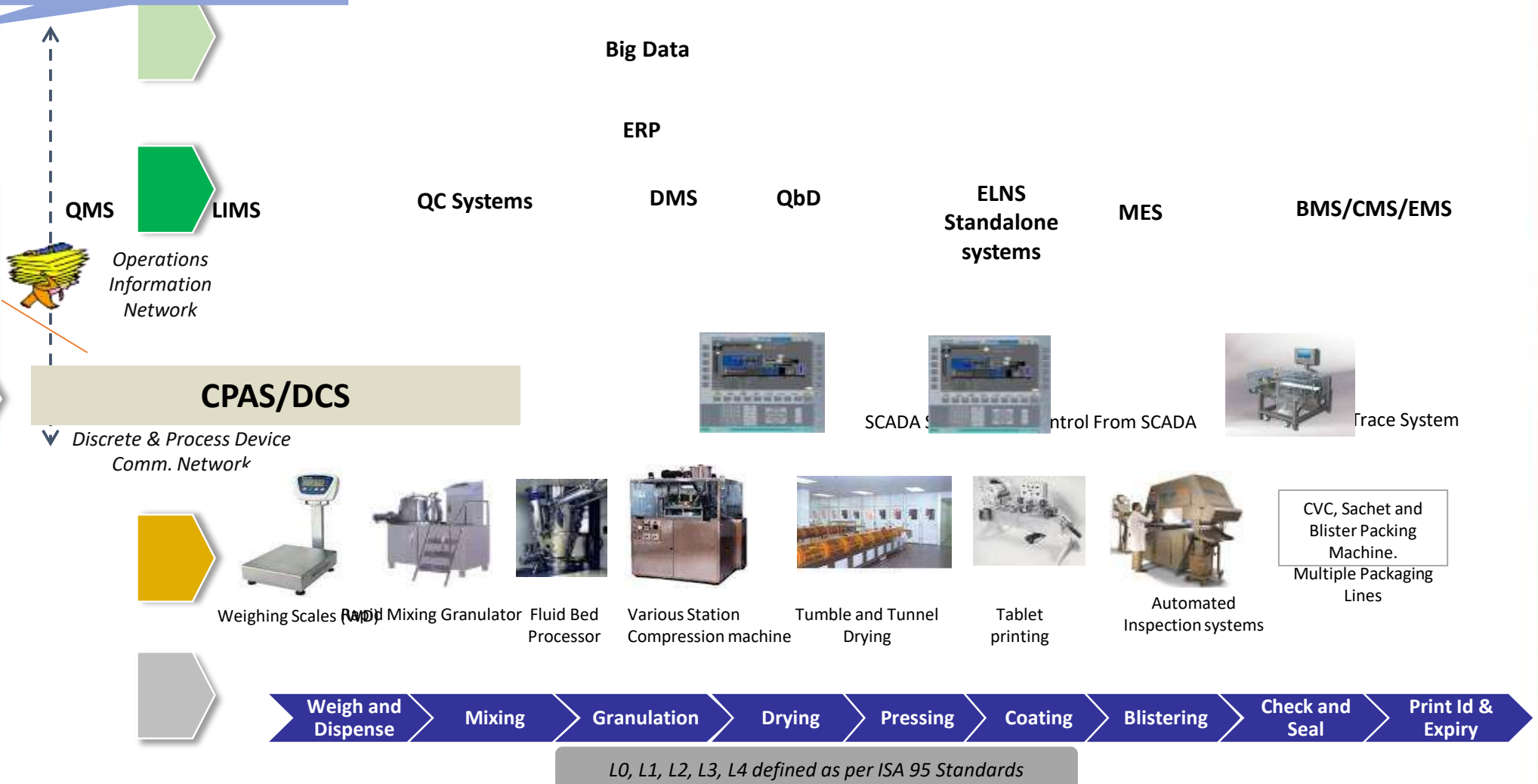
L5

L4

L3

L2

L1



L0, L1, L2, L3, L4 defined as per ISA 95 Standards

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PHARMA Mfg. Flow

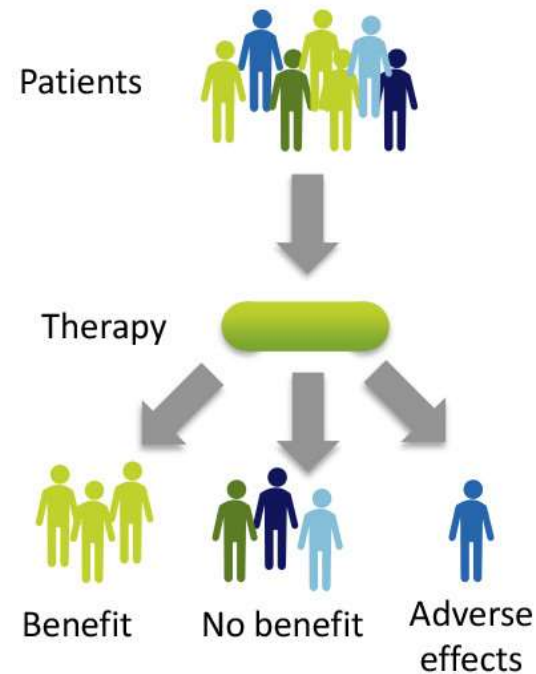


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Personalized Medicine

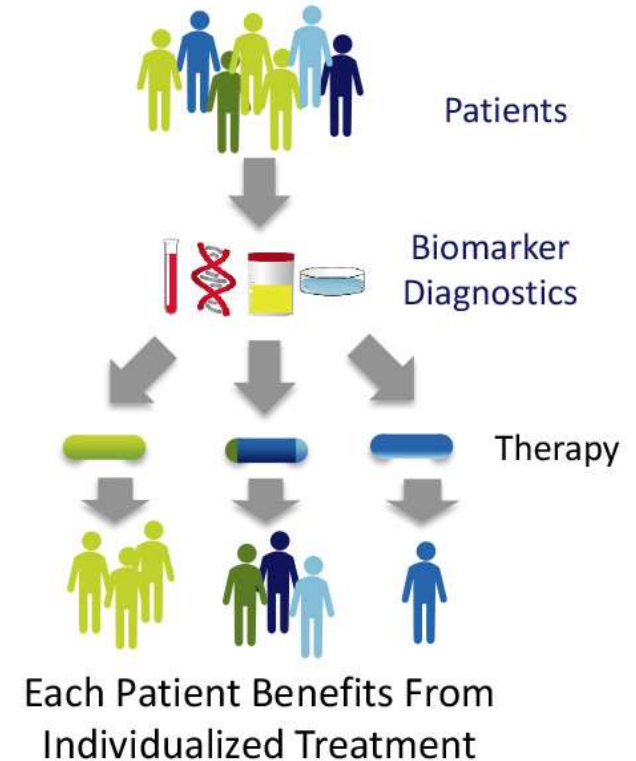
Without Personalized Medicine:

Some Benefit, Some Do Not



With Personalized Medicine:

Each Patient Receives the Right Medicine For Them

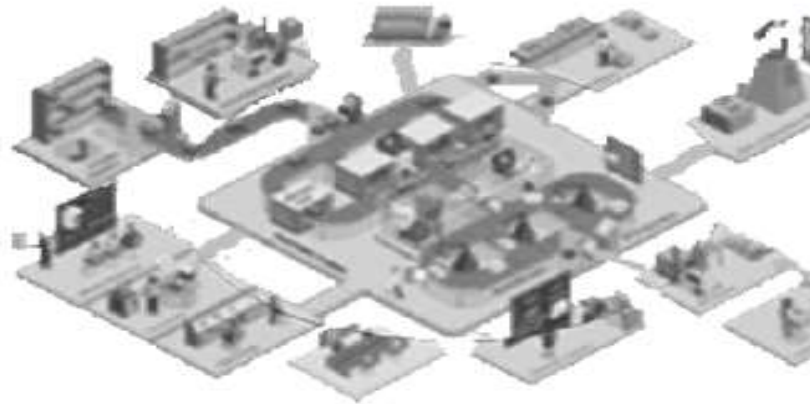


Biomarker is a measurable indicator of the severity or presence of some disease

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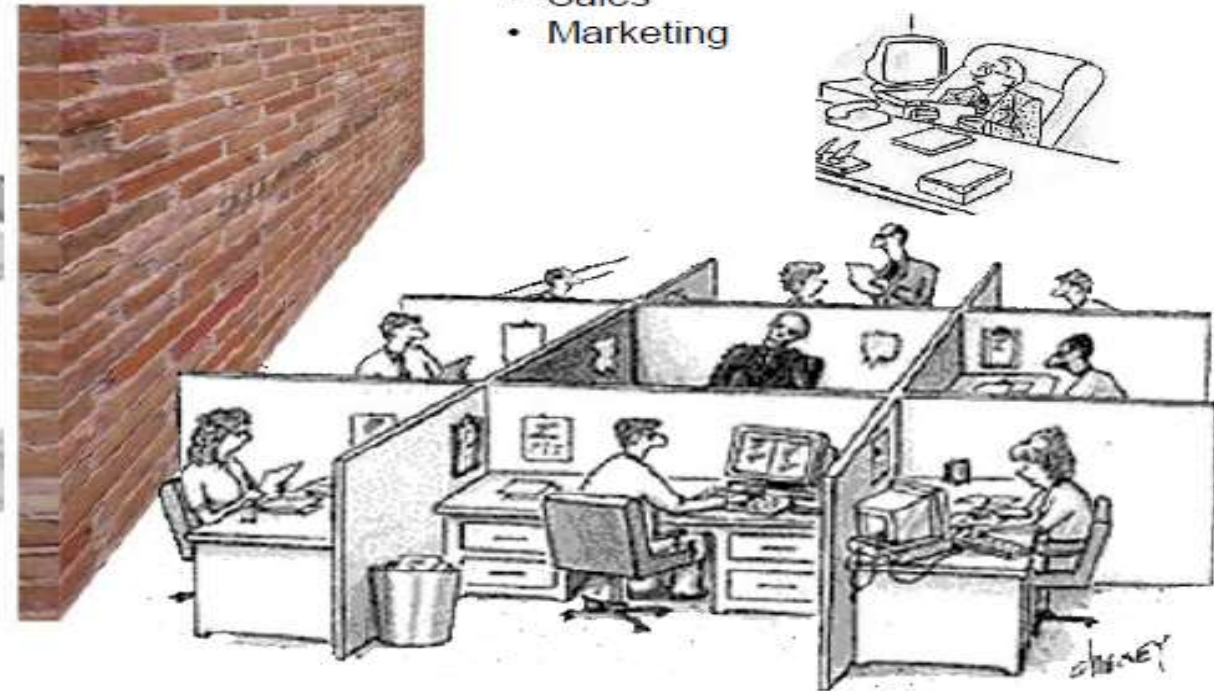
Manufacturing

- Production
- Testing
- Rework
- Inventory
- Shipping

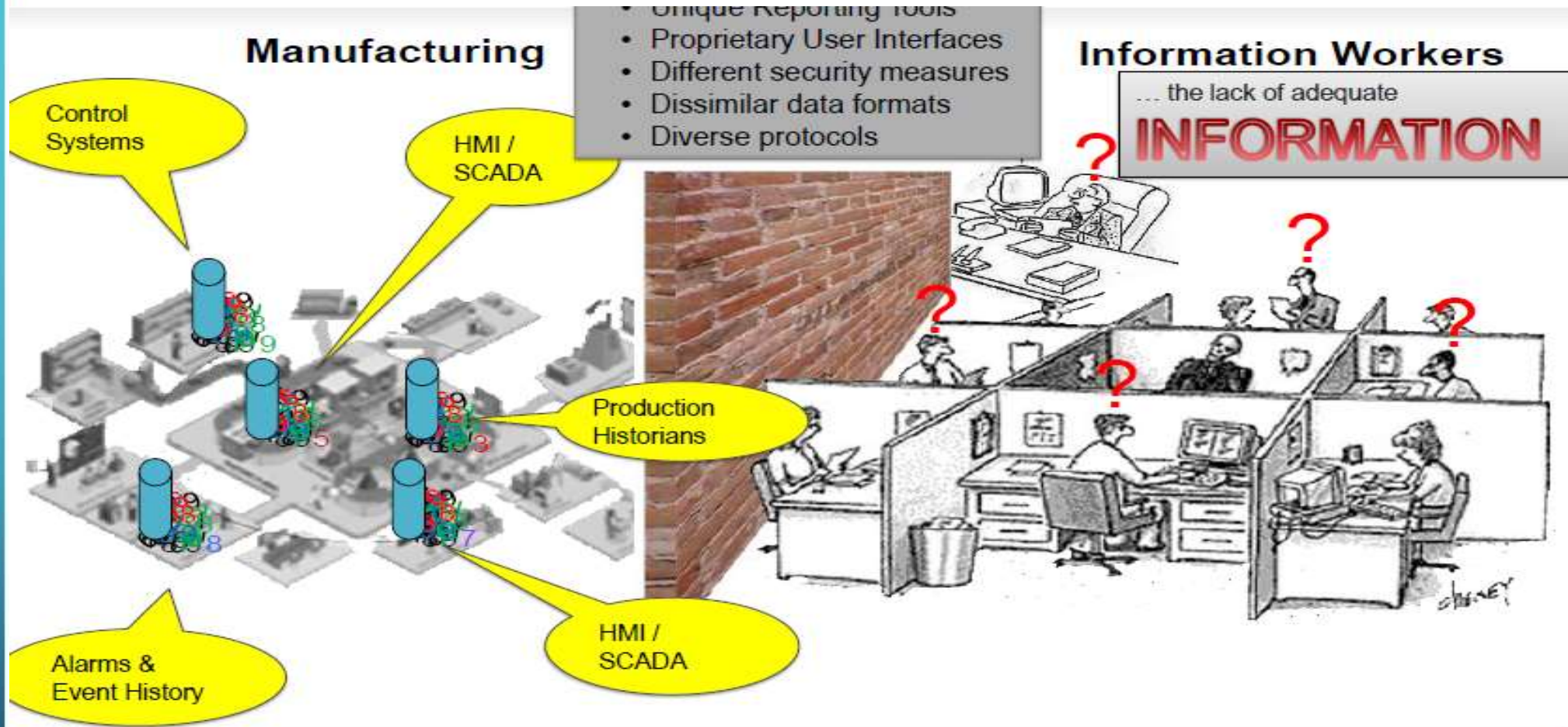


Information Workers

- Management
- Production Supervisor
- Quality Department
- Sales
- Marketing



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Challenges

Affordability

Legacy Equipment's
& Applications

Capabilities

Integrations

Compliances

Safety Regulations

Security Concerns

Ecosystem availability

Support & Services

Sourcing

Interoperability

Change

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SMART FACTORY OBJECTIVES

Productivity

Product Quality

Equipment Control

Supply Chain

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Technology Transformations

Technology Innovations

Collaborations

Networking of Devices

Consumerization

Customers/Suppliers

Employees

Regulatory

Previously, “technology was more a barrier than an enabler.” The current technology revolution, “will allow manufacturers to get closer to their supply chains and plants.”

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Technology Trends

Continuous Mfg.

Personalized Mfg

Predictive & Prescriptive
Analysis

3D Printing

Big Data & Analytics

Simulation

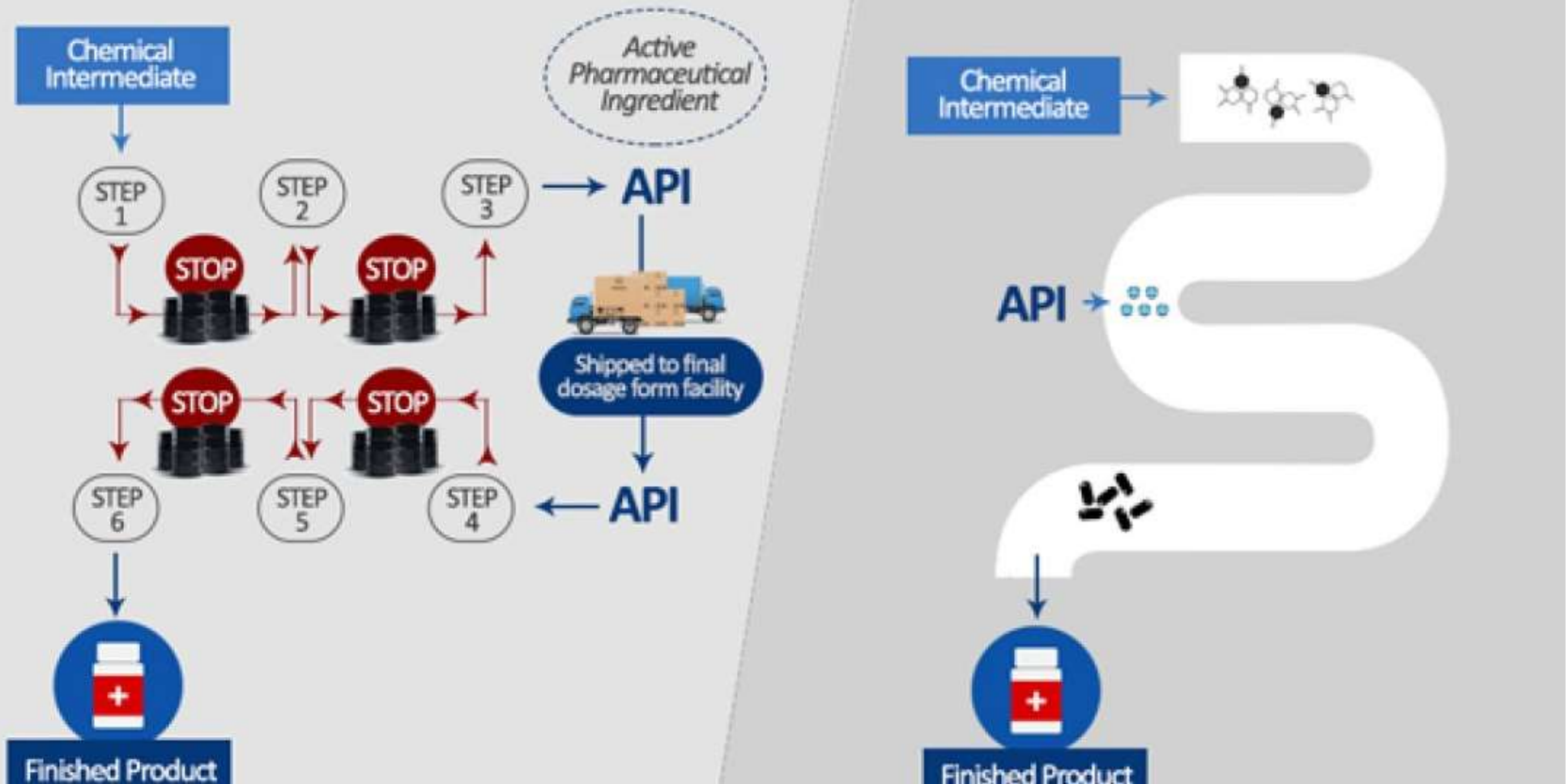
AI, Augmented, VR

Intelligent Devices

Paperless Mfg.

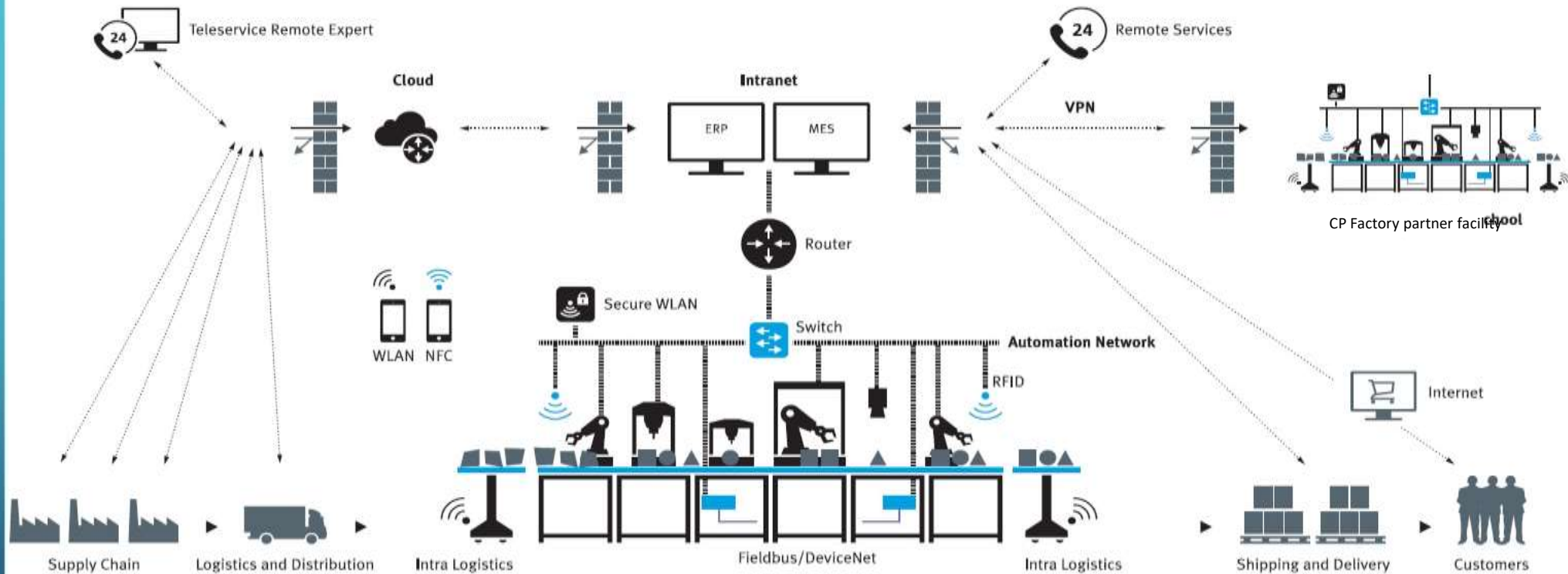
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Traditional Mfg. VS Continuous Mfg..



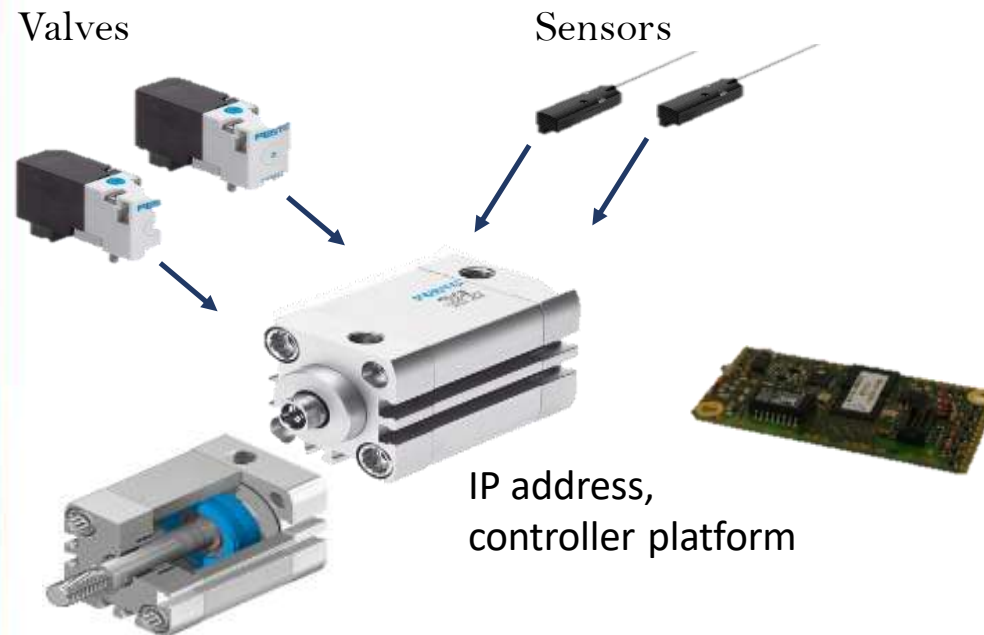
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The factory of the future



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Mechatronic systems are turning into cyber-physical systems



The Internet of things

+ IP capacity

Cyber-physical systems

- + Internet communication
- + machine-to-machine communication
 - Wireless communication
 - Semantic description

Integrated systems

- + sensors, actuators
- + integrated intelligence

Physical objects, devices

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Paperless Office

Integrated work flow
R&D, Pilot Plant, Bulk Mfg.

ELN ,E-BMR

Integrated LIMS

Integrated Automation

Integrated Alarm &
Condition Monitoring

Personalized Alarm
Management

Integrated QMS

Integrated IT & OT

Electronic

Continuous Mfg.

PAT

Continuous Quality
Verification

Smaller Foot Print

Improved yield with better
quality

Significant savings

Reducing waste

Flexible Mfg.

Single use & Flexible Mfg.

Reduced CIP

Cost Savings

Efficient Usage

Compliances

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M2M , M2P, M2L

M2M Communication

Condition Monitoring

Modeling, Predictive &
Control(MPC)

Reliability

Machine to People
Interaction

Planning

Batch Progress

Deviations/Quality Aspects

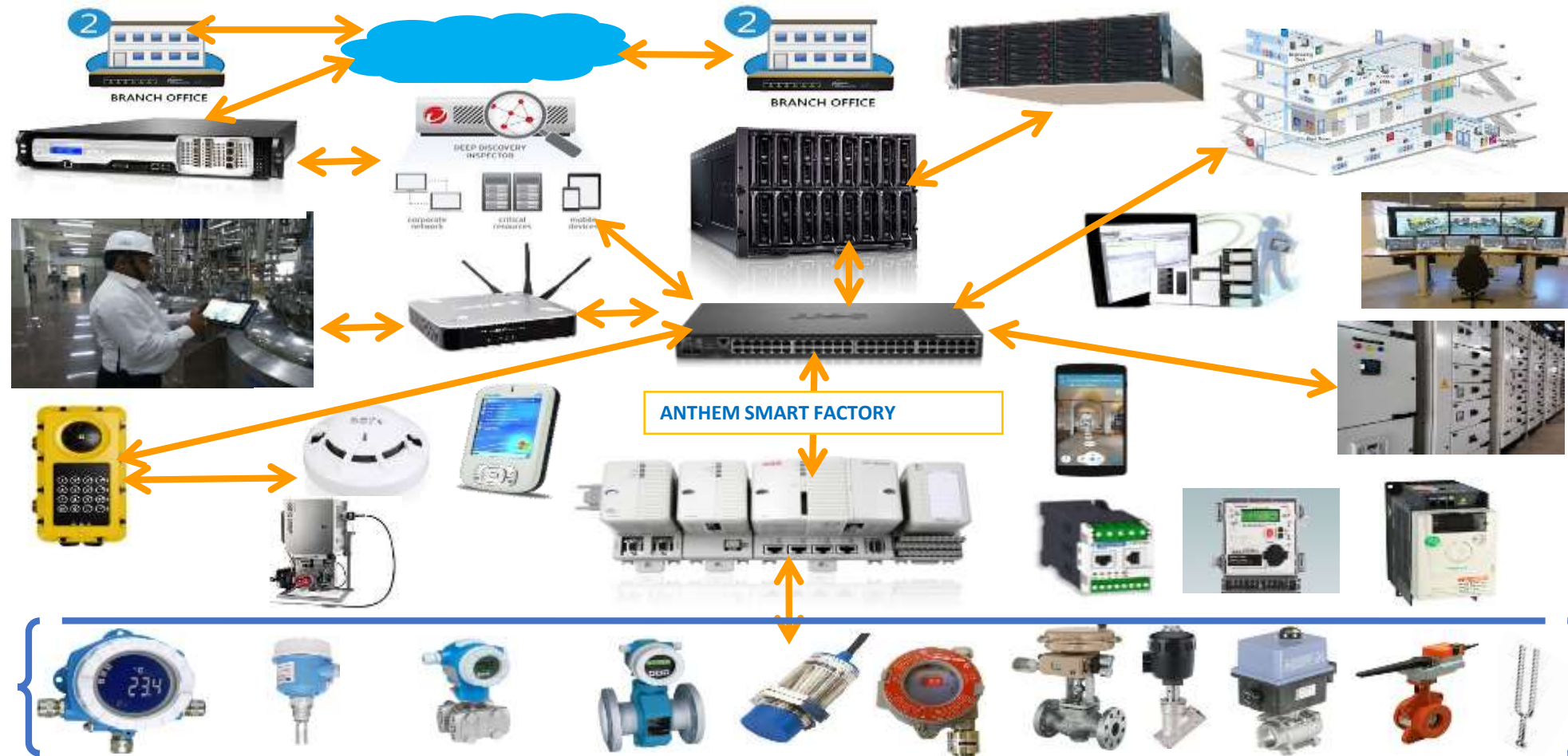
Work Flow

Electronic Review

Intelligent

Reporting

ANTHEM SMART FACTORY ARCHITECTURE



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Advantages of Integrated Automation & Virtualization

Operator Convenience

Operator Safety

High Availability

Reliability

Integrated Control

Regulatory compliance

Significant Savings

Remote Control

Easy to collaborate

E-audits

Integrated Alarm
Management

Less Maintenance
Efforts

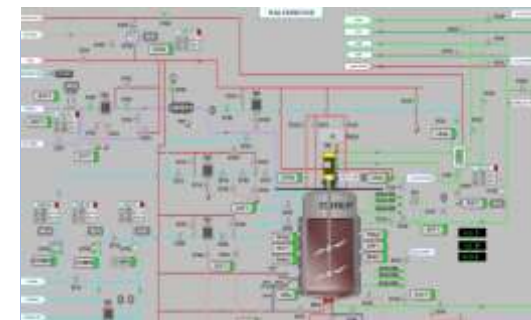
Integrated Automation



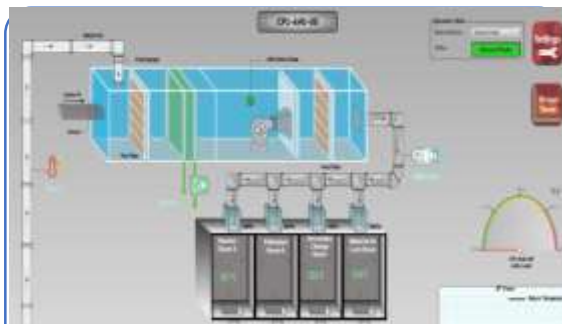
API



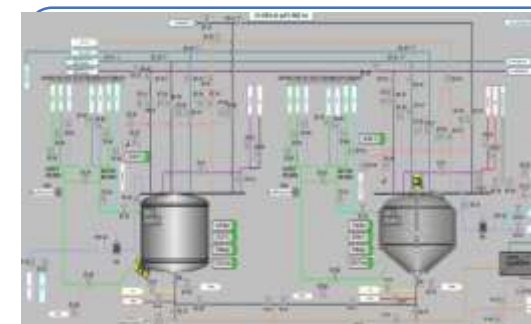
PEMS



Fermentation
Upstream



BMS



Fermentation
Downstream



Labs



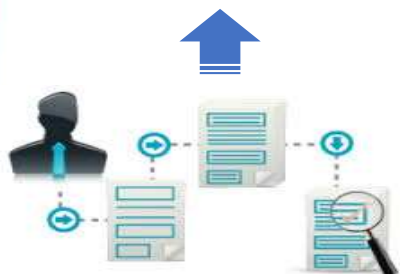
Knowledge Portal



Quality Assurance



Utility Data & BMS



DTS/DMS



Control Process Automation Systems

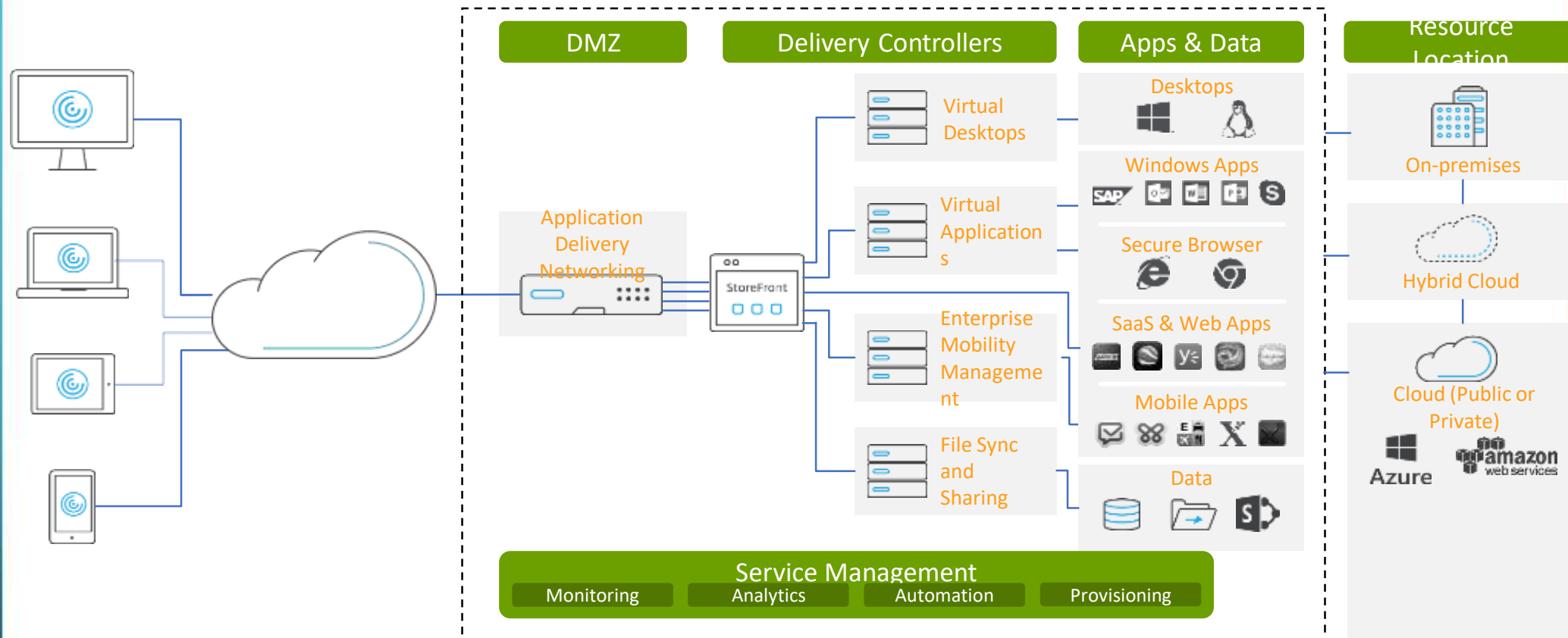
LIMS/QC



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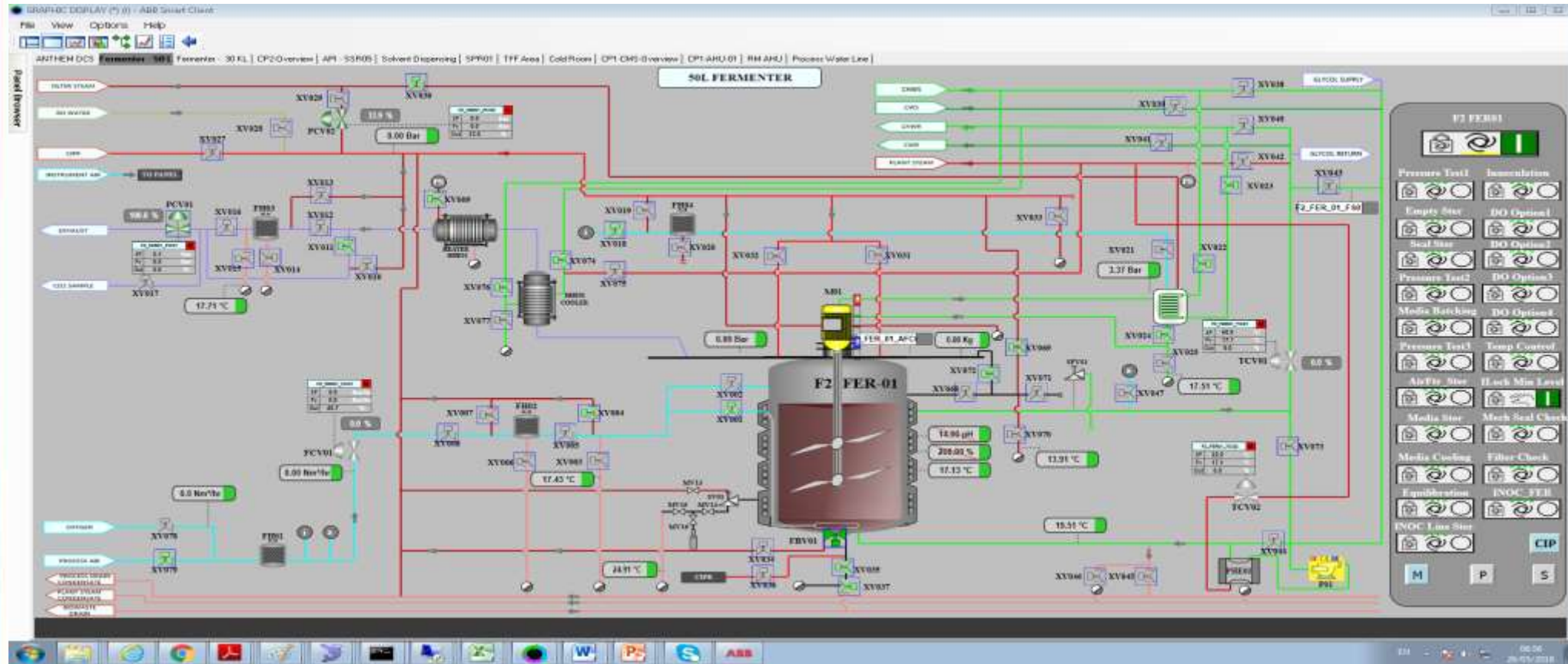
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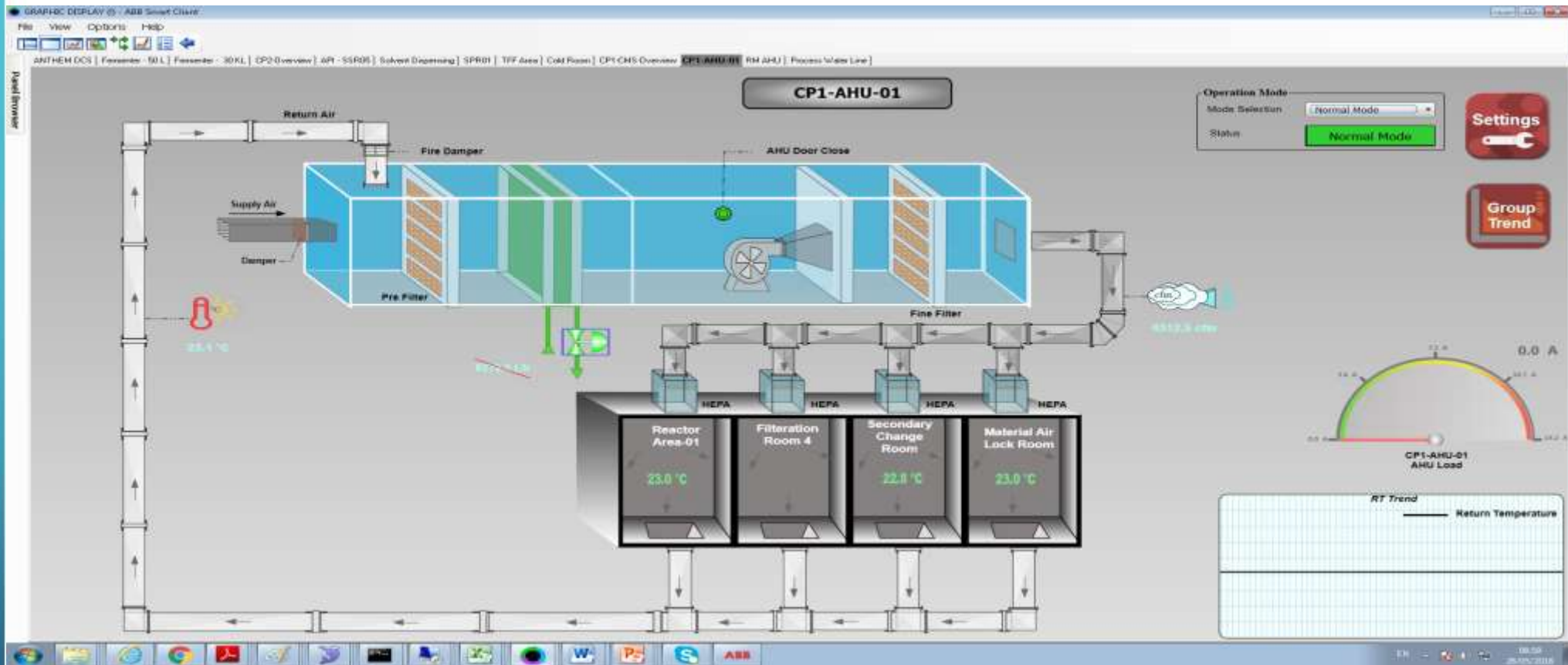
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Endress + Hauser
People for Process Automation



zenitel



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Thank You!

Q&A