



接軌國際的藥物製造策略



expanding **human possibility**®

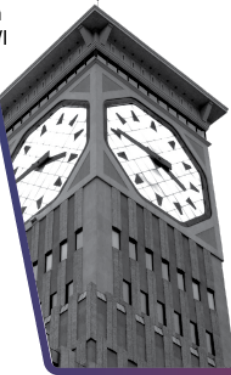
OUR HISTORY



1893
Lynde Bradley develops his first electric motor controller



1962
Four-sided clock tower is first illuminated in Milwaukee, WI



1923
Octagon logo debuts as company trademark

1969
Largest high current testing facility in world opens in Milwaukee, WI



1971
Centerline 2100 Motor Control Centers Launch

1992
First Automation Fair event held in Philadelphia, PA



1999
Low Voltage Panels Business formed



2001
Company renamed to Rockwell Automation

2006
ArcShield technology is launched

2000
IntelliCENTER software is launched

2006
Centerline 2500 Motor Control Centers are launched

2007
Global plants are equipped to build Centerline 2500 Motor Control Center offering

2007
Low Voltage Panels sold globally



2009
PlantPAX introduced

2008
First CENTERLINE 2500 order over \$1 million

2011
SecureConnect is launched

2018
Low Voltage Panels growth accelerates



2020
Rockwell Automation brings manufacturing to its global headquarters





Allen-Bradley components and integrated control systems **make your productivity automatic**

- Safety
- Sensing
- Industrial Control
- Power Control
- Motion Control



FactoryTalk software helps you **design, maintain, operate and innovate** your operations

- System Design
- Operations
- Plant Maintenance
- Analytics and IIoT



From assessment and implementation support to long-term maintenance, your lifecycle is covered with Lifecycle IQ Services

- Consulting Services
- Professional Services
- Connected Services
- Field Services
- Workforce Services

We help our customers achieve results



Increase revenue

Up to
10%



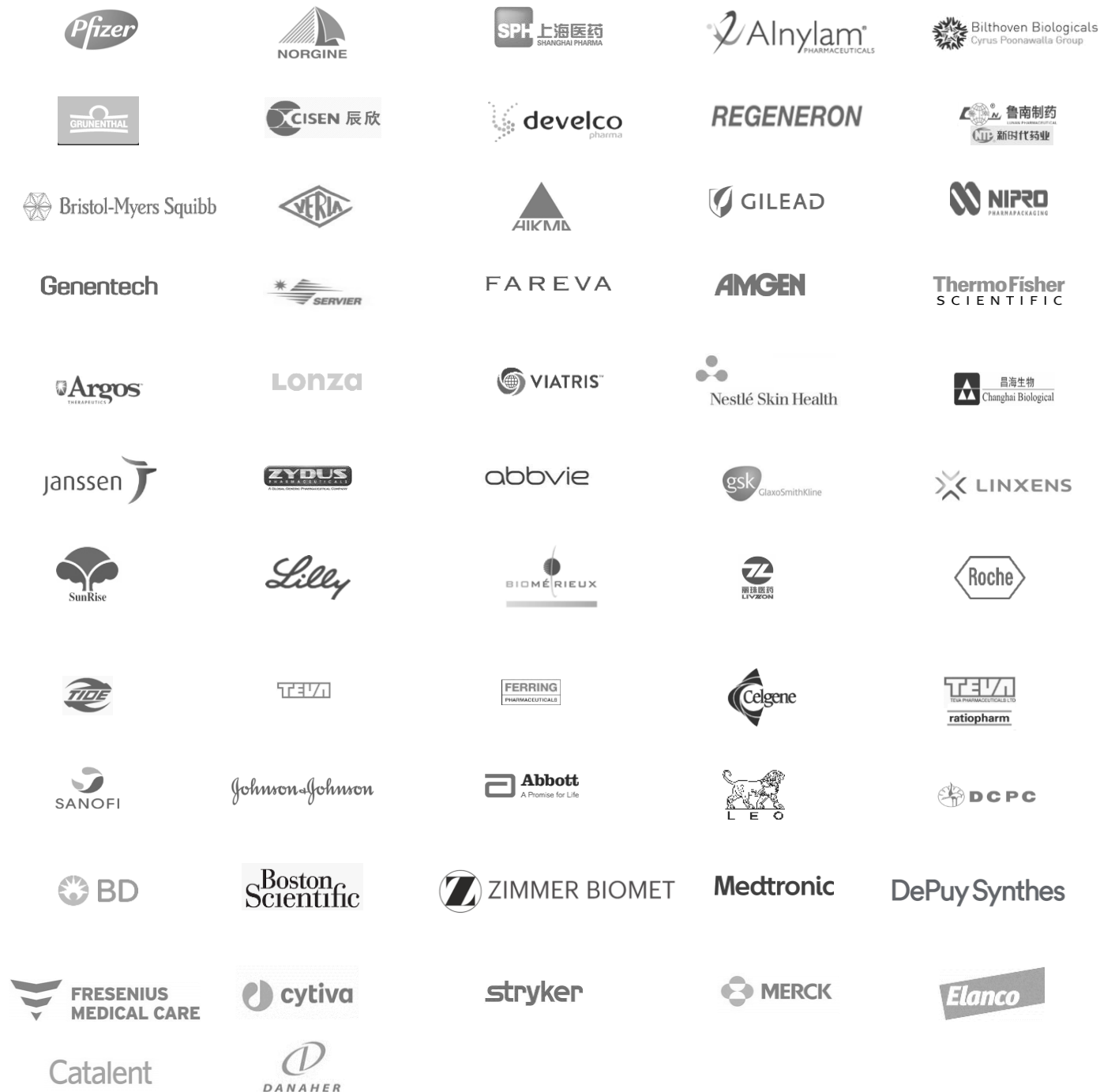
Decrease operating costs

Up to
12%



Decrease quality review cycle times

Up to
50%



製藥行業目前遇到的挑戰



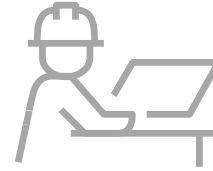
加速藥物核准

資料不連續，必須在整個產品生命週期中不斷重新建立



個人化藥物

從大規模、一體適用的製造轉變為小批次處理



勞動力短缺

預計到 2025 年將有 200 萬個製造業職缺



法規 遵從性

「經營權」

過程開發影響

盡可能減少代價高昂的數位主線中斷和重新建立資料的需要，以便加快救命藥物的上市時間

製造業影響

需要更大的製造彈性

勞動力影響

必須增加自動化程度並改進員工效率

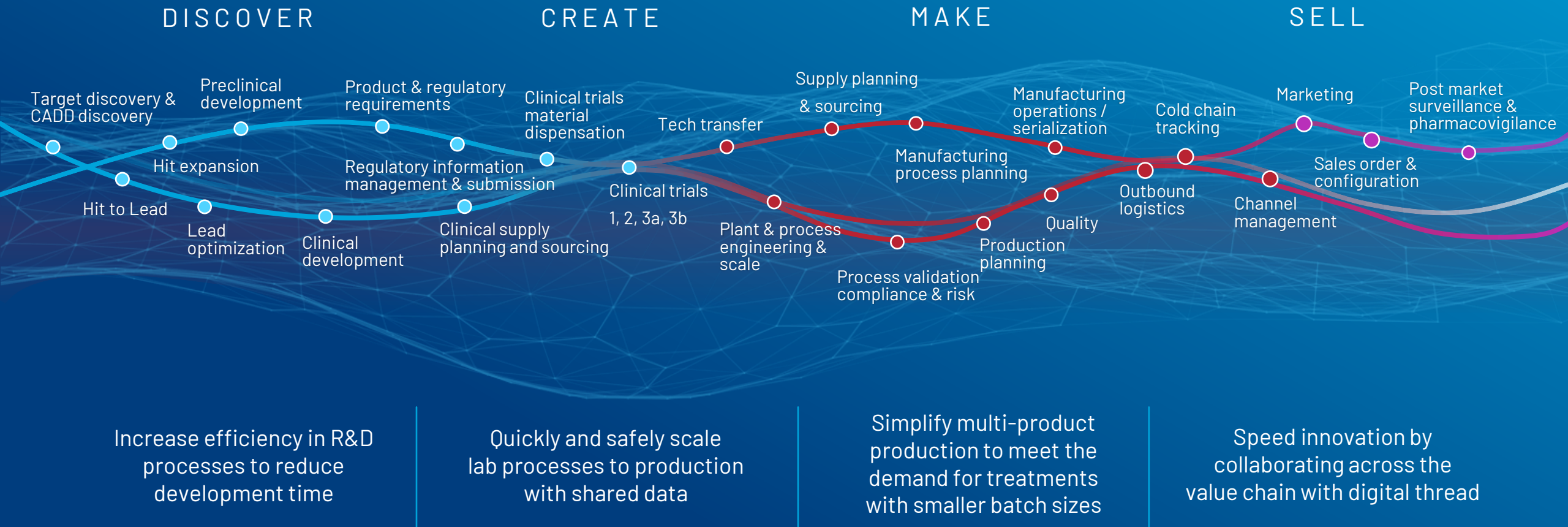
業務影響

阻礙改進營運效率的現代技術採用和加速



網路安全威脅

Pharma 4.0 Connect the Dots for your business



12 key digital themes underpin typical Lifesciences manufacturing process

1

Production planning

Simultaneous production planning & scheduling

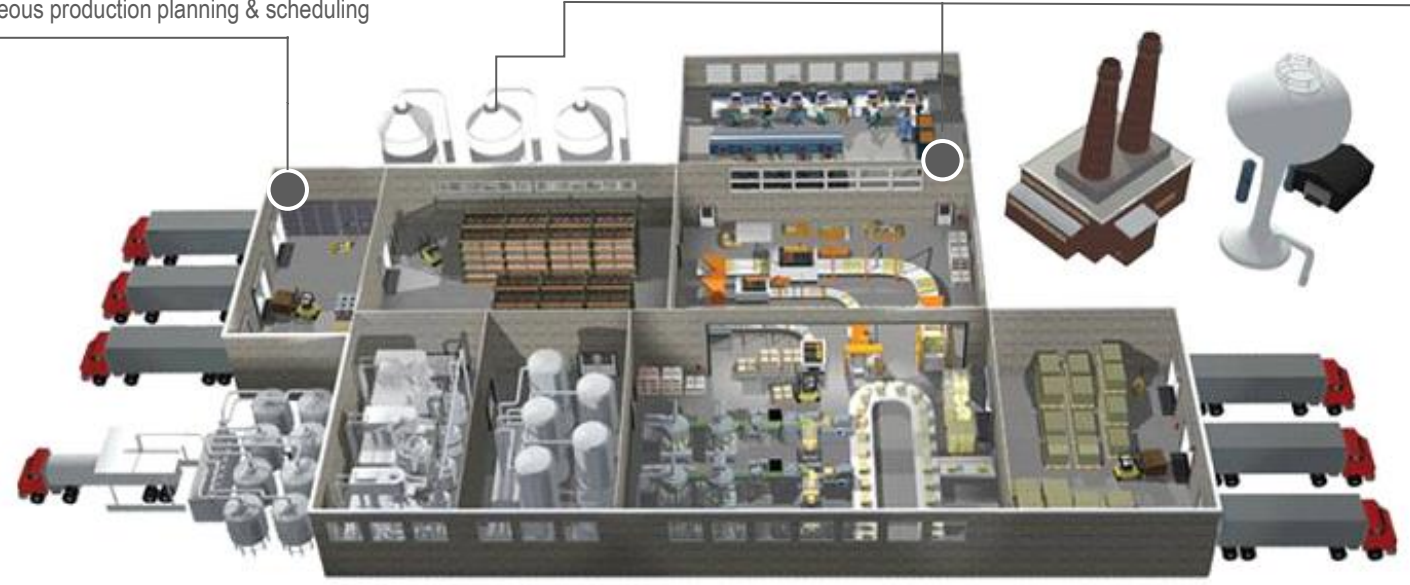
2 Optimization for critical processes (CPP & CTQ)

3 Throughput / Yield optimization
Generate higher throughput by maximizing yield while maintaining quality within specified limits

4 Quality management
E2E Paperless manufacturing to address

- Data Integrity
- Track and Trace
- Desktop / Virtual Audit

5 Information solutions & Emerging Technologies
Dashboards and machine connectivity
digital twin, Web access under high security



11 12

11 Safety & security management
Intelligent systems to ensure plant safety & data security

10

10 Production logistics
Automated storage & movement
Serialization

9

9 Intelligent energy management (PEMS)
Energy platform to optimize consumption across the plant

8

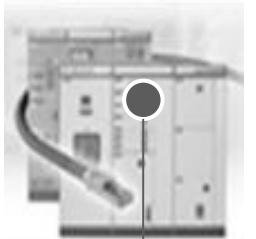
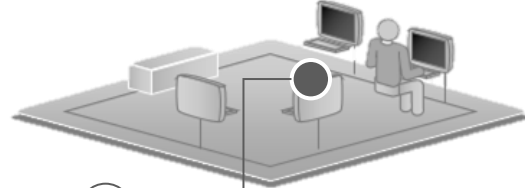
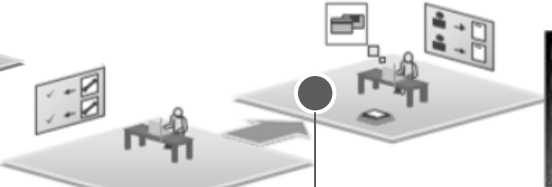
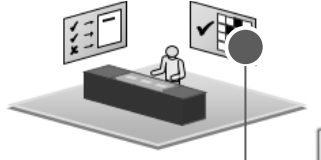
8 Labour productivity
Wearables & flexible workforce planning

7

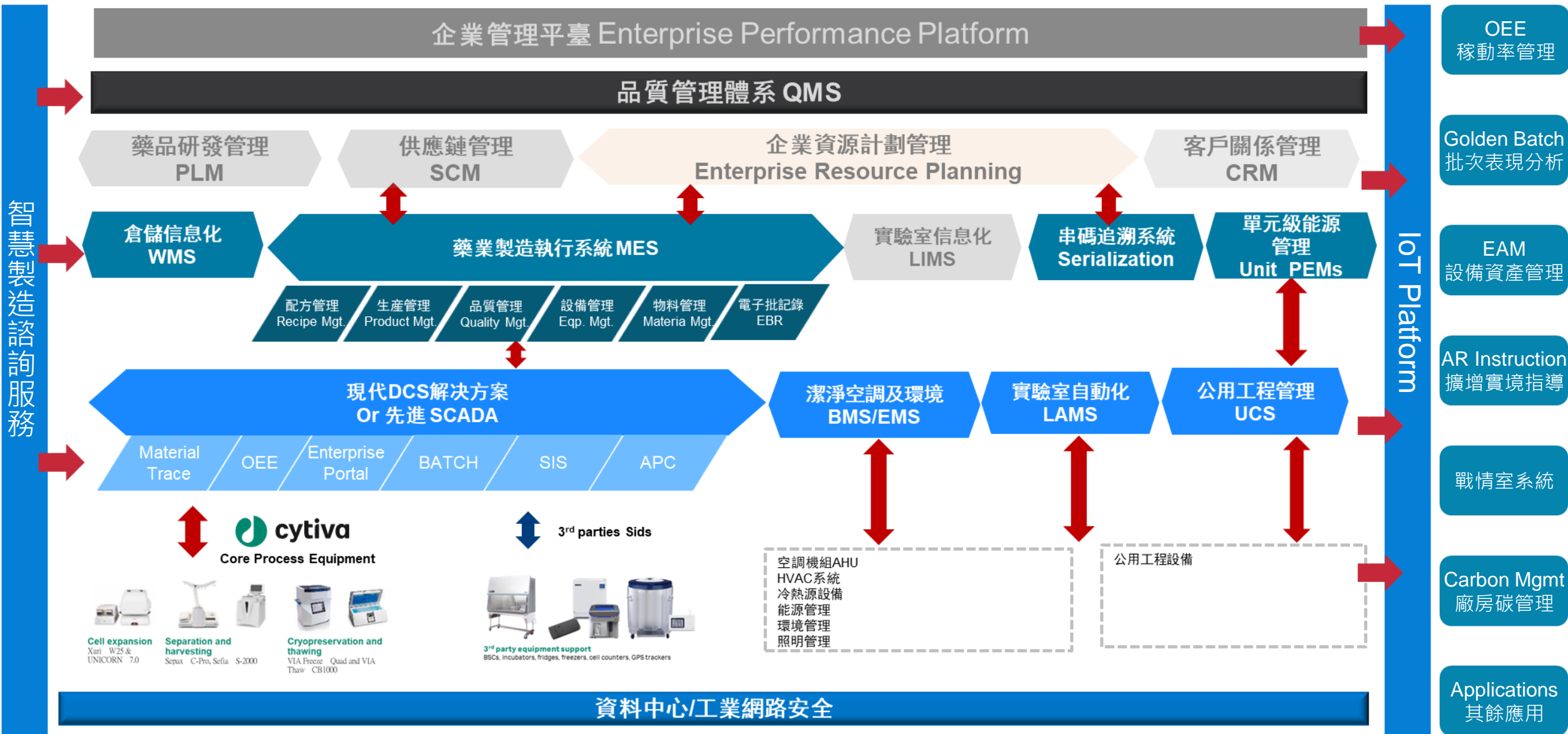
7 Predictive and remote maintenance/ monitoring
Analytics for conditions monitoring & remote maintenance of machine & processes

6


6 IT/ OT convergence
Enable secure, real-time actionable information/ data flow between machines (island of automation) & systems




國際製藥廠房標準解決方案




Agenda




無資料斷點
的數據流



高韌性
數位骨幹




自主可控彈
性生產



分析賦能生
產運營

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Rüstliste

Reinigung

Pkt.

Einteilung

Rockwell Software PharmaSuite - Production Execution

PHARMA AT ITS BEST INC. Dittmer (mdi)
000406WC01 - 000406ST01

3 3 6

1. Read current temperature **Confirm** ✓

Signature Tester Marathon Other (mt7) 03/08/2016 01:33:38 PM CET

2. Read presure **Confirm** ✓
High 45
Low 23

3. Review and Verify execution of all phases in this operation **Confirm** [QR Code]

4. Signature Tester

5. Read presure **Confirm** ✓
High 45
Low 23

F5 F6 F7 PgUp PgDn F8

Rockwell Software PharmaSuite™
06/03/2014 04:18 PM CEST

Inv.-Nr.: 004465

PHARMASUITE® CAPABILITY OVERVIEW

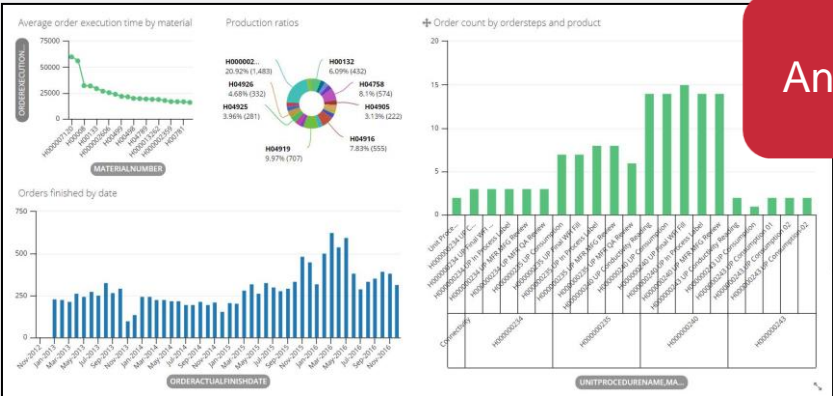


Holistic Electronic Batch Recording (EBR)

- › **GMP compliant** Material, Equipment and Personnel tracking
- › **Operator Instructions** minimize any human processing error
- › **Weighing and Dispense** reduces efforts for material preparation
- › **Material Control** ensures the right material, at the right place
- › **Equipment Control** ensures „fit for purpose“
- › **In Process Control** ensure process and product quality
- › **Integration** to the Automation and ERP layer
- › Deviations from the specified recipe raise **exceptions**
- › „**Review by exception**“ allows to reduce time for batch release from days to hours
- › **Cold Chain Tracking**

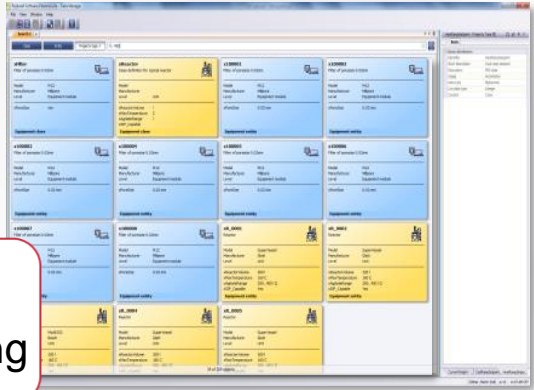
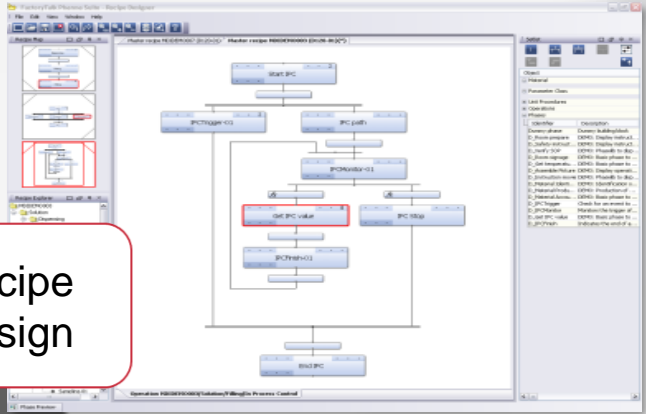
The screenshot displays the PharmaSuite software interface. The top window shows a process flow diagram with steps like 'Start IPC', 'IPC Trigger-01', 'IPC path', 'IPMonitor-01', 'Get IPC value', and 'IPC Stop'. Below this, a 'Production Execution' window is open, showing a 'Vial check [1.2795]' for '#MDI103-Filling - BX12'. The form includes fields for 'Average weight' (6 g) and 'Average temperature' (21 C°), and radio buttons for 'Visual appearance of samples' (Looks good, Acceptable, Looks funky, No, no, no). A 'Confirm' button and a QR code are also visible. The bottom of the screen shows navigation icons and the Rockwell Automation logo.

Continuous value creation by analytics

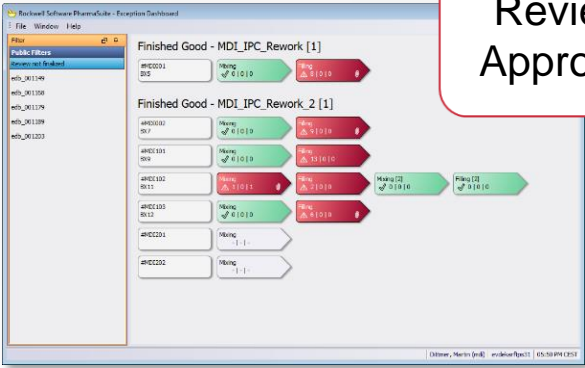


Analytics

Recipe Design



Review Approval



Recipe Execution



Planning Dispatching





Challenge

Digital silos and limited operational visibility, due to:

- Various reporting tools, unsustainable
- Knowledge trapped within systems
- Limited accessibility to equipment data

Pfizer had 30 legacy pharmaceutical companies to bring together, each with a **diverse ecosystem of systems and databases**

Solution

Connected plant and supply chain, with:

- One central data repository
- Knowledge sources unlocked
- Increased visibility and predictive capabilities

Pfizer connected their plant and supply chain through a **digital thread**, using **FactoryTalk® MES PharmaSuite®**

Results Achieved

3 million doses above plan

At a single manufacturing site, the digital transformation program has been credited with enabling the manufacture of 3 million additional doses of one product above what was planned.

Agenda

無資料斷點
的數據流

高韌性
數位骨幹

自主可控彈
性生產

分析賦能生
產運營

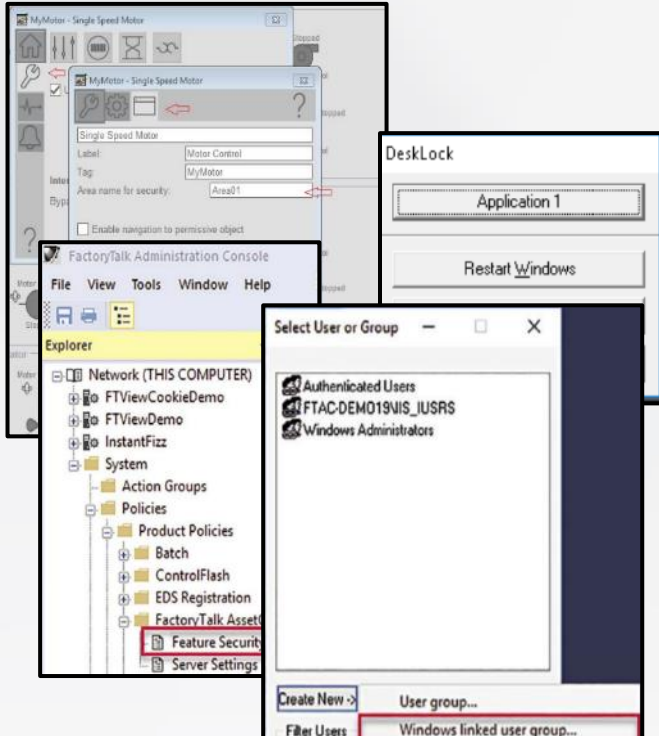
製藥業建築管理系統

- 整合過程控制和環境管理，藉以提升生產力、改善產品品質並降低能源成本。
- 預先設計和預先測試的 HVAC 控制模組、庫和範本有助於提供統一的資料結構，減少驗證和文件編製工作，並縮短上市時間。

合併您的 EMS 和 BMS
以改善資料能見度和
存取情況

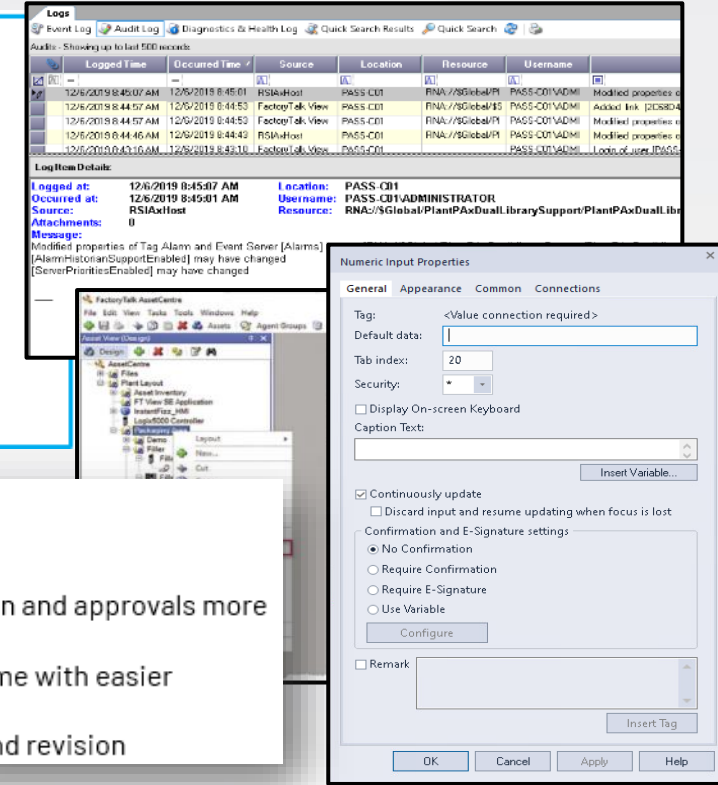
FDA 21 CFR Part 11 Compliance

Security Measure



Electronic Records and Electronic Signatures

- E-signature and audit trail functionality are native in FactoryTalk® View Site Edition (SE) components
- All HMI user actions, system developer actions, and system events are captured in a database for future retrieval
- Reverification of Operator Identity or Supervisor Signoff
- Change Management



Benefits

- ❖ Native functionality
- ❖ E-signature authentication and approvals more flexible to implement
- ❖ Decrease development time with easier implementation
- ❖ Consistent deployment and revision

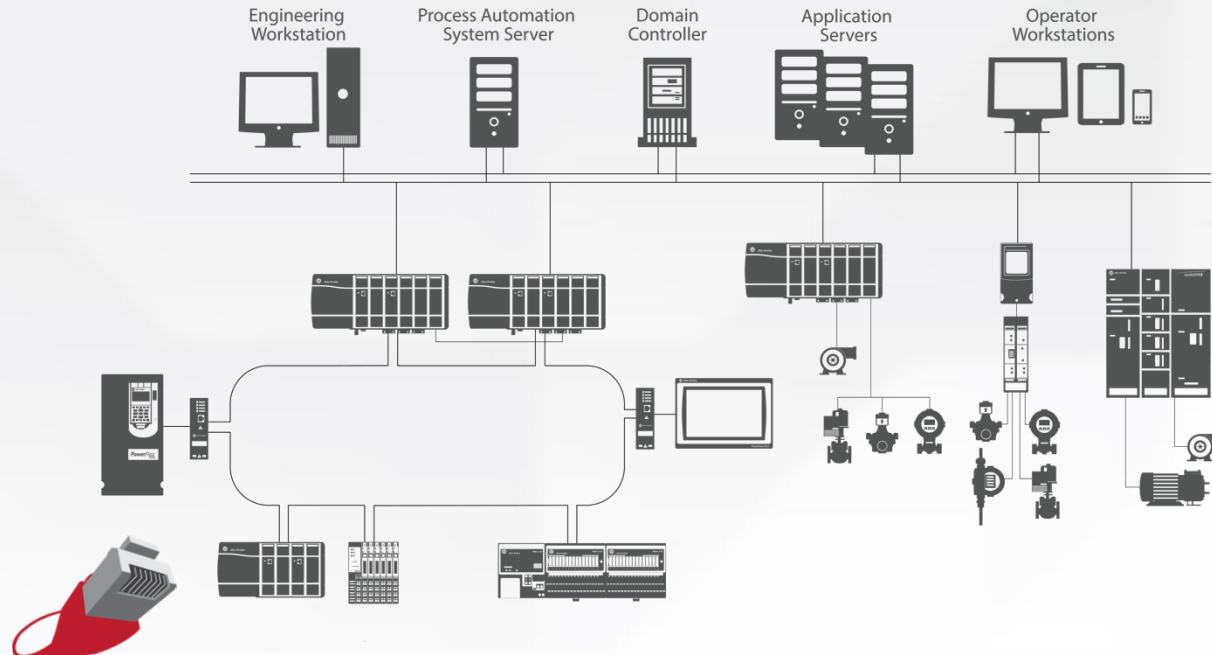
Benefits

- Highly flexible security configuration
- Password Management Tools native to FactoryTalk® applications

- FactoryTalk® Users or Windows Domain
- Automatic logout of HMI client after a period of inactivity
- Restrict Operating System Access
- PlantPax® Process Object Security

Future-Ready Resilient Facility System

Built on standard PlantPAx DCS architecture, delivered by Rockwell Automation Global Solutions



- ✓ **Increased** design reliability & consistency
- ✓ **Uniform** & intuitive user Interface
- ✓ **Reduced** engineering & start-up costs
- ✓ **Lower** lifecycle support costs
- ✓ **Reduced** project risk

**SECURE &
SCALABLE**

**MODULAR &
MULTIDISCIPLINARY**

**CONTINUOUS,
BATCH, DISCRETE**

*New installations &
DCS migrations*

OT設備資產管控

13



ARCHIVE & DISASTER RECOVERY

- Centrally manage versions of programs, files and folders
- Automate backup of automation assets
- Generate detailed difference detection reports of assets



AUDIT

- Track user actions – Who did what, when, where?
- Ad-hoc reporting associating users, assets, and programs
- Automate the reporting process via email



SECURITY

- Restrict viewing of artifacts
- Help prevent unauthorized access to make changes
- Help prevent unauthorized users from creating new versions



LIFECYCLE MANAGEMENT

- View Rockwell Automation® product lifecycle status information for your plant floor devices
- Compare and detect changes in deployed plant floor devices



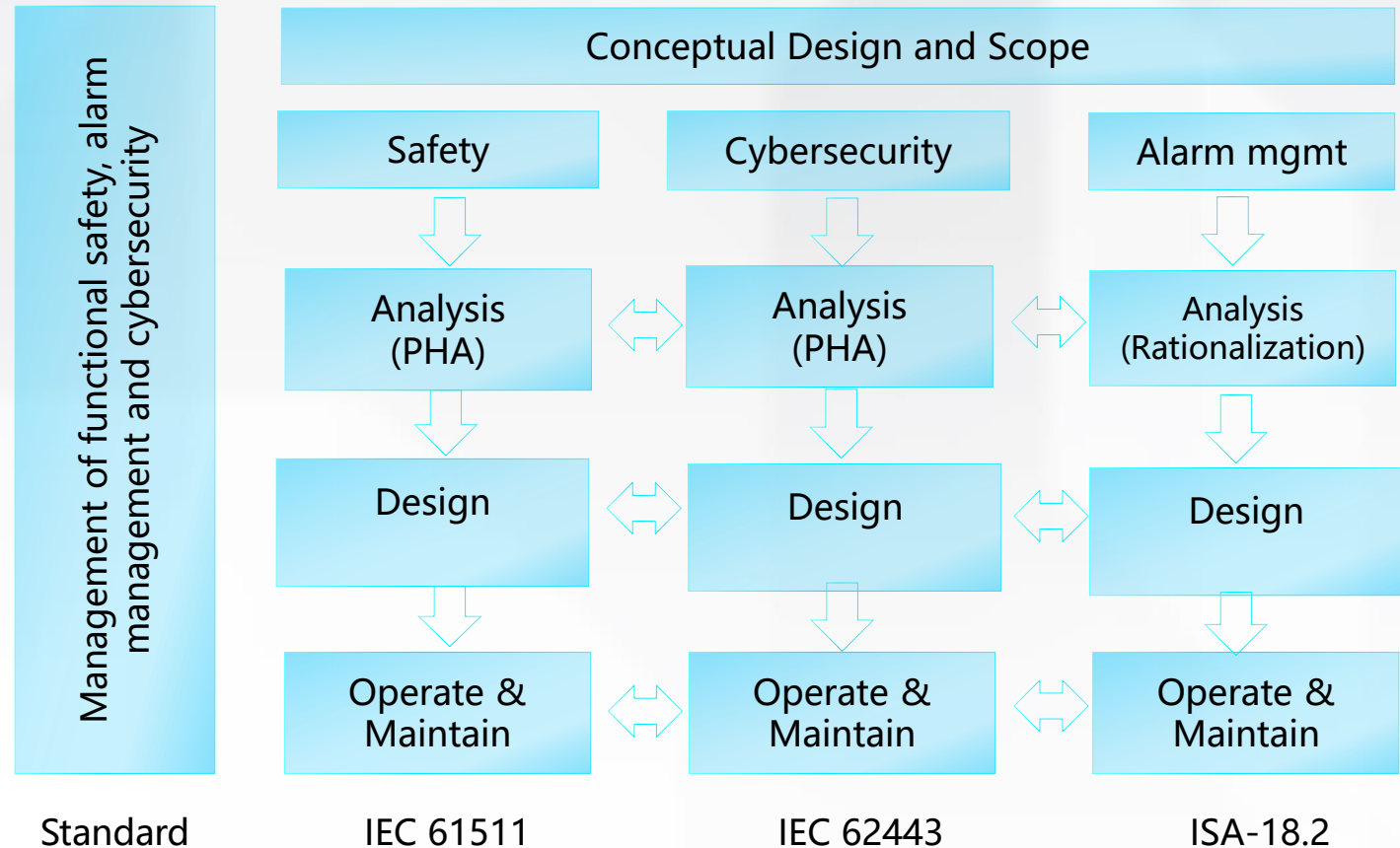
EXTENSIBILITY

- Ability to extend and add support for third party devices
- Web client available to track assets from a mobile device

數位化環境下廠房運營的風險管理

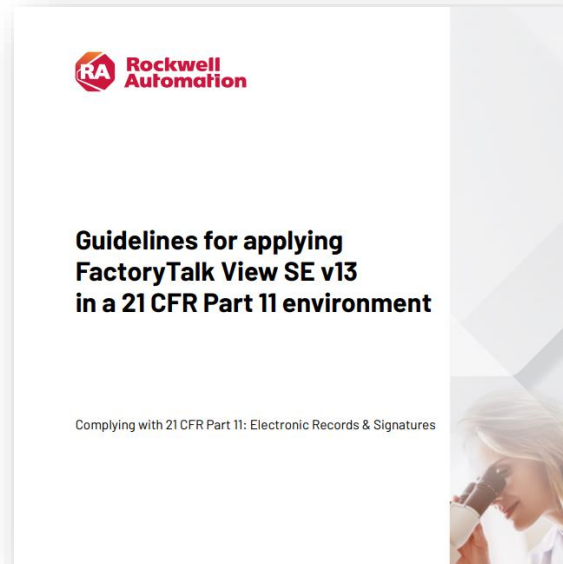
透過自動化整合廠房風險生命週期

- 挖掘所有在生產中所有的風險點並進行**持續性風險監測**
- 透過數位化風險管理縮短危機處理實踐並**降低溝通及流程成本**
- 透過風險點監測更完整掌握廠房整體狀態，協助**效能提升**

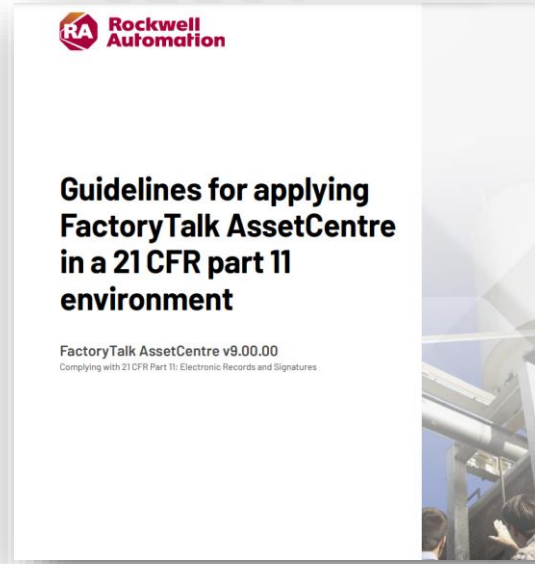




https://literature.rockwellautomation.com/idc/groups/literature/documents/wp/ftalk-wp016_-en-p.pdf



https://literature.rockwellautomation.com/idc/groups/literature/documents/wp/ftalk-wp024_-en-p.pdf



https://literature.rockwellautomation.com/idc/groups/literature/documents/wp/ftalk-wp001_-en-p.pdf

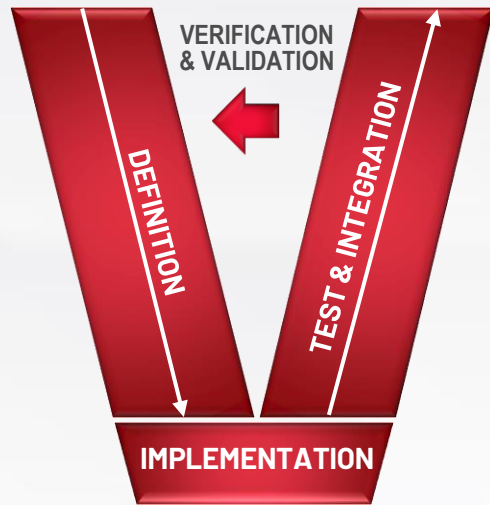


https://rockwellautomation.com/help.com/ci/okcsFattach/get/546757_5

Compliance and Regulatory

Based on PMI PMBOK® Guide & Standards, GAMP® 5 V-Model & ASTM E2500 Standard Guide

V-Model Project Execution

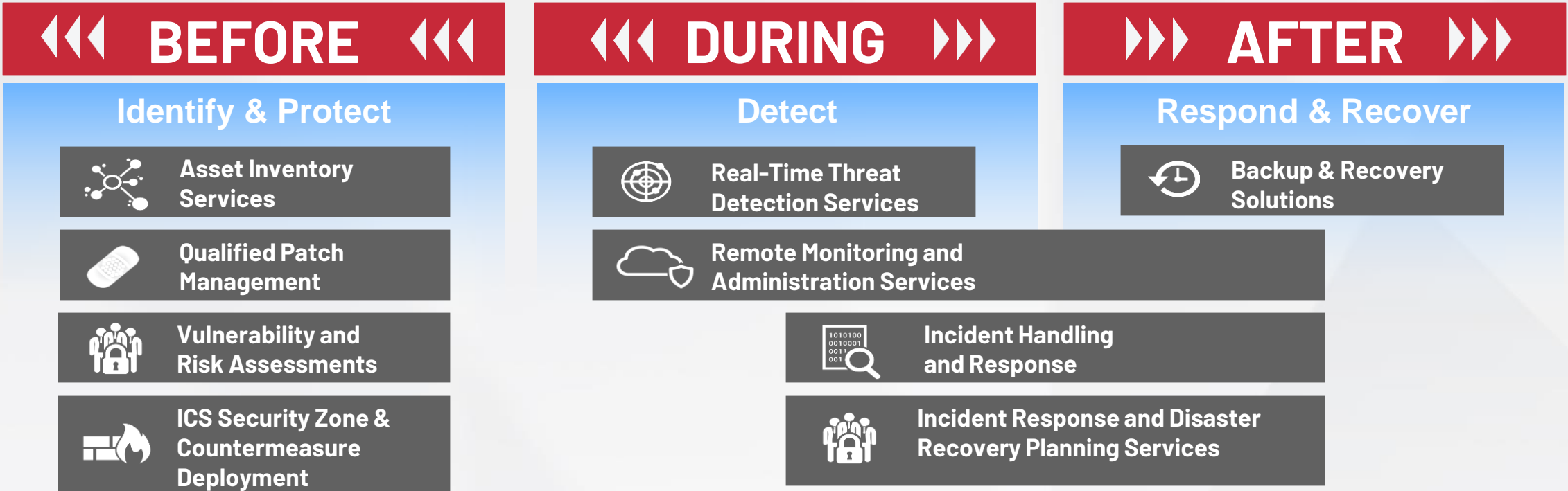


- 
 Validation Policies, SOPs, Test Packs & Reports
*Turnkey Upgrade **Projects***
- 
 Protocol Management & Execution
*New Production **Facilities***
- 
 cGMP & Validation Training
*Managed Remediation **Plans***
- 
 Ongoing Validation
*On-Site Staff **Support***

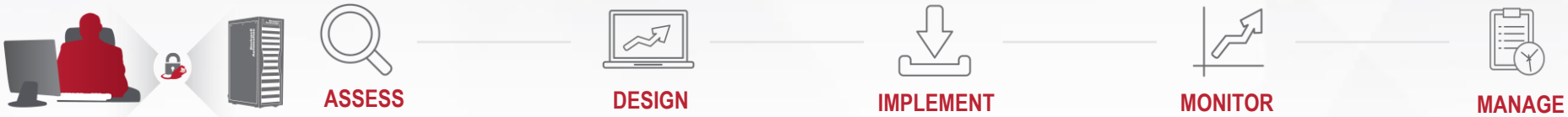
VALIDATION MASTER PLAN



Attack Continuum



BUILD A SECURE, ROBUST, FUTURE-READY NETWORK FOR YOUR CONNECTED ENTERPRISE



A holistic approach to help you design, deploy and manage your network infrastructure

FactoryTalk® AssetCentre



ARCHIVE & DISASTER RECOVERY

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- Generate detailed difference detection reports of assets



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EXTENSIBILITY

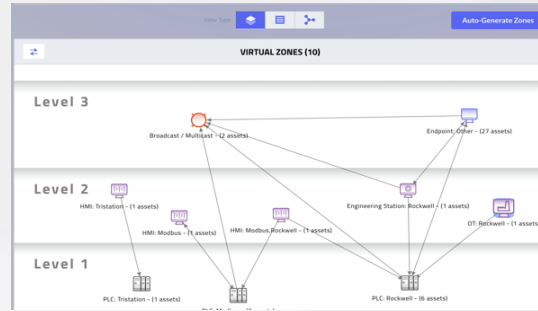
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Continuous Threat Detection (CTD) – 實時監控您的ICS網路

網路拓撲

網路拓撲層次化

不僅是顯示完整的網路拓撲架構，更進一步將資產在工控環境的類別分成五個層級表示



資產可視性

廣泛的資產清單

自動識別資產詳細資料，包含IP, MAC, 資產類型, 廠牌...等資料，可識別的資產協議近200種

NAME	IP	MAC	CLASS	TYPE	CRITICALITY	RISK LEVEL	VENDOR	NETWORK
00:80:43:07:10:02	00:80:43:07:10:02	IT	Endpoint	Low	Normal	Richard Hirschmann	Default	
00:80:43:56:89:56	00:80:43:56:89:56	IT	Endpoint	Low	Normal	Richard Hirschmann	Default	
00:80:43:56:89:55	00:80:43:56:89:55	IT	Endpoint	Low	Normal	Richard Hirschmann	Default	
10.4.0.38	10.4.0.38	00:8A77:9F:D3:8C	HMI	Moderate	Broadcom	Default	Default	
10.4.0.46	10.4.0.46	00:0E:3C:34:15:87	OT	HMI	Medium	Critical	Intel	Default
10.5.0.150	10.5.0.150	00:22:05:22:36:2A	OT	Controller	High	Normal	Emerson	Default
10.5.0.150	10.5.0.150	00:22:05:22:36:2A	OT	Controller	High	Normal	Emerson	Default
10.5.0.158	10.5.0.158	00:22:05:22:14:8E	OT	Remote ID	High	Normal	Emerson	Default
10.4.129.3	10.4.129.3	00:22:05:11:99:8E	IT	Endpoint	Low	Normal	Emerson	Default
10.4.129.2	10.4.129.2	00:22:05:11:88:CA	IT	Endpoint	Low	Normal	Emerson	Default
00:22:05:9C:1A:8A	00:22:05:9C:1A:8A	IT	Networking	Medium	Normal	Emerson	Default	

基準線自動學習

以基準線進行行為偏差檢測

在正常操作期間自動發現OT基準可以檢測偏差和惡意活動。

BASELINE NAME	FREQUENCY	SOURCE ADDRESS	DESTINATION ADDRESS	FIRST SEEN	LAST SEEN	COMMUNICATION TYPE	ACCESS TYPE	SHOW VALUES
Deliver ICS Serial Alarms Information (C)	Seconds	10.4.0.34	10.4.0.6	16/11/19 00:01	16/11/19 00:02	Protocol	None	0
Deliver ICS Query Named Parameter: ZONEDEFST_Std_CV	Seconds	10.4.0.6	10.4.0.70	16/11/19 00:01	16/11/19 00:02	Data Acquisition	Read	0
Deliver ICS Query Named Parameter: ZONEDEFST_Std_CV	Seconds	10.4.0.6	10.4.0.178	16/11/19 00:01	16/11/19 17:23	Data Acquisition	Read	0
Deliver ICS Query Named Parameter: ZONEDEFST_Std_CV	Seconds	10.4.0.6	10.4.0.50	16/11/19 00:01	16/11/19 00:02	Data Acquisition	Read	0
Deliver ICS Query Named Parameter: ZONEDEFST_Std_CV	Seconds	10.4.0.6	10.4.0.18	16/11/19	16/11/19	Data Acquisition	Read	0

事件偵測

實時偵測整個工控環境

- 資產變化
- 行為異常偏差
- 威脅事件
- 違反政策
- ...等更多異常事件

完整事件分析

提供所有必要的信息以進行分析和修復

完整串連警報的IT / OT事故，並將事故發生原因轉化成管理人員可讀的描述，而不是程式碼

STATUS	DESCRIPTION	DATE DETECTED	
Not Risky Change	New asset has been detected for 10.1.30.40	21/05/19 21:48	
Not Risky Change	New asset has been detected for 10.1.30.1	21/05/19 21:48	
Not Risky Change	CP - Asset attribute 'Vendor' value block of object Faulting	21/05/19 21:48	
Not Risky Change	CP - Asset attribute 'Status' of object Device	21/05/19 21:48	
Baseline Deviation	Not Risky Change	CP - Asset attribute 'Configuration' of object IOMap	21/05/19 21:48
Baseline Deviation	Not Risky Change	CP - Asset attribute 'Change Index' of object Change Log	21/05/19 21:48
Baseline Deviation	Not Risky Change	CP - Asset attribute 'Generator Count' of object Change Log	21/05/19 21:48
Baseline Deviation	Not Risky Change	CP - Asset attribute 'Model' of object Change Log	21/05/19 21:48
Baseline Deviation	Not Risky Change	CP - Asset attribute 'Vendor' of object Change Log	21/05/19 21:48
Baseline Deviation	Not Risky Change	CP - Asset attribute 'Vendor and Product Code' of object Change Log	21/05/19 21:48
Baseline Deviation	Not Risky Change	CP - Asset attribute 'State' of object IOD Definition	21/05/19 21:48
Baseline Deviation	Not Risky Change	CP - Asset attribute 'State' of object IOD Map	21/05/19 21:48
Baseline Deviation	Not Risky Change	CP - Asset attribute 'Model' of object IOMap	21/05/19 21:48
Baseline Deviation	Not Risky Change	CP - Asset attribute 'ThreatName/Status' of object Threat	21/05/19 21:48

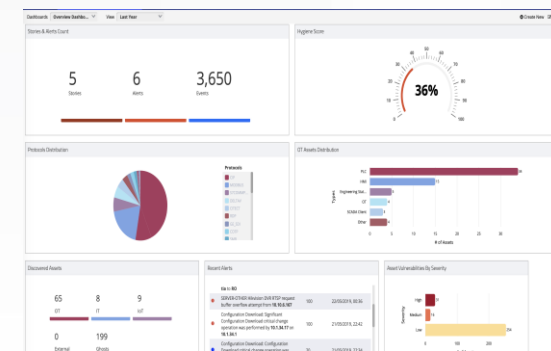
Configuration Download
An error may occur if you attempt to download configuration data from a PLC while the PLC is running and as a result steps functioning may be lost.

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客製化面板

提供有關OT網路狀態的信息概覽

客製化面板，可以根據不同角色顯示不同訊息



Pharmaceutical Industry Leader



DETECT

Threat Detection Services



64 Sites

Globally

Pharma leader takes pro-active security countermeasures

CHALLENGE

A renowned pharmaceutical company required a fast, scalable, and comprehensive OT cyber strategy to mitigate quantifiable business risk to their enterprise.

SOLUTION

The customer implemented network segmentation of their logical and physical networks at 64 sites across their enterprise. They then introduced Threat Detection Services to gain a daily inventory of system assets including vendor, model, OS, version, and firmware information - while creating a real-time threat intrusion view environment.

CUSTOMER OUTCOME

With the help of Rockwell Automation, the customer developed a comprehensive strategy across the attack continuum, changing their security culture while deploying solutions quickly, in a globally consistent manner.

Challenge

- Upgrade and merge aging EMS and BMS to optimize production and improve data visibility
- Maintain production and regulatory compliance during cutover

Obsolete systems were negatively impacting production and regulatory compliance and restricting data visibility and access.

Solution

- Unified system through PlantPax[®] DCS
- Strategic implementation schedule that optimized already scheduled plant shutdowns

A virtualized system environment was chosen to **improve reliability and maintainability.**

Results Achieved

Phase 1 cutover in only 7 days

Subsequent installations based on criticality, number of I/O points and shutdown duration.

Agenda

無資料斷點
的數據流

高韌性
數位骨幹

自主可控彈
性生產

分析賦能生
產運營

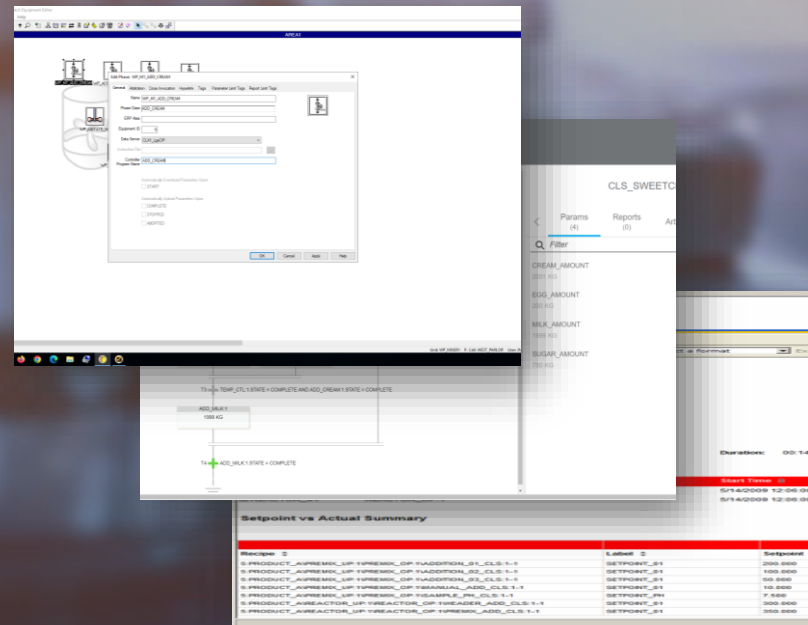
Automation

BATCH SEQUENCING

- Material Manager
- Phase Manager
- Sequence Manager
- Manual Procedure integrated
- 11 Standard Batch Reports
- Batch Phase Simulator
- Batch Performance Analytics
- Integration with ERP/MES
- Enable Golden Batch Application

Information

BATCH MANAGEMENT



先進批次控制系統

加速上市

少量多樣的批次生產

提升產能使用率

產品/批次參數可追溯

Robot and Independent cart technology

A Flexible and Worry-Free System

Vial filling

Compounding lab

Central fill pharmacy

Secondary packaging



MagneMover LITE transporting vials of blood between testing stations

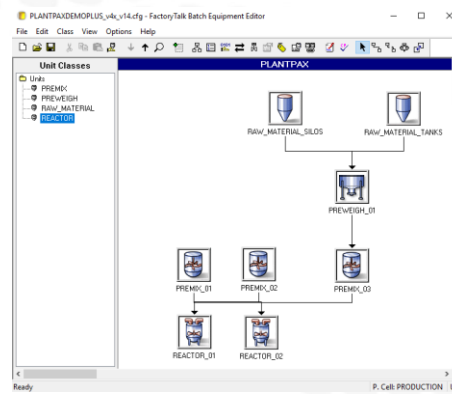
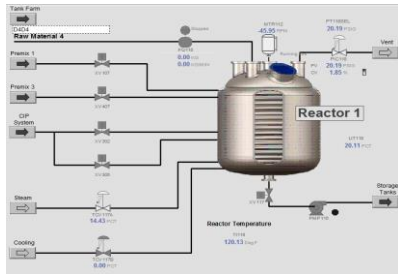
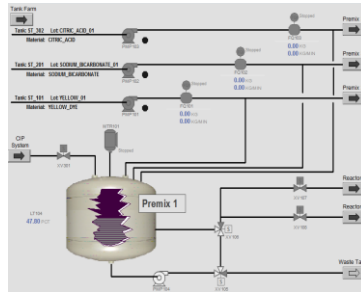
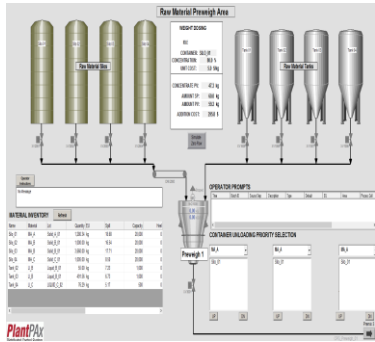
Higher
throughput

Built-in
traceability

Increased
uptime

Modular, clean
transport

S88物理模型劃分



預稱重



PREWEIGH_01

預混合



PREMIX_01

反應器



REACTOR_01

手動操作模組



PM01_MANUAL_ADD



PM01_SAMPLE_PH

攪拌模組



MTR112

0.00 RPM

Stopped

出料模組



PMP115

XV 117

溫控模組



Product Temp

TIC116

PV 71.80 DEGF

SP 0.00 DEGF

CV 17.85 %

TCV117A

0.00 %

Process Cell

Unit

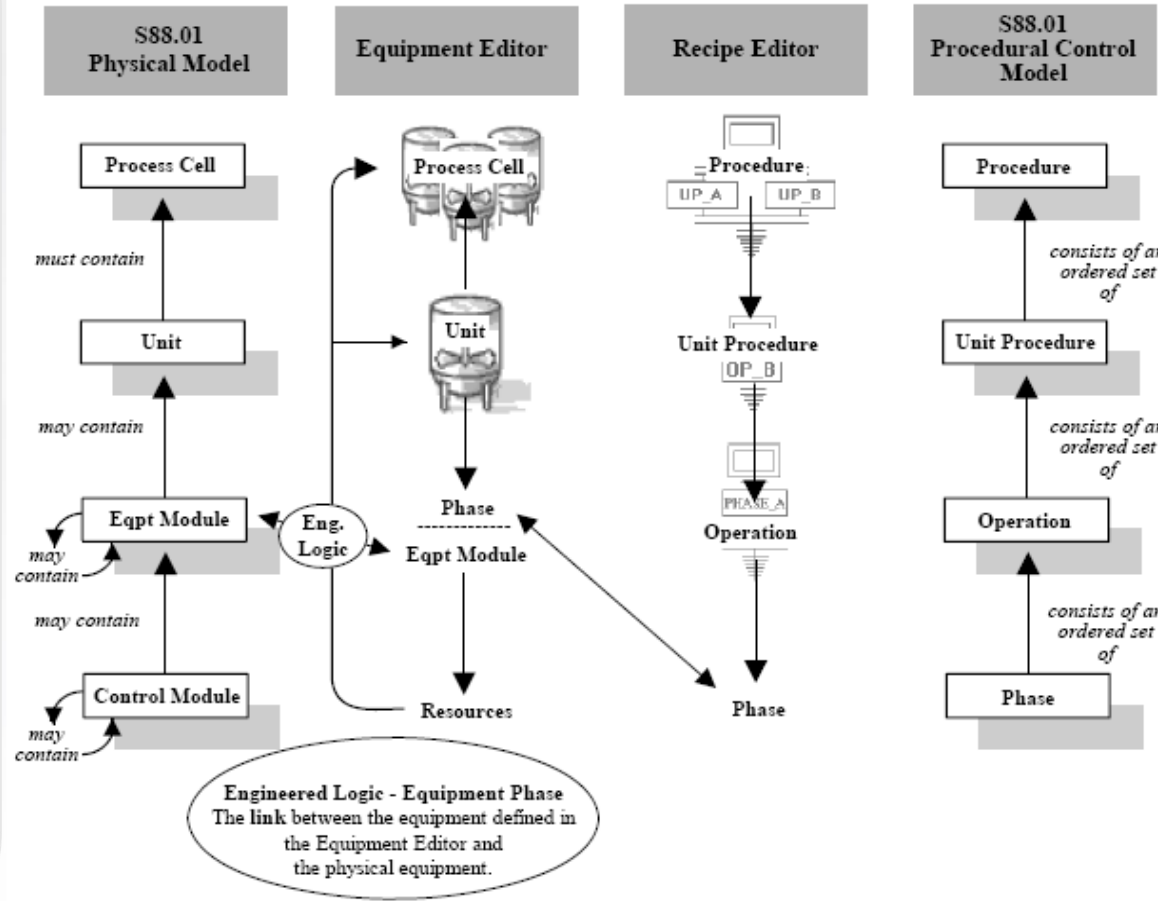
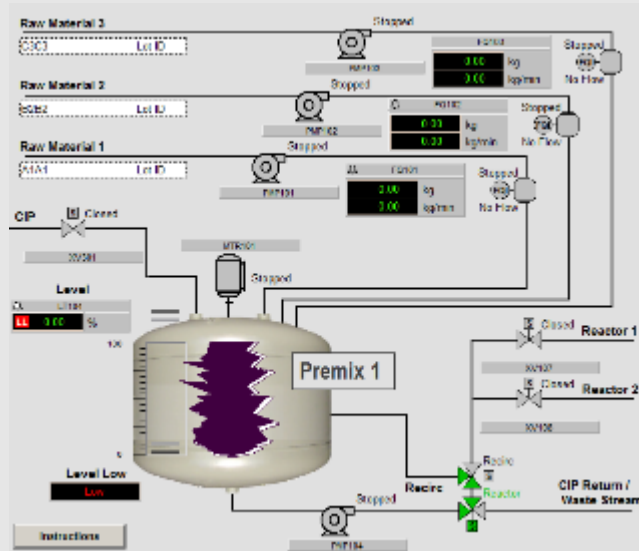
Equipment Phase / Module

Control Module

從S88模型到軟體架構的應用

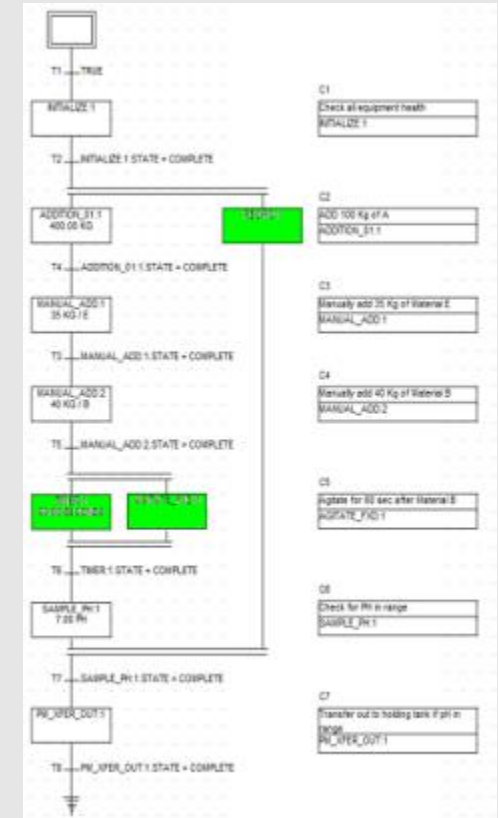
Equipment

What are the capabilities of my equipment (and personnel)?



Procedure

What are the steps?





產線工業設備整合

工業資產的即時連接

快速獲取標籤的走勢分析

各種廠房Protocol 串接

所有OPC伺服器安裝狀態監控

即時報告通信故障

對任何標籤資料在幾分鐘內定義警告

Driver List		
ABB Totalflow	GE Ethernet Global Data	SattBus Serial
Advanced Simulator	GE SNP	Scanivalve Ethernet
Allen-Bradley Bulletin 1609	GE SNPX	Siemens S5 (3964R)
Allen-Bradley Bulletin 900	Hilscher Universal	Siemens S5 (AS511)
Allen-Bradley ControlLogix Ethernet	Honeywell HC900 Ethernet	Siemens S7 MPI
Allen-Bradley ControlLogix Slave Ethernet	Honeywell UDC Ethernet	Siemens S7-200
Allen-Bradley DF1	Honeywell UDC Serial	Siemens TCP/IP Ethernet
Allen-Bradley DH+	IA Super SEL	Siemens TCP/IP Slave Ethernet
Allen-Bradley Ethernet	Idec Serial	Simatic/TI 505 Ethernet
Allen-Bradley Micro800 Ethernet	IEC 60870-5-101 Master	Simatic/TI 505 Serial
Allen-Bradley Micro800 Serial	IEC 60870-5-104 Master	Simulator
Allen-Bradley Slave Ethernet	IEC 61850 MMS Client	SIXNET EtherTRAK
Alstom Redundant Ethernet	IOtech PointScan 100	SIXNET UDR
Analog Devices	KraussMaffei MC4 Ethernet	SNMP
Aromat Ethernet	Lufkin Modbus Serial	SquareD Serial
Aromat Serial	Memory Based	System Monitor
AutomationDirect DirectNet	Mettler Toledo Serial	Telemecanique Uni-Telway Slave
AutomationDirect EBC	Micro DCI	Thermo Westronics Ethernet
AutomationDirect ECOM	Mitsubishi CNC Ethernet	Thermo Westronics Serial
AutomationDirect K Sequence	Mitsubishi Ethernet	TIWAY Host Adapter
AutomationDirect Productivity 3000 Ethernet	Mitsubishi FX	Torque Tool Ethernet
BACnet/IP	Mitsubishi FX Net	Toshiba Ethernet
Beckhoff TwinCAT	Mitsubishi Serial	Toshiba Serial
Bristol BSAP IP	Modbus ASCII Serial	Toyopuc PC2 Serial
Busware Ethernet	Modbus Plus	Toyopuc PC3/PC2 Ethernet
Contrex M-Series	Modbus RTU Serial	Triconex Ethernet
Contrex Serial	Modbus Slave RTU Serial	U-CON (user-configurable)
Custom Interface	Modbus TCP/IP Ethernet	Wago Ethernet
Cutler-Hammer D50/300	MTConnect Client	Weatherford 8500 Serial
Cutler-Hammer ELC Ethernet	ODBC Client	WITS Level 0 Active
Cutler-Hammer ELC Serial	Omni Flow Computer	WITS Level 0 Passive
Dataforth IsoLynx	Omron FINS Ethernet	Wonderware InTouch Client
DDE Client	Omron FINS Serial	Yaskawa Memobus Plus (SA85)
DNP Master Ethernet	Omron Host Link	Yaskawa MP Series Ethernet
DNP Master Serial	Omron NJ Ethernet	Yaskawa MP Series Serial
EFM Simulator	Omron Process Suite	Yokogawa Controller
Enron Modbus	Omron Toolbus	Yokogawa CX Ethernet
Fanuc Focas Ethernet	OPC DA Client	Yokogawa Darwin Ethernet
Fanuc Focas HSSB	OPC UA Client	Yokogawa Darwin Serial
Fisher ROC Ethernet	OPC XML-DA Client	Yokogawa DX Ethernet
Fisher ROC Plus Ethernet	Optimation OptiLogic	Yokogawa DX Serial
Fisher ROC Plus Serial	Opto 22 Ethernet	Yokogawa DXP Ethernet
Fisher ROC Serial	Partlow ASCII	Yokogawa HR2400 Serial
Fuji Flex	Philips P8/PC20	Yokogawa MW Ethernet
GE CCM	Ping	Yokogawa MX Ethernet
GE Ethernet	SattBus Ethernet	Yokogawa YS100 Serial

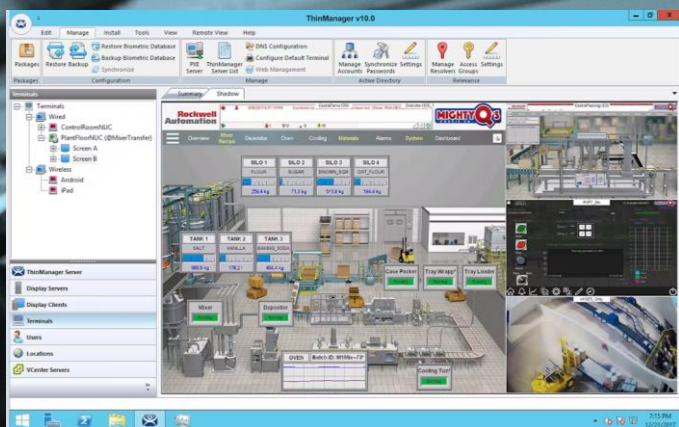
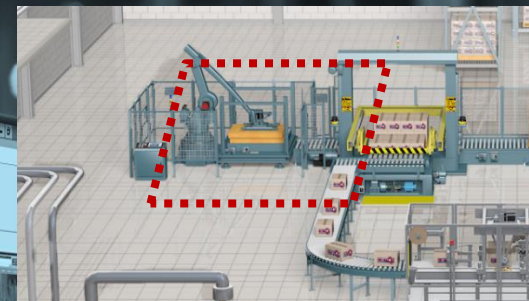
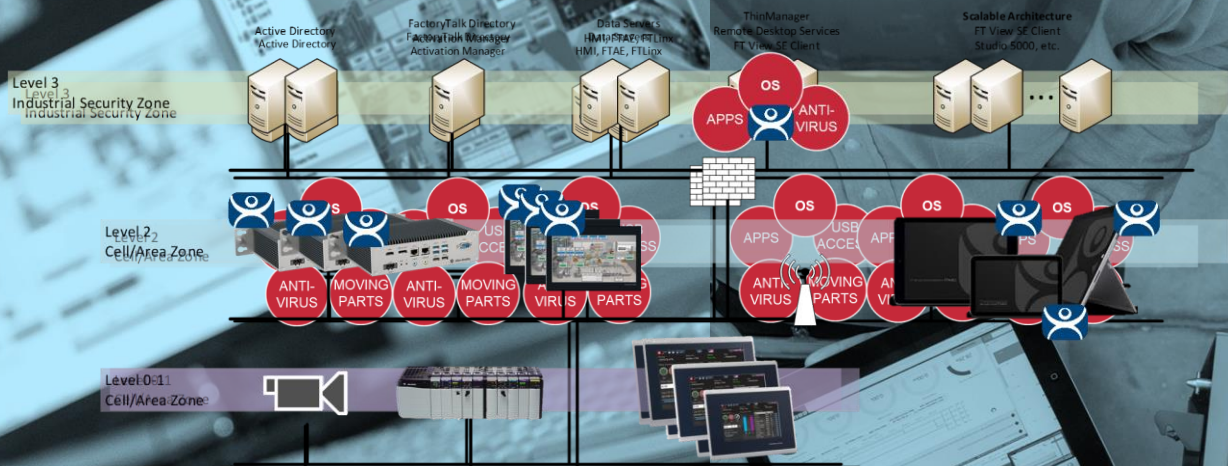
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中央管理裝置使用

行動化運營系統

SCADA/CCTV 連動整合



多系統/產線整合

HMI | Multiple SCADA | MES | ERP | Analytics Software | CCTV

Content Types

Remote Desktop
Server Applications



VNC Server
PanelView™ Plus,
Panelview™ 5000



Terminal Shadow



Web Content



IP Cameras
USB Cameras



Configuration



Management



Container Images



Hardware

Delivery

DEVICES



USERS



LOCATIONS



EVENTS



Events can be internal to ThinManager or from external sources and trigger a wide variety of actions

Biopharmaceutical Industry Success: BeiGene

IIOT platform

MES

Integrated
Batch

Track & Trace
Serialization

Production
Intelligence

Control system

QMS/BMS

IT/OT infra
Cybersecurity

MES Implementation



Integration between systems to reduce manual records

Realize data integration with about 700 points of DHS, automatic acquisition of process parameters in DS and DP production process, reduce manual input and reduce quality risk.

Realize the integration of Modbus of Sartorius scale in DP workshop preparation room I and preparation room II, and save the original offline manual recording work;

Realize the integration with E-Coding packaging finished product output data, save the original offline manual input work, and reduce the quality risk;

Interface integration for SAP.

Electronization of a large number of paper records to improve efficiency and reduce quality risks

The DP workshop generates a real-time material requisition according to the work order, which improves the material requisition efficiency and reduces the quality risk.

Realize the time control of stock solution transfer, cover opening, thawing and filtration in DP workshop, and record, calculate and control the defogging time and the exposure time of each pallet of products at room temperature in lamp inspection/packaging posts, so as to improve production efficiency and reduce quality risks;

When the batch record is released, it is judged that the key parameter report has been signed and reviewed, so as to improve the efficiency of QA batch record release and reduce the quality risk.

Control the use of non-BOM materials reused in DS and DP workshops according to the number of times, and scan, identify and consume substitute materials.

Automatic report generation, timely and accurate analysis

Exception Summary Report

Key Quality Parameter Report

Production Time Used Inquiry Report of Product Batch

DS Batch Record Summary Inquiry Report

Pallet Exposure Time Summary Report



Get to market quickly



Production Efficiency



Compliance



Quality

Automation

Agenda

無資料斷點
的數據流

高韌性
數位骨幹

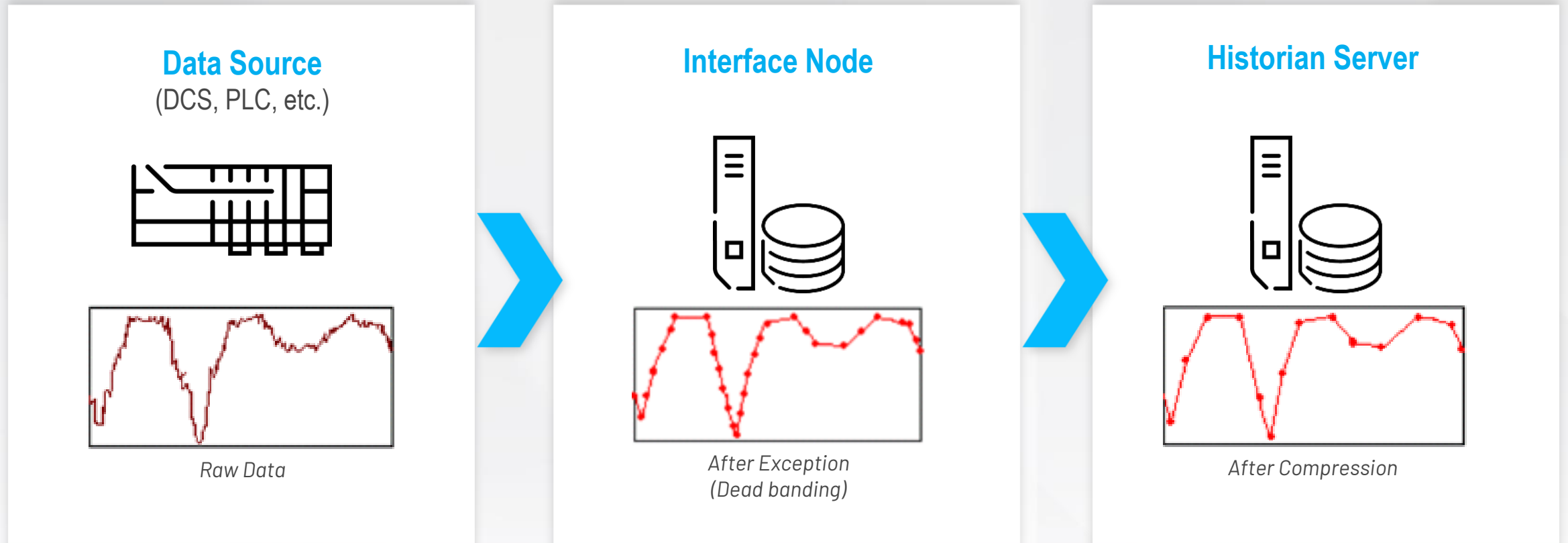
自主可控彈
性生產

分析賦能生
產運營

實時數據庫 vs 關係數據庫

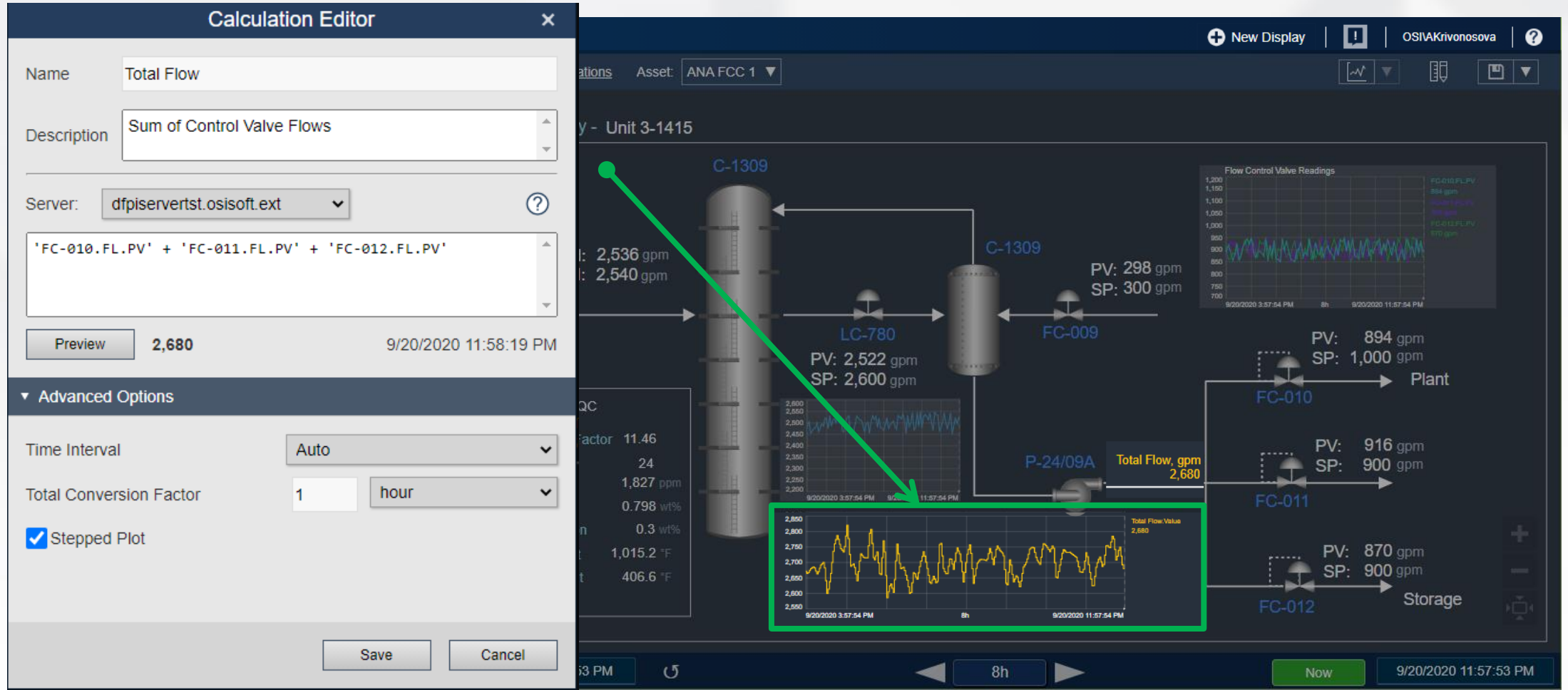
	實時數據庫	關係數據庫
應用領域	應用於電力、石油、化工、半導體、冶金、水處理、和醫藥等大量時序行數據領域	應用於電子商務、事務性管理、金融管理等領域
開發初衷	處理實時變化的數據。維護數據的實時性、真實性，滿足工業生產管理、實時應用的需要	處理相對穩定具有一定關係的數據。 維護數據的完整性、一致性。
運行方式	按時間序列儲存、查找	二維表格
讀寫速度 (/ 秒)	1,000,000	3,000
歷史數據壓縮	有	無
硬碟空間使用 硬碟大小: 4G 紀錄頻率: 1 次/秒 點數 : 100,000點	半年	5 小時

實時數據庫在廠房端的應用

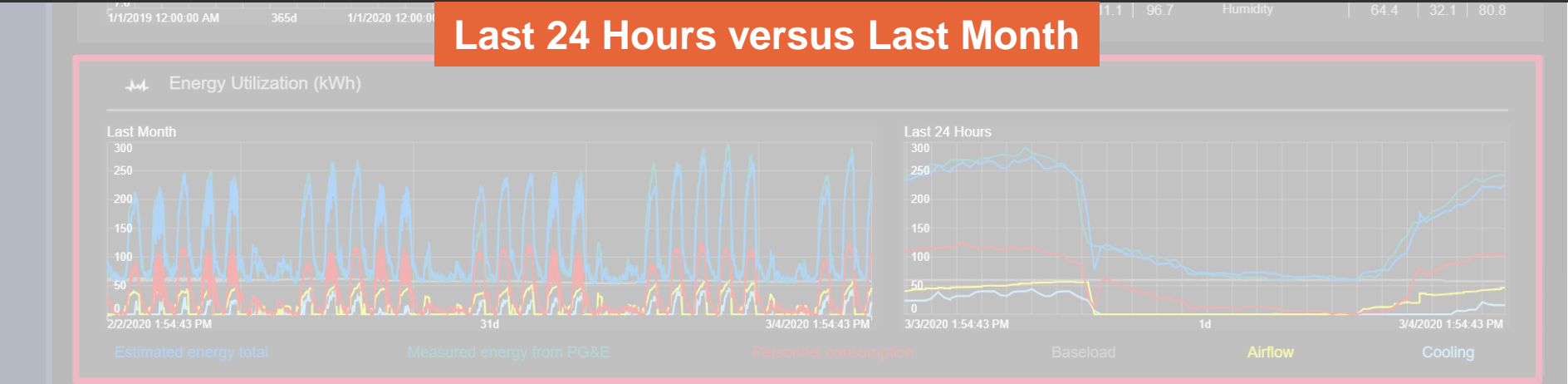
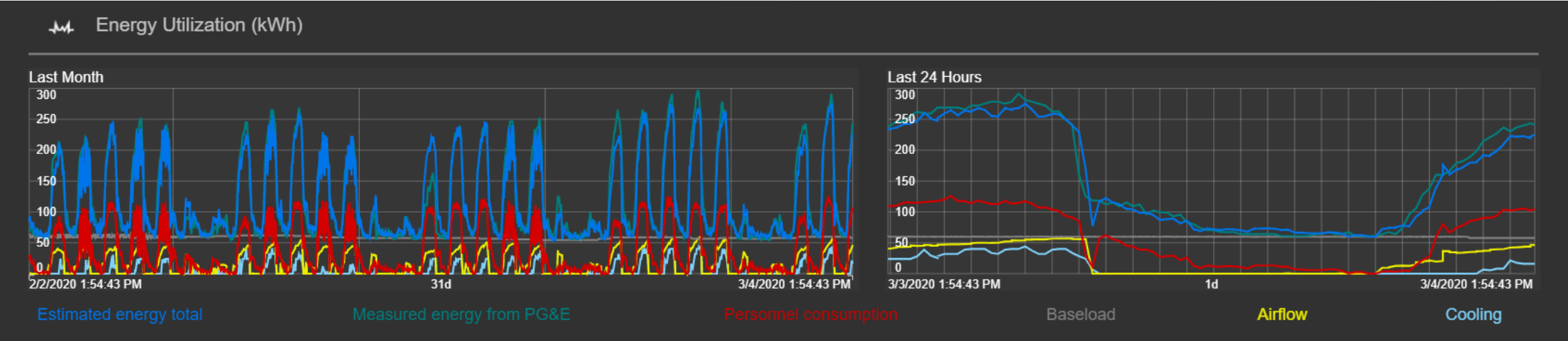


Data storage requirements greatly reduced with optimized fast retrieval compared to SQL database historians

Self-Service Dashboard 協助生產單位進行實時數據分析



Self-Service Dashboard 協助生產單位進行實時數據分析



透過OEE數據實現精實管理



Key Performance Indicator (KPI)

Available Time = $\frac{\text{Shift time} - \text{Unavailable Time}}{\text{Shift time}}$

Availability% = $\frac{\text{Running Time}}{\text{Available Time}}$

Performance% = $\frac{\text{Total} * \text{Ideal Cycle}}{\text{Running Time}}$

Quality% = $\frac{\text{Total} - \text{Scrap}}{\text{Total}}$

Overall Equipment Effectiveness (OEE) =
Availability x Performance x Quality



Time (One Shift)

Available Time

Running Time

Production @ Rated Speed

Good Production

OEE %

Sched
Unavail

Down
Time

Speed
Loss

Scrap

Lost
Capacity%



Loss Causes

Scheduled Unavailable Time
Breaks, meetings, maintenance, etc.

Downtime
Breakdowns, setups, changeovers

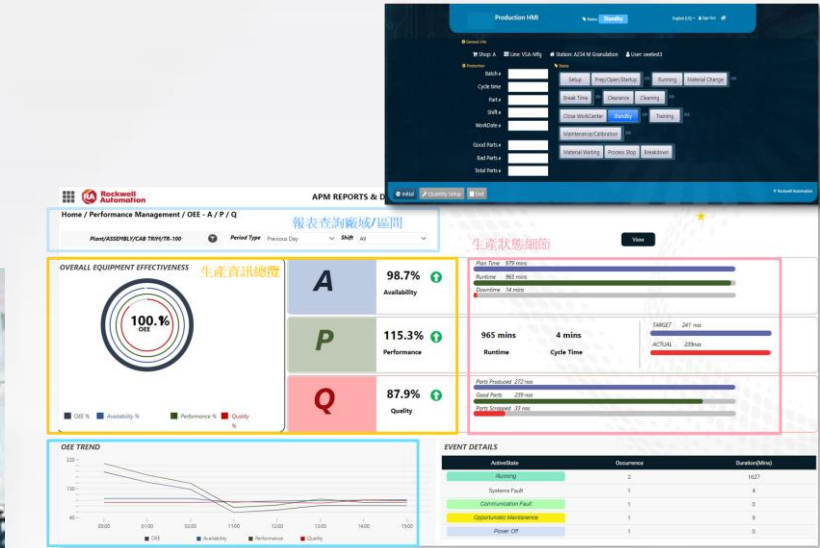
Speed/Cycle Time Loss
Reduced speed, cycle time variation

Quality Loss
Rejects, scrap

透過OEE數據實現精實管理



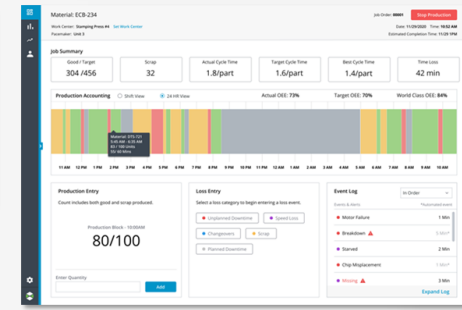
Paper based Manual OEE



工班狀態判讀

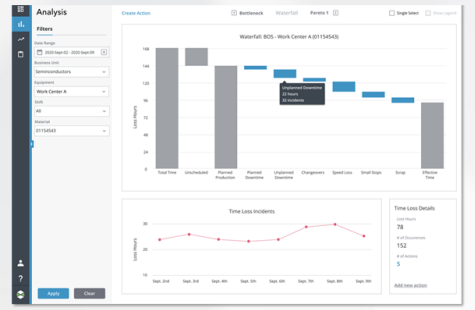
Digital OEE on a few key assets
Limiter causal information captured

Visualize



Extensive Plant/Line Digital OEE
Detailed causal information captured
OEE Reporting and analytics

Benchmark

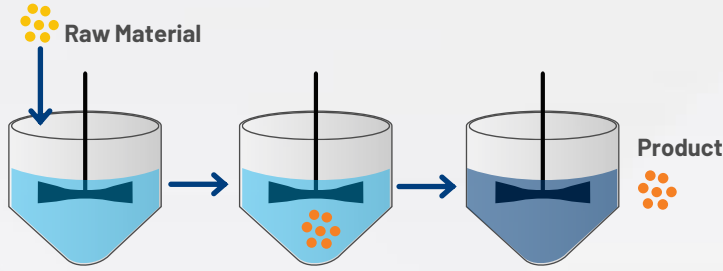


Enterprise OEE
Standardised Automatic OEE at sites and OEE rollup information across the enterprise

Optimize

透過批次表現分析進行生產最佳化

Control Process Variability through a "Golden Batch" Framework



Golden Batch		
t = 0.5 hours	t = 2 hours	t = 4 hours
t = 0.6 hours	t = 2.3 hours	t = 3.9 hours
t = 0.4 hours	t = 3.0 hours	t = 4.0 hours

Is the process displaying exceptional variation?

Process behavior control charts

How much variation? Where in the process?

Out of trends events analysis

Why? Are there any assignable causes?

Correlation analysis.
Predictive modeling

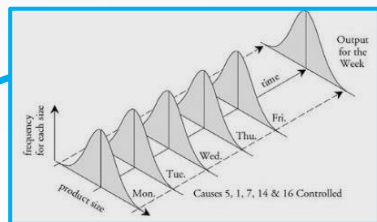
How can I fix it?

Manufacturing process
corrective actions

Is the fix effective?

1

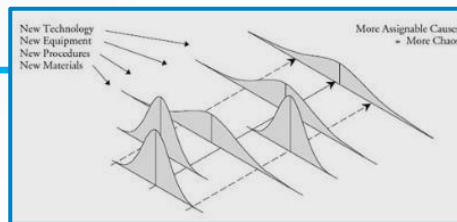
Establish / adjust baseline



Idealized concept of **routine variation** -> a process under control, predictable over time

2

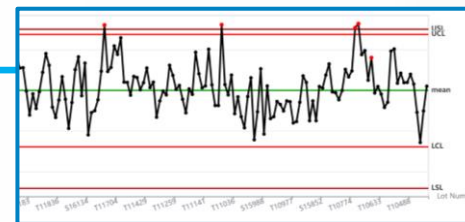
Detect and quantify variation



An illustration of **exceptional variation** -> a process out of control, unpredictable over time

3

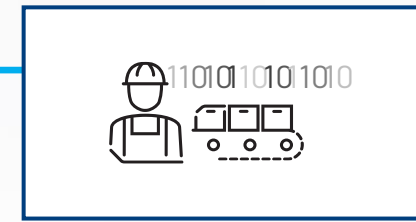
Identify root-causes



Real-time unit operation and batch performance against defined CPPs -> **temp out of control limits**

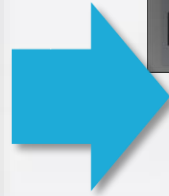
4

Take corrective actions



CPP adjustments through advisory closed-loop control

台灣某藥廠/生產精實管理



• 稼動計算

- 單機
- 產線
- 批次
- 工班

• 產線瓶頸分析

- Downtime
- Speed loss
- Availability
- Scrap
- Throughput

• 生產事件洞察

- MTTR/MTBF
- Alarm Analysis
- Shift Analysis

• 生產戰情

- ANDON
- 戰情室



Challenge

Reduce time from product inception to market by:

- Streamlining system deployment
- Reducing islands of automation
- Decreasing time gathering / cleaning data

A lot of time and money go into developing new pharmaceutical and medical products, and **there's a small window before patents expire.**

Solution

- Standardized digital libraries of tested code
- Data analytics that provide insights to improve operations
- Testing environment to iron out kinks before deployment

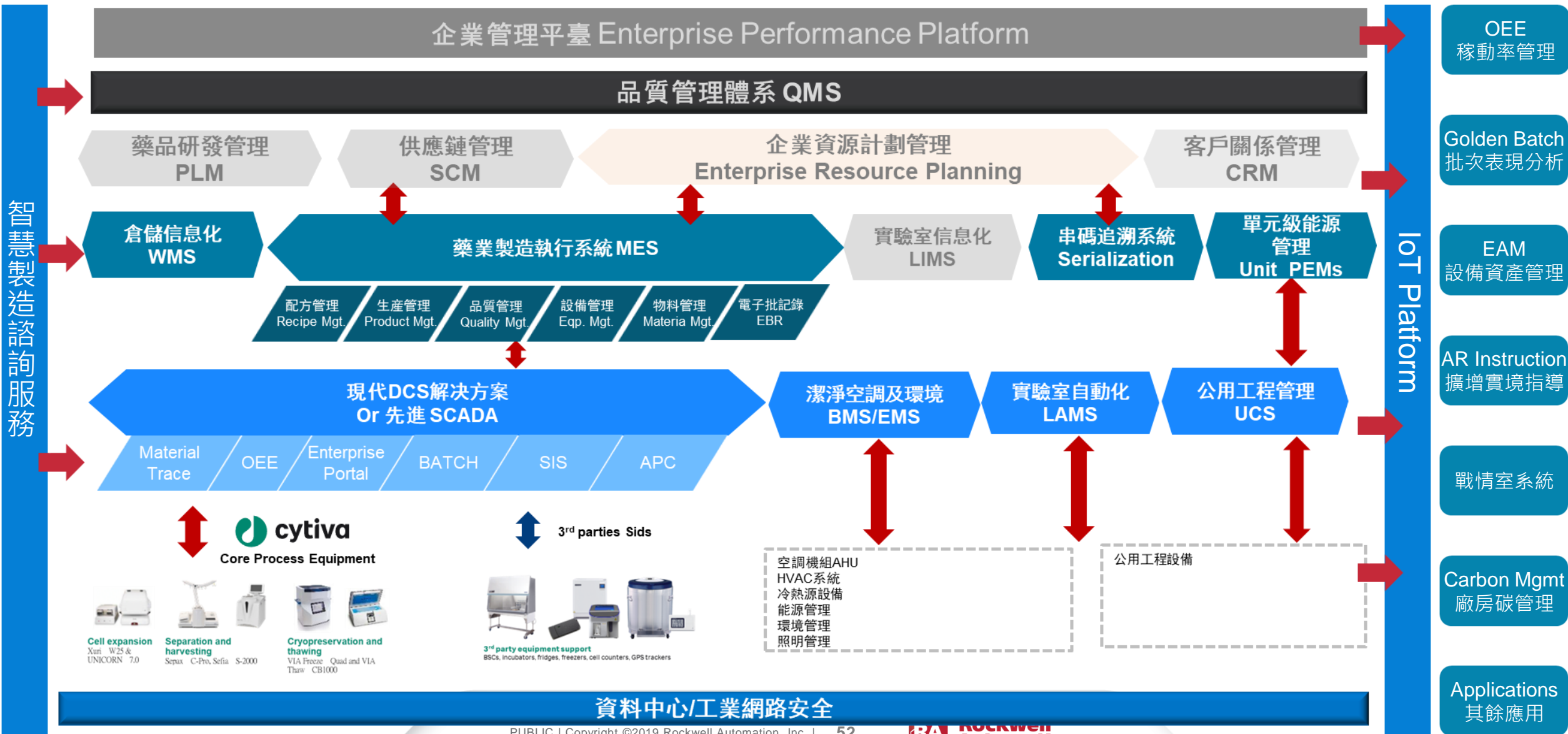
By automating processes and analyzing data, Cytiva helps customers **realize economies of scale with flexibility, efficiency and confidence.**

Results Achieved

**10 - 20%
increases in
production
throughput**

As well as 5 - 30% decreases in energy use, scrap material, batch release time, maintenance and downtime investigations.

國際製藥廠房標準解決方案



On a flexible, modular platform built with the future in mind

