



ROVISYS[®]

Automation & Information Solutions

**Data Integration –
Foundation for Digital Transformation**
資料整合 - 數位轉型的基礎

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Life Sciences



演講議程

1

公司概況

Company Overview

2

成熟度模型
數位化的推動因素

**Digital Plant Maturity Model
Drivers of Digitalization**

3

新興和現有設施對比
階段性實施-案例分享

**Greenfield VS Existing Facility
Stage Implementation - Case Study**

4

總結

Closure

Globally Located

North America



Ohio | Michigan | Illinois
North Carolina | Massachusetts
California | Texas | Georgia

Europe



Netherlands | Ireland

Asia Pacific



Singapore | Taiwan | Indonesia
Malaysia | Thailand



17

據點



1300+

員工



\$280MM+

營業額

4

業務規劃與物流

3

製造營運與控制

0,1,2

控制設備及裝置

- 批次系統 Batch
- 連續系統 Continuous
- 離散系統 Discrete

ERP – Level 4

- 生產計劃和訂單
- 生產計劃、庫存更新
- 生產能力、性能和成本
- 工業網絡安全& 網絡設計

製造執行 MES/MOM – Level 3

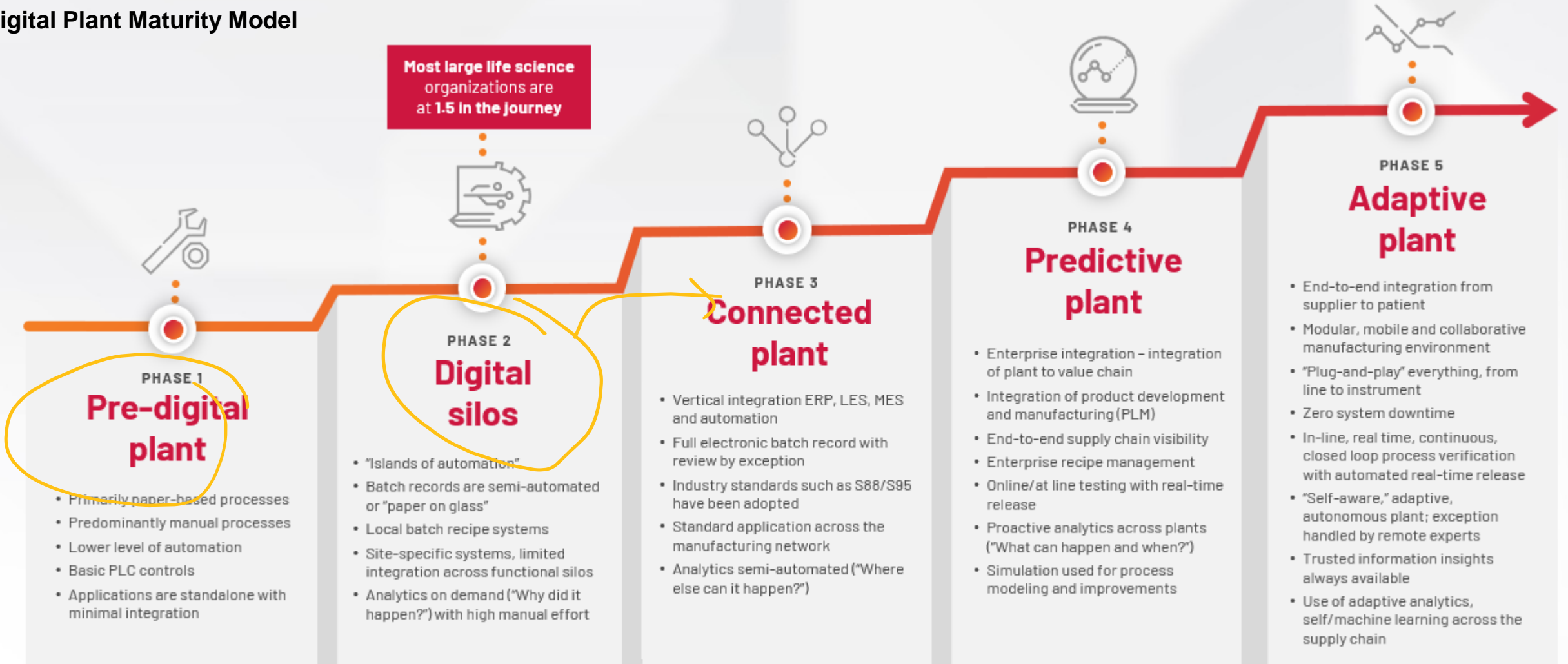
- 生產管理
- 性能分析
- 品質管理
- 生產跟蹤、樹狀圖、序列化
- 績效分析 – OEE、關鍵績效指標、停機時間
- 警報管理
- 即時品質系統 SPC/SQC/LIMS
- 文檔控制、電子批記錄
- 可視化
- 報告

自動化/製程控制 – Level 0, 1, 2

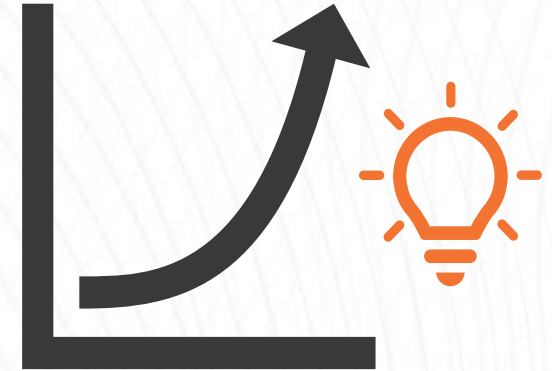
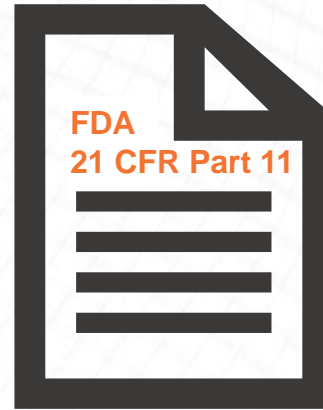
- 自動化規劃和設計
- 連續 & S88 批次控制與整合
- 電氣和網路設計
- 儀器儀錶規格
- 安裝/分接工程 & 管理
- 測試、試俾和驗證
- 培訓/支援

生物製藥 數位轉型 成熟度模型 階段

Digital Plant Maturity Model



數位化的推動因素 (Drivers of Digitalization)



- ▶ Increase process efficiency
- ▶ Reduce errors
- ▶ Eliminate Data Silos

消除數據孤島
提高流程效率
減少錯誤

- ▶ Data Integrity
- ▶ Quality Assurance and Compliance

數據完整性
品質保證與合規

- ▶ Actionable Intelligence
- ▶ Data-driven Decision Making

智慧化執行
以數據為導向的決策

新與現有設施對比 (Greenfield VS Existing Facility)



Greenfield Facility
新建設施

- 白板優勢 Blank Slate Advantage
- URS反映數位化目標 Digital Ambition in URS
- 自由採用最新技術 Latest Technologies
- 標準化 Standardization



Existing Facility
現有設施

- 老舊系統 Legacy infrastructure
- 異構環境 Heterogeneous Environment
- 數據孤島 Data Silos
- 整合複雜性 Integration Complexity
- 缺乏標準化 Lack of Standardization
- 遵從法規 Regulatory Compliance

我們應該如何開始？

案例分析 - 痛點 (Pain points)

L4
Business System Integration

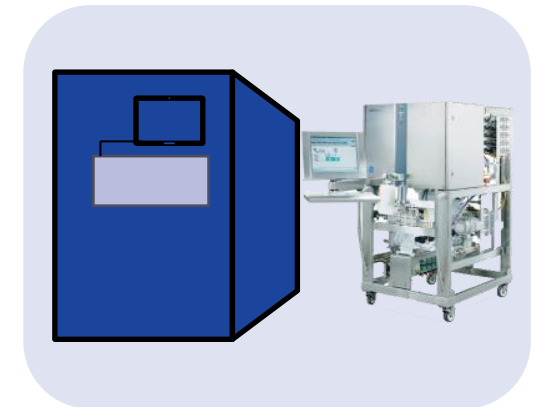
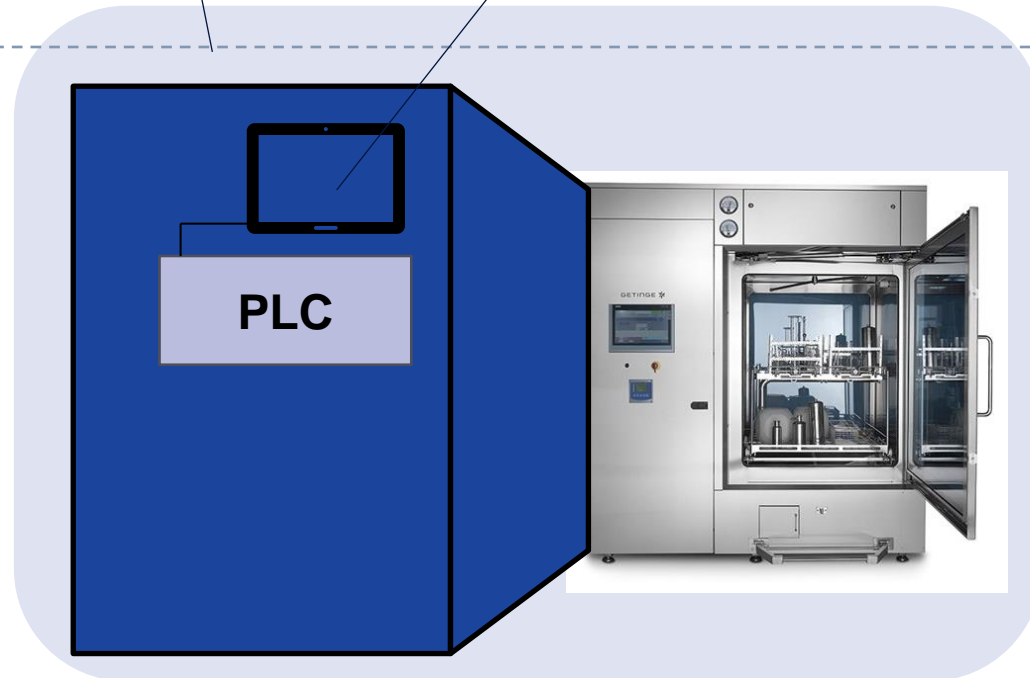
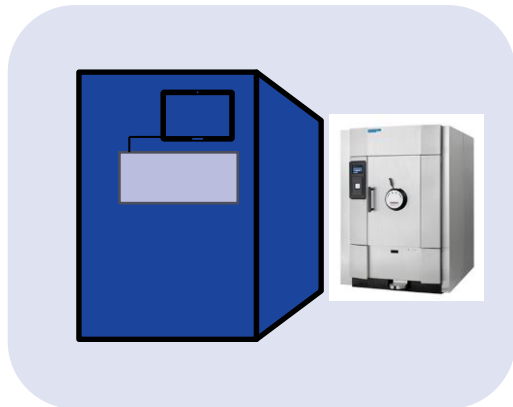
Data Data Data Data Data Data Data Data Data Data

舊式系統，數據孤島
無法即時遠端監控

資料分散，管理和傳輸，安全性風險高
許可權、密碼管理與維護
Windows 版升級

Data Data Data Data Data Data Data Data Data Data

L0 to L2
Supervisory Control
Process Control
Physical Plant Floor



案例分析 - 解決方案 (Solutions)

L4
Business System Integration

Data Data Data Data Data Data Data Data Data Data

Redundancy/Non-Redundancy



第 2 階段
數據整合與收集

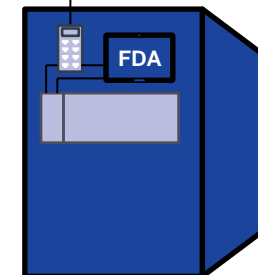
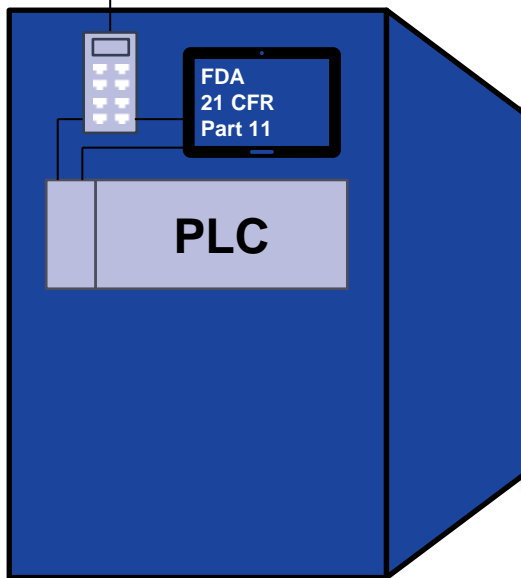
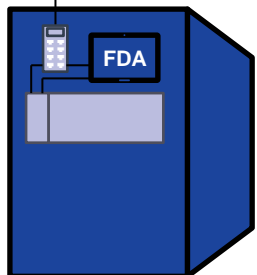
- Data Visualization & Analytics
- Batch Review by Exception

第 3 階段
數據可視化、報告及分析

Data Data Data Data Data Data Data Data Data Data

L0 to L2
Supervisory Control
Process Control
Physical Plant Floor

第 1 階段
評估與準備基礎設施



案例 – 第 1 階段

評估與準備 基礎設施

Assessment & Infrastructure Preparation



目的

舊系統升級
從廠房接入/連接

Upgrade of legacy system
Access/Connection to Shopfloor



挑戰

Windows 相容性
空間限制

Windows Compatibility
Space Constraints

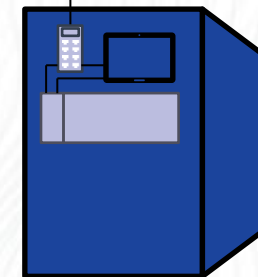
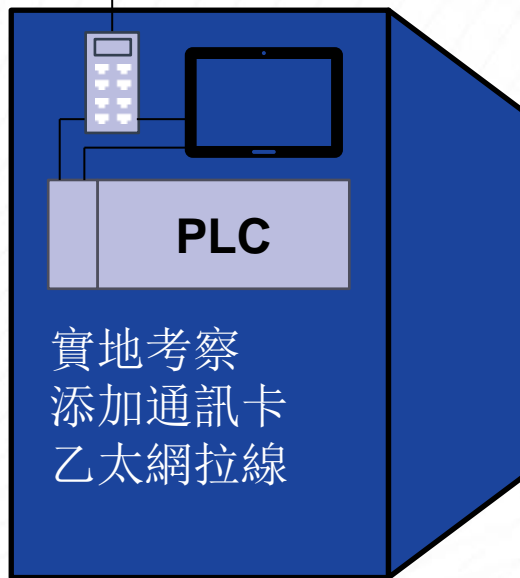
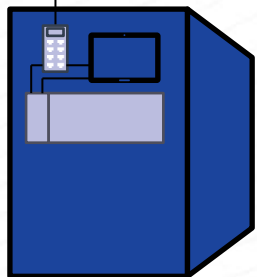
評估與準備基礎設施

L4
Business System Integration

Data Data Data Data Data Data Data Data Data

L0 to L2
Supervisory Control
Process Control
Physical Plant Floor

第 1 階段
評估與準備基礎設施



Data Data Data Data Data Data Data Data Data

評估與準備基礎設施

Automation / System Integrators



使用部門 System Owner

- Site visit (Physical Checkout)
- Downtime Availability
- SOP
- 實地考察
- 停機可用性
- 操作程序



IT部門 IT Stakeholders

- Compatibility with Windows OS
- Firewall Ports for Communication
- 軟體應與 Windows 操作系统相容
- 防火牆接口



QA部門 QA Stakeholders

- Migration Strategy
- Validation Plan
- 升級策略
- 驗證計劃

案例 – 第 2 階段

數據整合與收集 Data Integration and Collection



目的

數據整合與收集

數據完整性 糾正和預防措施

Data Integration and Collection

Data Integrity CAPA



挑戰

對系統的理解

不同的通訊協議

System Understanding

Different Communication Protocol

數據整合與收集

L4
Business System Integration



數據整合與收集

對系統的理解 (System Understanding)

- OEM 語言差異 Language Differences
- 引入哪類數據 Data to Collect

- Batch Info
- Recipe Parameters
- Critical Process Parameters (CPP)
- Critical Operations Alarm
- Abnormal States
- Data Type
- Units

滿足數據完整性的條件 (Data Integrity)

- 時間同步 Time Synchronization
- 使用者許可權 Domain User Access
- 密碼管理 Password management
- 審核軌跡 Audit Trail
- 資料存檔 Data Archive

- Traceable date, time and operator entries or actions.
- HMI time shall be able to synchronized automatically with the company time server.
- Logout user after 15 minutes of inactivity.
- Automatically locked after entering the wrong user password for 5 consecutive times.
- Access levels or user groups

案例 – 第 3 階段

數據可視化、 報告及分析

Data Visualization, reporting and analysis



目的

數據可視化
報告和分析

Data Visualization
Reporting and Analysis



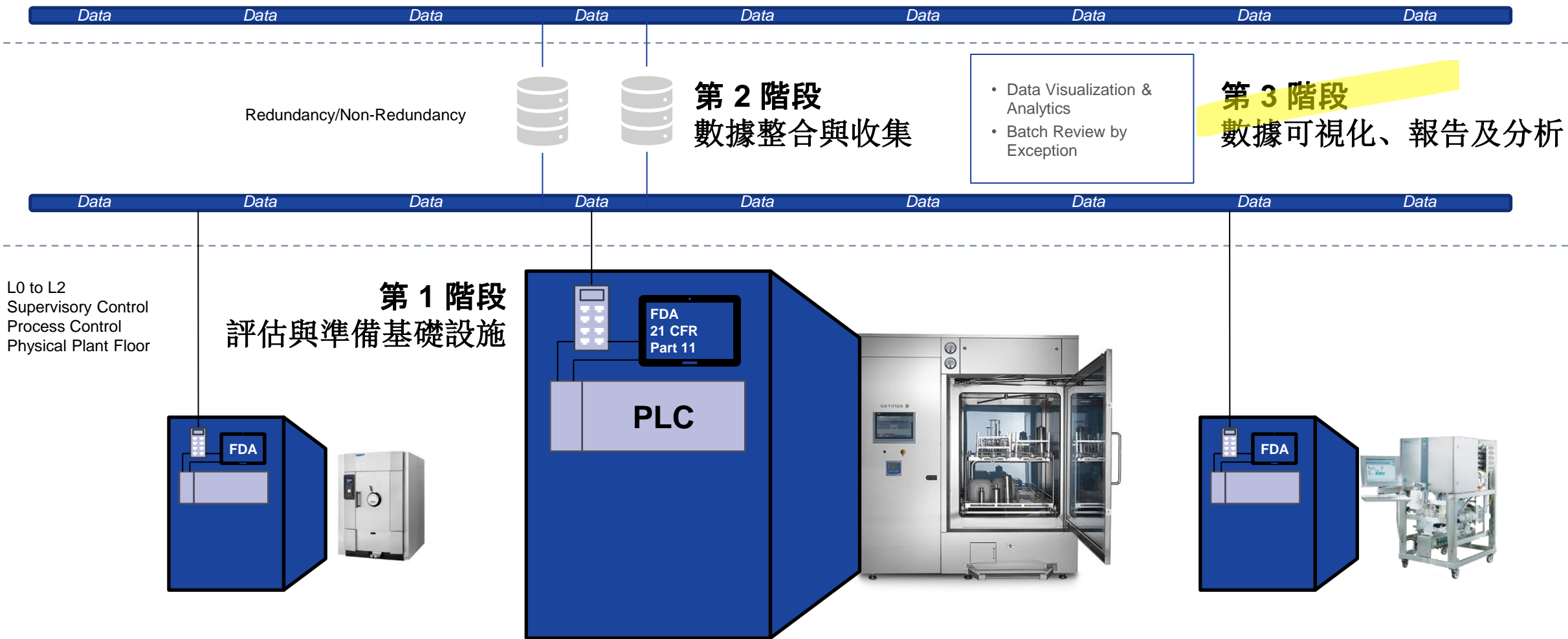
挑戰

儀表板與分析規劃
與不同的利益關係人協調報告模板

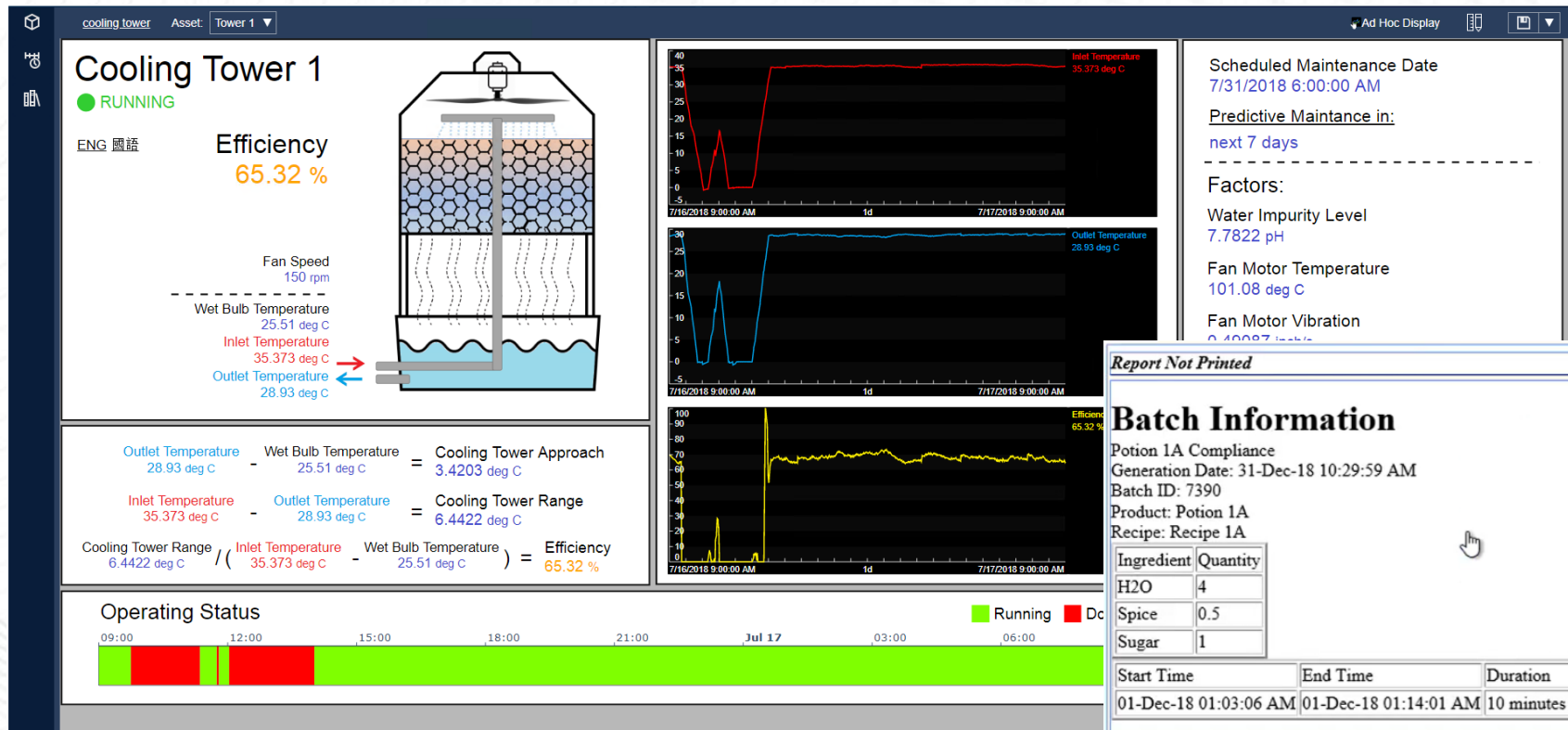
Dashboard & Analytics Planning
Coordination with stakeholders

數據可視化、報告及分析

L4
Business System Integration



數據可視化、報告及分析



不同的連接性和功能性

L4
Business System Integration



L3
Supervisory Control
Process Control
Physical Plant Floor

Redundancy/Non-Redundancy



Warehouse Management (wireless, barcoding)	<ul style="list-style-type: none"> • Recipe Management • Workflow Management • Track Production & Plant Performance 	<ul style="list-style-type: none"> • Process Historian • Data Visualization & Analytics • Batch Review by Exception 	Document Management
Enterprise Asset Management (Plant Maintenance)			Laboratory Information Management

L0 to L2
Supervisory Control
Process Control
Physical Plant Floor

Lab Instrument/Weigh Scales

Gateways & Communication Protocols
Water Bath, Magnetic Stirrer, Conductivity Meter, Filter Integrity Tester, Weigh Scale etc

Vendor Packaged Skid System

UF Skid, Chromatography, Autoclave, Partswasher etc

PCS/DCS, BMS/EMS

Downstream, Upstream, Utilities, BMS, EMS etc

Equipment Tracking

Equipment logbook, forms

階段性實施的範例 (Phase Implementation Example)



基礎階段 Foundation Phase

Goals

- Focus on **production execution** and **operational applications**, achieve **steady state operation**
- Lay **technical foundation** for cutting edge data analytics
- To realize **immediate returns**

Functionalities

- E-Log Book/Electronic Forms
- Migration / Upgrade of Systems
- Shopfloor Integration
- Process Historian
- Data Visualization



擴展階段 Extension Phase

Goals

- Further **enhance** production capabilities and workflows
- Realize further direct and indirect returns

Functionalities

- Achieve Dynamic Data / Reporting
- Critical Horizontal/Vertical Integration (SAP, LIMS, Equipment i.e. Scales)
- Recipe Management
- Product/Raw Material Tracking



規模階段 Scale Phase

Goals

- Leverage customer **scale of enterprise**
- Foundation for Data Mining
- Cutting edge **data analytics**

Functionalities

- Other Horizontal/Vertical Integration (Enterprise Data Integration)
- Additional Connected Digital Worker Applications
- Predictive Analytics

根據業務目標，決定功能在各個階段的配置



About Digital Transformation

Digital transformation the keyword is “**Transformation**”
核心重點是 “轉型” 本身

Instead of “One Size Fits All” approach,
customization is key
“一刀切” 的做法之外，接受客製化的必要性

Step by step, progressive.
Digital Evolution instead of digital Revolution
階段性實施。 進化而非數位化革命

Digitalization is **Not** Only an IT topic
數位化不僅僅是IT部門的責任

Infrastructure and Data Acquisition is first step of any
Digital Transformation
基礎設施和數據採集是數位化轉型的第一步