Next Generation Life Sciences Manufacturing

EcoStruxure™ powering digital transformation in regulated industries
Four key challenges faced by Life Sciences manufacturing

- **Time to market**: $2B@10yr
- **Compliance**: Up to $20M
- **Efficiency**: ~$50B
- **Flexibility**: ~1 day

Development cost and time for new entity¹
Warning letter costs, in worst case lost product and brand damage
Pharma waste per year due to inefficient manufacturing²
Future winners are building designs where changeover is done³

Sources: (1) McKinsey, (2) University research (3) Morten Munk, Director FUJIFILM
Think about it

What if you could:

• Associate a **digital twin** to the assets during their complete life cycle?
• Improve their **performance** and compliance before they are built?
• **Automatically** generate the code which will control them?
• Detect failures **before** they happen?
• **Train** and **guide** users in every task they must accomplish for operation and maintenance?

A digital twin can reduce simulation effort by 50% throughout a plant’s lifecycle.
EcoStruxure™ for Life Sciences manufacturing

Powering digital transformation in regulated industries and enabling factories of the future

DATA TRANSPARENCY
Real-time information aggregation across the value chain driving operations efficiency and agility

EMPOWERED WORKFORCE
Automate decision making and guide work processes for personnel

QUALITY and COMPLIANCE
Eliminate product and organization silos for improved yield and lead time, waste reduction and ease compliance, while ensuring safety and cybersecurity

DIGITAL and ENGINEERING
Improve asset utilization and OEE with adaptability, connectivity and digitalization of assets

INDUSTRIAL SUSTAINABILITY
EcoStruxure™ for Life Sciences manufacturing

Powering digital transformation in regulated industries and enabling factories of the future

**DATA TRANSPARENCY**
- Real-time information aggregation across the value chain driving efficiency and agility

**DIGITAL and ENGINEERING**
- Mitigate risks associated with potential failure of critical asset
- Minimize time with digitalization of GMP activities
- Ensure product attributes remain within compliance requirement
- Develop best-fit process to deliver consistent product quality
- Improve line performance and reliability

**ASSURE QUALITY and COMPLIANCE**
- Holistic approach across product life cycle and organization silos to reduce waste and improve lead time

**EMPOWER WORKFORCE**
- Automate decision making and work processes for personnel

- Real-time CQA measurement
- Digital aggregation, verification, analysis, and approval
- Real-time release testing
- Continuous material tracking
- Maintain and control operating condition within process spec.

- Developing best-fit innovative prototypes
- Deliver the right information at the right time
- Optimally allocate staff based on availability and competency
- Digital step-by-step guidance to ensure consistent actions
- Enable visualization of scenario to external expertise

*CAPA - Corrective and preventive action

Property of Schneider Electric | Page 5
EcoStruxure™ for Life Sciences manufacturing

Powering digital transformation in regulated industries and enabling factories of the future

**DATA TRANSPARENCY**
- Real-time information aggregation across the value chain driving efficiency and agility
- Data acquisition and management
- Advance business analytics and MVDA*
- Real-time visualization and dashboards
- Process orchestration for modular production
- Cybersecurity

**DIGITAL and ENGINEERING**
- Asset performance management
- Digital cloud-based validation
- Continuous process verification
- Digital twin
- Robotics and multi-carrier

**ASSURE QUALITY and COMPLIANCE**
- Holistic approach across product life cycle and organization silos to reduce waste and improve lead time
- PAT and inline monitoring
- Digital batch management and release
- Real-time release testing
- Continuous material tracking
- Advance process control

**EMPOWER WORKFORCE**
- Automate decision making and work processes for personnel
- Modelling and simulation
- Augmented and virtual reality
- Planning and scheduling
- Digital SOP and work orders
- Remote assistance and services

*MVDA - Multivariate Data Analysis*
Schneider Electric solutions enabling factories of the future

EcoStruxure for Life Sciences manufacturing

**DATA TRANSPARENCY**
- Real-time information aggregation across the value chain driving efficiency and agility
- Manufacturing Execution Systems (MES)
- HMI and data integration
- Real-time plant information system (OSI PI)
- Process control systems
- Packaging automation and robotics (incl. high speed)
- Supply chain traceability solutions

**DIGITAL and ENGINEERING**
- Ease compliance and improve OEE with adaptability, connectivity, and digitalization of assets
- Enterprise asset performance management
- Digital cloud-based validation
- Building Information Modelling (BIM)
- Integrated engineering design (CAD)
- Digital asset visualization
- Line and process optimisation

**ASSURE QUALITY and COMPLIANCE**
- Holistic approach across product life cycle and organization silos to reduce waste and improve lead time
- PAT and inline monitoring
- Digital batch management and release
- Electronic Batch Record Management (EBR and MBR)
- Materials inventory management
- Digital calibration management
- Clean-in-place management

**EMPOWER WORKFORCE**
- Automate decision making and work processes for personnel
- Operator training simulation
- Augmented and virtual reality
- Digital workflow management (AVEVA WORK TASK)
- Staff schedule management (POKA)
- Operator knowledge sharing
- Cybersecurity services

Property of Schneider Electric | Page 7
Data transparency

Real-time information aggregation across the value chain

**Improve performance with real-time data centric operations**
- Bring siloed data streams from plant to edge to cloud for enhanced analysis and automatic reporting of simple and complex situations
- Visualize real-time KPI performance, using tailored mobile-friendly dashboards and powerful graphics to drive data-driven business decisions
- Monitor and determine final production outputs, ensuring supply chain integrity from raw material acquisition to patient supply to plan and schedule effectively

**Minimize time and complexity for modular production**
- Employ pre-validated unit operations to interoperate with vendor-agonistic, data-centric, open automation standards enabling fast reconfiguration of lines to adapt to changing production requirement
- Synchronize coordination of process modules for batch orchestration and seamlessly integrate interfaces to databases from plant floor to ERP
- Leverage ready to use architectures templates and data framework minimizing engineering and validation effort, and simplifying complex control deployment
Digital and compliant

Ease compliance and improve OEE with adaptability, connectivity, and digitalization of assets.

Optimize from design and build to operate and maintain

• Merge real and virtual world data creating a digital twin, powered with simulation, to speed up design and construction, reduce costs, minimize risks, and foster greater collaboration over the entire project lifecycle

• Monitor assets operating conditions in real-time, identifying abnormalities and predicting failure points with advance data analytics to improve asset performance and life expectancy

Ease compliance with computerized systems

• Generate digital regulatory compliant reports ensuring data integrity with enterprise level reporting engine that is fully-configurable, enabling faster product release to market with exception reporting

• Reduce cost and time for validation using cloud technologies, automating the procedures and change management and enabling unprecedented levels of collaboration with remote management capabilities

Flexible packaging lines integrating robotics

• Synchronize activities of multiple machines and robots in the same line with single software suite, allowing easy line reconfiguration for faster product changeover and improved OEE
Assure quality and compliance
Holistic approach across product life cycle and organization silos to reduce waste and improve lead time

Minimize rejected product with built-in quality assurance
- Eliminate time-consuming and inefficient QC processes with real-time inline measurement of CQA’s, detecting early product abnormalities and adapt process parameters to avoid any potential product deviations
- Achieve consistent quality and higher yield with deep, root-cause analysis using multi-variate data analysis and control strategies that enable material tracking in both batch and continuous processes
- Automate flexible multi-stream recipe-controlled processes coordinating higher order process control and internal and external data sources, establishing a single view of all production event data, providing a fully compliant complete electronic batch record (EBR)

Reduce time and cost for bringing new product to market
- Evaluate fast scale-up control strategies for manufacturing, building upon deep product and process knowledge gained in development
- Fast track regulatory approval with complete data transparency and risk-based digital tools that use scientific methodology for decision making
Empower workforce

Automate decision making and work processes for the personnel

**Ease decision making with digital technology**

• Connect worker with digital tools such as augmented reality (AR) and virtual reality (VR) to train and guide on complex procedures and maintenance tasks, improving their productivity and safety

• Implement digital SOP workflow solutions, eliminating paperwork and human error prone procedures

• Reduce key process variability and increase profitability with Advance modelling and simulation tools

• Use cloud technologies to foster collaborations and knowledge sharing across enterprise, and better equip workers to adapt to changing production requirements

**Keep on track with planning and services**

• Leverage our expertise and field experience to assess risk and provide insight for performance improvement opportunities

• Enhance staff skills with training programs using practical, hands-on exercises replicating real scenarios

• Get remote assistance and spare parts availability 24/7 globally for faster resolution of issues
Defining the transformation model for Digital Plant Maturity

Digital Plant Maturity Model (DPMM) for bio manufacturers

Pre-digital plant

- Manual, paper-based processes
- Predominantly paper-based processes
- Low level of automation
- Basic PLC control
- Stand-alone application with minimal or no integration

Digital silos

- Islands of automation
  - Some manual processes
  - Batch records may be semi-electronic or “paper on glass”
  - Local batch-recipe system interfaced to PLCs
  - Site-specific systems; limited integration across functional silos
  - Analytics on demand, “why did it happen?” high manual effort

Connected plant

- High level of automation, integration and system standardization
  - Vertical integration
  - ERP, LES, MES, and automation layer are fully integrated
  - Full electronic batch record with review by exception.
  - Standard application platform adopted across plant network
  - Islands of real-time process analytics
  - Analytics semi-automated, “where else can it happen?”

Predictive plant

- Integrated plant network, pervasive real-time predictive analytics
  - Enterprise integration
  - Integration of product development and manufacturing
  - End-to-end supply chain visibility with limited external partner
  - Online/at-line quality testing with real-time release
  - Simulation used for process modeling and improvements
  - Integrated real-time process analytics and simulation
  - Proactive analytics, “what can happen and when?”

Adaptive plant

- Plant of the future, autonomous, self-optimizing, plug-and-play
  - Full end-to-end value-chain integration
  - IT supports manufacturing modes: Modular, continuous…
  - “Plug-n-play everything” from an instrument to a production scale
  - Zero system down-time (including upgrades) — continuous evolution
  - In-line, real-time, continuous, closed loop, process verification and control with automated real-time quality release
  - Self-aware, continuously adaptive, “Autonomous” plant
  - Pervasive use of adaptive analytics and self/machine learning
Digitization in Life Sciences industry

- **Optimize Operations**
  - Digital twin
  - Continuous process
  - Single use
  - In-line/PAT
  - Robotics
  - Power reliability
  - Environmental

- **Empower Employees**
  - IOT sensors
  - Analytics
  - Predictive process control
  - Digital recipe mgmt.
  - Performance mgmt.

- **Transform Offerings**
  - Real time visibility
  - Paperless operation
  - Monitoring/insights
  - Collaboration
  - Wearables (AR/VR)

- **Adopt New Business Models**
  - E2E visibility
  - Smart logistics
  - Smart sourcing
  - Integrated supply chain

- **Engage Your Customers**
  - Digital customer collaboration
  - Personalisation

---

Cost management

Revenue growth

Property of Schneider Electric | Page 13
1. Identify and develop a detailed roadmap to accelerate transformation of your operations to a fully adaptable digital Plant, through collaborative change management.

2. Justify business case with ROI and multi-year operational implementation plan.

3. Create real-time digital understanding through a data-centric source of contextualized data. Gain detailed visibility of plant status to make data-based decisions.

4. Connect workforce and machines through new technology adoption.

5. Improve Plant Efficiency, OEE, increase Production yield and assure quality compliance through QbD and real-time analytics.

Digital transformation consultancy

Accelerate the digital transformation of your operations with our industry experts’ support.
The future possibilities for Life Science Manufacturing with Industrial Sustainability

**Compliance**
100% paperless operations, cloud validation, upgrade in real-time, and digital conformance to data integrity

**Cost**
Drive value from CapEx improve asset utilization ~34% and OEE ~32%

**Quality**
10x transformation in process robustness and reliability to improve product quality and reduce the waste

**Speed**
70% reduction in new facility build times
80% reduction in production lead times
<1 day product release times

**Flexibility**
Product change over time: ~90% improved response to variability in demand and new products

---

Valpharma, San Marino
Development of the production technologies with drug prescription

Customer challenges
• Automated prescription management for production launch and production tracking
• Executable data record and management, meeting pharmaceutical regulatory standards
• BMS/EMS integrated in production

The solution
A complete EcoStruxure Plant solution, including:
• AVEVA software - system platform and InTouch software for HMI
• Prescription execution with Modicon PAC
• More than 60 inverters, soft starts
• Services: commissioning, start-up, procedure validation and maintenance

Customer benefits
• State-of-the-art system in terms of control electronics (15% paper reduction, 80% human error reduction)
• 100% paperless compliance with 21 CFR Part 11 and GAMP
• Full prescription confirmation
• Turn-key and trustworthy production data storage
• Faster (50% reduction in docs manual review) and safer operations

The results:
Life Is On with **increased and accurate production.**

Leading pharmaceutical developer and contract manufacturer with 40 years experience and a presence in 70 countries

The Schneider Electric industrial software business and AVEVA have merged to trade as AVEVA Group plc, a UK listed company. The Schneider Electric and Life is On trademarks are owned by Schneider Electric and are being licensed to AVEVA by Schneider Electric.
Customer challenge
• Need of an innovative solution enabling the diagnostic and maintenance of a syringe manufacturing machine
• Improve production machines performance to ensure quality of the product

The Solution
• EcoStruxure Augmented Operator Advisor

Customer benefits
• Real-time visualisation of all points of interest
• Contactless maintenance increasing operator safety
• Capitalize know-how in order to share with knowledge with all operator
• Efficient robust system for operations and better monitoring of production and ensure continuity of production with consistent quality
• Solution easy to integrate to existing machine

The results:
Life is On with the digital transformation of the maintenance, guaranteeing production continuity.

Link to video
Biotechnology corporation, US
Retrofit pharmaceutical manufacturing automation system

Customer challenge
Unpredictable downtime risk and low performance with aging hardware and high maintenance cost
- Distributed control system (DCS) with end-of-life in Oct 2020
- Hardware, software, and networks have limited capacity
- Spare parts scarcity and exponential price rise
- Certain third-party components no longer available
- Difficult to find skilled technical support and services

Solutions
Migration tool to Modicon M580 with very limited re-engineering; access risk and implement strategies for fast roll-out and lower downtime cost
- 100% like-for-like plug-in solution of current validated control logic software with same code structure and runtime behavior
  - Limited validation costs
  - Zero re-training of personals
  - Minimum impact on verticals such as HMI, batch manager, historian and MES
- Limited downtime and zero cabling errors with reuse of existing I/O terminals automated I/O mapping
  - Reuse of terminal assemblies to avoid re-cabling on site
  - Automatic generation of cable instructions

Customer benefits
- 20M$ savings in validation expected
- Keep unaltered all SOPs, trainings and all personnel knowledge on the process, debugging and coding
- Typical replacement of an individual controller in 20 minutes and full facility operation was restored in 2 hours

The results:
Life Is On with groundbreaking advancement in automation software engineering reduced retrofit risks and costs, and decreased unplanned downtime by 95%.
CVC technologies, Taiwan
Innovation through digitization

Customer challenges
To fully digitize their pharmaceutical liquid filling and capping machines with:
- Safer equipment
- Digital maintenance capabilities
- Visibility into machine status from anywhere at any time

The solution
CVC chose a complete EcoStruxure Machine solution, including digital services, because, unlike the competition, we could offer a full end-to-end IoT solution with strong technical support.

Customer benefits
- 30% faster commissioning
- Faster and more efficient maintenance, quality control and troubleshooting through real-time visibility into a machine’s status
- Improved safety and reduced human error by digitizing maintenance manuals
- Improved customer service to end user

The results: Life Is On with 100% digitized machines and 30% faster commissioning.

Video

World leader in the production of pharmaceutical packaging machines
Liaoning Chunguang Pharmaceutical Equipment Corp. Ltd.
China

Smart pharmaceutical packaging equipment solutions

Customer challenges
• Improve data traceability
• Improve machine performance, stability, and manufacturing capability
• Increase machine intelligence
• Accelerate R&D of new models to the market

The solution
Chunguang selected a full EcoStruxure Machine solution, including the digital services of EcoStruxure Machine Advisor, to digitize their pharmaceutical packaging machines.

Customer Benefits
• 50% reduction in energy consumption and costs
• 50% less downtime for higher production efficiency
• 50% faster commissioning time
• 50% less operating costs

The results: Life Is On with... 50% greater machine efficiency and 50% cut in energy usage.

“Schneider Electric’s EcoStruxure solution helps us become a ‘smart’ pharmaceutical equipment service solution expert in packaging.”

Bi Chunguang
Chairman, Chunguang Group

Leading builder of high-end, sustainable packaging equipment for the pharmaceutical, food, and chemicals industries, with 30 technology patents
Pressequip, France
Digital solution to produce protective masks

Customer challenges
• Pivot to new business stream after existing contracts were paused due to the pandemic
• Leverage workforce and expertise to design and improve mask production machines
• Contribute to fighting the pandemic by producing masks onsite for public use
• Digitize machines
• Fast and efficient solution for quick start-up

The solution
Having worked with Schneider Electric for over 15 years, Pressequip selected a complete EcoStruxure Machine solution for its 3-ply mask production machines, including the digital services of EcoStruxure Machine Advisor and the Modicon M262 IIoT-ready logic and motion controller.

Customer benefits
• 20% increase in profitability
• Optimized commissioning time
• Cybersecure, modular and flexible solution
• Full traceability
• Predictive maintenance to ensure production continuity

The results: Life Is On with new revenue stream and 20% increase in profitability.

Video
Blog

Designing and producing high-performance tailor-made cutting and stamping machines, robotics, and cobotics for maximum efficiency and profitability

Apps, analytics, and services
Edge control
Connected products

EcoStruxure Machine
EcoStruxure Machine Advisor
Modicon M262
Lexium LXM32
Customer challenges
• An integrated solution for building smart and compact packaging machines
• Ability to provide customized solutions for customers
• Improve efficiency and sustainability

The solution
OMAG selected to collaborate with Schneider Electric because it could deliver a complete, digitized EcoStruxure Machine solution that perfectly met their needs for motion control, automation, HMI, VVD, and robotics.

Customer benefits
• 20% energy savings
• Reduced cabinet space
• Integration of multiple solutions inside the same architecture
• Complete offer from single supplier
• Flexibility to tailor solutions and projects for customers
• Optimized maintenance processes

“Schneider’s offer has allowed us to compact our spaces, making our packaging machines more modular, high-performance, reliable, and today, it has also allowed us to make them ‘intelligent’ and interconnected with the cloud.”

Roberto FILIPPUCCI
Automation and Systems Manager
OMAG S.p.A.

Video

40 years of experience in the packaging industry, designing and building machines for sachet and stick packaging, filling, and complete lines for the pharmaceutical and food industries

EcoStruxure Machine

Apps, analytics, and services
Edge control
Connected products
PacDrive LMC Pro
Lexium ILM and ILD
Lexium ILM and robotics

“Schneider’s offer has allowed us to compact our spaces, making our packaging machines more modular, high-performance, reliable, and today, it has also allowed us to make them ‘intelligent’ and interconnected with the cloud.”

Roberto FILIPPUCCI
Automation and Systems Manager
OMAG S.p.A.

Video

40 years of experience in the packaging industry, designing and building machines for sachet and stick packaging, filling, and complete lines for the pharmaceutical and food industries

EcoStruxure Machine

Apps, analytics, and services
Edge control
Connected products
PacDrive LMC Pro
Lexium ILM and ILD
Lexium ILM and robotics

“Schneider’s offer has allowed us to compact our spaces, making our packaging machines more modular, high-performance, reliable, and today, it has also allowed us to make them ‘intelligent’ and interconnected with the cloud.”

Roberto FILIPPUCCI
Automation and Systems Manager
OMAG S.p.A.

Video