

Four key challenges faced by Life Sciences manufacturing



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?



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

EMPOWEREDWORKFORCE

Automate decision making and guide work processes for personnel



DIGITAL and ENGINEERING

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

QUALITY and COMPLIANCE

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

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

Data acquisition, integrity, and management

Root-cause analysis and CAPA

Monitor KPI progress and access actionable information

Maximize effective utilization of manufacturing capacity

Protect company IP and data integrity



DIGITAL and ENGINEERING

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

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

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.



EMPOWERWORKFORCE

Automate decision making and work processes for personnel

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





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

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

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





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



EMPOWERWORKFORCE

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





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 personals

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

Primarily paper-based processes

processes

Predominant manual processing

Low level of automation

Basic PLC control

Stand alone application with minimal or not integration

Digital silos

Islands of automation

Some manual processes

Batch records may be semielectronic 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, selfoptimizing, 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 w/ automated real-time quality release

Self-aware, continuously adaptive, "Autonomous" plant

Perv asive use of adaptive analytics and self/machine learning





Digitization in Life Sciences industry



Cost management

- . IOT cons
- Continuous process
- Single use

Digital twin

- In-line/PAT
- Robotics
- · Power reliability
- Environmental

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

- · Real time visibility
- · Paperless operation
- Monitoring/insights
- Collaboration
- Wearables (AR/VR)

- E2E visibility
- Smart logistics
- Smart sourcing
- Integrated supply chain

Digital customer

Revenue growth

- collaboration
- Personalisation



Digital transformation consultancy

- 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 datacentric 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.



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

Life Is Or



https://www.biophorum.com/wpc.ontent/uploads/bp_downbads.BioPhorum-TR-First-edition-biomanufacturing-executive-summary.pdf

^{2.} https://www.mckinsey.com/husiness-functions/operations/our-insights/fhe-hidden-value-of-improved-capital-expenditure-management-in-pharma

Eco ftruxure for Life Sciences: IoT-enabled platform for efficient manufacturing



Schneider Electric, Aveva, EcoStruxure, and Life Is On | Schneider Electric are trademarks of Schneider Electric SE, its subsidiaries, and affiliated comparies. All other trademarks are the property of their respective owners.

Version: June 2023





- 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

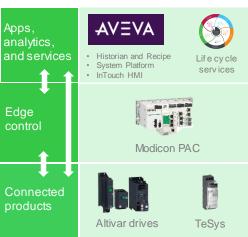
The results:

Life Is On with increased and accurate production.

Linkto video

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 Groupplo, 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."







- 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
- Captialize 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

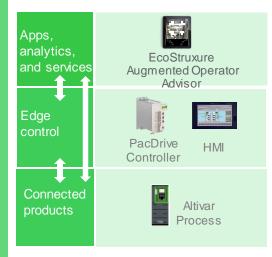
The results:

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

Link to video

Global medical technology company providing innovative solutions that help advance medical research and genomics









Unpredictable dow ntime risk and low performance with aging hardw are 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 low er 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 dow ntime and zero cabling errors with reuse of existing VO terminals automated VO 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 know ledge 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%.

Biotechnology facility, FDA licensed for production of seven vital life-extending drug products







- · In Batch
- Historian
- SCADA and HMI





Modicon M580

Connected products

Field control and measurement instrumentation

*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 licersed to AVEVA by Schneider Electric."







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

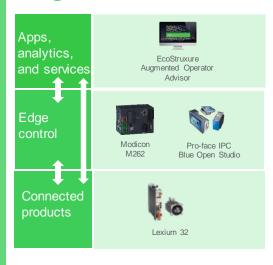
- 30% faster commissioning
- Faster and more efficient maintenance, quality control and troubleshooting through real-time visibility into a machine's status
- Improved safety and reduced human error by digitizing maintenance manuals
- Improved customer service to end user

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

Video

World **leader** in the production of pharmaceutical **packaging** machines

Eco Ftruxure Machine









- · 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

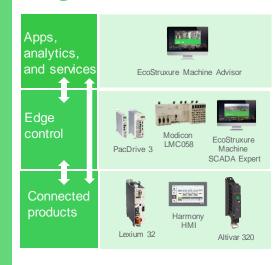
The results: Life Is On with...
50% greater machine efficiency and
50% cut in energy usage.

"Schneider Electric's EcoStruxure solution helps us become a 'smart' pharmaceutical equipment service solution expert in packaging."

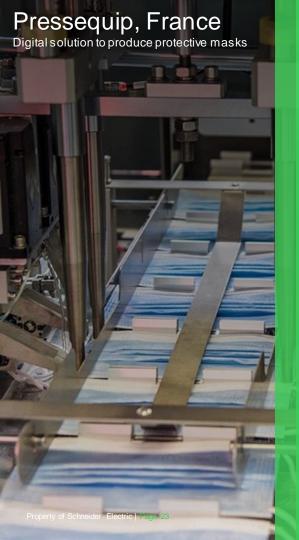
Bi Chunguang
Chairman, Chunguang Group

Leading builder of high-end, sustainable packaging equipment for the pharmaceutical, food, and chemicals industries, with 30 technology patents

Eco Ftruxure Machine







- 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 byproducing 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 IloT-ready logic and motion controller.

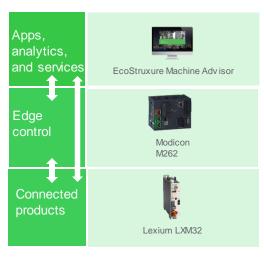
Customer benefits

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

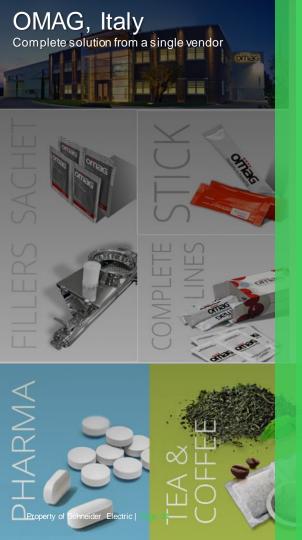
The results: Life Is On with new **revenue** stream and **20%** increase in profitability.

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









- 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.

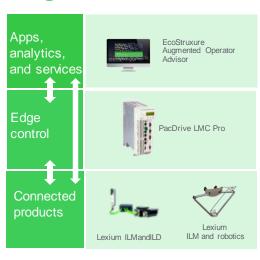
Customer benefits

- 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. **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

Eco Ftruxure Machine





Video

Life Is On Schneider

