SL CONTROLS
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WHITE PAPER

# Full Stack OT Platforms

## Why They Are Needed and Selection Criteria Best Practices

# Contents

# Introduction

The manufacturing software stack has been well-established for many years now. It has evolved over time, but there remain five distinct levels in the software stack starting with individual devices and equipment on the factory floor all the way up to the most comprehensive ERP systems.

The traditional manufacturing software stack is not specific to pharmaceutical or medical device manufacturing, but it is an industry standard that is broadly adhered to.

This whitepaper puts forward the argument that we need to move forward, flattening the traditional software stack to make it more suitable to the needs of modern manufacturing facilities today, and the needs those facilities will have in the future.

This whitepaper focuses on two of the five levels of the traditional manufacturing software stack:

- The supervisory control level, i.e., SCADA systems
- The plant management level, i.e., MES solutions

Using our direct experience at SL Controls of real-world projects in the life sciences sector, we will present the case for flattening these two layers of the traditional software stack, replacing the separate SCADA and MES approach with a single solution – a Full Stack OT (operational technology) Platform.

Our experience shows there are technologies that not only make it possible to flatten the stack, but that also offer considerable benefits over the traditional approach. We also provide a process in this whitepaper for selecting the best Full Stack OT Platform for your needs.

# Redefining SCADA for Modern Manufacturing Organisations

SCADA stands for Supervisory Control and Data Acquisition. It does what it says on the tin, to borrow a cliché, as SCADA systems collect and analyse data as well as controlling large-scale processes. This includes the processes required on high-speed, high-volume production lines in pharmaceutical and medical device manufacturing facilities.

SCADA systems have their origins in the 1950s and 1960s, although they did not become a distinct technology until the 1970s. Technologies have evolved rapidly since those early days, bringing us to the 1990s when the International Society of Automation (ISA) started working on an international standard for enterprise and control systems.

The aim of this work was to establish common terminologies to describe the exchange of data between manufacturing systems (operational technologies, or OT) and business systems (information technologies, or IT). This work produced the ISA-95 standard.

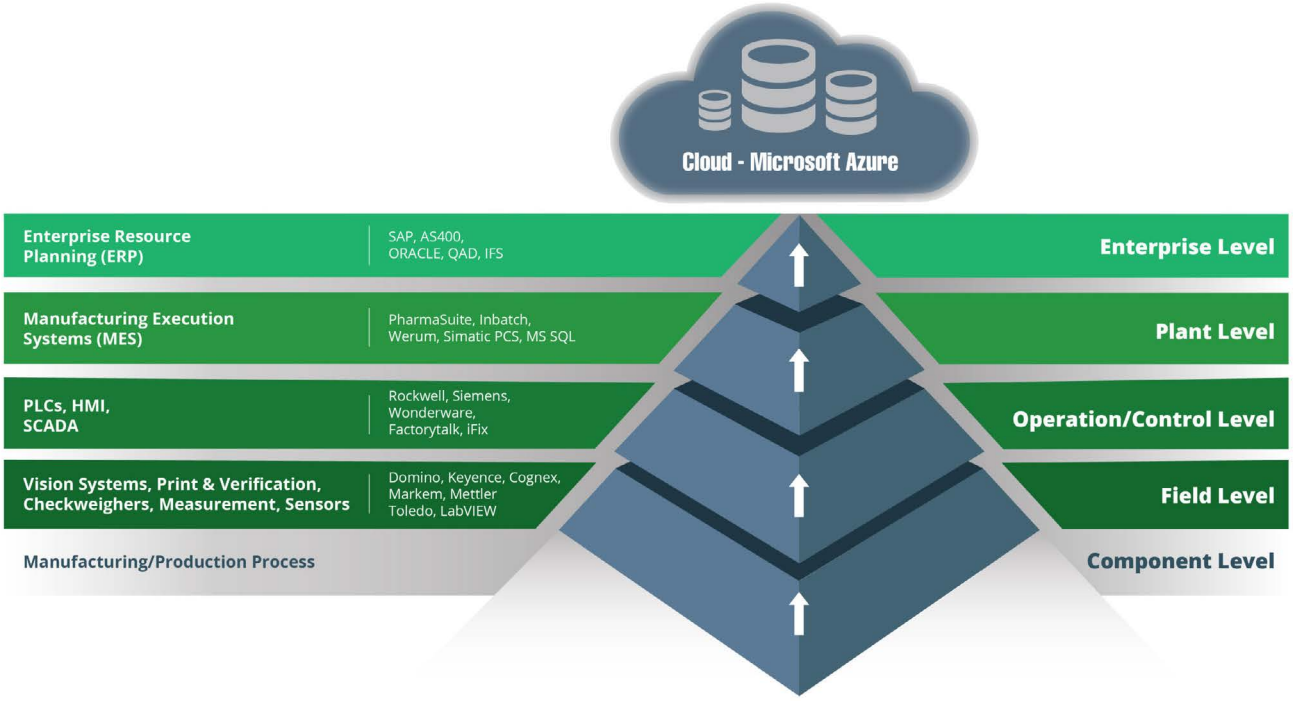
ISA-95 has and continues to evolve as new technologies become available. After all, the technologies that are available today are considerably more advanced than those 10 years ago let alone in the 1990s.

While there has always been evolution in the ISA-95 model, we are currently going through a period of significant change, where SCADA itself is being redefined.

To fully understand these changes and the influence they are having on the pharmaceutical and medical device manufacturing industries, it is beneficial to first go through a brief overview of the traditional ISA-95 manufacturing software stack.

## Traditional Structure

The ISA-95 manufacturing software stack is typically represented as a pyramid. Here's our version at SL Controls:




There are five main layers in the pyramid:

### Level 0

The Component Level represents factory floor production processes, from the movement of a robotic arm to the rotation of a pump to any other physical manufacturing level process.

### Level 1

The Field Level includes sensors, actuators, vision systems, and other intelligent equipment that create and/or capture production process data.

### Level 2

The Operation and Control Level (otherwise known as the Supervisory Control Level) is, traditionally, where SCADA systems reside, in addition to PLCs (programmable logic controllers) and HMIs (human-machine interfaces). The systems in this level of the software stack monitor and control the interconnected processes on a production line. Operators can use data from these systems to drive production line actions and improve performance while monitoring processes.

### Level 3

The Plant Level (otherwise known as the Management Level) includes systems involved in manufacturing operations management, or MOM. This includes Manufacturing Execution Systems (MES) that integrate the enterprise systems of Level 4 and the operation and control systems of Level 2. Systems at Level 3 are concerned with activities like tracking production, quality management, inventory management, and maintenance management.

### Level 4

The Enterprise Level features the systems that manage the entire business. This includes Enterprise Resource Planning (ERP) systems as well as Customer Relationship Management (CRM) systems, Supply Chain Management (SCM) systems, and other enterprise-level systems. Systems at this level are focused on areas like order scheduling and long-term business strategy.

As this whitepaper is about redefining SCADA for modern manufacturing organisations, we are going to focus on Level 2, the Supervisory Control Layer, and Level 3, the Management Layer.

## What is the Supervisory Control Layer?

The Supervisory Control Layer of the ISA-95 manufacturing software stack includes systems that are crucial for overseeing and coordinating the operations, processes, and equipment on production lines.

They can be viewed as a bridge between the real-time, physical world of manufacturing and the plant-level decision-making in an organisation.

Examples of functions included in systems at the Control Level include:

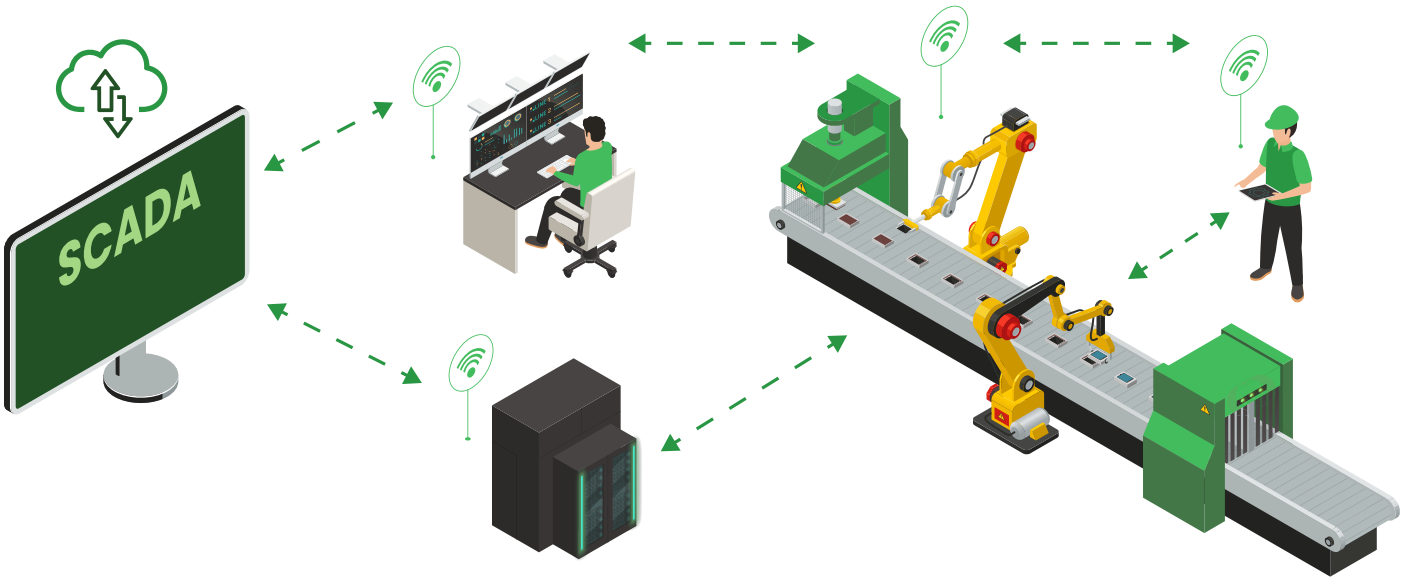
- Process monitoring – features that continuously monitor processes through Human-Machine Interfaces (HMIs) and similar systems. With these systems, operators can see real-time data from the field, such as temperatures, pressures, flow rates, tank levels, and much more.
- Control – providing operators and managers with a higher level of control. Examples include starting or stopping processes or switching between automatic and manual control modes.
- Alarm management – presenting alarms to operators, often with prioritisation, if a parameter goes beyond a target range or if a system identifies an anomaly.
- Batch control – batch management functions to ensure each step in a process is carried out in the right sequence and under the right conditions.

## What is SCADA?

It is important to point out that the following is a definition of a traditional SCADA system. We'll then use this to explore the functionality overlaps between a traditional SCADA system and the MES systems that reside at the next level up in the ISA-95 model. This will lead us to the modern, future-proof, full-stack alternative.

A traditional SCADA system captures OT data to automate industrial processes.

Typically comprising both hardware and software, SCADA systems use technologies such as sensors to monitor manufacturing equipment, from motors and valves to conveyors and weighers. This enables the control and monitoring of manufacturing processes both locally and in remote locations, as well as the processing of real-time data.




The four main functions of a SCADA system include:

- Data acquisition
- Data communication
- Data presentation
- Control

## Data Acquisition

SCADA systems collect data from sensors, meters, and other equipment and devices on production lines and within manufacturing facilities. This can include data like temperature, weight, pressure, flow rate, or the status of a switch.

## Data Communication

The collected data is transmitted between machines and operators, enabling centralised control of multiple devices, equipment, and machines. This can be done using wired or wireless technologies, and the data can be transmitted at specified intervals or in real-time, with the latter becoming the more common approach.

## Data Presentation

The data is presented on an HMI in a way that operators can easily understand and act upon. SCADA systems also continuously monitor the state of controlled processes, alerting operators when those processes fall outside target operating ranges.

## Control

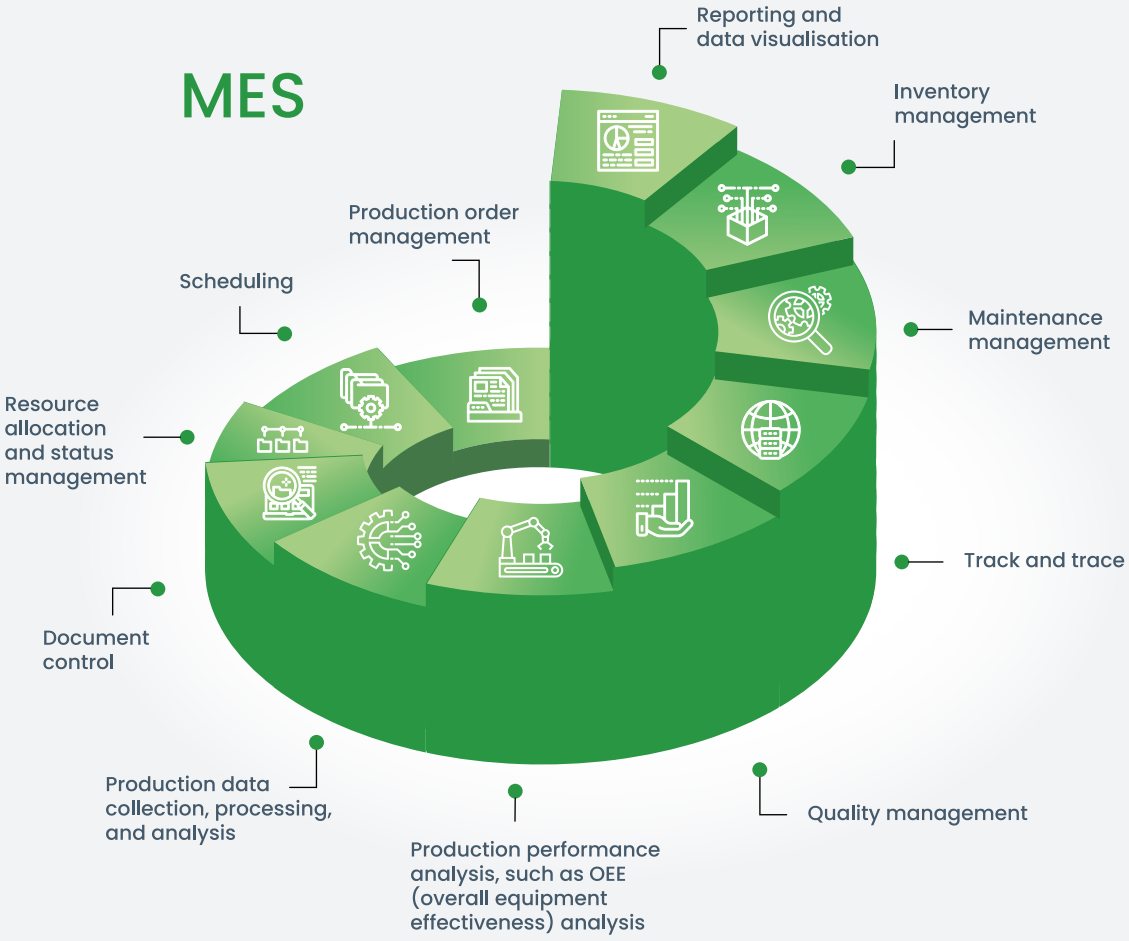
SCADA systems can send commands back to equipment and devices on the production line based on either the data that has been received or inputs from human operators. Examples of this control include turning a device on or off, adjusting settings, or triggering alarms.

## What is an MES?

As mentioned previously, SCADA systems are often used as a bridge between physical manufacturing processes and organisational decision-making. MES solutions are increasingly integral to plant-level (single-plant or multi-plant) decision-making processes.

Traditional MES solutions make use of the production data captured, processed, and produced by SCADA systems. An MES will use this data for a range of functions, from analysing performance metrics to managing track-and-trace systems.

As MES solutions also interact directly with ERP systems, they are traditionally used as a bridge between the Control/SCADA layer of the software stack and the Enterprise layer.



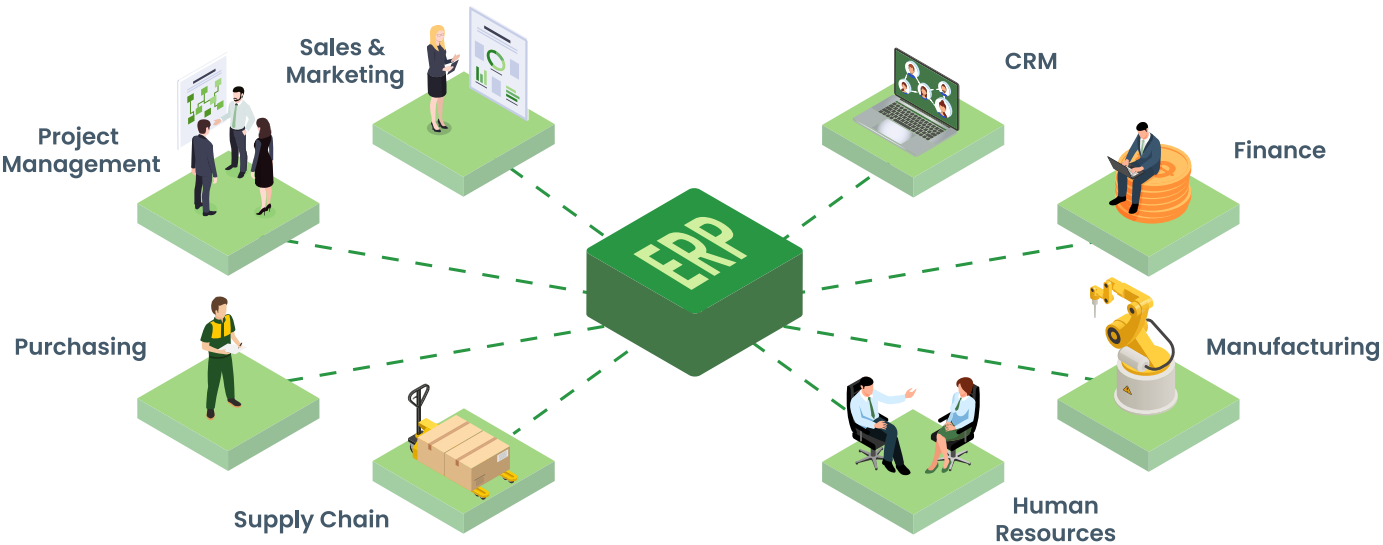

The key functions of a traditional MES solution include:

- Production order management
- Scheduling
- Resource allocation and status management
- Document control
- Production data collection, processing, and analysis
- Production performance analysis, such as OEE (overall equipment effectiveness) analysis
- Quality management
- Track and trace
- Maintenance management
- Inventory management
- Reporting and data visualisation

## What is ERP?

ERP systems typically sit at the top of the manufacturing software stack. They are enterprise-level systems that centralise and streamline processes and data into a single unified system.

One of the main objectives of ERP systems is to break down the information silos that often exist in large organisations, improving efficiency, consistency, and operational visibility.




In the traditional manufacturing software stack, MES and ERP solutions are integrated. In general terms, therefore, ERP systems get production and operational information from MES systems.

## Challenges and Restrictions of the Traditional Model

For the purpose of this whitepaper, we are going to narrow our focus to the challenges of having separate layers in the manufacturing software stack for:

- Supervisory control of the production line
- Plant-level oversight and management

The main challenges centre on the use of data, i.e., how data is processed and used when you operate a traditional model with a SCADA system at the supervisory control level and a separate system, such as an MES, at the plant level. A specific example of the challenges that commonly exist is production-level data not making its way to the ERP system. Even when data does make its way from the production line to an ERP system, it often arrives with a time delay and/or inaccuracies.

It is helpful to explore why challenges such as this exist. A lot of it comes down to the way IT and OT are managed in manufacturing organisations.

Traditionally, they are kept separate, with IT doing its thing with its systems and technologies while OT goes about its business separately, with largely separate systems and technologies.

MES solutions at the plant level of the software stack go some way to bridging the gap between IT and OT, but the gap still remains.

There are also additional challenges with the traditional model when you consider where SCADA systems reside in the stack. Those challenges are primarily about increased levels of complexity when you have different systems at the supervisory control level and wider plant level.

Multiple systems create additional data security and privacy risks while increasing the complexity of equipment systems integration. The latter point has greater importance in well-established pharmaceutical and medical device manufacturing operations as these facilities often have complex architectures that have evolved over many years and that feature difficult-to-navigate and/or replace legacy systems.

Using multiple systems also increases the validation and compliance burden on pharma and MedTech manufacturers.

## Functionality Overlaps of SCADA and MES

SCADA systems are primarily concerned with machine control. However, modern manufacturing organisations need more than supervisory control of equipment on the factory floor.

Putting aside the challenges presented in the previous section, MES solutions are now increasingly popular because they offer the additional functionality, oversight, and control that manufacturers need.

As MES solutions have evolved, it has become clear there are now considerable functionality overlaps between traditional SCADA systems and the best MES technologies.

In simple terms, both focus on data acquisition, data visualisation, and putting data to use.

For a lot of the information that is captured and processed, both SCADA and MES systems need to be connected to the same data. This applies even in situations where the purpose of the connection differs. For example, SCADA wants to connect with data to monitor a machine or process while an MES wants to connect to the same data for higher-level business considerations.

This presents an important question: why have separate SCADA and MES systems when they are both connecting to and using a lot of the same data?

## The Case for an Alternative Approach

SCADA functionality remains essential, but why should modern manufacturing organisations be limited to traditional SCADA systems when more advanced solutions are available? This includes solutions that offer everything a SCADA system does plus much more.

In other words, utilising platforms that enable your organisation to move beyond the HMI screen to significantly enhance data integration and take advantage of the power of cloud technologies. This can open up a wide range of other technologies, including the Internet of Things (IOT) and the Industrial Internet of Things (IIOT), as well as edge device control and performance optimisation.

Modern platforms also make it possible to unleash the true power of data in your organisation through data historian technologies, advanced analytics, and reporting capabilities, and by enabling automated decision-making.

# Flattening the Stack

Agile development methodologies mean the software industry long ago abandoned hierarchical approaches when creating and updating technologies. A similar principle should also apply to the supervisory control and management layers of the manufacturing software stack, i.e., the hierarchical structure of the traditional model should be abandoned.

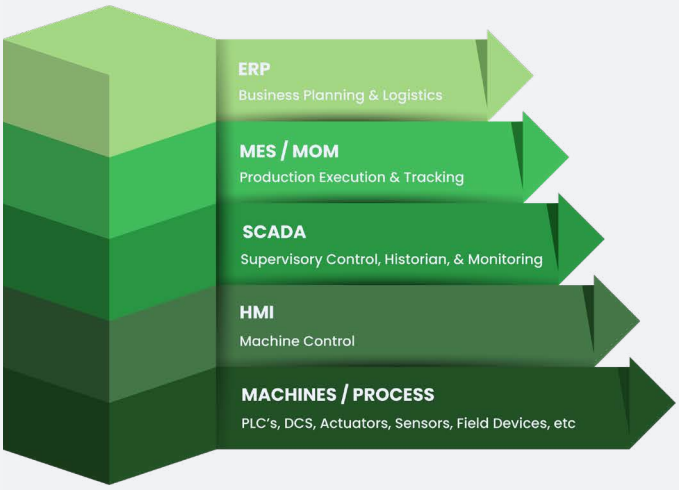
The traditional structure's hierarchical philosophy is no longer the best option for manufacturers in the pharmaceutical and medical device industries, i.e., manufacturers who want to optimise processes and make full use of data today, while securing their operations for the future.

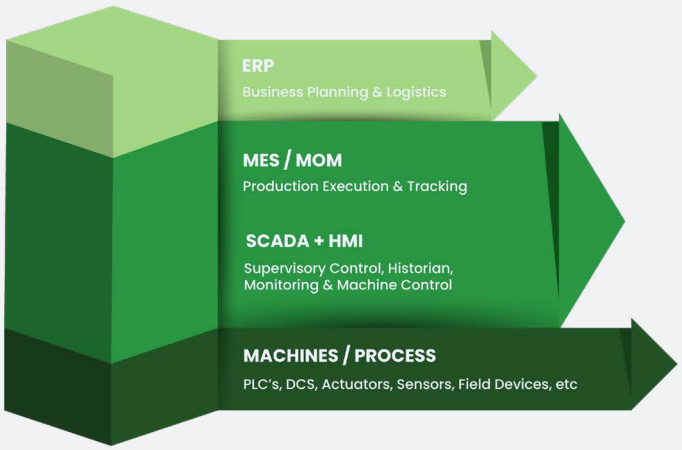
The best option is to flatten this part of the manufacturing software stack by merging the control and management layers.

In other words, implementing a solution that is more of an eco-system rather than straightforward systems with standard (but separate) SCADA and MES functionality.

Eco-system solutions lift the restrictions organisations face using the traditional approach, while also fully bridging the gap between IT and OT.

What does flattening the stack mean in practice? It means going beyond identifying and implementing a modern SCADA solution in your production facility. Instead, it involves implementing a system that delivers SCADA functionality while also taking into account wider operational and business needs not just today, but also in the future.




That's what it means in practice, but what exactly should you be looking for? How do you define the type of system that will deliver on the requirements described above?

At SL Controls, we use the terminology Full Stack OT Platform to define systems that deliver on both production-line-level supervisory control and plant-level management functionality.

## Benefits of Full Stack OT Platforms

Full Stack OT Platforms offer a range of benefits compared to the traditional approach:

### Addresses the Connectivity Challenge Head-On

One of the biggest challenges in MES projects is establishing real-time and structured connectivity between the MES platform and manufacturing processes. Connectivity is also often the most expensive challenge to resolve and is a leading cause of project failure.

Using a traditional MES solution approach, establishing the right connectivity requires a large number of stakeholders and the whole process can fail for a range of different reasons, both technical and non-technical.

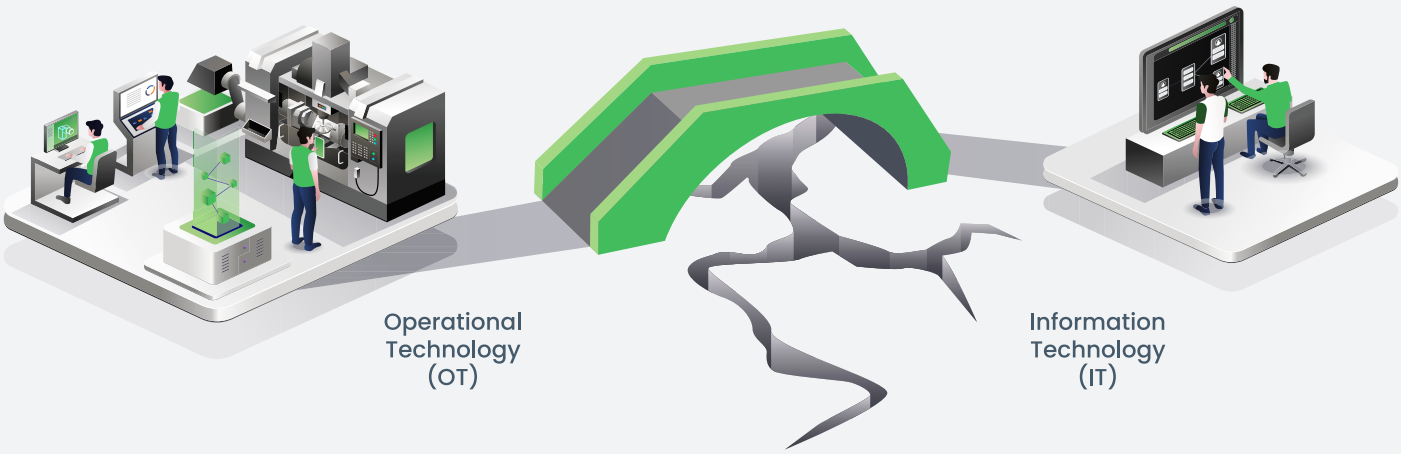
The end result in a failed project is typically a paper-in-paper-out system, where a huge investment is made to get an MES solution up and running only for the reality to involve manual data entry and reporting.

A single, bottom-up, full stack OT platform addresses this connectivity issue head-on as connectivity is achieved within the platform itself.

The result is automated data capture and process monitoring, with reporting by exception.

## Existing SCADA Functionality Remains

Full SCADA system functionality is retained in a Full Stack OT Platform, including machine and process control, batch control, track and trace, and recipe management.




You can achieve full stack connectivity that bridges the gap between IT and OT and ensures data from the furthest edges of the production line makes its way fully up the stack to ERP and other enterprise systems.

## Future Protocol Support

Future protocol support can be included as standard, including MQTT (Message Queuing Telemetry Transport), the modern and ultra-efficient data transfer protocol designed specifically for the IIOT.

## Enhanced Audit Trail Compliance

A single system streamlines all areas of compliance, from track and trace functionality to document control.

## Cloud Integration

Streamlined cloud integration capabilities that facilitate advanced system architectures.

## Optimised Manufacturing Analytics

Enhanced manufacturing analytics with detailed data presented in real-time in easily digestible formats, facilitating a switch to full data-driven decision-making.

## Reduced Costs

Reduced operational costs. This includes immediate savings with reductions in licence and hardware costs. There are also longer-term cost savings achieved through improved operational efficiency, better decision-making, and enhanced control through the entire software stack.

## OEE Optimisation

Improvements in performance at all levels of the production process, including Overall Equipment Effectiveness at component, machine, and line levels.

## Reduced Process Complexity

A single system significantly reduces complexity, management, and the learning curve for operators. For example, with fewer screens required, you can implement a more efficient and effective single point of control.

# Selecting a Full Stack OT Platform with SCADA and MES Functionality

At SL Controls, we have developed a criteria and process for selecting a Full Stack OT Platform that includes SCADA and MES functionality. We have implemented this process in real-world projects, delivering tangible results for our life sciences sector clients.

The main requirement for a Full Stack OT Platform is that it offers all the capabilities of a traditional SCADA system. This means full machine and process control. From that starting point, additional functionality can be added.

The following five-step process will ensure the right solution is selected.

## Steps for Selecting a Full Stack OT Platform in the Life Sciences Sector

### Step 1 – Define what is required

The starting point is to define the requirements of the project:

- What do you want to achieve?
- What are the must-haves and the nice-to-haves?
- What is the make-up of the current infrastructure?
- What platforms are currently in use?
- What systems, including legacy systems, need to be integrated both upstream and downstream in the software stack?
- What resources are available and what are their skills and capabilities both in terms of project implementation and ongoing use of the new system?
- What budget is available for the project?

### Step 2 – Create a vendor shortlist

The next step in the process is to evaluate vendors at a high level to create a shortlist. The shortlist should only include vendors who meet the essential basic requirements of a Full Stack OT Platform, starting with traditional SCADA functionality. The MES functionality can then be built out in the following steps.

As an example, the vendors we put on a shortlist for a recent project were Ignition by Inductive Automation and Wonderware. Both met the baseline criteria – excellent SCADA capabilities with options for additional MES functionality.

## Step 3 – Define the criteria for comparison

Before comparing the solutions from the shortlisted vendors, it is important to define the criteria for comparison. Defining comparison criteria ensures the selection process remains firmly focused on the customer's needs, i.e., the needs of your facility, production lines, and management operations.

The following questions are important to answer as part of the process of defining the comparison criteria. They are asked from the perspective of a pharmaceutical or medical device manufacturing organisation.

- *Are we implementing the solution on a green field site with modern equipment, machines, systems, and technologies? Or will the new platform be implemented in an established site with existing equipment and, more often than not, legacy systems? In terms of the latter, what are the communication capabilities of the existing hardware?*
- *What do we want to achieve with this project? Are those aims in line with the organisation's wider technology roadmap?*
- *Are we focused on innovation, or do we take a more cautious approach with well-established and proven technologies?*
- *Where is our technology roadmap taking us in terms of a move to data-driven decision-making? What are our plans for using manufacturing analytics, implementing advanced technologies like artificial intelligence (AI) or the IIOT, and utilising protocols such as MQTT?*
- *What resources do we have available? Do we want to retain and deploy existing engineering staff on the new platform?*
- *What is the makeup, state, and configuration of the current infrastructure, both IT and OT?*
- *What are the scalability requirements? Do we have plans to increase the number of products manufactured at the facility? Are there plans to add additional lines in the future or increase capacity through other methods, such as additional shifts or increased automation? Will additional sites be added to the platform?*
- *What is the level of investment that is being proposed, both upfront and ongoing?*

Turning to the platform solutions, examples of the criteria for comparison that we have used when selecting Full Stack OT Platforms include:

- Functionality – the various functions of the product as well as the scalability of those functions, the connectivity capabilities of the product, and the solution's architecture.
- Licensing structures – how the pricing is structured, and the costs involved, with calculations on costs tailored to your requirements as the customer.
- Useability – useability at a day-to-day operational level as well as the engineering useability of the platform to build out the features and processes that are required.
- Security – security measures and protocols that have been implemented in addition to the cybersecurity risks that come with bridging the IT/OT gap. How are those risks mitigated?
- Cloud compatibility – can the platform be fully integrated into cloud solutions commonly used in the pharmaceutical and medical device industries?
- Development capabilities – covering areas from customising graphs and charts to templating to version control and documentation management.
- Operation – this includes common considerations when analysing software solutions, such as the reliability of the platform, levels of redundancy, and operational stability. For pharmaceutical and medical device manufacturers, compliance is also essential, so 21 CFR Part 11 and validation considerations are crucial comparators.
- Support – what level of support is provided, for how long, and at what cost? What is the standard of the service desk and knowledgebase? What is the updates policy of the platform, particularly in relation to legacy versions?
- Vendor – it is also essential to move beyond the platforms and their capabilities to also look at the vendors. Where do they sit in the marketplace and are they financially secure? What are their commercial and growth strategies, and where are their core areas of focus?
- Experience – how much experience does the vendor have, particularly in regulated industries? How many projects have been delivered for pharmaceutical or medical device customers?
- Training – what training is available and how is that training structured? Is it online or instructor-led? Is the training generic or tailored to your requirements? How much training is included and are there any additional costs?

## Step 4 – Evaluate vendors on the shortlist

This step involves getting into the details of evaluating the shortlisted vendors. The main areas for evaluation that we investigate, analyse, and rate include:

### Scalability

It is important that any Full Stack OT Platform meets the needs of your organisation today. However, scalability is just as important to ensure the solution meets the evolving needs of your business. The best Full Stack OT Platforms are both compatible with and adaptable to everything from small systems up to large enterprises.

### Ease of Use

We assess Full Stack OT Platforms in two main areas. The first is how easy the system will be for your operators to use once everything is up and running. Training will be required and there will be an inevitable learning curve, but the training shouldn't be too intensive or the learning curve too steep.

The other ease of use assessment that we make relates to the setting up and configuring of the system. The amount of time and resources to adapt and customise the platform according to your needs will impact the cost and, ultimately, return on investment timescales. Ease of setup and configuration will also have ongoing cost implications as your use of the platform scales and evolves.

Examples of the questions that we ask in relation to ease of setup and configuration include:

- Does the platform offer configuration wizards?
- How much scripting is required?
- Is there ample documentation or guidance?

### Security

Cybersecurity is an essential consideration for all software applications, particularly in the highly sensitive life sciences sectors where things like patient data or highly valuable intellectual property are at risk. As a result, it is important to assess the security credentials of the shortlisted platform vendors, including how long their platform has been available, and the makeup and nature of their cybersecurity features and protocols.

It is also beneficial for Full Stack OT Platforms to offer added security such as integration with Microsoft Active Directory.

### Cost

Though cost should not be a deciding factor, it is an important one. Two critical areas to investigate in terms of cost include:

- The cost of add-on modules and if they are covered in version upgrades.
- The structure of licenses and pricing, and how that structure will impact overall costs, especially as your use of the platform changes over time.

### Interoperability

Interoperability is arguably the most important factor when deciding on the best Full Stack OT Platform for your needs. Whether the system will be implemented on a green field site or into existing operations, it is best to choose a platform with a vendor-agnostic approach as integration with other systems and equipment will be much more viable. The availability of multiple communication drivers also helps to maximise the flexibility of the system.

### Graphics and Templates

Platforms that provide a multitude of graphics and templates save you time while also reducing costs.

### Support

The value of support should never be underestimated. The best support structures give you access to locally based experts in addition to high-quality documentation and knowledge centres. Free version upgrades are also highly preferable.

### Compatibility

Does your vendor offer backward compatibility? The main point with this consideration is to be careful of vendors that drastically switch up programming in a way that leaves older versions not only outdated, but incompatible. This approach leaves you no option but to rip-and-replace, making backward compatibility a highly desirable feature.

## Step 5– Decision

The final decision-making process will be unique from facility to facility and business to business. In a recent project, for example, the two platforms that made our shortlist were Ignition and Wonderware. Both are fantastic solutions. However, after considering comparison factors and customer requirements, the decision was made to go with Ignition SCADA alongside Sepasoft's MES modules.

The final decision is, of course, important, but it is only one step in the process of first deciding that a Full Stack OT Platform is the preferred solution and then working through the process outlined above to identify the best vendor.

# Conclusion

SCADA systems have served manufacturers well over the past years and decades, including manufacturers in the pharmaceutical and medical device industries. Modern SCADA systems are powerful tools that offer high levels of supervisory control at the production line level, but technologies never stand still.

The needs of business are also changing. Drivers for these changes in business include the power and potential of data alongside advances in digitalisation – from straightforward process digitalisation through to digital transformations of entire business structures.

The traditional ISA-95 manufacturing software stack has also served the industry well, but it too needs to be adapted to the needs of modern manufacturing organisations. In addition to traditional requirements, the modern manufacturing software stack must achieve the following aims:

- Ensure well-defined and structured connectivity across all equipment, processes, and platforms.
- Make better use of data vertically through the stack in both directions and including both extremes (from the furthest edge devices to the most all-encompassing ERP system), as well as horizontally through supply and distribution chains.
- Reduce the complexity of systems and their integrations, particularly in relation to operational technologies.
- Bridge the gap between OT and IT.
- Focus on scalability and future needs in addition to today's requirements.

All the above leads us to a conclusion that involves flattening the manufacturing software stack, replacing separate supervisory control and management systems with a single Full Stack OT Platform – such as the platform Ignition by Inductive Automation.

The flexibility and adaptability of this approach are much more suited to a world where technologies such as the IIOT and AI are commonplace. Full Stack OT Platforms are also more suited to other business realities. Examples include:

- The increasingly competitive markets that we see in life sciences.
- Business environments where data-driven decision-making is essential.
- Changing production structures in areas like product customisation and mobile manufacturing technologies.

There is a process that must be worked through to ensure you get the right solution for your requirements, and there should be no compromise on the traditional capabilities of SCADA systems. It is also important you have support from industry partners with direct experience in implementing Full Stack OT Platform solutions under the real-world conditions of highly regulated manufacturing environments.

SL CONTROLS
AN NNIT GROUP COMPANY

**SL Controls Ltd.**
IDA Industrial Park, Collooney, Co. Sligo, Ireland, F91 WF53

T +353 (0)71 91 340 40
E sales@slcontrols.com

**slcontrols.com**