Digital Manufacturing Managed Services

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Digital Manufacturing in Technology Consulting

Our Digital Manufacturing Managed service is designed to support the critical IT and OT infrastructure and applications in the manufacturing environment, sustaining high levels of stability and reliability, with a cost effective, compliant solution, ensuring that the site delivers the products on time as planned. Our focus is on optimising the total cost of ownership over the lifecycle of the assets, both software and hardware, allows clients to maintain the performance levels achieved on day one. We can provide 24 X 7 support for all control assets for your day-to-day operations needs in manufacturing, with our front-line support team. We help your manufacturing processes and businesses to attain new heights of efficiency and competitiveness leveraging our **expertise in cybersecurity**, **infrastructure management**, and **staff training**. We will optimize your **plant performance**, elevate the **business agility** and raise **quality and compliance**. *Together, we help solve your biggest challenges in manufacturing processes quickly, sustainably and cost effectively.*

What EY can do for you

We help our clients in managing their current automation challenges in manufacturing

Integration	‣ Production shopfloor have been left to deal with paper, spreadsheets and other standalone systems ‣ Poor communication between disconnected information systems like ERP, MES, learning and quality management systems
Data management	‣ 27% of manufacturers reported that data obtained remains in silos ‣ 20% of executives in manufacturing operations management cite disparate systems and data sources among key challenges
Change management	‣ Implementing a change can involve significant changes to an organization's processes and procedures
Scalability	‣ Difficult for manufacturing companies with distributed multi-site operations to enforce standards for data collection and best practices
Cost	‣ Unstable and unreliable costs for managing your automation needs
Training	‣ Employees need to be trained on how to use the new automated manufacturing system effectively which can be time-consuming and expensive
Quality	‣ Quality testing and batch release accounts for upwards of 70% of manufacturing lead time mainly due to manual processes, disconnected instruments and non-standard paper-based documentation and control procedures.
Security & Compliance	‣ Manufacturing systems are often connected to a variety of other systems and can be vulnerable to cyber-attacks and required to be GxP compliant.

As a global organisation, EY has significant experience of supporting customers across all business-critical applications and infrastructure. Manufacturing facilities with highly automated processes are becoming more and more complex and many businesses require external support to ensure that their IT and OT systems operate optimally with high levels of reliability and availability, to avoid manufacturing downtime.

Our Digital Manufacturing Managed service is design to support the critical IT and OT infrastructure and applications in the Manufacturing environment, sustaining high levels of stability and reliability, with a cost effective, compliant solution, which ensures that the site delivers the products and medicines that the business needs. Our focus on optimising the total cost of ownership over the lifecycle of the assets, both software and hardware, allows clients to maintain the performance levels achieved on day one. We can provide 24 X 7 support for all control assets for your day-to-day operations needs in manufacturing, with our front-line support team. Our change team can process systems changes across all platforms e.g. DCS, MES, PLC's, that are required to correct issues and improve plant performance, in compliance with the client procedures. Our support extends to control system administration, small capital projects, validation services and compliance support, including training capability management and automation system validation.

We help your manufacturing processes and businesses to attain new heights of efficiency and competitiveness leveraging our expertise in cybersecurity, infrastructure management, and staff training. We aim to optimize your plant performance, elevate the business agility, and raise quality and compliance.

EY Ireland will provide full range of services for Digital Manufacturing Managed Services

Our Managed Services

System Administration

- Security of systems, applications and data
- User management of systems
- Proactive event management and preventive maintenance
- Execution of System changes
- Lifecycle management

Change Management

- Non-Conformance (NC) investigation support
- Driving Corrective And Preventive Actions
- Execution of all software changes
- Creation of all Knowledge Based Articles
- On-Call Support for the FLS Teams

Small site-based capital projects

- PM Scope, Budget and Schedule
- Resource Management
- Plan, Design, Code, Accept
- Project & Portfolio Reporting (Earned Value, SPI, CPI, etc.)

Automation System Validation

- Periodic review and execution of the Distributed Control systems (DCS) Manufacturing Execution systems (MES), Laboratory Information management systems (LIMS), PLC & SCADA
- IS Compliance

Validation Services & Compliance Support

- Computer System Validation & Consulting Services
- Lab Instrument Validation
- Quality and Compliance Consulting

Lab IT Support

- Day to Day Lab IT sustaining work
- Lab IT Projects – software and OS upgrades etc.

Automation Front Line support

- First line shift support for incident triage
- Support for documentation of incidents
- Functional escalation (on-call) for difficult incidents
- Active coordination of support team

Training and capability Management

- Create KBA's
- Custom e-learning
- Custom Instructor Led Training
- Focus on Cross Training

Presently 10+ Engineers on Sites Supporting GMP Manufacturing sites

System Admin

Troubleshoot problems with the application software/configuration to support the manufacturing processes. Resolve problems in collaboration with engineering and operations. Implement approved interventions in the system operation in support of the manufacturing processes. Initiate escalation processes as required. Document problem resolution and contribute to knowledge development.

Service Offerings:

IAM, User Access

EY helps in managing user identifies and their level of access to applications or data within your company. EY's IAM approach help to protect your company's data both from internal and external sources. Having an IAM policy defined by EY professionals and customised as per our client organisation structure in place provides an elegant solution to the problem of data security within the organisation.

System Changes

EY help in aligning with the systemic change. specially, where relationships between different aspects of the system have changed towards new outcomes and goals. And it's driven by transformational, not incremental change. EY understand your requirement for system changes and always help in growing your business by managing data efficiently.

Cyber Security

EY framework incorporates a proven methodology which is based around Business, Threats, and their Capabilities. We help in achieving the business goals/objectives by mitigating cyber risks. The EY Cyber Capability Model is based around the knowledge that organisation cannot just be sealed against cyber threats, but also vigilant and resilient, and have a sufficiently robust strategy for managing cyber risks.

Life cycle management

EY's life-cycle management is the administration of a system from provisioning, through operations, to retirement. Every Business/Industry system, resource, and workload has a life cycle. EY's Life-cycle management delivers reliability in an automated and scalable manner for all systems, assets and subscriptions.

Automation Frontline Support

EY's front line support team will be embedded into your organisation, supporting day to day manufacturing operations on the same shift cycles working hand in hand with your manufacturing team to solve and resolve IT and OT automation issues. Our team will respond to incidents, complete approved interventions, investigate incidents and send a report to the relevant parties for the next step in the investigation. While on shift, our team can provide automation training to the manufacturing team and continuously enhance their knowledge and familiarity with the manufacturing process.

Service Offerings:

Incident Management

Through our partner ServiceNow we can provide automation to streamline the incident management process end-to-end. This requires the use of a business event (e.g., a ticket getting created) that sets off real-time outcomes (e.g., a ticket getting assigned to our team). Our solutions will address incident management, case investigations, root cause analysis and risk management. We provide you with the right people, process, and technology to manage incident response process with a proven methodology, in the ITIL framework, which enable us to monitor and report performance against Service levels agreements. Reporting our performance to the senior management and all key stakeholders. Provide breakdown of incidents by category and developing improvement projects to improve response planning and address repeat root causes. We can also Automate and integrate Alerts and Notifications.

Intervention Management

EY combines the simplicity of intervention management with all the advantages of computer-aided maintenance management. We will train our team in multiple vendors software platforms to offer this service. This shortens response times and optimizes the execution of curative and preventive actions on site. The result: productivity gains, avoidance of manufacturing downtime and improvements in service quality.

On Call and out of hours support

EY can provide on call support, during shift hours (escalation support) and out of hours on call support. On call escalation support is essential for the continued operation of the plant when serious issues arise that affect the process. Our on-call support, from more experienced resources, can apply their experience and knowledge to resolve a critical situation in a timely manner, avoiding manufacturing downtime for the client.

Lab IT Support

EY intends to become a leading provider of Lab IT support, technical assistance and maintenance services for information technology systems and equipment within a laboratory environment. We have expertise in range of activities aimed at ensuring the smooth operation and optimal performance of computer systems, software applications, network infrastructure, and other technology-related resources used in a laboratory setting. It is our goal to address and resolve all the technical issues promptly, minimize downtime, and support the efficient functioning of laboratory operations.

Service Offerings:

Hardware and software troubleshooting

We identify and resolve issues related to computers, servers, printers, scanners, and other laboratory equipment.

Network and connectivity management

Our services involve a range of activities aimed at designing and maintaining a robust network infrastructure within a laboratory environment. We have expertise in LAN, VLAN, subnet, Lace boxes, remote access, Lab benchtop systems, backup and recovery, system administration for Lab applications, qualification, and validation activities.

Software and application support

EY Lab IT support will help you installing the necessary software applications on laboratory computers and systems meeting the operating system and any hardware requirements. We provide technical assistance, specific to lab applications such as Empower, Nugenesis, and LIMS (Laboratory Information Management System). Our team will keep track of software updates, patches, and new versions ensuring all the software applications within the lab are up to date to ensure assets are reliable, accessible, and secure.

User support and training

EY Lab IT support will support your lab staff by addressing questions, resolving issues, and troubleshooting software-related problems. We can also conduct training sessions or create documentation to help lab members understand and utilize the software's features and functionalities.

Troubleshooting and Issue Resolution

We provide on-call or onsite support, as needed, for 24/7 commercial operations. We follow up on incidents raised in a ticket management software such as ServiceNow. You can raise tickets for changes, incidents, problems, and asset management activities for the support of equipment in laboratory and manufacturing.

Validation Services & Compliance Support

Data reliability and integrity is crucial in heavily regulated industries such as pharmaceuticals, life sciences, and the food and nutrition sector. EY services can assist in ensuring compliance with regulatory requirements, such as Good Laboratory Practices (GLP) and Good Manufacturing Practices (GMP). Our domain experts have deep knowledge of 21 CFR part 11, EU annexure 11, GAMP 5, GDP, cGMP guidelines. We help organizations develop and implement validation strategies, conduct risk assessments, and perform validation activities to meet regulatory standards.

Service Offerings:

Validation Strategy and Planning

We help you to develop a comprehensive validation strategy and plan tailored to your specific needs. We will assess the scope of validation activities, define validation requirements, establish validation protocols, and develop a roadmap for the entire validation process. We support the development of validation documentation, including validation plans, user requirement specifications (URS), functional requirement specifications (FRS), design specifications, test scripts, and traceability matrices.

Risk Assessment and Remediation

We conduct risk assessments to identify potential risks and hazards associated with systems, processes, and equipment and help you in developing mitigation strategies and implement corrective action.

Documentation Development and Review

We will support the development validation documentation, including validation protocols, qualification documents, standard operating procedures (SOPs), and test scripts. We will ensure that the documentation aligns with regulatory requirements, industry standards, and best practices.

Quality and Compliance Consulting

EY will assist in the execution of validation activities by providing qualified validation experts. Our experts will perform installation qualification (IQ), operational qualification (OQ), and performance qualification (PQ) tests, ensuring compliance with validation protocols.

Computer System Validation & Consulting Services

We provide specialized expertise to assist organizations in validating and maintaining computer systems in compliance with regulatory requirements. Our experts will ensure the compliance with data integrity requirements, including electronic records (21 CFR Part 11).

Change Management

EY's Change Management service support involves assisting in all stages of an organizations change procedure and effectively managing and implementing changes to their processes, systems, and tools.

Our experts can assist you in Non-Conformance (NC) investigation support, completing root cause analysis, risk assessments, developing Corrective and Preventive Actions (CAPA), execution and testing of all software changes, creation of all Knowledge Based Articles.

Service Offerings:

Purpose of change and evaluate the Change plan

EY Team will Determine and document the scope and change category and conduct an assessment to identify the potential impact of the proposed change on various aspects of the manufacturing operations, and document details and risk assessment.

Change Communication and approval

EY team will develop a comprehensive communication plan to effectively communicate the purpose, benefits, and implications of the change. We will seek the approval from all the required department stakeholders across the site and present the change to quality for review and approval prior to executing the change plan.

Execute the change plan and Change Implementation Support

Execute the change plan and providing support during the implementation phase of the change. Assisting with activities such as system configuration, data migration, process adjustments, and other technical tasks required to implement the change effectively. Monitoring progress, addressing issues, and ensuring a smooth transition.

Change Evaluation & Conduct post implementation review

Post implementation review of the change must be completed to confirm it has achieved the desired result. Collecting feedback from client and stakeholders to identify areas of improvement and gather lessons learned for future change initiatives. Using this feedback to refine change management strategies and processes.

Change Documentation and Knowledge Management

Documenting the change process, including change requests, impact assessments, communication materials, training materials, and lessons learned. Creating a knowledge base or repository to capture valuable insights, best practices, and documentation related to change management.

Small site-based capital projects

EY Small Project Managed Service is a dedicated solution tailored to support the efficient management and execution of small-scale projects. Our experienced team of project managers ensures that each project is meticulously planned, coordinated, delivered on time and within budget. We handle all aspects of the project, including procurement, subcontractor management, scheduling, and quality control, allowing clients to focus on their core business operations.

Service Offerings:

Physical Infrastructure Upgrades

EY aims to enhance client site's overall functionality, reliability, and efficiency by undertaking physical infrastructure upgrades. These upgrades involve enhancing various aspects such as control systems, networking infrastructure, and security systems. These enhancements are geared towards maximizing productivity, ensuring seamless operations, and meeting the evolving needs of EY's stakeholders.

Application Enhancements and Upgrades

EY's services extends to enhancements and upgrades of critical software applications. We work with all OEMs to deliver approved enhancements and upgrades, that bring new features and new functionality for your manufacturing processes. Our structured, compliant approach to these projects with the appropriate experts ensures reliable and on time project delivery.

Technology Deployments

As part of our managed services, EY facilitates the seamless deployment of new technology or the expansion/upgrading of existing technology at designated sites. Our comprehensive approach includes implementing cutting-edge hardware, software, and communication systems to optimize operational efficiency and address specific business needs. With a focus on leveraging innovative technological solutions.

Equipment Procurement and Installation

EY offers services that encompass procurement and installation of new equipment or machinery at designated sites. This enables our client to augment production capabilities, optimize operational efficiency, and replace outdated equipment. By introducing advanced technology and ensuring seamless integration into the existing infrastructure, our objective at EY is to enhance overall performance and productivity.

Automation System Validation

Our automation system validation service ensures that organizations enhance their validated automated system or software, meets its intended requirements, and performs as expected.

Our experts are involved in verifying and documenting that the system complies with regulatory standards, industry best practices, and user requirements. We are providing support on validated systems change execution, for Distributed Control systems (DCS), Manufacturing Execution systems (MES), Laboratory Information management systems (LIMS), PLC & SCADA, IS system Compliance, Change pack review and Creation and management of test templates.

Service Offerings:

Validation Planning

Our services can help in developing a comprehensive validation plan tailored to the specific automation system and its intended use. This plan outlines the validation strategy, scope, deliverables, and responsibilities of different stakeholders.

User Requirement Specifications (URS) Creation and Design and Configuration

Defining and documenting the user requirements, including functional and non- functional criteria, that the automation system must meet and assisting in the design and configuration of the automation system to meet the predefined requirements and regulatory guidelines.

Test Planning and Test script creation

Defining and documenting the test plan and it include test strategies, objectives, schedule, estimations, deadlines, and resources required to complete that project. Creating detailed test scripts (IQ/OQ/PQ) to conduct various tests and simulations during the validation process.

Test Execution and Documentation

Performing the validation tests (IQ/OQ/PQ), documenting the results, and maintaining detailed records for regulatory compliance. Our team can work in partnership with you to complete FAT's, SAT's and the full cycle from Installation Qualification (IQ), Operational Qualification (OQ) and Process Qualification (PQ).

Compliance with Regulations

Ensuring that the validation process aligns with relevant industry regulations, such as FDA's 21 CFR Part 11 for pharmaceuticals and medical devices. Our manufacturing and validation expertise means that we can validate your equipment and systems to regulation ensuring that they are compliant with Good Automated Manufacturing Practice 5 (GAMP®5), FDA 21 CFR 11 and Annex 11.

Training Capability Management

EY's Training Capability Management optimizes training activities, identifying needs, developing customized programs, and tracking progress. With our expertise, we enhance employee skills, drive growth, and foster a culture of continuous learning. EY streamlines training processes, maximizes resources, and delivers a seamless training experience.

Service Offerings:

Learning Management System (LMS) Administration

EY, as a managed service provider, assumes responsibility for the administration, maintenance, and technical support of an organization's learning management system.

Content Development and Curation

EY creates diverse training materials, including e-learning modules, videos, and relevant resources, to meet specific training needs and objectives. With our expertise, we enhance the overall learning experience, supporting organizations in continuous development and growth.

Learner Support and Help Desk

EY delegates possesses the capability to offer a dedicated support team exclusively available to assist learners with technical issues, troubleshooting, or inquiries pertaining to learning platforms and materials.

Learning Strategy Consulting

EY provides consultancy services to assist organizations in developing effective learning strategies. We align training initiatives with business goals, identify unique learning needs, and offer valuable guidance for optimized learning and development.

Training Delivery and Facilitation

EY provides flexible training delivery options, offering both virtual and in-person formats. Our services include live sessions and pre-recorded materials, ensuring diverse and engaging training experiences.

Learning Analytics and Reporting

EY's managed service incorporates analytics capabilities to track and evaluate training program effectiveness. We gather data on learner progress, engagement, and performance, generating comprehensive reports and valuable insights for informed decision-making.

Contact Us

To find out more about EY Ireland's Digital Manufacturing Managed Service offerings, please contact:

Vikram Kunnath
Partner, Digital Manufacturing,
Technology Consulting
vikram.kunnath@ie.ey.com

Simon Capewell
Director, Life Science Sector,
Advanced Manufacturing, Supply Chain
& Technology Consulting
simon.capewell@ie.ey.com

Denis O'Dwyer
Director, Life Science Sector,
Advanced Manufacturing, Supply Chain
& Technology Consulting
denis.o.dwyer@ie.ey.com

Vivek Kasture
Director Digital Manufacturing
vivek.kasture@ie.ey.com

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