Cognizant's ONEPlant™ solution makes end-to-end, integrated plant operations a reality.

**Complexity of the Pharma Manufacturing Environment**

The pharmaceutical (pharma) industry is experiencing a tectonic shift. Its current environment is being challenged by intense scrutiny on price hikes, regulatory uncertainty, empowered patients, personalized medicine, influx of tech giants, patent cliffs, and the associated rise in generics.

These forces are pushing pharma companies to increase spending on specialty drugs, broaden their R&D strategies, create bigger mergers and acquisitions, and adopt a data-driven approach towards quality and regulatory compliance. Consequently, introducing high-performance products, faster than ever with industry leading quality and optimized price points is a constant challenge.

As a result, these tremendous pressures are increasing margins. For example, acquiring and merging new companies for new capabilities is a complex undertaking, usually involving disconnected legacy systems, disparate technologies, and a lack of process standardization from one plant to the next. Even if individual plants or business units have adopted the latest technologies and created unified processes, very few have integrated the manufacturing value chain end-to-end to achieve operational efficiencies and increased collaboration.

Thus, as pharma companies need to find innovative ways to cut costs, manufacturing operations naturally becomes a key area for optimization. With an eye on efficiency, pharma manufacturers need to adopt a comprehensive approach to transform plant operations for more in-grained agility, predictability, and responsiveness. Cognizant’s unique framework addresses today’s challenges, enabling you to rewire operations and help change the way manufacturing is done.
Cognizant’s ONEPlant solution is a unified approach to achieve a truly integrated manufacturing operation, aligning people, process, compliance, and technology towards one common vision and goal. Our team harmonizes the operations management and operations technology components to align with core ERP systems, and supply chain solutions.

Our maturity framework guides leading manufacturers in designing an operations transformation journey and helps address pain points across plants. Digital accelerators help integrate manufacturing data with multiple business systems already in place and address GxP requirements.

The framework guides how and where to effectively and efficiently adhere to compliance and quality standards in the manufacturing environment. The solution aids in automating electronic batch record (EBR) and traceability, to create a collaborative workflow for the pharma manufacturer to establish a paperless shop-floor operation in a GxP environment.

ONEPlant can also address pharmaceutical drug serialization—with an approach to quickly deploying a serialization solution across multiple sites or packaging lines in parallel for consistency and compliance.
Getting Started – Vision toward Manufacturing Excellence

Our business and technology advisory services for pharma manufacturing encompass: maturity assessments, blueprinting, product evaluations, roadmap definition for global implementations, and ongoing support.

In working with leading global manufacturers, Cognizant recognizes that operational maturity levels vary by company. In order to best understand where your operation stands, we recommend starting with our ONEPlant Maturity Framework. This structured approach, aided by our proprietary tools and templates for maturity assessment, will articulate and benchmark the current state of operations across all areas.

From there, we can identify opportunities for improvement and better define the transformation roadmap with a cost benefit analysis.

The components of ONEPlant are augmented by Cognizant’s Quality Management solutions (QMS) which drive a progression away from “Quality as a Department” to “Quality as a Responsibility.”
## Success Stories to Pharma Manufacturing Excellence

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<th>Outcomes</th>
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| **World’s Largest Research-Based Pharmaceutical Company**
**Unifies Manufacturing Execution Systems for Real Time Manufacturing**

- Large scale acquisitions had led to multiple, disparate MES system across sites
- Lack of standardization and multiple versions of truth due to system redundancies and architectures
- Increased cost of quality, compliance, manufacturing operations, and IT support – need to rationalize processes, Systems

- The client selected our ONEPlant solution framework to lead this transformation program
- Leveraged proprietary PACE Methodology for accelerated deployment of global MES platform across 70+ sites globally
- Utilized a standard solution template – Collaborative development (Core + Site teams) of standard MES template
- Roadmap based for phased and modular MES roll outs at sites

- Transformed Manufacturing IT (MES/WMS/EMI/Quality) landscape end-to-end and standardized diverse application portfolio to common next-gen technologies to enable “right first time” processes
- Increased predictability of manufacturing operations
- Better alignment of production execution and production planning
- Enhanced compliance with 21 CFR Part 11
- Greater ROI: Reduced implementation time through customized accelerators: Data Migration tool, Language Translation tool and Material Master Mass Update tool

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| **Manufacturing IT Roadmap Definition for a Pharma Major In US**

- Shift in business strategy that moves from large volume of products to higher number of low volume products
- Reduce new product introduction (NPI) cycle time
- Focus on business and operation excellence to drive margins
- Move towards modular and disposable technologies for manufacturing
- Pioneer towards newer technology in packaging and devices

- Assess the current state of manufacturing processes, systems and establish the maturity of key functions
- Benchmark the maturity of business functions with other pharma organization
- Analyze the current state with best practices and future needs to identify gaps and improvement opportunities
- Perform cost - benefit analysis to quantify potential benefits
- Advise on future strategy and roadmap for manufacturing IT

- Cognizant identified opportunities and developed a four-year roadmap aimed at improving 14 key result areas.
- We provided a cost savings roadmap for attaining $5 million/year per site in the areas of production, quality, maintenance, inventory, recipe management, KPI management and governance model

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| **Harmonized Golden Instance on the Cloud for US based Pharmaceutical Contract Manufacturing Company**

- Application infrastructure hosted on the Cloud
- Global standardization (global blueprint) of workflow process
- Streamlined implementation as opposed to current dispersed approach
- Harmonize QMS and audit business process by building new process on TrackWise and reporting on Crystal Reports and Cognos

- Application version installation of TrackWise 8.7.12
- Workflow standardization and global harmonization of QMS and Audit processes
- Automation of paper based investigation and regulatory process workflows
- Integration and interfaces with 14 ERP systems
- Validation metrics and analytical reports creation

- Allows scalability for M&A activities
- Improves data visibility, metrics and analytics
- Integrates with other enterprise software systems
Driving Outcomes that Matter

Cognizant’s ONEPlant framework is helping pharma manufacturers to transform plant operations and drive greater efficiency, while integrating the enterprise to fully operate with agility and speed. Potential outcomes include:

• Highly collaborative enterprise that shares and leverages best practices across plant operations
• Flexible paperless manufacturing execution
• Flexible EBR that is highly responsive and compliant to ever-changing manufacturing landscape and agility in recipe update
• Intelligent decision capability with meaningful metrics and KPIs. Predict what will happen and deliver first-time right products
• Standard repeatable processes for cost optimization and increased efficiencies
• Simplified technology landscape that is scalable to future needs and easy to maintain
• End-to-end traceability of material, processes and packaging serialization