Cognizant

Solution Overview

Cognizant OnePlant

How to pivot your silo-based pharmaceutical manufacturing operations to a more integrated framework capable of dealing with new requirements for manufacturing excellence.

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 value but lower volume products, such as biomedicines, orphan drugs and advanced medical devices, 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 reduce 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 in the way facilities or plant operations are structured, to a reliance on continuous manufacturing for more in-grained flexibility, predictability, and responsiveness. **Cognizant's unique framework addresses today's challenges, enabling you to rewire and scale up operations to meet an ever-increasing demand for drugs from a rising population.**
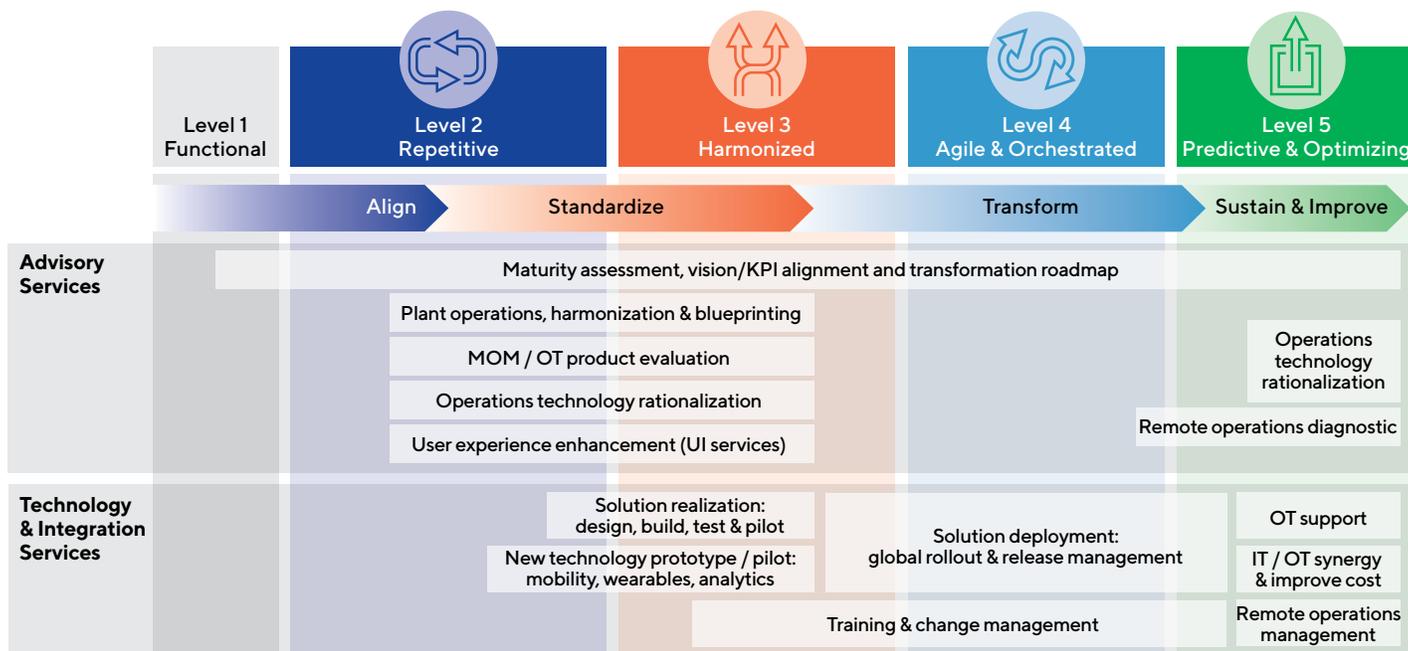
Cognizant OnePlant™

Unified. Quality Driven. Consistency.

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.

Cognizant OnePlant framework

Level 1 Functional	Level 2 Repetitive	Level 3 Harmonized	Level 4 Agile & Orchestrated	Level 5 Predictive & Optimizing
	Align	Standardize	Transform	Sustain & Improve

Advisory Services

	Maturity assessment, vision/KPI alignment and transformation roadmap			
	Plant operations, harmonization & blueprinting			Operations technology rationalization
	MOM / OT product evaluation			
	Operations technology rationalization			Remote operations diagnostic
	User experience enhancement (UI services)			

Technology & Integration Services

	Solution realization: design, build, test & pilot		Solution deployment: global rollout & release management	OT support
	New technology prototype / pilot: mobility, wearables, analytics			IT / OT synergy & improve cost
		Training & change management		Remote operations management

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.

Cognizant 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.
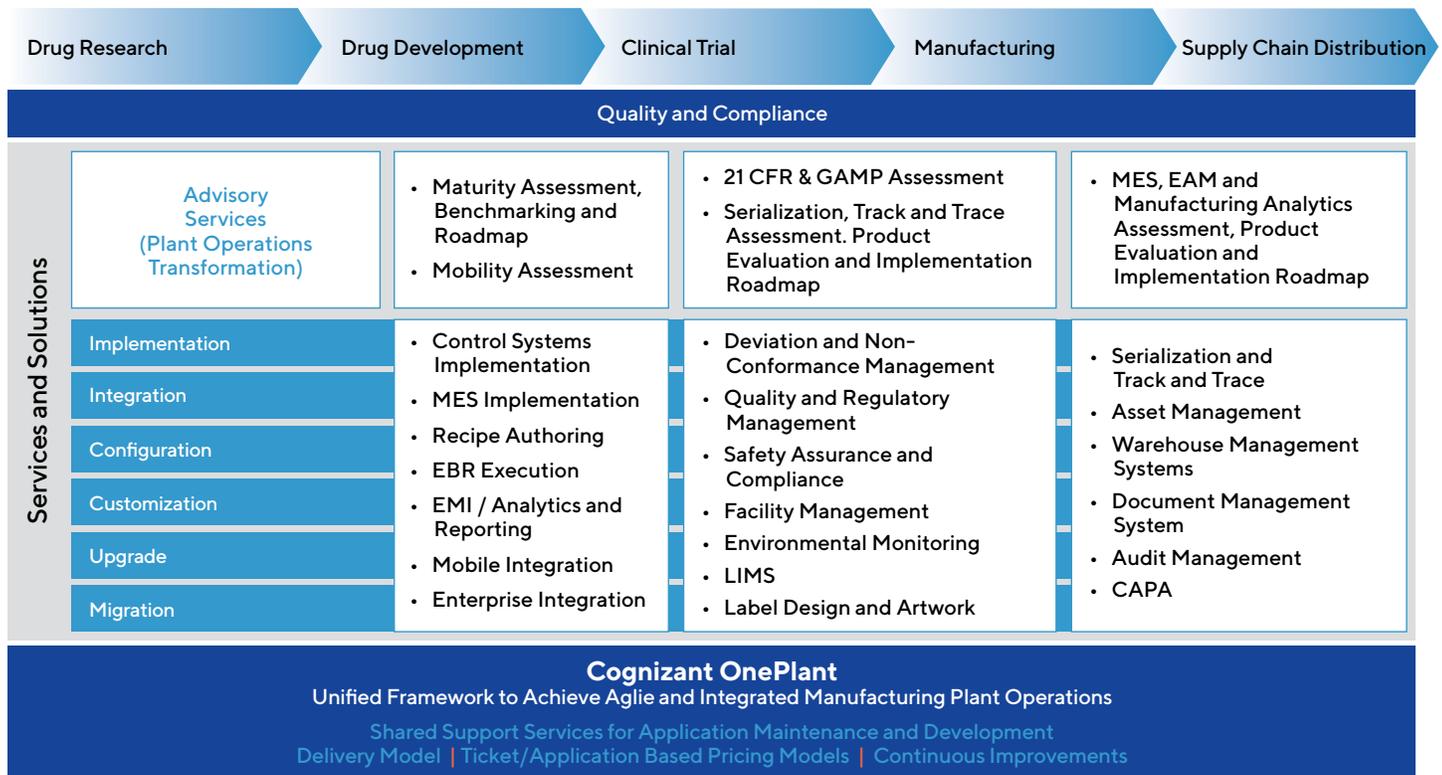
Getting started — vision toward manufacturing excellence

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."

Delivering end-to-end services across the pharma lifecycle

Drug Research	Drug Development	Clinical Trial	Manufacturing	Supply Chain Distribution

Quality and Compliance

Services and Solutions	Advisory Services (Plant Operations Transformation)	• Maturity Assessment, Benchmarking and Roadmap • Mobility Assessment	• 21 CFR & GAMP Assessment • Serialization, Track and Trace Assessment. Product Evaluation and Implementation Roadmap	• MES, EAM and Manufacturing Analytics Assessment, Product Evaluation and Implementation Roadmap
	Implementation Integration Configuration Customization Upgrade Migration	• Control Systems Implementation • MES Implementation • Recipe Authoring • EBR Execution • EMI / Analytics and Reporting • Mobile Integration • Enterprise Integration	• Deviation and Non-Conformance Management • Quality and Regulatory Management • Safety Assurance and Compliance • Facility Management • Environmental Monitoring • LIMS • Label Design and Artwork	• Serialization and Track and Trace • Asset Management • Warehouse Management Systems • Document Management System • Audit Management • CAPA

Cognizant OnePlant
Unified Framework to Achieve Aglie and Integrated Manufacturing Plant Operations

Shared Support Services for Application Maintenance and Development
Delivery Model | Ticket/Application Based Pricing Models | Continuous Improvements

Success stories: Pharma manufacturing excellence

World's Largest Research Pharma

Challenge

- Large scale acquisitions had led to multiple disparate MES systems 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 systems and processes.

Solution

- The client selected Cognizant OnePlant solution framework to lead this transformation assessment.

- Leveraged propriety PACE methodology for accelerated deployment of global MES platform across 70 sites.

- Utilized a standardized solution template to collaborate the development of a comprehensive MES template.

- Roadmap based on phased and modular MES roll outs at site locations.

Outcomes

- 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 planning.

- Enhanced compliance with 21 CFR Part 11.

- Greater ROI: Reduced implementation time through custom accelerators, data migration tools, language translation tools and material master mass update.

Manufacturing IT Roadmap Definition for US Pharma Major

Challenge

- Shift in business strategy that moves from large volume of products to higher number of low volume products.

- Reduce new product introduction 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.

Solution

- Assess the current state of manufacturing processes, system and establish the maturity of key functions.

- Benchmark the maturity of business functions with other pharm organizations.

- 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.

Outcomes

- Cognizant identified opportunities and developed a four year roadmap aimed at improving 14 key result areas.

- We provided a costs savings roadmap for attaining $5M per year per site in the areas of production, quality, maintenance, inventory, recipe management, KPI management and governance model.

Driving KPIs 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.

Key Performance Indicators	Opportunity Value
Reduce scrap & rejects	25% – 40%
Reduce batch review & release time	40% – 65%
Reduce overtime (cost)	10% – 20%
Reduce paper & printing cost	60% – 70%
Reduce plant inventory	10% – 20%
Increase throughput	10% – 20%
Increase yield	2% – 8%
Reduce cycle time	5% – 20%
Reduce data recording & reporting time	45% – 60%
Reduce machine downtime	5% – 20%
Increase DLU	5% – 15%
Reduce cost of deviation	10% – 25%
Reduce testing, validation & deployment time	40% – 50%
Reduce recipe authoring & configuration time	60% – 70%

About Cognizant Life Sciences

Cognizant's Life Sciences business unit is dedicated to building solutions to healthcare challenges and improving the lives of patient around the world. Serving 30 of the top 30 global pharmaceuticals companies, 9 of the top 10 biotech companies and 12 of the top 15 medical device companies, Cognizant is helping the life sciences industry accelerate the shift to digital in research, clinical development, manufacturing, supply chain and commercial operations. The practice provides domain-aligned consulting, business process improvement, systems integration, collaborative platforms and software-as-a-service solutions globally. Visit us at http://cognizant.com/life-sciences.

About Cognizant

Cognizant (Nasdaq-100: CTSH) is one of the world's leading professional services companies, transforming clients' business, operating and technology models for the digital era. Our unique industry-based, consultative approach helps clients envision, build and run more innovative and efficient business-es. Headquartered in the U.S., Cognizant is ranked 195 on the Fortune 500 and is consistently listed among the most admired companies in the world. Learn how Cognizant helps clients lead with digital at www.cognizant.com or follow us @Cognizant.

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