Today's Medical Devices Manufacturing Environment

Rapid shifts in the economic environment in the last decade has made a profound impact on the medical devices manufacturers. Competitiveness and market leadership depends largely on forward thinking strategies, intelligent technology adoption and continuous business process optimization through standardization. Best in class companies and market leaders are evolving into global enterprises focusing on integrating remote plants, factories, global supply chains and processes.

Medical device companies are constantly challenged with introducing high performance products faster than ever with industry leading quality and optimized price points. With industry consolidation and ‘design anywhere -build-anywhere’ approach, plant, process and supply chain integration gets even more complex.

Mergers and acquisitions and product rationalization strategies have added multiple layers of disconnected legacy systems disparate manufacturing technologies and lack of standardization from one plant to the next within the enterprise. While individual plants or business units might have adopted latest technologies and unified processes in their operations, very few organizations have integrated the manufacturing value chain to achieve operational efficiencies and collaborative success.

To meet ever increasing and constantly shifting demands of the market, medical device manufacturing needs to a comprehensive approach to transform plant operations for more in-grained agility, predictability, and responsiveness. Cognizant has a unique framework to enable your company to rewire your operations and helps to transform the way you make products.


Cognizant’s ONEPlant™ framework is a unified approach to achieving truly integrated manufacturing operations that aligns people, process, compliance and technology, towards common vision and goal. We harmonize operations management and operations technology, aligning plants with the overall ERP and Supply Chain.

Cognizant’s ONEPlant™ takes manufacturing through a transformative journey to address end to end challenges existing in the Medical Device Manufacturing. Our frameworks and accelerators help you integrate manufacturing information with multiple business systems already in place and
meets GxP requirements, accelerating time-to-market for competitive differentiation.

Our Unified framework ensures effective and efficient compliance & quality, and aids in automating device history record (eDHR) and traceability, enabling a collaborative solution for the medical industry to establish a paperless GMP environment.

The FDA mandate on Unique Device Identification (UDI) requires manufacturers to implement UDI for Class III & Class II devices by Sep. 2016 & for most of the class I devices by Sep. 2018. Our implementation approach and solution frameworks help in quicker deployment across multiple sites in parallel and in consistent manner.

**Comprehensive offerings for Transformation Strategy**

Our services encompass maturity assessments, blueprinting, product evaluations, roadmap definition for global implementations and ongoing support. Through structured approach aided by our proprietary tools and templates for maturity assessment, we ensure your transformation journey is smooth and seamless from an end-to-end perspective. We define maturity across 5 levels from level 1, where plants are more reactive, to level 5, in which plants are agile and predictive. Key components of Cognizant’s ONEPlant™ framework include:

- **FloorTrack™**: Mobile enablement for the shop floor, delivering Analytics & Reporting, Quality & Maintenance and Material tracking in finger tips
- **Asset Performance Excellence (APEX)**: A Predictive Maintenance and Remote monitoring platform built over on a smart platform, providing single integrated view of enterprise information management
- **Manufacturing Service Bus**: enabling flexibility, reliability and collaboration within plants
- **ONEPlant Implementation Methodology**: set of proprietary tools, processes and accelerators that help in quick deployment turnarounds for Global rollouts of plant floor systems. Our well-defined processes, and techniques ensure alignment of plant strategy with the company’s vision, mission and goals.

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## Services across the Medical Device Lifecycle

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A Unified framework to achieve AGILE and integrated Plant Operations

Shared Support Services, Managed Services for Application Maintenance & Development Global Delivery Model | Ticket/Application based Pricing Models | Continuous Improvements

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solutions overview
Success Stories:

We routinely help solve manufacturing challenges and create business opportunities for a wide range of companies across different industries. Leading global manufacturers choose to partner with Cognizant for our known technology and delivery capabilities in the manufacturing domain. Below are some of the examples of engagements where we have helped our customers transform their operations landscape:

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| **Global manufacturing platform transformation strategy for a leading diversified manufacturer** | • Developed Next Gen MOM System across 80+ sites to replace 30 years of legacy systems  
• End to end system transformation strategy: MOM blueprinting, Road map definition, Build | • Developed a robust and scalable GLOBAL MOM Platform aligned with SAP  
• Lower Total cost of ownership for MOM platform: new system to enable production management, quality management and floor inventory management  
• Hassle free transformation: Robust Deployment Strategy with minimum plant disruptions during changeover |
| **Re-Platforming MES for World’s largest research-based pharmaceutical company to achieve Real Time Manufacturing System** | • The client selected the ONEPlant™ solution framework to lead this transformation program  
• Leveraged proprietary PACE Methodology for accelerated deployment of global MES platform across 70+ sites globally  
• Standard Solution Template - Collaborative development (Core + Site teams) of standard MES template  
• Roadmap based for Phased and Modular MES Roll Out at sites | • Transformed Manufacturing IT (MES/WMS/EMI/Quality) landscape and standardized diverse application portfolio to common next-gen technologies to enable Right First Time  
• 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 like Data Migration tool, Language Translation tool and Material Master Mass Update tool |
| **Harmonizing Complaint Management Processes for two distinct business groups for Global medical company, to achieve Single Global Organization** | • Disparate Compliant Management Systems and MES across 2 distinct business units  
• Multiple processes and no unified view across plants and BUs | • Harmonized complaint management processes for two distinct business groups within the client organization by building a new scalable Complaint Management System  
• Process and system standardization and deployment: Aligned design per product type across multiple BU  
• estimated volume of complaints: Apprx. 100,000 annually  
• Estimated numbers of users: 1000 with 200 concurrent users globally (75+ sites)  
• Global integrated complaint management system to facilitate single global organization  
• Increased level of compliance and quality of product delivery, accountability and response time to customers |
Benefits to Clients

The ONEPlant™ framework enables manufacturers to transform their Plant Operations and drive efficiency, helping to create a Unified Enterprise that is Agile and Fully Integrated:

- Highly collaborative enterprise that shares and leverages best practices across plants operations
- Flexible paperless manufacturing execution and eDHR that is highly responsive and compliant to ever-changing manufacturing landscape
- Enables 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: Real time UDI data availability in EQMS for FDA's Global Unique Device Identifier Database (GUDID)
- Integrated product R&D - manufacturing - supply chain resulting in faster NPI cycle time

About Cognizant

Cognizant (NASDAQ: CTSH) is a leading provider of information technology, consulting, and business process outsourcing services, dedicated to helping the world’s leading companies build stronger businesses. Headquartered in Teaneck, New Jersey (U.S.), Cognizant combines a passion for client satisfaction, technology innovation, deep industry and business process expertise, and a global, collaborative workforce that embodies the future of work. With over 100 development and delivery centers worldwide and approximately 218,000 employees as of June 30, 2015, Cognizant is a member of the NASDAQ-100, the S&P 500, the Forbes Global 2000, and the Fortune 500 and is ranked among the top performing and fastest growing companies in the world. Visit us online at www.cognizant.com or follow us on Twitter: Cognizant.