

LARRY R. LUDENSKY

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- Expertise in electronics and instrumentation manufacturing, new product introduction, and 510K, IDE and PMA submissions for Class II IVD and Class III implantable medical devices in ISO 13485, FDA, cGMP, QSR, and DOD environments.
- Senior-level, Black Belt trained, Lean Six Sigma Manufacturing, Supply Chain, and Operations executive, using a data-driven, hands-on, engineering management and problem solving approach.
- Over 20 years of experience in startup companies, new product introduction, project management, lean manufacturing and operations, supply chain, and engineering.
- New Facility Design, Commissioning, Management and Maintenance including Class 7 and Class 8 cleanrooms
- Change agent leading roll out and deployment of New Products, Lean Six Sigma and other business process improvement programs in commercial, military and government environments and cultures.
- Keen understanding of the interconnectedness and dependencies, of all levels and all functions of the organization and how important it is to develop and maintain a collaborative and cooperative culture

Manufacturing, Operations and Project Management

- Acting as Chief Coordinator, Communicator and Collaborator in large public, small start-up companies as well as start-up environments within established companies
- Director of Operations and Program Manager with responsibilities for managing, maintaining, coordinating, adherence to schedule, and development of metrics for all aspects of New Product Development and Introduction as well as ongoing production including the coordination of:
 - 510(K) approval
 - Process Development, Verification and Validation New Facility build out, commissioning and qualification
 - New Facility Design, Commissioning, Management and Maintenance including **Class 7 and Class 8 cleanrooms**
 - Supply Chain Management and Supply Chain Risk Management
 - Contract Manufacturing
 - Regulatory and Compliance organizations
 - Marketing Product Launch
 - Vendor and Contract Manufacturing qualification
 - Technical Support
 - Customer Service
- Managed design transfer, design control, and configuration management for the transition of multiple new products from development to full commercial production including 510K, IDE and PMA submissions for Class II IVD and Class III implantable medical devices in ISO 13485, FDA, cGMP, QSR, and DOD environments
- Management of Design, Service, Manufacturing and Sustaining organizations including CAPA administration
- Keen understanding of the interconnectedness and dependencies, of all levels and all functions of the organization and how important it is to develop and maintain a collaborative and cooperative

Medical and Scientific Devices

Class 3 IVD, Cervical Cancer Screening

Class 3 Implantable Drug Pump

Class 2 Blood Cell Analysis IVDs, Automated Hematology and Lab automation devices

Project Management – BRAC Construction of new research facilities

Haptically enabled vascular access and surgical simulators

Laser Scanning Confocal Microscopy

Non - Medical

Supply Chain Risk Management - US Air Force - Pentagon

Security Printing (Vital Records and Brand Protection)

Anti-counterfeit protection, Tamper Evident Seals, Track and Trace product authenticity

Sekuworks, (TSA, DHS)

New Product Introduction

- Managed design transfer, design control and configuration management for the transition of multiple new products from development to full production including full support and coordination of all aspects of New Product Introduction, contract manufacturing, vendor and inventory management, service and technical support. Champion of DFA/DFMA processes

Operations and Project Management

- PMP trained (still need to take exam)
- Management of Multi Million Operational Budgets
- Contact Manufacturer and External vendor development and qualification
- Customer Care and product support
- ERP implementation

Through Lean Six Sigma Initiatives

- Improved yield from 65% to over 90% as part of continuous improvement program
- Reduced COGS by 45%
- Achieved an 18%, \$1.1 MM variance in the first year
- Achieved annual savings of \$1.9 million by converting batch manufacturing to JIT processes using Lean Six Sigma Techniques

Lean Six Sigma Process Development, Implementation and Execution

- Using Toyota Production System (TPS) lead Corporate Programs in Lean manufacturing and supply chain organizations, 5-S, DMAIC, PDCA, six sigma, JIT and Continuous Process Improvement techniques