

EUGEN DINU

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ENGINEERING MANUFACTURING QUALITY OPERATIONS EXECUTIVE

◆Leadership ◆Medical Device Manufacturing ◆FDA QSR cGMP ISO 13485 ◆Design Control ◆Validation Management ◆Sterile Manufacturing/Packaging ◆ Management of multi-site operations ◆ International experience in Europe and Asia

Results-driven operating executive with over 30 years of progressive experience in manufacturing, research and development, and engineering management in FDA regulated environments. A highly effective professional possessing broad experience in the medical device and other industries demonstrating a strong ability for the management of technical and financial resources, resolution of complex technical problems and appreciation of the commercial aspects of business. A strategic thinker with proven leadership abilities of multi-cultural teams in changing business environments. An experienced coach and mentor with demonstrated results in developing the talent of individuals and forming successful specialist teams. An entrepreneur combining modern engineering, design and manufacturing philosophies and systematic approaches to consistently deliver strong operating and financial results.

EXPERT QUALIFICATIONS

- Certified Quality Manager (CQM)
- Certified Project Management Professional (PMP)
- Operations and General Management
- Research & Development & Engineering Management
- Manufacturing and Engineering support for multiple plants
- Data-based analysis and decision making
- Financial Oversight -- Profit and Loss Responsibility
- Certified Lean Manufacturing Six Sigma Black Belt (CSSBB)
- Medical Device Manufacturing cGMP & FDA QSR
- Class 100 Clean Rooms, Lyophilization
- FDA Class II and Class III implantable devices
- Quality Assurance, ISO 9001-2015, 13485-2016 & CE
- Long Range Strategic Planning
- Fluent in Romanian, French, Conversational in German

EDUCATION

- M.B.A., Rutgers University, NJ - Major in Business Management, Minor in International Business
 - M.Sc. Mechanical Engineering, Polytechnics University, Bucharest, Romania - Major in Boilers and Pressure Vessels
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PROFESSIONAL EXPERIENCE

PULSE TECHNOLOGIES, INC.
Quakertown, PA

2017 - Present: **DIRECTOR OF QUALITY ASSURANCE**
(Consulting Assignment)

Reporting to the CEO on an interim basis, in charge of the Quality System and Quality Strategy for company's product portfolio, ensuring that short and long range quality strategy, plans, goals, annual operating plans and budgets are aligned with the business. Serve as the "Management Representative" as prescribed in the Quality System Regulation (QSR 21 CFR 820), ISO 13485:2016, and ISO 9001-2015. Create and implement process improvement programs and projects. Lead and Manage a top-performing team of Quality Engineers, and Inspection personnel; mentor, train, and coach. Develop in-process and finished product inspection data using SPC, providing trend analysis and improvement opportunities. Ensure quality product is available to customer through new process design, design review, engineering, customer/vendor relations, manufacturing quality, cost reduction, inspection, environmental monitoring, calibration, training, product serialization, customer complaint management and MDRs. Develop and implement systems that monitor the Quality Management System (QMS) and report to management weekly on audit results, corrective actions, and performance. Follow up and support of employees and teams to ensure corrective actions are initiated, implemented, and measured for effectiveness. Oversee customer complaints, resolve complaints and returned products investigations, analysis, and corrective actions.

- Performed gap analysis and ensured QMS readiness for transition to ISO 13485-2016, ISO 2001-2015, and AS9100 Rev D; Played a major role in getting the company certified to the new version of the ISO 13485 standard
- Built world class quality organization which attracted clients over more established and larger competitors. Collaborated with clients to consistently meet or exceed performance requirements and expectations.
- Created policies related to quality for the organization while assessing appropriate levels of risk associated with specific policy requirements. Improved quality systems by reducing complexity and increasing effectiveness.
- Proactively identified and alerted executive management of quality issues/complaints in time to resolve potential adverse effects to the customer, company image/reputation and/or the business.
- Integrated the SPC computer software platform with the various automated measuring devices' (Keyence, Smart Scopes, CMMs, etc.) output to increase efficiency and eliminate reporting errors.

MERCER GASKET & SHIM
Bellmawr, NJ

2016 - 2017: **DIRECTOR OF OPERATIONS**
(Consulting Assignment)

Hired by the company owner to increase efficiency, reduce costs, increase customer base and market share for this 80,000 sf. specialty gasket manufacturing facility. Site-level responsibility for safety, quality, delivery and cost. Direct supervision of 6 managers responsible for Manufacturing, Quality, Supply Chain, Manufacturing Engineering, Environmental/Health/Safety, and Administration. Total indirect responsibility for 50 employees.

- Maintained 98+% on-time delivery through robust supplier selection and management, visible and data-driven milestone/performance evaluation and direct ownership within operational work cells and teams.
- Achieved 3 consecutive quarter-over-quarter improvements in profit above baseline forecast as well as multi improvements in Sales per Employee and Sales per Square Feet productivity metrics
- Led Lean Daily Management System via Gemba walks to identify and resolve constraints, ensure continuous product flow, foster communication/teamwork and enable on-time delivery of quality products
- Implemented robust CAPA process to ensure root causes of non-conformances are identified via 5-Why and/or Ishikawa diagrams and corrective actions are implemented
- Ensured a safe work environment through monthly process audits including 5S and Job Hazard Analyses.

TRIANGLE TUBE, a division of
ACV INTERNATIONAL GROUP (Belgium), *Blackwood, NJ*

2014 - 2016: **SENIOR DIRECTOR OF TECHNICAL SERVICES & QUALITY**

Responsible for establishing and executing the overall technical strategy for North America in support of ACV International Group's business plan. Lead, plan, organize and direct new product introduction and certification activities, as well as Tech Support, R&D and Engineering, Quality, Documentation, and Warranty Management in support of manufacturing and distribution of European company's residential and commercial products. Responsible for managing, supporting, and providing direction and leadership to project teams and functional leaders as well as taking a hands-on approach in the execution of all Technical Services duties. Responsibilities included:

- Oversight for all technical services in US and Canada for residential and commercial high efficiency boilers and water heating products; established and implemented best practices within the function; realized over \$1.5M/ year in savings
- Support to European corporate R&D and Operations for the advancement of products and services and product launches in the NA market; introduced 2 new product lines and a line extension increasing sales revenue by 17%
- Develop technical specifications for the NA market and interface with R&D and operations in Europe for quality assurance, performance improvements, and regulatory certification of all products; troubleshoot and improve product design and functionality for quality, cost, and compliance;
- Conduct quality audits, resolve discrepancies and problems, and verify corrective action relating to product quality and conformance issues; report trends and concerns to European corporate Quality

ACCURATE INDUSTRIES, a division of
WASTEQUIP LLC. *Erial, NJ*

2012 - 2013: **DIRECTOR OF ENGINEERING AND QUALITY** (Consulting Assignment)

Managed several functional areas within \$85 million operating division that includes leadership of 11 direct and 24 indirect reports within R&D and New Product/Process Development, Sustaining Engineering, Product Support, Manufacturing Engineering, Cost Estimating, Tooling Design, Quality Assurance, and Process Excellence. Manage products and processes for the entire lifecycle.

- Performed successful benchmarking project comparing flagship product line to main competition and used lessons learned to design world-class new compaction product
- Saved \$650,000 annually by redesigning the compaction product line and manufacturing process
- Established Lean Manufacturing practices utilizing cell manufacturing (Kan Ban) and point-of-use inventories resulting in 18% inventory reduction and 38% increase in on-time delivery performance.
- Led strategic engineering planning for the development of new production lines and transfer of multiple product lines following divisional consolidation; streamlined product offering by combining best product designs and features
- Established Lean Program for Operational Excellence focusing on continuous improvement and reduction of waste;
- Developed Quality Management System with Quality Manuals and Operating procedures/policies
- Led culture change initiative that implemented Lean and Six Sigma, engaging employees at all levels
- Developed Operational Metrics emphasizing Key Performance Indicators and Voice of the Customer and aligned division KPIs with corporate goals and expectations
- Restructured Engineering department across the five manufacturing plants to better respond to customer needs in local markets; led team in meeting/exceeding goals on metrics that included on-time delivery, customer satisfaction, safety, operational performance, and profitability.

INTEGRA LIFESCIENCES
Plainsboro, NJ

2007 – 2011 **ENGINEERING MANAGER**

Responsible for management of the Engineering group in support of all manufacturing operations and product development activities in NJ and sister plant in Puerto Rico. Manage activities of planning and development of strategic projects and initiatives aimed at current and future developments in manufacturing, processes, and new product introduction. Manage group of Engineers to assess feasibility of and develop new manufacturing processes for new and existing products, lead development, review, and implementation of new manufacturing processes and equipment, lead and coordinate development of specifications for new manufacturing and testing equipment, coordinate verification and validation of equipment and processes. Manage activities of planning and development for equipment and processes to meet the demands of manufacturing operations and new product research and development.

- Delivered over \$3.5 million in savings in a 4-year period by focusing efforts on productivity increases, cost reduction, scrap

reduction and elimination, implementation of Lean Manufacturing techniques and Six Sigma quality processes. Managed continuous improvement efforts in manufacturing and engineering operations, implemented SPC control system. Implemented advanced manufacturing systems which reduced labor, increased quality, and boosted efficiency levels.

- Introduced several new technologies and products and increased overall sales by 27%. Owned Design Control process, interface with corporate R&D, Voice of Customer process, and Manufacturing process. Implemented risk analysis and problem solving skills to identify potential issues, assess their impact and develop and implement mitigation and resolution.
- Amplified productivity 12% per year and accelerated first-pass yields from 86% to 92% through new process, automation, and tooling improvements.
- Established standards and structure for new product development efforts. Implemented cross-functional teams that evaluated/conducted business risk analysis, proposal development, and manufacturability assessment. Ensured Lean Product Development and Design Control processes and procedures. Completed product development for successful 510(k) registration and launch of five new products in both US and ROW markets. Reduced product development cycle for new products from 12 to 8 months on average.

TWO TECHNOLOGIES, INC.
Horsham, PA

2006 – 2007

DIRECTOR OF ENGINEERING
(Consulting Assignment)

Hired to spearhead the mechanical design and development of a new generation of hand-held computers. Provide leadership and management of the Mechanical Engineering Group to achieve:

- Customer satisfaction - Successful execution of mechanical design projects and the delivery of the design data packages and prototype hardware projects that meet or exceed customer expectations
- Business goals - by executing electro-mechanical design projects within budget, schedule, and meeting technical requirements; Developing potential clients
- Leverage the design effort into production contracts, and improve Manufacturing profit margin
- Managing a team of engineers and designers

PREMIER MEDICAL MANUFACTURING, a division of
PREMIER DENTAL PRODUCTS COMPANY, *Philadelphia, PA*

2002 – 2006

GENERAL MANAGER

Top level executive with overall responsibility for the coordination of all manufacturing division's departments, including the quality system, production, new product design and development, sales, and administration. Member of corporate Executive Committee and major contributor in capitalizing market opportunities, mergers and acquisitions, new product lines implementation into manufacturing. Provide leadership to guide company through the strategic planning and practical implementation of initiatives aimed at increasing manufacturing efficiency, improving process transfer practices, creating a lean and flexible customer-focused manufacturing organization, improving product quality and reliability, reducing time to market, eliminating redundancy and enhancing vendor management practices. Develop long term manufacturing strategies, provide tactical leadership to meet contract (private label) manufacturing commitments, manage cost reduction programs, develop and administer capital and expense budgets. Liaise with all appropriate corporate groups to ensure success of corporate goals. Direct all manufacturing activities to ensure a compliant, safe, efficient, high quality operation. Lead process re-engineering to enhance productivity and increase efficiencies. Provide technical expertise and managerial guidance in the areas of technology transfer, project management, quality assurance, process development and scale-up, validation, manufacturing management, equipment engineering, facilities design, supplier development, contract management, and medical device design and development. Interface with federal and local governmental agencies for medical device and environmental safety compliance monitoring.

- Increased overall sales by 24% by diversifying product offering and process capabilities, addition of new product lines, while reducing costs by 12 percentage points through automation and robotics, changing supply methodologies, competitive bidding, revising product specifications, and securing alternative vendors
- Grew contract manufacturing (private label) sales by 45% within a two year period and maintained increased level by effective customer management and consistent good quality and on-time delivery
- Developed and implemented strategies for the technical transfer of four acquired companies with complimenting products, three of which are medical device manufacturers. Coordinated equipment, process, and product validation, verification, and transfer, including equipment for sterile packaged products
- Forged strategic alliances with overseas suppliers of tooling and components, significantly reducing manufacturing cost

OTHER EXPERIENCES:

T&S DENTAL AND PLASTICS, a division of
KEYSTONE INDUSTRIES, *Cherry Hill, NJ*

8/99 - 12/01: **VICE PRESIDENT OF ENGINEERING**
5/99 - 8/99: **PRODUCT DEVELOPMENT MANAGER**

GARLOCK VALVES AND INDUSTRIAL PLASTICS,
a division of BF GOODRICH -- *Camden, NJ*

1998 - 1999: **ENGINEERING MANAGER**
1995 - 1998: **SENIOR PROJECT ENGINEER**

MUELLER STEAM SPECIALTY, a division of
CORE INDUSTRIES -- *St. Pauls, NC*

1993 - 1995: **PROJECT ENGINEER**
1991 - 1993: **PRODUCT DEVELOPMENT/R & D ENG.**