

Ryan Bauer

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Authorized to work in the US for any employer

Work Experience

Director, Medical Device & Pharmaceutical Solutions

Siemens AG

April 2019 to Present

Global strategy and solutions role for Siemens Digital Industries Software in the definition, application, and solution development of the Siemens software portfolio to address engineering and manufacturing needs for the life sciences industry. Provide leadership for enterprise digital transformation (Industry 4.0) by using deep medical device development experience to tailor and apply software applications such as PLM, ALM, CAD, EDA, MES, Simulation, IoT, Lo-code, etc to industry needs.

- Example solutions developed include: Medical device Labeling tool integration & UDI (Unique Device Identifier) data management; QMS (Quality Management System) and RIMS (Regulatory Information Managements System) accelerators; PLM based ISO 14971 integrated risk management; Low-code apps to augment core data processing such as UDI submission or QMR; & SaaS/Cloud PLM for Medical Device industry solution for product development
- Define and provide input to product roadmaps across the business units for industry solutions.
- Partner with global sales and marketing to establish 'digital threads' to showcase digital transformation vision for customers and stakeholders and support in bridging the technical solution and industry needs.
- Assess strategic actions to partner, acquire, and/or build out solutions to resolve customer needs aligned with market opportunity.
- Partner with regulators and industry groups to provide thought leadership to mature industry practice

Vice President, R&D

Halo Innovations | Aden + Anais - Minnetonka, MN

August 2018 to March 2019

Provided R&D leadership, engineering expertise, and quality/regulatory experience for mixed medical device and CPG company. Successfully launched partnership with GE Healthcare for novel Class II bassinets. Defined product roadmap, process, and project execution for both Halo & A+A brands. Executed organizational development re-definition/implementation to support transition as a medical device company. Additionally, oversaw Quality function including overhaul and deployment of Quality Management System, 1st successful FDA inspection, and served as Management Representative.

Director of Product Development

Medela LLC

September 2013 to June 2018

Direct product development processes and innovation strategy tied to NPD and sustaining engineering within the Human Milk business unit. Business unit includes both retail and professional (hospital)

channels. Global role reporting to CTO that oversees distributed teams to achieve global strategy. Responsible for organizational development and strategic input/evaluation/execution within global R&D team. Core member with CTO for technology and product & platform roadmap development. Facilitate regular Global Product Steering Committee meetings to ensure appropriate project governance. Products successfully developed and launched for US, Europe, China, and Australian markets. Developed first platforms for next generation pumps and applications with re-use across retail and hospital channels.

R&D resource owner for all US based product development personnel including sites in California and Illinois. California site closed end 2017 (enteral feeding business acquisition) and managed R&D transition to McHenry team. Direct and indirect R&D reports approximately 24 full time employees with one digital projects lead report in Switzerland. Team consisted of Mechanical, Electrical, Software, System, Test, DevOps Engineers; Project Management, Product Care (Sustaining engineering), engineering process controls / infrastructure roles, and technicians.

Example achievements over multiple roles:

- Development of new strategic breast pump architecture, product launch, 510(k), and Bluetooth connected app launch (iOS & Android) with global rollout. Recent launch included versioned product for China with country specific app integrated with WeChat.
- Ethnographic research with paradigm shifting products for the NICU, resulting in accretive core product lines and business, including milk warming and management technologies.
- Instrumental in successful 2011 FDA Warning Letter quality system overhaul and remediation efforts. Remediated design & risk controls and significant portions of production and process Controls, supplier management, risk management, and sterilization program. Recently demonstrated MDSAP audit compliance.
- Major cost reductions and quality improvements on core products for lifecycle management
- Design enhancements and DFM to scale products and shift portfolio mix due to massive impact of the Affordable Care Act in terms of volumes, commoditization, reduced ASP
- Significant maturation and establishment of organization development and capabilities. Includes additions of in-house electrical, systems, & software engineering. Re-organization and personnel management to develop lean world-class team.
- Implementation and integration of best in class R&D engineering tools and associated processes such as requirements management, PLM/PDM, statistical techniques, FEA, CFD, etc.
- Established successful co-operative education program with Marquette University since 2013 to train, develop, and employ students from biomedical & engineering disciplines.
- Multiple patents granted and pending

Manager of Product Development

Medela LLC

June 2010 to September 2013

Manage product development department within the breastfeeding business to support new product initiatives within retail and professional channels as well as support existing product lines to maintain productivity, cost effectiveness, and sustainability. Manage & match project resources to strategic initiatives, enable individuals and teams, & provide technical guidance. Resource and prioritize projects, ensuring strategic alignment. Primary engineering member of change review board. Lead and developed R&D organizational processes including harmonization with global teams and compliance to regulations. Additional responsibilities taken on in Operations, Quality, and Regulatory to remediate products, processes, and Quality Management System to successfully address FDA warning letter.

Engineering Team Lead

Medela LLC

July 2008 to June 2010

Supervisory and execution responsibilities for new product development with particular emphasis on hospital channels. Technical lead for new market opportunity explorations, proof of concept, and product definition. Cross functional oversight including project management, ME/SE/EE internal & external resource management, systems architecture, NPD process compliance, & quality and regulatory compliance. Researched, executed, & launched multiple new products for hospital & NICU market ranging from simple parts to complex electromechanical assemblies & associated disposables.

Product Development Engineer

Medela LLC

May 2006 to July 2008

Responsible for core line product improvements, cost reductions, technical investigations, engineering analysis, & project management of breast pumps & accessories.

New Product Group Leader

Juno Lighting - Des Plaines, IL

November 2005 to May 2006

Supervise development work including problem resolutions, design of new models, mechanisms, and adaptations for a wide variety of special and unusual lighting equipment. Work usually involved the application of more than one electric, electronic, optical, or mechanical factor. Manage product engineering team to create new and innovative lighting products and streamline NPD process.

Sr. Mechanical Engineer

Motorola Inc - Deer Park, IL

June 2000 to November 2005

Mechanical program responsibilities for automotive transmission controller modules and cellular infrastructure (custom electronics design/housing/packaging). Responsibilities included customer interface and support, program team coordination, specification development and validation, quoting, sourcing, mechanical design, thermal and structural analyses, reliability, six sigma analyses, environmental testing, packaging, cost reductions, manufacturing support, acoustic testing, new technologies research, platform development, and other development engineering functions.

Mechanical Engineer, Purdue University Co-op Design Engineering Program

Dane Systems Inc - Stevensville, MI

June 1995 to December 1999

Design, Detail & Check of turnkey automation systems. Design of custom automation for various industries integrating assembly lines, vision systems, and robots. Lead designer on a variety of projects. Some designs include brake caliper assembly stations, vacuum potting chambers, robotic loaders, welding and heat stamping operations, pallet conveyance design, and various test stands.

Education

M.S. in Product Development

Northwestern University - Evanston, IL

B.S. in Mechanical Engineering

Purdue University - W Lafayette, IN

Skills

- R&D Strategy Development and Execution
- Leadership/management of technical staff
- Medical device regulatory compliance
- Manufacturing Automation & Implementation
- Stage Gate Process Development & Execution
- Cross-Discipline Aptitude & Communications
- Intellectual property management/strategy
- Risk Assessment & Management
- Statistical Processes & Tools
- Project Management
- Quality Methods (Systems & Implementation)
- Structured problem solving (8D)
- External resource management
- Electromechanical, Reusable, & Disposable Development