Megan Del Rosario, PMI-ACP, CSSBB

Solutions & Systems Engineering Leader

A Solutions & Systems Engineering leader with deep technical expertise delivering enterprise-scale system transformations in regulated medical device environments. Proven success supporting international product expansion, modernizing and optimizing manufacturing and supply-chain platforms, and driving measurable cost, quality, and efficiency improvements through system enhancements and process optimization. I specialize in architecting and validating FDA- and ISO-compliant software and cloud-based platforms, building and scaling high-performing teams, and aligning technical design with business outcomes. Shaped by experience in start-ups and high-growth organizations, I bring a hands-on, lean, and agile engineering approach with a diverse background and end-to-end operational depth across manufacturing systems, supply chain operations, new product introduction and design transfer, and enterprise business systems. I operate comfortably at both the architectural and execution layers, partnering cross-functionally to translate complex requirements into scalable, compliant, and resilient solutions that enable sustained growth.

www.megandelrosario.com

www.linkedin.com/in/meganlyndelrosario

meganlyndelrosario@outlook.com

Whittier, CA

Master of Science
Electrical & Computer Engineering
University of Colorado Boulder

Bachelor of Science
Electrical Engineering
California State University, Long Beach

Bachelor of Science
Biomedical & Clinical Engineering
California State University, Long Beach

- Process & Systems Development
- Requirements Engineering
- Integration
- Risk Management
- Verification and Validation
- Configuration Management
- Compliance (21 CFR Part 11, 21 CFR Part 820, ISO 13485, ISO 14971)
- Lean Six Sigma
- Data Analysis & Programming (SPL, Python, MATLAB, HTML, CSS, XML, JSON, C, Java, WPF)
- Systems (Salesforce, QAD, AWS, SAP, Splunk, Dell Boomi, Workato, GitHub, Bit Bucket, JIRA, JAMA, Confluence)
- Stakeholder & Project Management

Experience

iRhythm Technologies, Inc. | Cypress, CA

Staff Solutions Engineer | 2024 - Present

Leads enterprise solutions engineering initiatives defining system architecture, integrations, and validation strategies in regulated environments. Drives cross-functional alignment to deliver compliant, scalable platforms that improve operational performance and enable global growth.

- Built and scaled the Solutions Engineering organization as the inaugural role, defining the function's technical charter, career ladder, and level-based skills matrix (entry through principal), while leading recruitment, technical interviews, and team formation.
- Spearheaded an enterprise Business Continuity Planning initiative sponsored by the EVP of Business Operations, partnering with cross-functional leaders to map end-to-end value streams and identify critical process and system dependencies and risks. Developed BCP governance procedures, Business Impact Analysis (BIA), supply chain and value stream risk assessments, enterprise risk register, and a scalable Business Continuity Management System (BCMS) implementation strategy—providing executive and c-suite leadership with a structured, risk-based framework to strengthen operational resilience and business continuity.
- Owned technical delivery for multiple international product expansions, enabling compliant market entry across Europe and Asia. Owned system integration testing and validation across regulated manufacturing and clinical systems. Defined and executed SIT, UAT, process validation, and system validation strategies while developing project timelines and aligning cross-functional stakeholders.
- Owned the design, validation, and implementation of an intelligent document processing pipeline. Architected a machine-learning and generative AI–enabled solution to extract and summarize symptom log data and established a sustainable AI operating model, including model performance monitoring, continuous improvement, and controlled change management within a regulated medical-device environment. The solution resulted in reducing data center processing time by roughly 80% and enabled recurring cost savings projected to exceed $3M by 2028.

- Led enterprise systems transformation to streamline core manufacturing and supply-chain processes by reducing legacy customizations and standardizing workflows through SAP. Established a scalable digital foundation enabling future MES deployment and smart manufacturing capabilities.
- Drove global 3PL and 3rd party distributor implementations across the Netherlands, Japan, and the U.S. in support of international business growth and market expansion. Acted as the point of contact for cross-functional and regional issue resolution, owned ERP-to-3PL and 3rd party distributor integration requirements, defined standardized inventory replenishment and control processes, and led system and process validation to enable scalable, compliant global operations.
- Led execution of the implementation strategy and owned cross-functional coordination across IT, Quality, and Operations to stand up a U.S.-based intake data center in response to volume growth in addition to driving process and system validation activities ensuring compliant, production-ready operations.
- Owned closure of a validation CAPA for the Splunk Cloud Platform, defining and executing the validation strategy for the Splunk Cloud Platform establishing a compliant, risk-based validation framework clearly delineating core platform features and service provider responsibilities versus business configuration ownership ensuring traceability, audit defensibility, and a sustainable re-validation strategy for ongoing platform changes.
- Developed the initial implementation strategy for a battery reuse and re-certification program and served as a technical advisor to a peer Staff engineer who led execution. Guided stakeholder alignment, delivery and resource planning, timelines, and technical decision-making. Wrote code to generate inspection reports used in receiving inspection, enabling serial-number-level traceability and risk-based sampling to verify battery reuse counts against defined acceptance thresholds. The program reduced battery costs delivering approximately $2.8M in initial avoided costs with recurring annual savings.

Senior Systems Engineer | 2018 – 2024

Systems engineering leader responsible for the architecture, integration, and validation of enterprise manufacturing systems. Defined system, data, and integration requirements; led risk management and computer system validation; and delivered compliant, scalable solutions supporting global operations and new product introductions through cross-functional partnership with Manufacturing, Quality & Regulatory, IT, Product & Systems Development, and Supply Chain.

- Led a multi-phase transformation of outbound fulfillment operations, spearheading warehouse re-layout and system-driven shipping process optimization using Lean, Agile, and value stream mapping principles. Reduced home enrollment order cycle time from 76s to 22s (~71%), increasing per-station throughput ~3.45x, and improved in-clinic shipping cycle time from a 6.5-minute weighted average to 4.0 minutes (~38%), increasing per-station throughput ~1.6x. Cut home enrollment shipping process labor requirements by 50% and enabled parallel in-clinic shipment processing by deploying ERP-integrated print-and-apply labeling, with the ERP integrated to multiple shipping carriers to automate label creation, validation, and shipment confirmation across multiple concurrent shipping stations. Expanded shipping stations from 8 to 14 (+75%), delivering a ~6.0x increase in total outbound shipping capacity for home enrollment and a ~2.9x increase in total outbound shipping capacity for in-clinic fulfillment, while reducing manual handling, improving shipping accuracy, optimizing space utilization and material flow, and supporting scalable 3PL inventory replenishment.
- Implemented ERP System Shipping Controls to meet regulatory compliance requirements for product introduction into international markets.
- Defined and led validation and implementation strategy, created project timeline, and authored functional, data, and integration requirements for a supervisory control and data acquisition (SCADA) system.
- Chaired weekly OEE meetings focusing Production, Manufacturing Engineering and Product Development resources, improving OEE from the low 40's into the 80's on a critical new product line.
- Closed critical CAPAs by leading ERP system enhancements and validation in partnership with development teams and designing, developing, and validating new production and intake software applications (C#, XAML, Windows Presentation Foundation), strengthening process controls and reducing labeling errors, incorrect shipments, and patient/product traceability risks.

Production & Intake Supervisor | 2017 – 2018

Front-line operations leader responsible for daily production, testing, and intake of wireless ambulatory ECG devices. Managed and developed a team of 26 operators while owning production and intake data center scheduling, KPI tracking, and continuous improvement initiatives to improve efficiency, yield, and throughput in a GDP/GMP-regulated environment.

Certifications

- PMI Agile Certified Practitioner (PMI-ACP) | Project Management Institute
- ASQ Certified Six Sigma Black Belt | American Society for Quality (ASQ)
- Medical Device Non-Product Software Validation & QMS for Medical Devices (QSR & ISO 13485) | Oriel Stat A Matrix
- AI For Business Leaders Nanodegree | Udacity School of Artificial Intelligence