SR. STAFF - BUSINESS PROCESS OWNER, DESIGN CONTROLS

Becton Dickinson (BD)

June 2024 - Present

In BD's Infusion organization, I serve as Business Process Owner for Design Controls. I work across quality, regulatory, R&D/product development, labeling, document control, operations, quality systems, CAPA, and audit teams to make design-control processes compliant, coherent, usable, and scalable.

This is primarily design-controls business-process and QMS-integration leadership rather than day-to-day device design. I apply a product-systems view to the connections among user needs and requirements, risk, traceability, verification and validation, labeling, issue and change control, design transfer, training, and controlled-document release. Key skills and experiences:

- Design-control process ownership
- Requirements and traceability
- Verification-impact strategy
- Labeling process integration
- CAPA and change control
- Audit readiness and support
- QMS digitization
- Applied AI and knowledge systems

Design-Control Process Ownership and QMS Integration

Restructured interconnected procedure and template suites for design inputs, design review, design verification, design outputs, and related lifecycle records. The work included simplifying instructions, introducing or revising templates, removing redundant content, and clarifying how the documents fit together across the product-development lifecycle.

Built visual schedules, impact assessments, trackers, decision logs, and release-readiness views to make dependencies, owners, approvals, blockers, and downstream changes visible. I use these systems to coordinate controlled-document changes while protecting consistency across risk, requirements, traceability, verification, labeling, training, and document control.

Requirements, Traceability, Risk, and Verification Strategy

Helped define future-state requirements and traceability workflows, including requirement levels, attributes, rationales, parent/child relationships, deliverables, and interim operating methods while digital implementations were incomplete. Authored a major traceability-matrix overhaul that clarified complete requirement coverage and parent/child relationships.

Developed and substantially supported verification-impact instructions and templates that make software and system change decisions more systematic. I also identify cross-document or system gaps, connect change assessments to risk and verification evidence, and escalate recurring traceability problems rather than treating them as isolated document defects.

Labeling Development and Change Processes

Authored and released a quality plan for labeling development and change, facilitated current- and future-state workflow mapping, and coordinated process updates across technical publications and related labeling deliverables.

Developed and implemented a labeling inspection worksheet and verification-report flow to strengthen traceability of labeling content and evidence. Connected labeling requirements and changes to design inputs, risk controls, verification, release, issue tracking, and change records, then built an onboarding and transition plan for the incoming labeling process owner.

CAPA Execution and Audit Readiness

Contribute to CAPA investigation, action planning, execution, and closure when design controls, labeling, requirements, traceability, or verification are affected. I translate corrective actions into coherent changes to procedures, templates, data fields, training, and system workflows, and have completed documented actions on or ahead of their stated due dates.

For a verification-impact CAPA, audited draft instructions, identified invalid references, built a multi-document impact assessment, authored two supporting matrix templates, and coordinated release of the linked document package before the deadline. For a separate requirements-traceability CAPA, authored and released the traceability-matrix overhaul described above as an interim solution when the planned digital system slipped.

Supported multiple corporate and external audits through pre-request packages, document retrieval, subject-matter-expert coverage planning, process explanations, and front-room or back-room coordination depending on the audit.

QMS Digitization, Data, and Process Improvement

As a core product-development QMS representative, translated controlled processes into system-supported workflows and launch scope for enterprise digital tools. Built impact assessments, decision logs, current/future-state bridges, and must-have versus later-phase classifications, then authored the launch-critical design-control documents needed for the initial rollout.

Challenged document count as a proxy for QMS burden by evaluating the complexity and page impact of a multi-year change set. The analysis showed that most changes reduced complexity and that corrective actions drove most complexity increases; I proposed complexity and page count as more meaningful measures.

Training, Governance, and Cross-Functional Leadership

Developed design-review training content and delivered a multi-session training series for the Infusion organization. I also coach teams on design planning, requirements, risk controls, traceability, verification evidence, and controlled-document execution.

Work across distributed quality, R&D, regulatory, labeling, document control, IT/quality systems, and operations teams. I use written recaps, visual schedules, decision logs, explicit ownership, and structured working sessions to turn complex process questions into decisions and released work.

Applied AI and Knowledge Systems

Designed and deployed an internal, source-grounded QMS chatbot after completing licensing, access, governance, and non-GxP classification work. The assistant directs users to current controlled sources and supports navigation, comparison, and summarization; human review and the controlled QMS remain authoritative.

Built reusable prompt, comparison, and evidence-classification workflows for QMS harmonization, change-context summaries, procedure explainers, and structured work synthesis. I train colleagues to use these tools responsibly and position AI as a workflow and productivity differentiator, not a regulated decision-maker or customer product.

QUALITY ASSURANCE & SYSTEMS ENGINEERING LEAD

Riva Health

April 2022 - June 2024

At the medtech startup, I worked closely with the Director of Quality as a two-person quality team. In addition to establishing quality systems and processes, I guided the engineering team on design controls, risk management, testing strategy, requirements, compliance, and DHF documentation. Key skills utilized:

- Risk Management
- QMS processes
- Product Development Process
- Design Controls
- SOP & template development
- Documentation strategy

Medical Device Process Guidance

One of the most challenging aspects of my role at Riva was that nearly all of the 25-employee team had no medical device experience. Since the engineering team came from consumer software backgrounds, it was an ongoing effort to teach and reinforce the principles of medical device QMS processes and risk management. By breaking down processes to their simplest elements and providing frequent coaching and feedback, I was able to guide the team through project phases with the appropriate DHF documentation.

Risk Management & Traceability

In the start-up environment, we looked for every opportunity to streamline and automate the complex QMS processes. One such opportunity came in the realm of risk management and traceability. Using Coda as a web-based software tool, I was able to generate and connect information from the Hazard Analysis, UFMEA, DFMEA, User Needs, Product Requirements, Software Requirements, and Traceability Matrix. The result was an interconnected system that would propagate changes across documents to ensure consistency and reduce the need for manual document updates.

Documentation Strategy

Riva's fast-paced dynamic environment led to many unique challenges in the product development processes. Unexpected technical issues forced us to think creatively about our documentation strategy, and I frequently played the role of "bad cop" in guiding the team toward compliance. In some cases, we needed to stick to the letter of the law. In other cases, the spirit of the law could serve as compass as we generated rationales for late-stage design changes and unconventional validation strategies.

SENIOR SYSTEMS ENGINEER

Cantel Medical

September 2017 – November 2021

2020-2021

As the project's Technical Lead, I managed the assessment of Cantel's Endoscope Reprocessor products against ISO 15883-4, including design changes, testing, and other activities to achieve compliance.

Key skills utilized:

- Compliance gap assessment
- Translating standards into requirements
- DHF remediation
- Team leadership

Requirements Generation & Gap Assessment

Cantel had seven product lines that fall subject to ISO 15883-4, and no detailed assessment of the standard had ever been completed. I started the process by translating the standard, line by line, into ~150 specific product requirements. We then performed a systematic gap assessment for each product against the requirements, identifying any areas where new evidence needed to be generated and gaps that necessitated design changes. This framework set the scope of the remaining work, which proved to be substantial. The process of gap closure involved engineering analysis and rationales, managing testing with external labs, in-house verification and validation, and coordinating software/firmware design changes.

Design Changes to Released Products

The design changes triggered by the 15883-4 gap assessment spanned five product platforms with dozens of SKUs. For each substantial change, I created a scaled-down design development plan (DDP) that outlined the scope of work, testing, documentation updates, and implementation plan. The rollout involved coordination between R&D (mechanical, software, chemistry, and microbiology), manufacturing, marketing, sales, and regulatory across multiple geographies.

Leading a Globally-Distributed Team

The project team had members spanning five countries, from the U.S. to Italy, so communicating virtually across time zones and language barriers was critical to our success. I managed the project using videoconferencing, document sharing, and other digital tools, but the most crucial factor was clear communication. We were able to succeed through ample use of meeting minutes, checklists, action items, dashboards, crystal-clear emails, and concise purposeful meetings.

2019

As the project's Technical Lead, I coordinated the design feasibility efforts of our next-generation endoscope disinfection product.

Key skills utilized:

- User needs
- Design feasibility
- Testing strategy
- Root cause analysis

Deriving Feasibility Questions from User Needs

With a new product offering, there was considerable uncertainty about what customers wanted and what the product should deliver. Working closely with stakeholders in Marketing, I guided the definition of user needs, considering tradeoffs and timelines. From those user needs, a handful of must-haves stood out as being technically challenging. Those became our key feasibility questions which drove the testing strategy.

Testing Strategy

With limited time and shared resources, we had to be strategic about how we gathered data to reduce technical risk. I implemented a strategy of iterative testing, following a flowchart to narrow our focus and answer targeted questions with each new study. Utilizing statistical tools to determine sample sizes and halting tests as soon as the results became statistically significant, we were able to drive down the technical risk and answer key feasibility questions with minimal time and cost to the company.

Root Cause of Failed Sterilization

With this product, we hoped to raise the bar of endoscope reprocessing from "High Level Disinfection" to "Sterilization". This proved to be a challenge as sporadic failures appeared in the data. This led us to reassess the results and test method from the ground up, using cross-functional brainstorming, fishbone diagrams, 6 M's, 5 Why's, and targeted experiments to determine the root cause of the failures. We successfully identified the root cause and dispelled the belief that these were test method errors, leading to fundamental changes in the way we approach the problem of sterilization.

2017-2018

As the project's Technical Lead, drove the successful redesign, characterization, verification, validation, and launch of the Scope Buddy Plus product.

Key skills utilized:

- Product development process (PDP)
- Requirements generation
- Traceability
- Design for manufacturability

Schedule and Team Management

This project involved a product that had been launched and then withdrawn because of quality issues. As the team inherited the product, I coordinated the redesign scope, technical plan, schedule, and execution using visual schedules, action tracking, and cross-functional decision-making. The work progressed through redesign, characterization, verification, validation, and design transfer before relaunch.

System Architecture & Risk Assessment

Seeing the product with fresh eyes, I started by establishing the system architecture, mapping the components and interfaces with a detailed boundary diagram. This provided a foundation for the DFMEA and risk assessment based on those failure modes. The DFMEA drove new requirements and design changes that proved to be critical to the product's quality and reliability.

Requirements Management

The product was re-assessed from the ground up, starting with user needs, leading to product requirements and design specifications. I utilized Jama as a requirements management tool, as well as a more traditional traceability matrix. These requirements drove every part of the redesign and V&V process, and the organized traceability matrix allowed for greater clarity and understanding during design reviews.

Design Transfer

The original product was designed in a vacuum without much input from manufacturing. Naturally, that resulted in a time-consuming error-prone assembly process. With manufacturability in mind, we involved production engineers early in the design process. We established documents, checklists, reviews, and educational tools to ensure posterity and a smooth transfer of the design to manufacturing.

DIRECTOR OF OPERATIONS

Motion Physical Therapy

April 2016 - April 2019

Working nights and weekends with the company's founder, I implemented systems and processes to launch, manage, and scale the physical therapy practice, growing the company to three locations and twelve employees in three years.

Key skills utilized:

- Business process development
- Financial analysis
- Business analytics
- Website development

Implementing Business Systems & Processes

In a small business, you wear many hats, but my most important role in the company was developing and implementing the systems and processes to become the backbone of a lean and efficient business. This included payroll, benefits, company communications with Slack, project and task management with Trello, online patient scheduling system, employee onboarding and training processes, paperless patient intake, financial reporting, and a variety of other processes that needed to be clear and simple enough for a new employee to hit the ground running. I found great joy in developing ways to simplify and automate tasks to make employee's lives easier.

Financial Modeling & Sensitivity Analysis

Decisions needed to be made with some amount of uncertainty, but I continually sought to provide clarity and confidence in those decisions using data analysis. In one case, I used our first few months of financial data to create a model simulating all expenses and revenues. I could then perform a sensitivity analysis to illuminate the business variables that had the greatest impact on our bottom line. That information allowed us to direct our time and money to the most important factors. These financial models also became useful in setting salaries for new physical therapists, deciding when to open another clinic, setting budgets, and negotiating contracts with service providers.

Business Metrics & Analytics

Being a newcomer to the world of private medical practices, I often brought a new perspective to clinic operations. Notably, I was able to apply my engineering expertise to draw insights from readily-available data. After establishing relevant performance metrics, I created various dashboards using Power BI that allowed us to track clinic performance, see trends in patient demographics, better prioritize referral sources, and quickly gauge the financial health of the business. These dashboards visualized the data in a way that was easily understood and actionable for clinicians and the business owner. They became such a useful tracking tool that other clinic owners reached out wondering if they could have the same dashboards made for their own practices.

SENIOR MECHANICAL ENGINEER

Medtronic

January 2015 – September 2017

2017

As the Development Lead on a CAPA project, I led the development and testing of motor reliability design improvements for Medtronic's SynchroMed II implantable drug infusion pump.

Key skills utilized:

- Root cause analysis
- Feasibility testing
- Data-driven decision making

Design Concept Feasibility

The leading failure mode of the SynchroMed II pump motor was wear at the gear/pinion interface. This was a high-harm failure mode that required a reliable solution. Our team downselected from several design concepts, and I led the efforts to evaluate the technical feasibility of the three remaining designs. This involved testing strategy, supplier relations, test method development, measurement system analysis, DFMEA activities, and various statistical analyses to make data-driven decisions.

CAPA Closure

The motor-reliability CAPA had remained open after several design changes. I analyzed historical reliability data and used FMEA methodology to evaluate remaining design alternatives and build an evidence-based risk argument for leadership and regulatory review. The work demonstrates my ability to combine product data, reliability analysis, risk reasoning, and technical decision-making in a high-stakes remediation program.

2015-2016

As the Mechanical Lead on a design remediation project, I led design characterization and verification for the mechanical aspects of Medtronic's SynchroMed II implantable drug infusion pump.

Key skills utilized:

- Statistical test strategy
- Data analysis (Minitab)
- Design Verification
- DRM blackbelt tools & methodology

Strategy for Reducing Testing Burden

These implantable devices were expensive and time-consuming to test. In an effort to reduce testing time and cost, I produced a variety of data, analyses, and rationales that successfully minimized sample size and verification test complexity. In one case, we performed a DOE to investigate the interaction effects of environmental conditions that impact infusion accuracy. This demonstrated a lack of interaction effects, which reduced future test durations by 75%.

Other examples:

- First-principles analysis and rationale for using H2O or saline for infusion tests rather than drugs
- Weibull analysis of historical data to find minimum cycles needed to demonstrate durability
- Repeatability rate sensitivity study showing no significant difference in repeatability across infusion rates, reducing future test duration ~80%

Characterization & Verification Testing

Under an FDA Consent Decree, there was considerable pressure to produce airtight device data to demonstrate the safety and quality of the product. I planned and coordinated the design characterization testing (DCT) and design verification testing (DVT) of various mechanical performance aspects of the device, including durability, infusion accuracy, leak testing, repeatability, shipping, and cyclic fatigue. This also included Monte Carlo analysis of DCT data to predict the probability of DVT failure, revise specifications, and determine minimum sample sizes for DVT. Both phases of the project were completed on-time and under-budget.

Root Cause Analysis

Product failures can provide valuable learnings if a root cause is identified. The complexity, small size, and hermetically-sealed nature of this infusion pump often made it difficult to analyze failures. In one case during DVT, I was able to successfully identify a root-cause by utilizing DMAIC tools (e.g. Contradiction Matrix) and detailed analysis of raw instrument data. The result allowed us to exclude that sample, saving the 4-month accelerated life test from having to be repeated.

Other examples:

- During Design Characterization, successfully identified and mitigated root cause for under-infusing pumps, resulted in test method change (venting of the inner chamber) which resolved the issue for DVT.

PROCESS ENGINEER II

Boston Scientific

January 2014 – December 2014

In the Process Development group, I worked to create, implement, and improve the methods used to build and measure Boston Scientific's next generation Watchman LAA device (cardiac implant).

Key skills utilized:

- Test method development
- Measurement system analysis
- PFMEA
- Cycle time reduction

Test Method Development – Implant Geometry

The nitinol implant had a complex shape that resembled a pumpkin made of chicken wire. In particular, the tiny hook-like anchors protruding from the sides needed to be of a specific height, diameter, and angle. Using a SmartScope optical measurement system, I developed a program, test method, and fixture design for measuring the anchor dimensions. This included Gage R&R and test method validation.

Test Method Development – Fabric Port Size

The design included a cross-weaved PTFE fabric covering the distal end of the implant. This fabric needed to have a specific pore size to balance the tradeoff between Push Force (for trans catheter delivery) and epithelial cell growth. Using a SmartScope optical measurement system, I developed a program and test method for measuring the distribution of fabric pore sizes. This included Gage R&R and test method validation.

Inspection Time Optimization

Building the implants was a manual process with low yield and long inspection cycles. I implemented statistical tracking of production metrics, streamlined visual inspection instructions, and helped lead implementation of a custom optical measurement system for the most time-consuming measurements. Contemporaneous review records document approximately a 50% reduction in the primary SmartScope measurement cycle.

Design, Build, Test

Working closely with the R&D team, I participated in the cycle of build, measure, and learn as we improved the implant and evaluated design tradeoffs. These activities included root cause analysis, evaluation of design changes, bench test, and observation of animal studies.

ENGINEERING INTERN

Spine Wave

May 2013 – December 2013

Working remotely with the VP of Engineering & Business Development, I investigated technical issues and business opportunities for Spine Wave's new synthetic bone graft product.

Key skills utilized:

- Synthesizing medical research studies
- Product failure analysis
- Identifying market opportunities
- Analysis of competing products

Analysis of Field Issues

The new synthetic bone graft product had fewer than twenty implant cases, so there was limited data on product failures, issues, and feedback from surgeons. I used the details of each case combined with existing research on bone biology and graft materials to identify possible root causes and procedural improvements.

New Product Applications

The company had a handful of biologics technologies with potential applications in spinal surgery. I synthesized information from hundreds of medical research studies to identify the clinical applications that were most promising, and those that should not be pursued.

Analysis of Competing Products

Using any information that is publicly-available (published research, FDA product events, competitor marketing, etc.), I analyzed competing products to identify strengths, weaknesses, and areas where our product had a competitive advantage. This info was used to develop messaging and resources for Sales and Marketing.

Support for FDA Responses

After inquiry from the FDA, I synthesized literature evidence to construct arguments for responding to each question.

MECHANICAL ENGINEERING CO-OP

Medtronic

October 2011 – August 2012

As a full-time engineer on the mechanical design team, I worked on the development of Medtronic's next generation implantable drug infusion systems (NGIIS).

Key skills utilized:

- Test method development
- Statistical analysis
- Failure analysis
- Technical writing

Test Method Development for Particle Counter

There was a need to count the small number of particles on passivated device parts. The existing method introduced particulate contamination, which raised the noise level to a point that made it impossible to obtain accurate measurements. I developed a new test procedure, reducing contamination by 96% and allowing for accurate particle counts.

Pump Calibration Optimization

The device required a multi-point calibration during manufacturing. Some calibration points greatly improved the accuracy but were very time-consuming to measure. Others were quick but resulted in a less accurate calibration. I worked with another engineer to develop a mathematical model (using Crystal Ball) to optimize the calibration procedure for time and accuracy.

Supplier Quality Management for Spring Pin Components

Worked with multiple suppliers to solidify a design for a spring pin connector, utilizing tolerance stack-ups and Monte Carlo analysis to set specifications and control quality.

Product Failure Analysis

Using product complaint data, I organized and analyzed failures for multiple pump models to identify common failure modes, differences between product iterations, and possible impact of design changes. Applying those learnings, I reviewed and revised the teardown process for returned product to better identify and categorize common failures. This included a new process of extracting fluid from the pump chamber, allowing for volume measurement and chemical analysis.