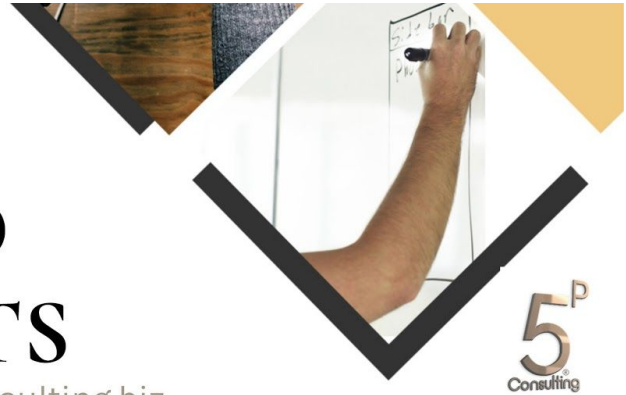


TAKE YOUR BUSINESS TO NEW HEIGHTS

www.5Pconsulting.biz



M&A: Regulatory Complaints System

OVERVIEW

As a global medical device manufacturer, 5P's client is required to support FDA and HIPAA regulations. Following an acquisition, our client grew significantly in both product lines as well as its customer base. In the acquisition process, company A would maintain its operations and process while divesting products and customers to company B. Company A's legacy processes and systems to manage regulatory requirements needed to stay in place and Company B needed a mechanism similar to ensure customer service management and compliance regulations post divestiture.

With the new acquisition, Company B needed to transform how they dealt with complaint handling for their product lines and ensure they had a technology solution that rolled up into their overall architecture from a design and support perspective as well. The industry business processes the company must follow included capturing inquiries, complaints, and escalation for investigation review for products internally, as well as reporting to the FDA regulators.

WHAT WE DID

Together, the company's Information Technology, Regulatory Organization, and 5P architected and delivered an industry solution. The solution streamlined and automated the unique FDA regulatory requirements process for medical device manufacturers. The partnership between the client and our rock star consultants led to a re-engineered *FDA Regulatory Complaints Handling System*.

HOW WE DID IT

Salesforce Platform

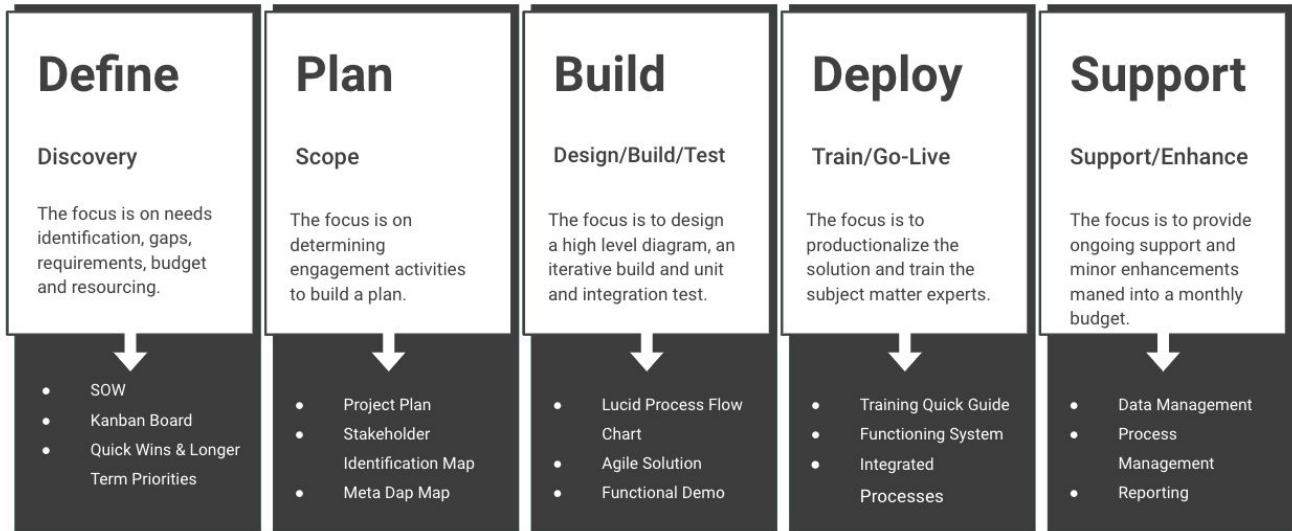
5P expanded on client B's Salesforce investment on the *Sales* process side and built a custom solution for the *Service* side of their business. By leveraging the platform, the client would benefit from an integrated solution across the company with shared master data, including customers, distributors, products, and sales. The user experience aligned with other tools the user community leveraged in their Salesforce CRM. At the end of the engagement, since Salesforce was already their CRM, the company would be positioned to support the solution with an integrated approach in their Information Technology team.

5P's Salesforce experts architected and delivered a custom industry solution to support the entire business flow as depicted below. From a technical perspective, leveraging Salesforce's platform allowed for the rapid delivery of functionally through available standard objects throughout the build. To fulfill the solution's complex requirements, the team was challenged to deliver an extensive number of custom objects, multiple Visualforce pages, flows, processes, workflow automation, validation rules (both standard and Apex), approval processes, and a complex data security model.

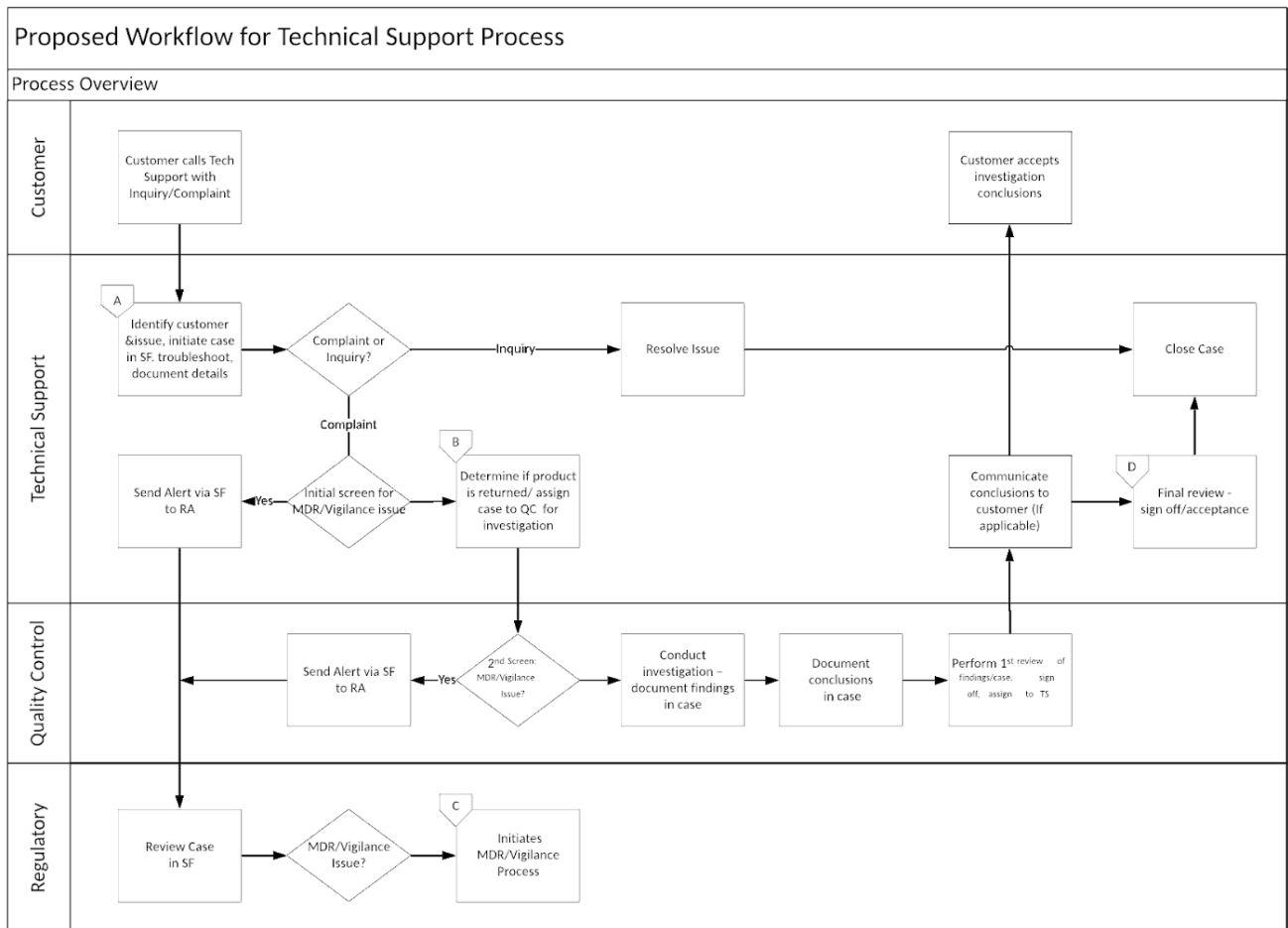
5P's Lean Framework

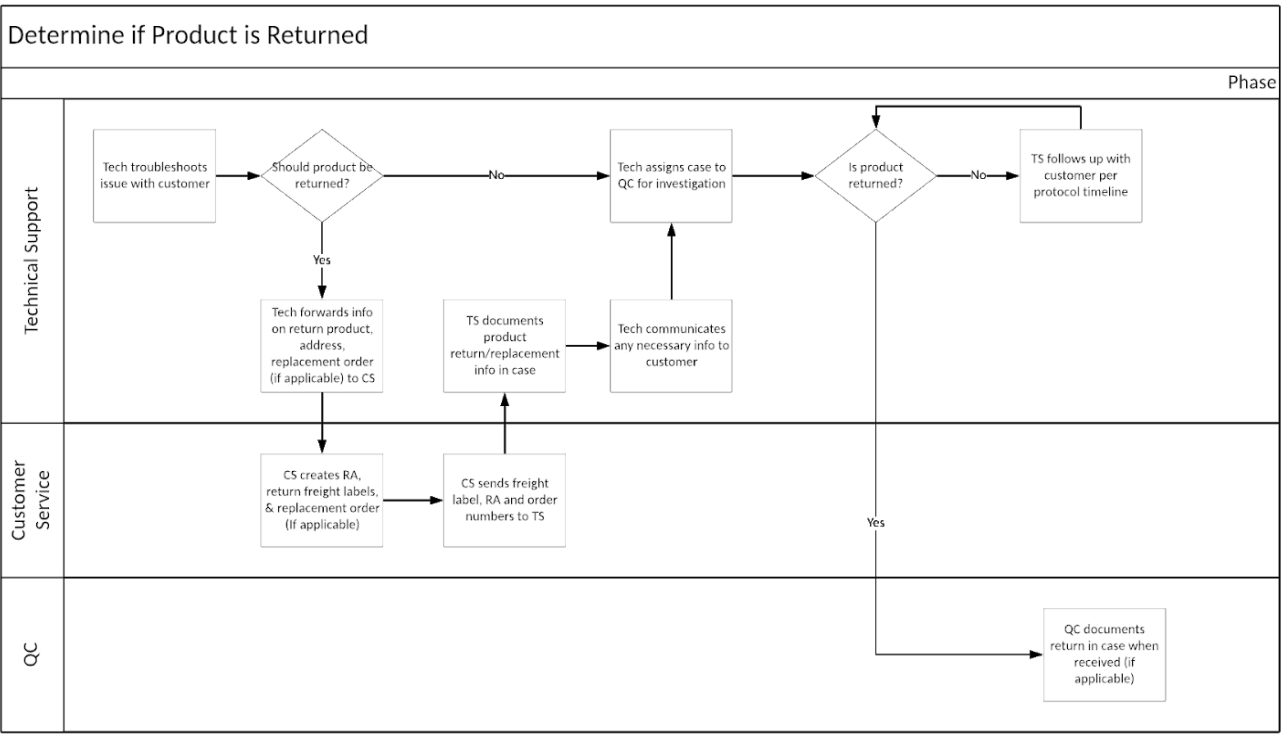
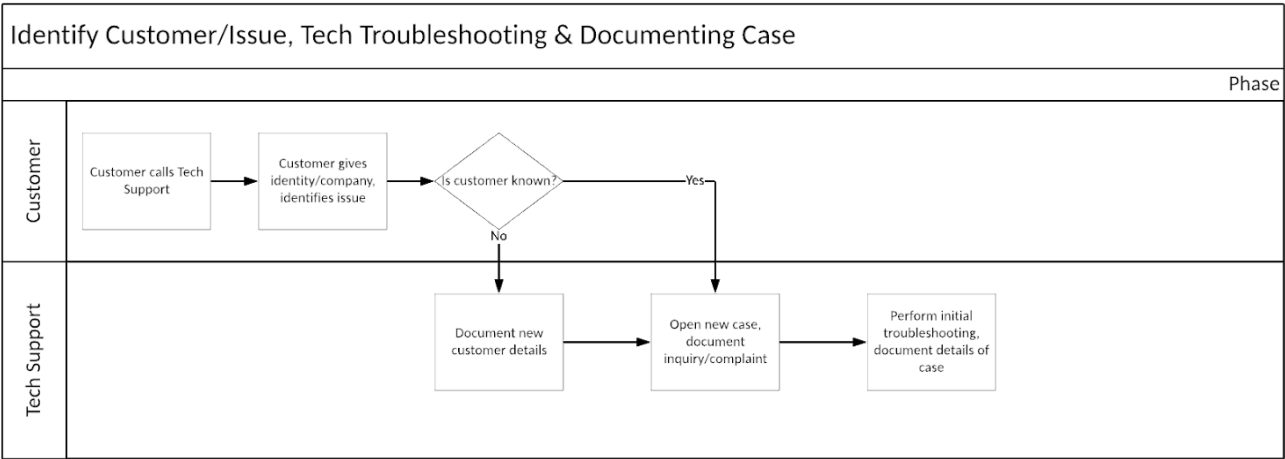
Leveraging 5P's 'Lean Framework', 5P partnered with the client's organizations including Quality, Manufacturing, and Regulatory Affairs to design and deliver a custom solution to handle the client's regulatory processes.

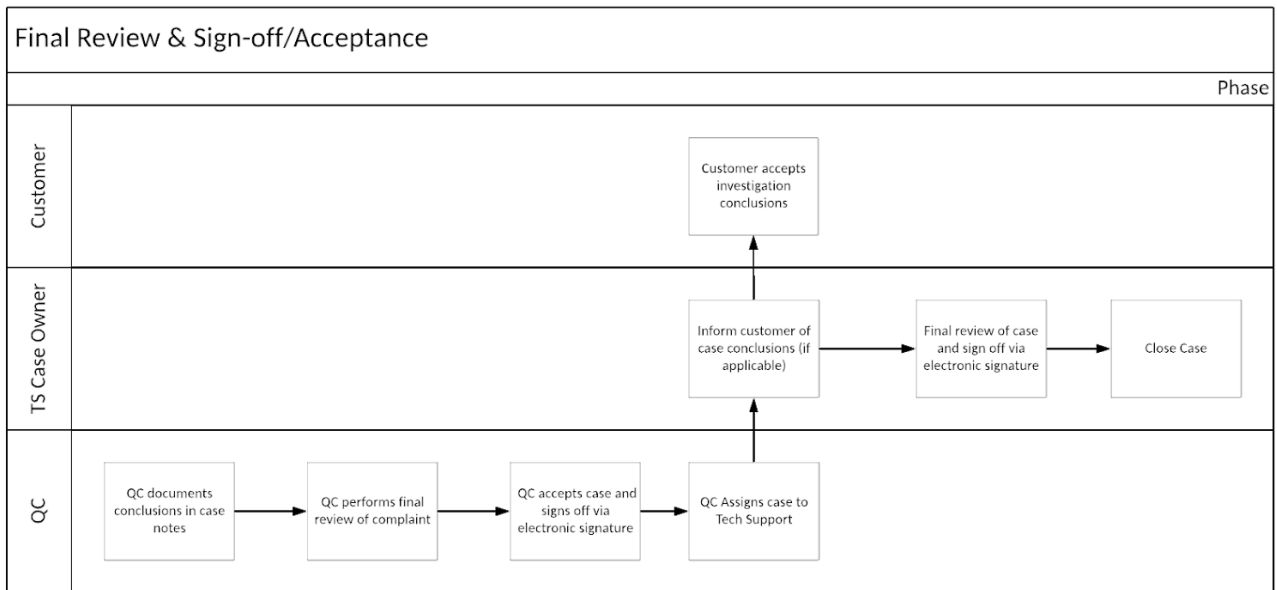
5P's LEAN Framework enabled our team to break down complex processes into delivery components in an Agile fashion. Additionally, our framework ensured clear requirements, design, as well as ensuring the user community's involvement as change agents throughout the engagement. Most importantly when the engagement completed the user community was fully able to run their business and support the solution. The framework was built on the best of breed tools including **Monday.com**, **Jira** and **5P's PM reporting framework** which ensured visibility to the client throughout the engagement for alignment of solutions from activities, risks, and budget to actuals.



BUSINESS PROCESS WORKFLOWS







RESULTS

This industry-specific solution has unique requirements to manage FDA regulated and HIPAA compliant processes. Some of the key components of this solution include:

- ◆ Supports international operations across 5 countries including the US, Europe, and Asia.
- ◆ Streamlines complex escalation and investigation between the case owners, technicians, regulatory representatives, and the FDA.
- ◆ User experience aligned with the organization for simple-to-follow pages throughout the process.
- ◆ Automation for manual tasks including notifications and follow-up tasks.
- ◆ Executive dashboards for monitoring case progression and complaints trending for product lines and international regions.
- ◆ Delivered operations manuals for the various roles and training to ensure adoption.

LEARN MORE

5P is a Business Transformation Firm delivering solutions through process and technology. We are a Salesforce Certified Consulting Partner that delivers business and digital transformation initiatives on the Salesforce Platform. For more information reach out to us at info@5pconsulting.biz.