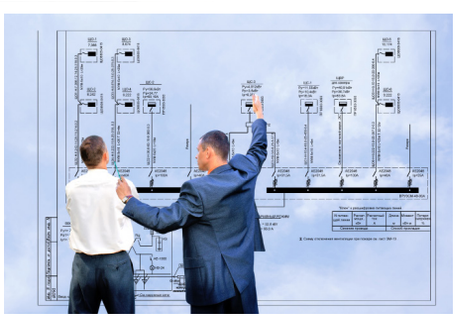
Stericycle®
GxP Solutions™



Automation Support Managed Service

ABOUT US

Stericycle GxP Solutions provides world-class compliance and validation services to multinational clients in regulated industries. Leading businesses in the biotech, medical device and pharmaceutical industries choose us to achieve regulatory compliance.

We have a deep understanding of product lifecycles, regulatory issues and technology from the Life Science Industry. Our expertise comes from years of serving the needs of regulated industries, allowing us to provide Compliance Consulting Services that create strategic value, reduce ownership costs and ensure compliance.

"Thank you for displaying the very highest levels of professionalism and flexibility."

- Site Director, US Based Medical Device Manufacturer

"Your in-depth knowledge of validation within this corporation was vital to the success of this project."

- Director of Engineering, Multi National Medical Device Manufacturer

"We are extremely impressed with the quick delivery of this software validation project."

- Quality IT Director, Irish Based Pharma Manufacturer

"Your team have consistently delivered each project on time and within our set budget"

- Validation Manager, Irish Pharma Manufacturer

ISSUE

Our customer wished to consolidate the provision of automation services at their production facilities from multiple vendors to a single source managed service. A similar arrangement was in place at another of the customers' sites in Ireland.

We offered to work with their site personnel by providing resources, expertise and guidance in the area of managed service provision and develop this offering to the satisfaction of all stakeholders.

SOLUTION

Stericycle GxP Solutions used our experience in managing this type of service from an existing agreement with another large multinational across a number of their sites.

We were able to draw on a number of key strengths to ensure an effective service:

- Proven reliability and continuity
- Ability to meet surge capacity demands & offer innovation in pursuit of process and performance improvement
- Commitment to improvement targets that are measurable & consistent
- Capacity to take work off site where appropriate
- Willingness to take on fixed scope assignments
- Experience across all levels of GxP Automation & Compliance
- A measurable contribution to year on year cost of service

Cost Solution

Our engineers were made up of every level of expertise at rates that were dependent on the number of deployments.

These scalable rates allowed for a flexible and managed approach to the scope of work required across multiple and projects.

Rates were based on a typical salary, benchmarked against industry - guaranteeing a utilisation of engineers with sufficient notice for non-utilisation ("Bench" resources).

The pricing structure was based on a sliding scale of deployment; as headcount increases we reduce rates accordingly.

There was an ongoing reduction of headcount as systems were qualified and taken into the production environment.

Changeover & Business Process Mapping

The implementation phase was delivered through a dual process.

Stream 1:

Initially, existing contractors were migrated to the new arrangement. This was carried out through an assessment of their skill sets against requirements.

We subsequently agreed an offer and negotiated a changeover with their employers.

Stream 2:

Stericycle GxP then had to map the various processes used by the automation function of the business.

This allowed an independent assessment of the scope and breadth of the work loads and identified areas where reductions could occur.

This process took three months to fully assess the scope and recommend improvements to the daily functioning of the automation team.

All internal and external stakeholders were involved, which allowed a structured and cost effective deployment.

Resources

After completing our assessments, we determined that the make up of the automation team was top-heavy. Through judicious use of resources, the structure of the team was altered to be more balanced.

We utilised a panel of bench resources for short term engagements so that any extra workload was managed & training was completed to ensure that all of our customers regulatory requirements were met.

Operational Improvement Approach

Our key aim here was to increase efficiency and quality leading to improved performance and service offering which ultimately would reduce costs. The leading methodology proposed here is business process mapping.

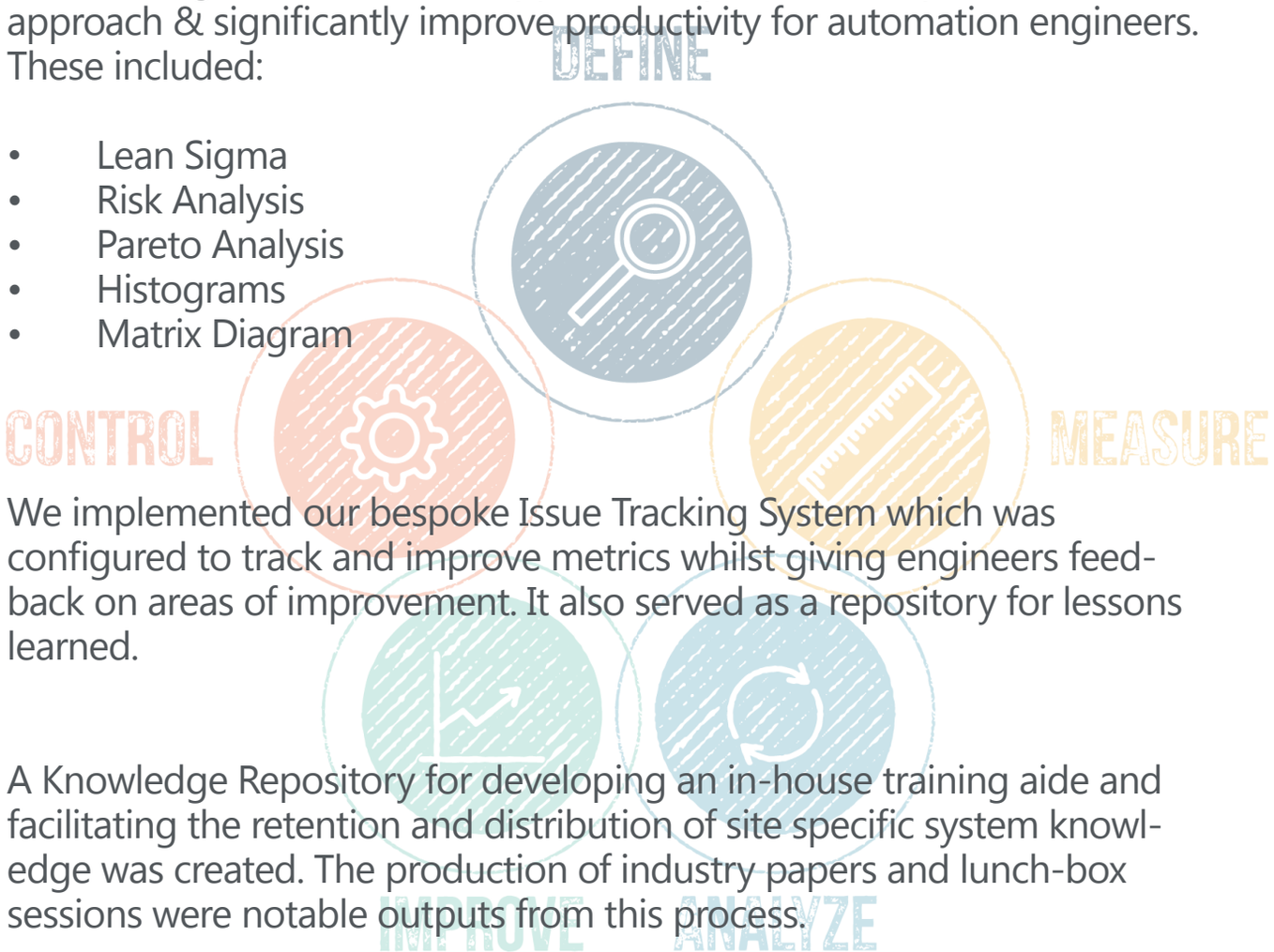
One of the key issues that the majority of organizations struggle with is the presence of a high level of tacit knowledge. Process mapping supports the drive towards capturing this knowledge. A comprehensive understanding of the 'as-is' situation was required when adopting a true Lean approach to re-engineering the processes & removing non-value add activities.

The main benefits of the mapping were:

- Understanding and documenting what was currently done (AS-IS)
- A collaborative approach between Stericycle GxP & our Customer in understanding and documenting the future state (TO-BE)
- Identify where the IT systems can support the process and hence provide a starting point for the design of those systems or enhancement of incumbent systems.
- Become the basis for training staff and act as a key learning tool for the organisation
- Become a repository for knowledge regarding the business processes
- Identify where other departments and processes interface with the automation department
- Implement a communication structure with these departments to ensure efficiencies across internal customers
- Improve team morale

In addition to process mapping, we recommended a combination of methodologies and tools to support the operational improvement approach & significantly improve productivity for automation engineers. These included:

- Lean Sigma
- Risk Analysis
- Pareto Analysis
- Histograms
- Matrix Diagram



We implemented our bespoke Issue Tracking System which was configured to track and improve metrics whilst giving engineers feed-back on areas of improvement. It also served as a repository for lessons learned.

A Knowledge Repository for developing an in-house training aide and facilitating the retention and distribution of site specific system knowl-edge was created. The production of industry papers and lunch-box sessions were notable outputs from this process.

Customer Requirements

An ongoing requirement involved issues raised in the RFP and subsequent workshops which require specific attention. We evaluated & measured the scale and scope of these problems, suggesting the solutions which need further investigation and agreement.

MIR Closeout

Following discussions with the on-site automation engineers, it was apparent that a large percentage of the engineer's time was spent managing MIRs to closeout stage. The engineers felt that much of this work did not add value and pertained to review and approval cycles of the document rather than root cause analysis and preventative action.

We reviewed the standard of the documentation produced by the automation engineers, including a review with the Quality Dept. when errors were repeated. We also assessed the technical skillset of reviewers with Quality.

We implemented an electronic review system where each reviewer's comments were seen by the next reviewer.

The system allowed us to track the dates and responsibilities for MIR closeout and escalate and/or add resources to any MIRs nearing close-out date.

This improved the standard of documents drafted by the automation team.

Type 2 Committments

Type 2 commitments were managed on an internal system. The Automation department had a number of such commitments to meet.

We recommended that a report on due commitments was to be viewed weekly. The Site Team lead was to take any necessary action to escalate/add resources to complete all commitments on time.

Change Control

The engineer drafted the change control documentation and presented to the Change Control meeting. Each concerned area attending the meeting would add requirements to the change control. Meeting these requirements was delaying the closeout of change controls.

We reviewed existing templates for making changes to control systems and developed standardised high quality templates. We subsequently trained the engineers in a standardised approach to raising and closing change controls.

GMP & GCA Audit Actions

The Automation Department had a number of open Audit commitments.

Stericycle GxP collated all the Audit commitments & created a team responsible for the closeout of each committment. Each team identified actions arising out of the commitments, including any actions/changes that could impact on other departments or areas. We also monitored each team carefully to ensure that all commitments were completed by the due date..

Forms & templates bi-annual review

Our Customer required that certain GMP documents were to be reviewed bi-annually.

The Site Lead formed a list of forms and templates, due for bi-annual review in the year. We met with the document owners and an assigned automation resource to agree and make alterations, including further reviews and approvals. A dedicated administrator managed the progress through the system by liaising with the reviewers and approvers to ensure timely review and approval of the document.

Training

An initial review of all outstanding/overdue training was carried out by us. This involved the review of training requirements for each engineer and removal of modules not required for their role.

Stericycle GxP Solutions' Site Lead also co-ordinated induction training and on the job training so that resources could begin work at short notice.

FINAL RESULTS

Each initiative undertaken by Stericycle GxP had a lasting effect on the automation function at the customer site.

The total headcount & cost of the Automation Department was reduced significantly and developed into a leaner, more effective unit.

The Business Process Mapping exercise removed any activities that were not adding value to any operational activities.

When determining the customers own requirements, we defined a number of KPI's:

- MIR completion
- Type 2 Commitments
- Post Change Commitments
- GMP Audit Actions
- Training Commitments
- PPG for bi-annual review
- GCA Audit actions
- Forms & Templates

Each KPI defined would ultimately aim to achive a number of goals & objectives:

- Work element cost reduction
- Change control process streamlining
- Customer satisfaction
- Creation of a database of lessons learned

By implementing the MIR Review System, key achievements included:

- 100% MlR's closed out on time
- Increased productivity of Automation Engineers on high payoff activities
- Improved quality of documentation
- More efficient use of Approvers time

Our review of the existing Change Control Process being used by the customer allowed us to:

- Reduced level 2 commitments
- Reduced post Change Control commitments
- Reduce Engineers time on the Change Control process
- 100% closeout of change controls on time
- Increased productivity of automation engineers

Furthermore, all GMP & GCA Audiit Actions along with commitments made to develop and complete training programs were finalised in accordance with every agreed timeline.

FOR FURTHER INFORMATION, PLEASE CONTACT:

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