Stericycle®
GxP SOLUTIONS™

QUALITY SYSTEM IMPLEMENTATION CASE STUDY

THE REGULATORY COMPLIANCE EXPERTS

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 earned a reputation for excellence and reliability by maintaining a team of the top engineering and project management experts in the regulated industry. When combined with our innovation and targeted technology, this expertise enables us to create strategic solutions and deliver results in competitiveness and compliance.

We have a deep understanding of product lifecycles, regulatory issues and technology in the Life Science Industry, our expertise comes from years of serving the needs of regulated industries. This unique fusion of expertise allows 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

Following completion of the validation of a number of computerized systems at their manufacturing facility, our customer required assistance with the facilitation of quality systems improvements as the company enhanced their practices in line with FDA and ISO requirements for the manufacture of medical devices.

SOLUTION

Stericycle GxP Solutions offered a strong combination of compliance knowledge, technological competence, and project management expertise. We agreed to provide project management and validation services to our customer.

Following a consultation process, the following key areas were identified as requiring improvement:

- CAPA Resolution Plan
- Validation System
- 21 CFR part 11 policices & procedures
- Training
- IT systems validation & software redesign consultancy
- IT systems validation overview and approval cycle
- QSR Procedures Implementation

CAPA Resolution Plan

A CAPA plan was generated, implemented and resolved to address an issue which required regulatory approval. Production and distribution was not affected in any way.

Validation System

The revision of the current SOP's and templates to implement a more lean and scalable approach to validation for our customer. This increased efficiency across all validation and compliance activities onsite and was prioritized as it would have a positive effect on the reduction of validation timelines on all areas.

21 CFR Part 11 Policies & Procedures

The development and implementation of 21 CFR 11 policies and procedures based on the ISPE risk based approach.

Training

We developed a training plan on 21 CFR Part 11 regulatory requirements for the site. Aspects of the training included a complete site awareness programme along with identification of the main systems to be risk assessed.

IT systems validation & software redesign consultancy

Using the new validation system redesign of policies and procedures and the training rolled out on these (as outlined in this table), Stericycle GxP Solutions facilitated and guided a working group of Quality, IT and Software Operations to draft the URS and design the software.

We continued to consult on regulatory requirements in conjunction with the redesign of the software and complete the validation of the systems post the redesign.

IT systems validation overview and approval cycle

Stericycle GxP Solutions provided input into the review cycle of these validations and ensured regulatory compliance. The customers own in-house engineering team performed the validation of the software under our guidance.

QSR Procedures implementation

Facilitation of the implementation of the FDA QSR procedures and practices to follow on from the in-house training that we conducted. We provided a sunject matter expert to act as both a point of contact and a mentor to assistour customer with the implementation of some of the more intricate procedures.

The approach included:
- Categorising the areas involved - Software Risk Assessment, FMEA's, Change and Configuration Management, 21 CFR Part 11
- Facilitate one training session per area

The QSR Procedures Implementation provided "System Owners" for each area involved which facilitated plant-wide adoption of these procedures outside of the Quality Department.

RESULT

Stericycle GxP solutions provided full project management services to the customer. The Quality System was fully implemented across the site in accordance with regulatory requirements. All relevent documents were generated and approved. Other aspects of regulatory compliance improvements and system updates emerged during the project and were highlighted to the customer.

FOR FURTHER INFORMATION, PLEASE CONTACT:

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