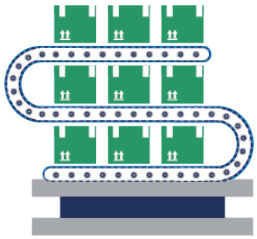
Stericycle®
GxP SOLUTIONS™

TECHNOLOGY TRANSFER 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

A multinational medical device manufacturing company had a requirement to transfer a production line from their facility in California to a new site in China. They were to continue to use the existing raw material suppliers.

SOLUTION

Stericycle GxP Solutions assigned a Senior Validation Engineer, who would lead the validation of the assembly line and write the required validation documentation alongside a Project Manager, who would oversee the implementation of the line.

The assembly line consisted of a number of subassembly and test stations where the stents are assembled into a Finished Assembly and then packaged and labelled to form the Finished Goods.The Batch Control System is electronic (21 CFR Part 11 compliance requirements) and the labels are printed automatically as appropriate to the Finished Good being produced.

The initial Phase of the project was for the customers' own in house engineering team to define and specify the existing equipment and assist in the creation of the User Requirements Specification. Our Senior Engineer assessed the new site for GMP readiness and reported on compliance gaps and remediation activities.

The customers engineering team designed the new equipment in conjunction with the original vendors - along with creating a plant layout drawing for the new cleanroom facility - where the locations of each standalone piece of assembly equipment and associated test equipment (pressure testers, leak testers, destructive testing stations) were to be identified.

The customers own team conducted shipping studies for high risk raw materials and Stericycle GxP Solutions created the documentation for the studies.

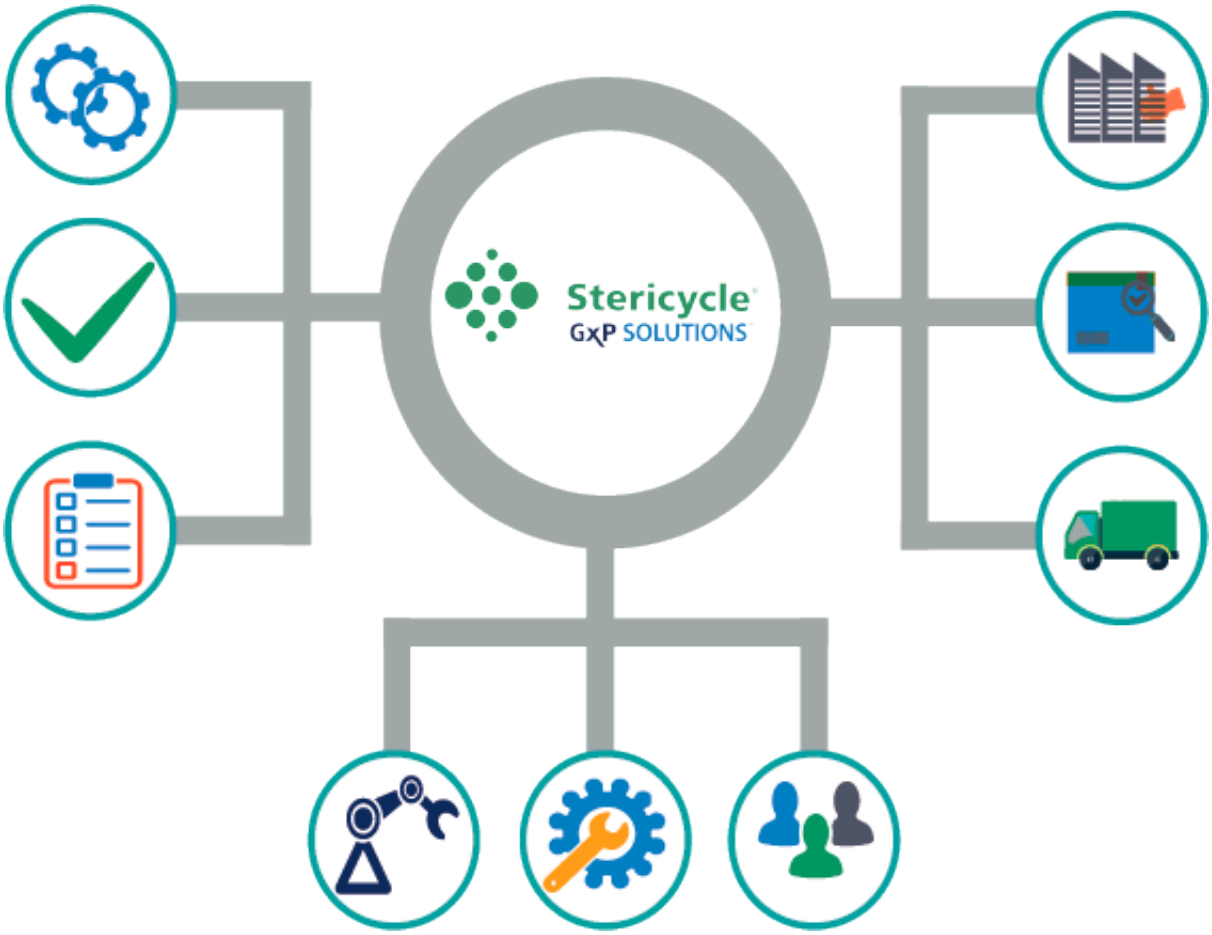
We created the Factory Acceptance protocols that carried out functional testing on the equipment, and functional testing was completed at OQ stage. The Vendors installed and commissioned the equipment on site.

Stericycle GxP Solutions wrote the remaining protocols Installation Qualification (to establish that the equipment was installed correctly and that all processes and procedures were in place for the equipment. The Operational Qualification verified that the equipment performed as expected. The Performance Qualification verified that the whole line performed as required and replicated three full production runs. Operator input was required to complete this.

Shipping studies of finished goods were executed to the final shipping locations (in the Netherlands and US). The ERP system and label printing system was validated in compliance with 21CFR11.

RESULT

The customers production line was transferred successfully and all validation was successfully executed. All the test protocols and quality documentations to test the individual pieces of equipment were written. The entire production line was tested once it became operational and all corresponding regulatory requirements were documented and signed off.



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