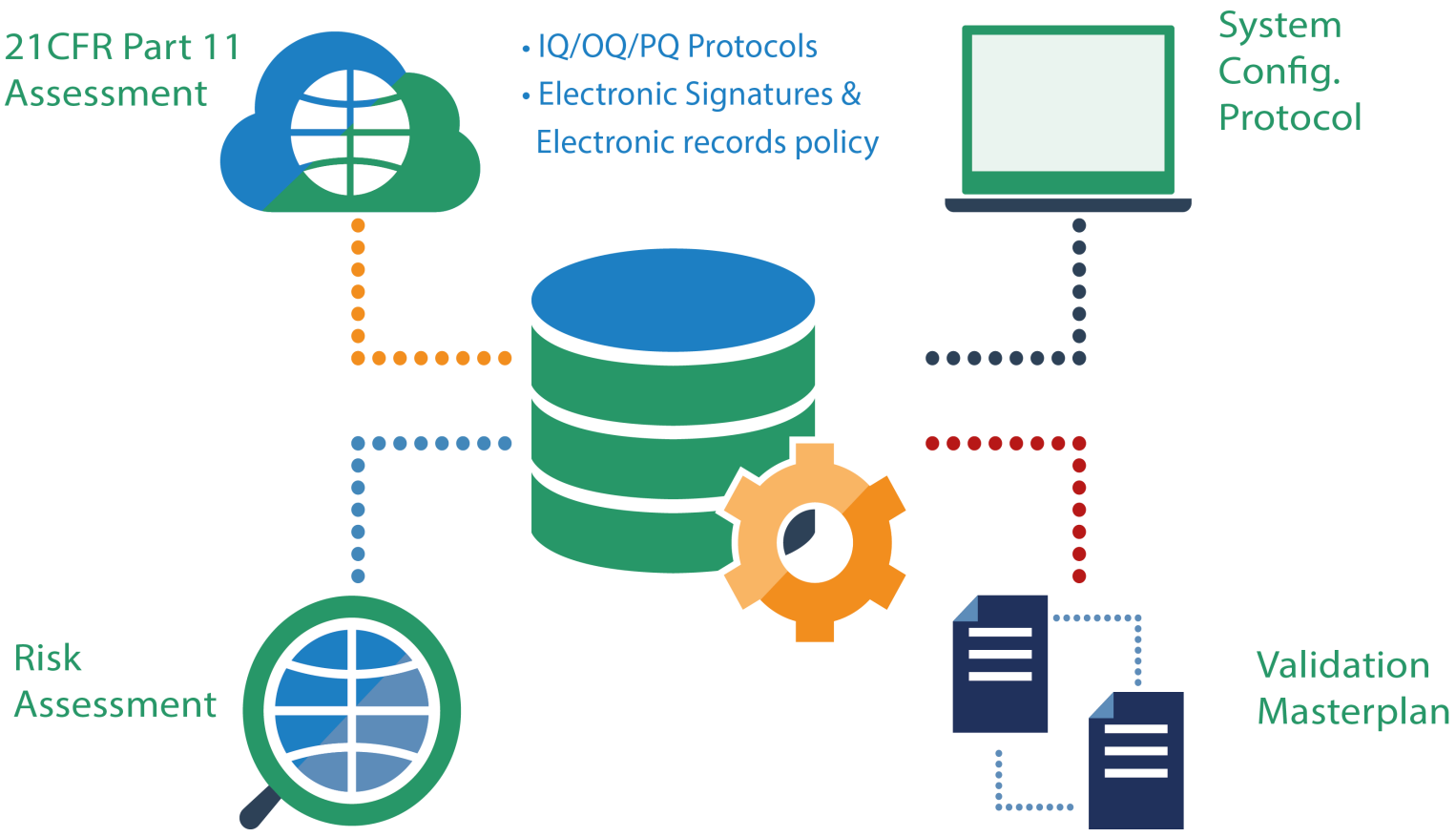
Stericycle®
GxP SOLUTIONS™

ERP SYSTEM UPGRADE 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

"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 is a medical device company that designs and manufactures innovative aerosol drug delivery systems for the respiratory care market.

Since their foundation in the late 20th century, they have grown to become the global leader in high performance drug delivery. Because of an upgrade of all equipment in use at the plant, they required a project team to complete CSV activities related to the installation of an ERP System.

SOLUTION

Stericycle GxP Solutions provided a strong combination of compliance knowledge, technological competence and project management expertise.

Requirements of key interest from a validation perspective included:

- A User Requirements Specification (URS)
- A Risk Assessment of all aspects of the URS
- A Validation Master Plan (VMP)
- A traceability matrix
- IQ/OQ/PQ as called for in the VMP
- Final Reports

Task List

IQ Protocol (OQ DB) - DCR

Script for Installation of Personalisations - Project File

System Config Protocol - DCR

Commercial Reports Installation Test Scripts - DCR

SSRS's Installation Test Scripts - DCR

Configuration Test Scripts - DCR

OQ Data Migration Protocol - DCR

21 CFR Part 11 Assessment - Project File

Sys Config PROD IQ Protocol - DCR

Sys Config PROD Test Scripts - DCR

PROD Data Migration Protocol (Update OQ) - DCR

PROD Data Migration Test Scripts (Update OQ) - DCR

PQ Protocol (PROD) - DCR

PQ Report (PROD)

Configuration Management SOP

Change Management SOP

IT/IS Change Control (Form and SOP)

Client Management - DCR

Electronic Signatures & Electronic Records Policy - DCR

RESULT

The project was completed in accordance with all set schedules and deadlines. Because of internal requirements regarding their Quality Management System, the customers staff were available for reviewing and approval of documents as needed. All tasks requiring involvement from the customer were completed, and a fully validated ERP System was declared fit for use

FOR FURTHER INFORMATION, PLEASE CONTACT:

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