FACILITIES VALIDATION CASE STUDY

Stericycle®
GxP SOLUTIONS™

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

Our customer, one of the leading medical device manufacturers in the world, were expanding their operations to cater for the transfer of manufacturing from 3 global location to their existing site in Ireland.

The Irish location was required to take over all aspects of the manufacture of reagents and to bring the facility in line with FDA and international regulatory requirements. In addition, the site team will be the technical owners of the products. A capital budget was approved to upgrade the facility to cater for the increased volume and to enhance operations.

SOLUTION

Our customer had a requirement for a team of engineers capable of assisting them with the qualification of the upgraded facilities including new cleanroom and equipment and a new laboratory for chemical and incoming commodity testing.

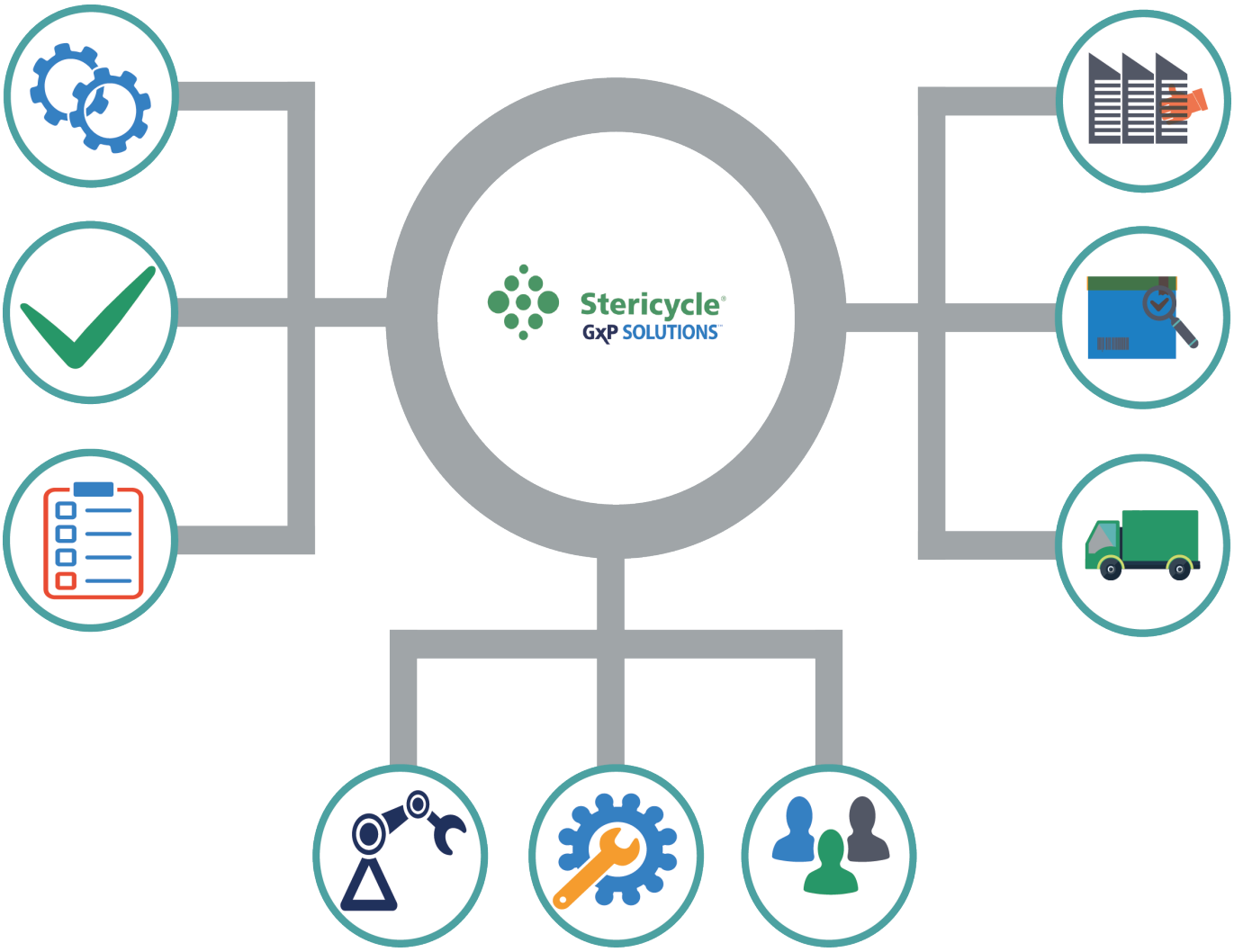
Stericycle GxP Solutions provided 2 highly skilled eneineers to assist in the qualification and commissioning on the capital project. Our in-house Subject Matter Experts priovided expertise and guidance in regulatory compliance and GAMP 5 as well as facilities including clean rooms, QBMS and associated equipment.

The Engineers joined the existing site team to commission the new facility/utilities (including the QBMS, Clean Water, various compressed air and gas systems, environmental monitoring including viable/non-viable particulates, chillers, etc.) whilst adhering to corporate/site procedures and requirements , which included liaising with the engineering and project management team.

Every engineer had wide experience of facilities/utilities qualification/commissioning in an FDA regulated environment along with strong cGMP knowledge and excellent communication skills.

RESULT

Stericycle GxP Solutions authored and executed all relevant test protocols and wrote the subsequent reports. The clean rooms and associated equipment were all in compliance with FDA standards and a subsequent audit confirmed that all was in order.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FOR FURTHER INFORMATION, PLEASE CONTACT:

JOHN DORAN

GENERAL MANAGER

+ 353 21 4215 050 JOHN.DORAN@STERICYCLEGXP.IE

DAMIEN HANLEY

MARKETING MANAGER

+ 353 21 4215 050 DAMIEN.HANLEY@GXPSYSTEMS.COM

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