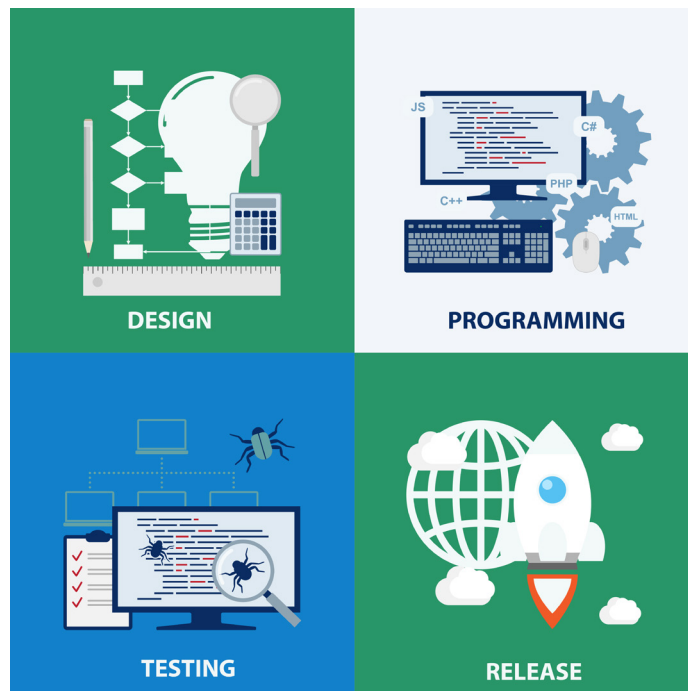




**Stericycle**<sup>®</sup>  
GxP SOLUTIONS<sup>™</sup>

# SOFTWARE VALIDATION CASE STUDY



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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 is a research-based global pharmaceutical company and cited as one of the world's largest, operating in three business segments.**

Production processes, distributed across a number of locations in Ireland, operate to strict regulatory requirements, conforming to cGMP and is subject to FDA regulation. As part of a newly built Waste Water Treatment Plant, our customer required a SCADA system to control the plant efficiently and safely to regulated standards and specifications.

## SOLUTION

Stericycle GxP Solutions delivered a fully integrated and scalable solution with SCADA front end and an embedded historian data server.

The project scope included Functional Design, PLC & SCADA Configuration, installation & commissioning. The control system used in this project was a SattCon PLC with a SCADA operator interface consisting of a server and client NT workstations running FIX Dynamics connected to the PLC. The workstations are connected to the PLC via a 'SattBus' Network. The link was implemented using I/O server software.

The software was built on a modular basis, with the lowest level at 'Device Module'. At this level each device was assigned a graphic dynamo consisting of all possible animation effects for the particular device on the SCADA platform with control and fault logic running in the PLC on a similar modular basis.

The second level of design involved the building of the graphic screens to represent a particular area or process stream and the building of loop controllers to handle complicated control of devices.

The third level deals with the navigation, data manipulation, record keeping and communication between devices. It allows the operator to move from one screen to another, log-on to the system, print reports etc.

The graphic user interface facilitates the manipulation of all devices in each section of the process plant. It allows the input of set points and alarm levels to the controlling PLC, as well as fault acknowledgement and manipulation of data for trending and reporting.

This project was delivered ahead of schedule.

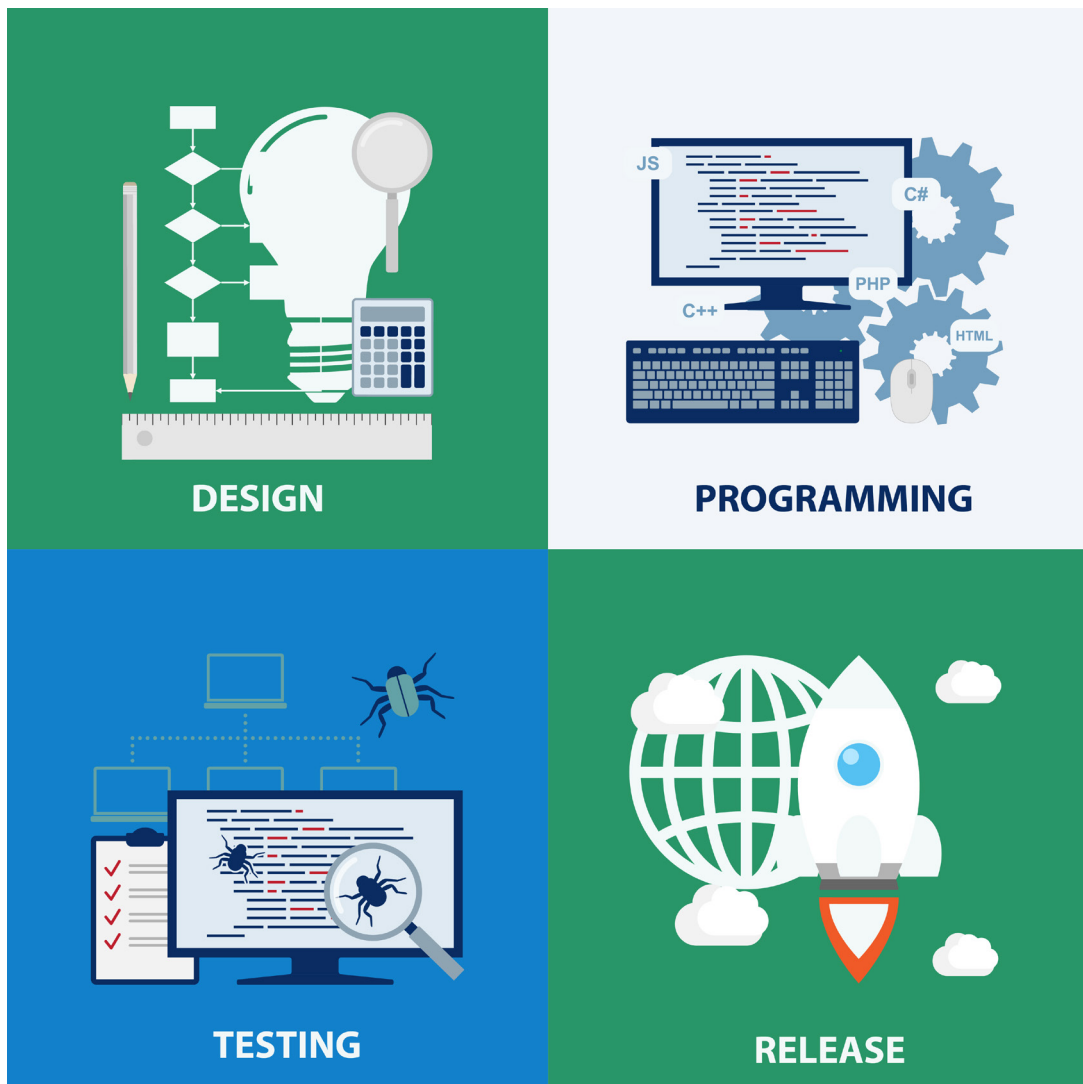
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## RESULT

Our Customer now has a Process Control System, which is fully compliant with required regulations. The solution offers a reporting system which monitors and analyses data available from the new system. The system triggers alarms to alert key personnel in deviant situations. It is a fully validated and qualified system, which complies with regulatory requirements



FOR FURTHER INFORMATION, PLEASE CONTACT:

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