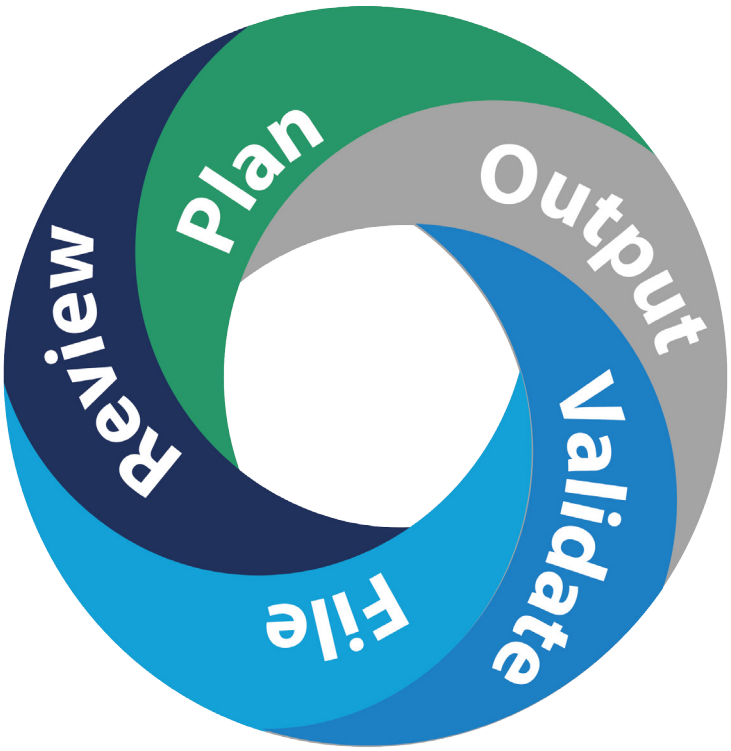
Stericycle®
GxP SOLUTIONS™

DESIGN REMEDIATION 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 a corporate acquisition, our customer, a global provider of medical devices used for vascular access, surgery, respiratory and cardiac care relocated their in-house R&D department to Ireland. This necessitated the transfer of all design history documents to one central location.

The aim of the project was to document design inputs & outputs for the Design History File (DHF) for a particular product range and to address any validation and verification deficiencies.

SOLUTION

Stericycle GxP Solutions delivered the project in two distinct phases. Phase 1 focused on documenting the design inouts & outputs and addressing the validation & verification issues. Phase 2 involved adding additional design requirements to the DHF.

The following activities were completed:

Phase 1:

DESIGN & DEVELOPMENT PLAN:

Define the overall strategy for the remediation activities.

User needs & design requirements:
The current identified user needs and design requirements will be
transferred into the new organizational templates. Existing design requirements will be reviewed to ensure that they are :

1. Specific enough that design outputs can be verified to meet inputs.
2. Sufficiently described to address device functionality, performance and safety

Design Outputs
A Traceability Matrix was be created that will trace each design output to the design requirements. Design outputs will be reviewed to make sure they are complete such that acceptance criteria are clearly defined. Essential outputs will also be defined. This will be linked to risk.

DESIGN VERIFICATION & VALIDATION

Some of the existing studies for one of the devices were focused on confirming that the design input is met, and do not confirm that the device design through the design outputs meet the design inputs.
A Design V&V plan was created to document the extent of the design verification & validation activities.
Document Design V&V Protocols were used to create the relevant protocols to address the existing gaps. Existing gaps within the design validation were addressed through risk analysis, which involved utilising customer related data.

DESIGN HISTORY FILE INDEX

A Design History File Index (DHX) was created that referenced all the documents and records associated with the DHF for the product.

DESIGN REVIEWS

Three design reviews were completed after the following phases:

Phase 1: Planning and Inputs
Phase 2: Design Outputs
Phase 3: Design Verification & Validation

These design reviews were used as a gate prior to entering the next phase of the project and were documented.

Phase 2

The aim of Phase 2 was to add any additional design requirements to the DHF.
To complete this, the following activities were completed:

DESIGN & DEVELOPMENT PLAN

The D&D plan that was created during phase 1 will be revised to include the new activities.

USER NEEDS & DESIGN REQUIREMENTS

User needs and design requirements that are missing from the existing documents will be added. This will include requirements such as cleanliness and packaging.

DESIGN OUTPUTS

The Traceability Matrix that was created during phase 1 will be updated to include the missing design inputs. Where required corresponding design outputs will be created to meet these design inputs.

DESIGN VERIFICATION & VALIDATION

A Design V&V plan was be created to document the extent of the design verification & validation activities. Document Design V&V Protocols were used to create the relevant protocols.

SOFTWARE VALIDATION

Changes were made to the firmware & the software validation was repeated. This involved the generation of the relevant plans, software requirements, risk analysis and software verification/validation activities. This was completed as per the relevant customer procedures.

DESIGN HISTORY FILE INDEX

The Design History File Index (DHX) was updated to include the new design documentation.

DESIGN REVIEWS

Design reviews were completed as required. These design reviews were used as a gate prior to entering the next phase of the project and will be documented as per the current SOP

RESULT

Third party auditors certified the clients' equipment and process validation procedures were compliant. The client resolved the issues to the satisfaction of FDA and resumed business as usual.

FOR FURTHER INFORMATION, PLEASE CONTACT:

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