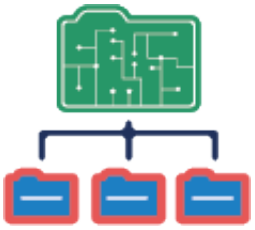
Stericycle®
GxP SOLUTIONS™

DATA INTEGRITY AUDIT & ASSESSMENT 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

SUMMARY

The customer transferred a number of methods from their former site in UK to Ireland.

These methods are used to test manufactured Active Pharmaceutical Ingredients (APIs) in order to provide evidence that the manufactured products tested using these methods conform to established specifications for identity, purity and quality and comply with pharmacopeia and current Good Manufacturing (cGMP) requirements for pharmaceutical products for human use.

The particular test methods have been in use for at least five years on the previous site and have been validated according to the guidelines published by The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) in Quality guideline Q2 Analytical Validation, or the United States Pharmacopeia (USP).

The project report describes the activities observations and recommendations of a project to examine and review the policies, procedures, practices and computer systems associated with assuring the integrity, reliability and trustworthiness of the data and records created during the manufacturing and testing of Active Pharmaceutical Ingredients, on the customers manufacturing site in Ireland.

The project was carried out in two phases. The first phase entailed reviewing documented policies and procedures in order to identify the customers approach to data integrity. In addition, validation reports associated with the installation and operational testing of the computer systems were also reviewed to identify the validation and qualifications activities that have been performed in order to provide a high degree of assurance that the data and records created or stored by are reliable and trustworthy.

The second phase consisted of an onsite audit of the computerised systems on site and the practices used to manually capture data and information during manufacturing or QC testing. The finding of the document review and the onsite audit were then compared with the generally accepted requirements for assuring the reliability and trustworthiness of records and data and a gap analysis was performed to identify and deficiencies.

The site was able to demonstrate a high level of assurance that the records and data created during manufacturing and testing operations is reliable and trustworthy. However, some deficiencies were noted which could have the potential to cause difficulty for the site to demonstrate full and comprehensive data integrity compliance. The principle deficiencies noted included:

1. A lack of documented evidence of testing of the functionality, associated with assuring data integrity, of computerised systems.

2. A lack of site policies and procedures associated with the management of electronic records and 21 CFR Part 11 as required by corporate global policies.

3. A requirement for reviewers to log on to the chromatographic data system as users, with full user privileges, in order to review online chromatographic data.

4. A lack of instructions on what entries in an audit trail should be reviewed during the checking of OQ laboratory analysis.

5. Lack of instructions on what constitutes acceptable integration processes.

6. Lack of documented instructions on what elements should be included in chromatographic reports.

7. No documented file naming conventions or locations where files should be saved to for electronic data files created in the QC laboratory

8. No instructions on what elements of the audit trail should be reviewed during the checking of laboratory analysis. Some suggestions have been included at the appropriate point in the report. However, it is recommended careful consideration be given in order to identify the critical audit trail entries which should be reviewed

9. No instructions on what should be reviewed during the checking of laboratory analysis.

It was recommended the site develop a portfolio of policies and procedures to control and standardise the practices associated with data integrity and 21 CFR Part 11.

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