APPLYING QUALITY SYSTEMS TO COMPUTERISED STOCK MANAGEMENT SYSTEMS

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Abstract

OBJECTIVES To investigate the impact of applying quality systems to an established computerised stock management system of a local pharmaceutical wholesale dealer.

METHOD An established computerised stock management system was analysed to determine the compliance of recorded data with actual stock. A risk assessment of all the steps for each parameter was carried out and a risk management plan was established as necessary following risk evaluation. After a one-year period, the same parameters were re-evaluated using the same methodology and compared with baseline.

KEY FINDINGS All parameters showed an improvement from baseline at the end of the study.

CONCLUSION The application of quality systems to computerised stock management systems should be a mandatory requirement to ensure data reliability in line with Good Distribution Practice (GDP)[1] ensuring batch traceability and reconciliation throughout the storage, distribution and recall procedures and other GDP-related activities.

KEYWORDS computerised stock management, expiry dates, quality systems, standard operating procedures, stock balance

The application of quality systems to computerised stock management systems may be considered as a mandatory requirement to ensure compliance with Good Distribution Practice and safeguard public health

Introduction

Pharmaceutical companies have established computerised stock management systems on which critical activities related to GDP rely. These include invoicing, purchasing, batch recalls, crediting of returned stock, stock-taking and control of expired medicines. IT systems (hardware and software) may be adequate to satisfy the new GDP requirements.[1] Inappropriate data inputting procedures may result in unreliable data being present in the system. This leads to repercussions including sale of medicines which are expired, frequent out-of-stock situations, loss of batch traceability, over-stocking, lack of regulatory compliance of invoices and stock abuse by employees. Apart from placing the company in a precarious regulatory position, this may lead to patients' health being placed at risk especially when products with serious safety issues have been distributed by the company and cannot be traced.

The introduction of quality systems to computerised stock management systems aims at identifying the risks associated with data inputting, data processing and reports retrieval to ensure that all GDP-related activities which rely on the IT system can be carried out in a reliable manner. The aim of this study was to investigate the impact of applying quality systems to an established computerised stock management system of a local pharmaceutical wholesale dealer.

Method

Using the database of a well-established wholesale dealer's stock management system, a number of parameters related to stock management were chosen as 'Targets' for which quality systems were applied. Parameters targeted included stock database (check for duplicate cards or inaccurate descriptions), batch accuracy, expiry date accuracy, stock quantity accuracy and client database accuracy. A comparative target analysis was carried out to determine whether the quality systems put in place after baseline were successful by the pre-set deadline. After a one-year period, the same parameters were re-evaluated using the same methodology and compared with baseline.

Results

All chosen parameters indicated a statistically significant improvement from baseline values to the second data point (1 year after baseline) at the end of the study period, ranging between 1 and 17% improvement after quality systems were introduced (Figure 1).

Discussion

This study revealed that notwithstanding that the computerised system under study was established and used for several years before the study was undertaken, the lack of established quality systems to direct its implementation resulted in several serious failures. The weaknesses which were identified at baseline and which were improved after the 1 year period included the aspects that procedures took a very long time to be carried out and procedures not carried out in line with GDP (e.g. batch numbers were not adjusted after stock taking as their traceability would be lost within a few weeks due to poor data inputting practices). The presence of unreliable historical data, the lack of reporting features that were important for monitoring stock activities and data inputting procedures were identified and to this effect, the software had to be upgraded by the program developers to ensure that the required reports could be generated by the system. Several existing features of the IT stock management system were not being exploited by the employees leading to less efficient operations and duplication of work. The IT manager and employees who had access to the system were not applying safe data inputting practices and the system contained a number of bugs which had not been previously identified by other employees since such bugs were only activated when certain data processes were carried out.

Further studies could look at the financial implications and determine the financial viability of applying quality systems to IT stock management systems. The lack of reliable historical IT data and other factors such as changes in stores employees, national economy and methodology to determine the cost of man-hours of various employees involved in stock management would make it difficult to establish financial viability in a reliable manner.

Conclusion

This study revealed that well-established computerised stock management systems contain unreliable data resulting from human error. These lead to shortcomings that could have an impact on public health and financial repercussions on the company. The application of quality systems to the running and use of computerised stock management systems results in reduction of stock abuse and better stock management leading to efficient employment of financial, human and logistic resources.

The application of quality systems to computerised stock management systems may be considered as a mandatory requirement to ensure compliance with Good Distribution Practice and safeguard public health. It is in the company's financial interest to ensure that a reliable stock management system is in place so as to safeguard its assets and improve reconciliation of stock and stock accountability.

Reference

1. European Commission. Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use [Online]. Official Journal of the European Union 2013;343/1 [cited 2016 Feb 02] Available from: URL: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:343:0001:0014:EN:PDF

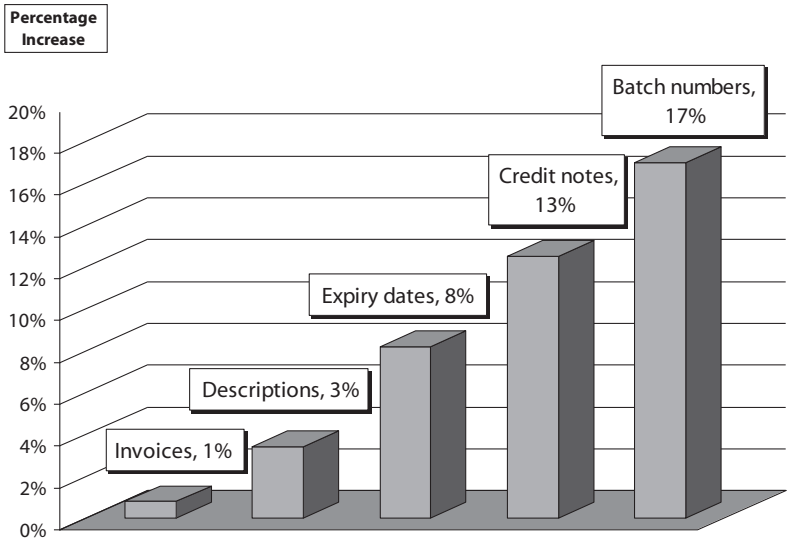

Figure 1: Summary of results for each parameter