Developing a GMP Compliant Training Documentation System for a Pharmaceutical Manufacturer

S. Farrugia[1], A. Zahra[2], R. Cassone[2], F. Wirth[1], M.C. Zammit[1], A. Anastasi[1], A. Serracino Inglott[1], M. Zarb Adami[1], L.M. Azzopardi[1].

[1] University of Malta, Department of Pharmacy, Msida MSD 2080, Malta, email: sfar0002@edu.mt
[2]Arrow Pharmaceuticals Ltd. HF 62, Hal-Far Industrial Estate, Birzebbugia BBG 3000, Malta.

University of Malta

Introduction

Good Manufacturing Practice (GMP) requires a training documentation system to be in place. This is sustained and stated by bodies including the World Health Organisation (WHO, 2006a) and the European Commission (EudraLex, 2009) routinely, however, it is not always well documented, hence providing no evidence that the training was actually done (WHO, 2006b).

Methodology

The study was initiated at Arrow Pharmaceuticals when the company was in its third year of operation in Malta. At the time 55 staff members were employed . Training on Standard Operating Procedures (SOPs) continuously needed updating and tracking documents was becoming an endless task. A method for improving the current documentation system of training consisted of a software where training data could be easily inputted and used to generate reports.

A local software development house was approached with a user requirement specification outlining the company's current and long-term needs. The developed software was tested by inputting real data versus a parallel run of the paper-based system and was completed and debugged over a period of six months. All SOPs were linked to the job positions built-in the software and all SOP training done by the employees was inputted. By using the total number of SOPs on the training needs per department and the amount of SOPs read by the employees, the percentage of training completed was calculated.

Statistical analysis was undertaken using Microsoft® Excel® 2007 and SPSS® version 17.0 using the paired sample t -test. A ($p<0.05$) was considered as statistically significant.

Validation of software

A software validation protocol was written and endorsed. The software was validated using the uploaded real data and the actual job positions. The limits of the software were challenged with all the possible scenarios. Once all testing and raw data inputting was completed, the system was considered as valid. The software was migrated to the company's intranet to form the basis of its new training system.

Results and Discussion

Figures 1 and 2 show the percentages of SOPs read based on the training needs for each department one year apart. One week following implementation of the software, an average of 76% of SOP training of all departments was documented (Figure 1).

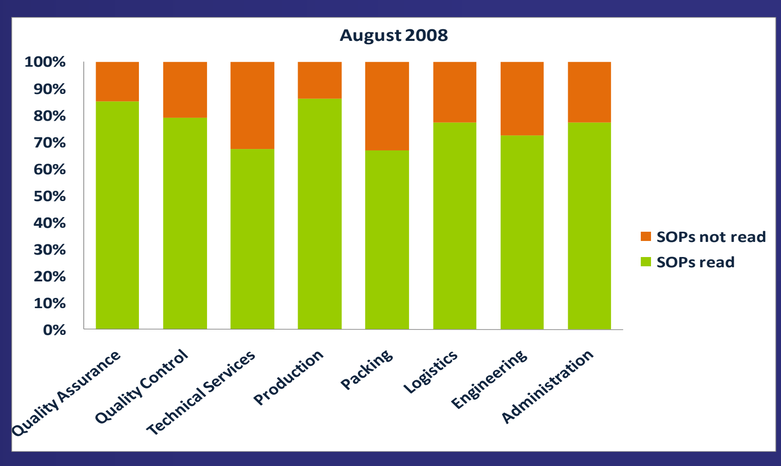

Figure 1: SOP Training Gap Analysis by Department, August 2008

Six months following implementation, all departments had an average of 89% of SOP training completed. The number of SOPs read in August 2008 and February 2009 were compared, resulting in a statistically significant improvement ($p < 0.05$). On comparing September 2009 (Figure 2) to February 2009, no statistical significance was obtained ($p>0.05$).

Figure 2: SOP Training Gap Analysis by department, Septmeber 2009

The developed training documentation system:

- Provided regular and faster update of training needs for each new employee
- Improved GMP compliance by proper documentation of training
- Enhanced traceability of employee training records
- Allowed training personnel to concentrate on new GMP training projects rather than on documentation
- Promoted development of monthly training reports

References

[1] World Health Organization (WHO). WHO expert committee on specifications for pharmaceutical preparations. Geneva (2006a).

[2] EudraLex. Vol. 4: GMP guidelines, Ch. 2: Personnel. [cited 2010 Feb 25] Available from URL: http://ec.europa.eu/enterprise/sectors/pharmaceuticals/files/eudralex/vol-4/pdfs-en/cap2en200408_en.pdf. Brussels (2009).

[3] World Health Organization (WHO). A WHO guide to GMP requirements Part 3: Training. Geneva (2006b).