

Introduction

The pharmaceutical field is one of the highly regulated areas in the world today. This approach is adopted to ensure safety in drug use and quality to satisfy its intended purpose. Quality is a subjective term and may therefore be quite difficult to define clearly. As defined by ISO 9000, quality is the “essential nature of a thing and the totality of its attributes and properties which bear upon its fitness for its intended purpose”¹. Therefore quality is the ability to satisfy the established requirements.

Aim

To identify potential quality improvements within the pharmaceutical chain of Good Distribution Practice (GDP).

Methodology

- Analysis of the history and examination of legislations and guidelines concerned with the present distribution in Malta was performed.²
- Three wholesale dealers were identified to participate on the basis of willingness to share the Standard Operating Procedures (SOPs) related to GDP and whether observation of the activities was possible.
- The activities which were then performed at the wholesalers so as to improve the SOP templates that were previously compiled³ are illustrated in figure 1.

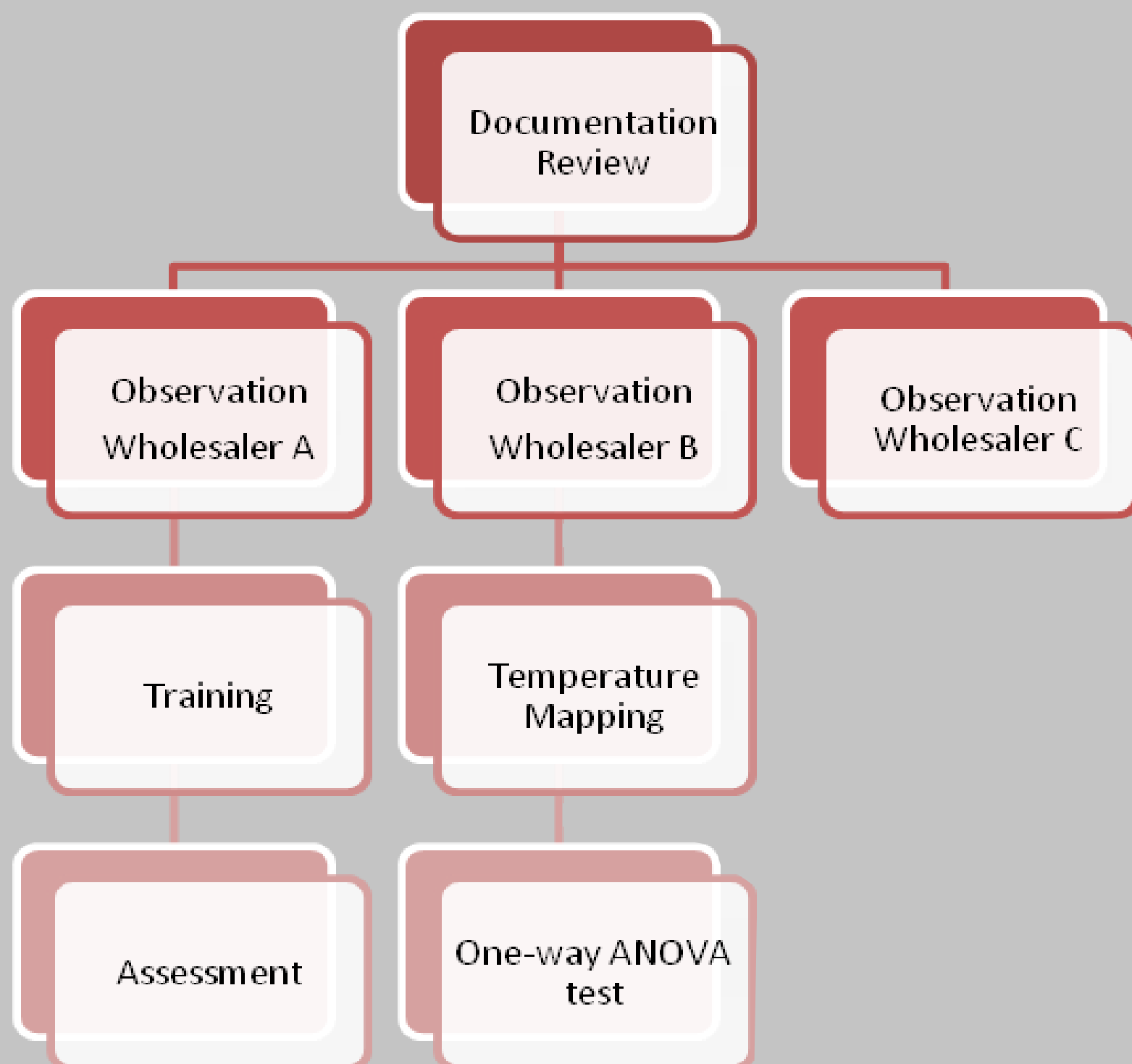


Figure 1: Observations carried out at the wholesalers

- All the personnel at wholesaler A were trained on the following topics in relation to their duties. This was followed by an assessment.
 - ⇒ Principles of GDP and the importance of maintenance of the quality of pharmaceutical products
 - ⇒ Medicines Act and all its subsidiary legislation relevant to the activities of the distributor and the products handled
 - ⇒ SOPs relevant to their individual roles and responsibilities
- Temperature mapping of the stores at wholesaler B was performed in December 2010 and August 2011. Each temperature logger was assigned a number from 1 to 9 as shown in Figure 2.

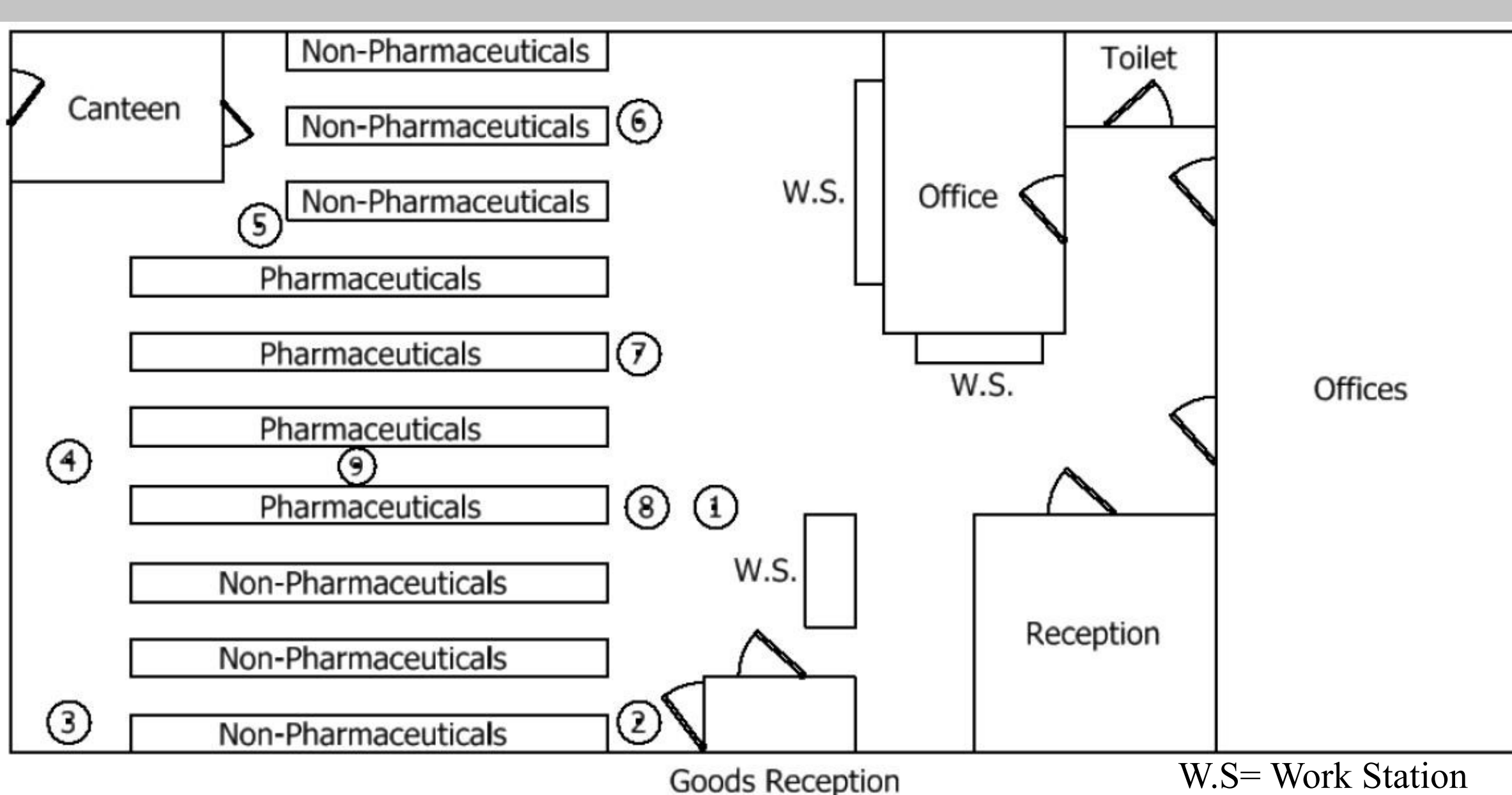


Figure 2: Location of the different temperature loggers at wholesaler B

Results and Discussion

- The personnel working at wholesaler A achieved a mean mark of 97% in the assessment. This indicates that the personnel attained a good understanding of their duties.
- The mean temperature recorded in December 2010 and August 2011 were 17.1°C and 24.04°C respectively.
- The mean temperature recorded by the 9 different temperature loggers in December 2010 ranges from 16.7°C (temperature logger 1) to 17.5°C (temperature logger 6).

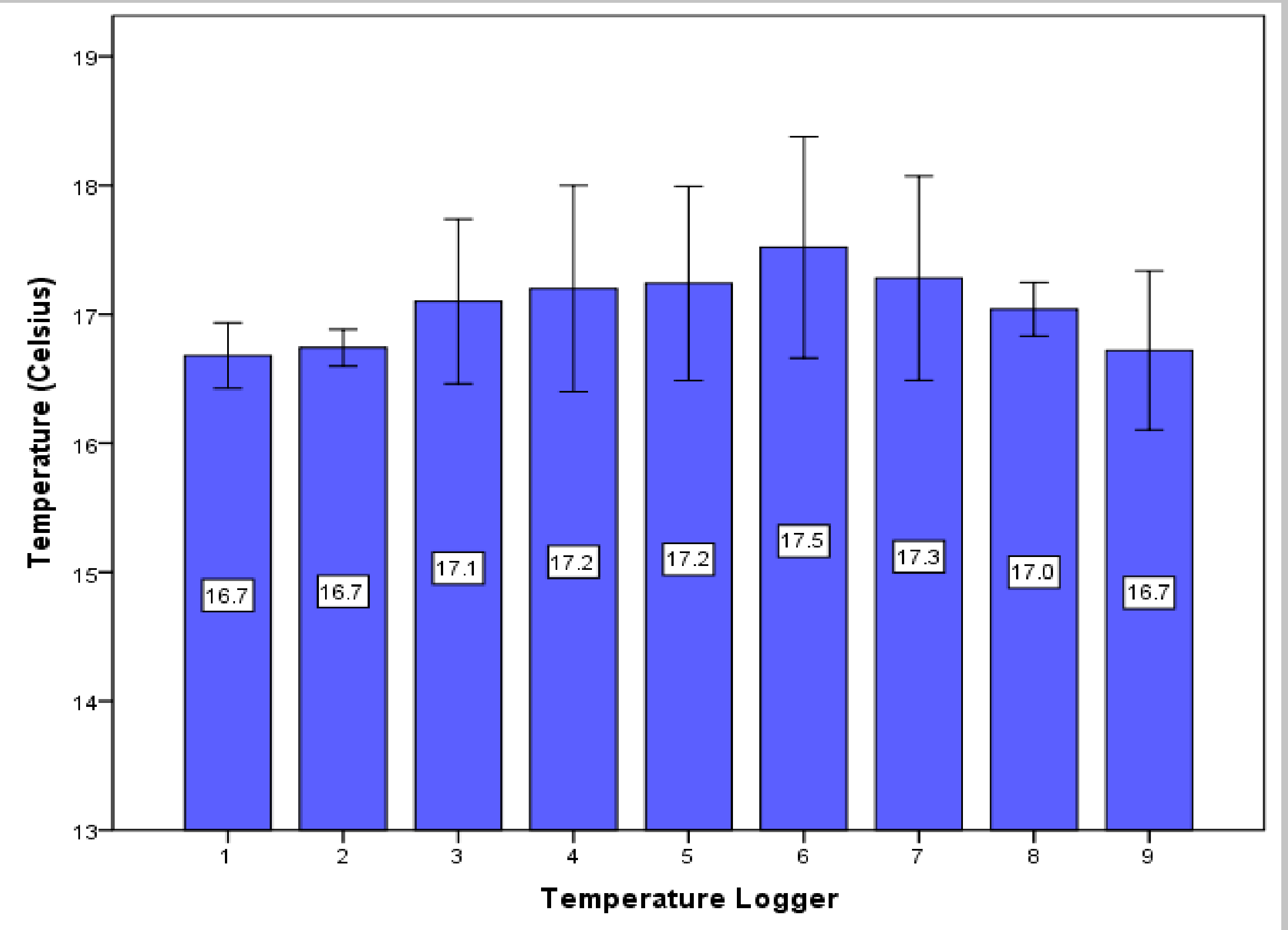


Figure 3: Temperatures (Celsius) recorded by the nine temperature loggers in December 2010

- The One-Way ANOVA test was used to compare the mean temperature between different temperature loggers and between the different days in December 2010 (p-value = 0.137 and 0.003 respectively). This indicates that throughout successive days, the temperature changed due to changes in the ambient temperature. The latter effect was expected to be significant during the tests performed in August 2011 (figure 4).

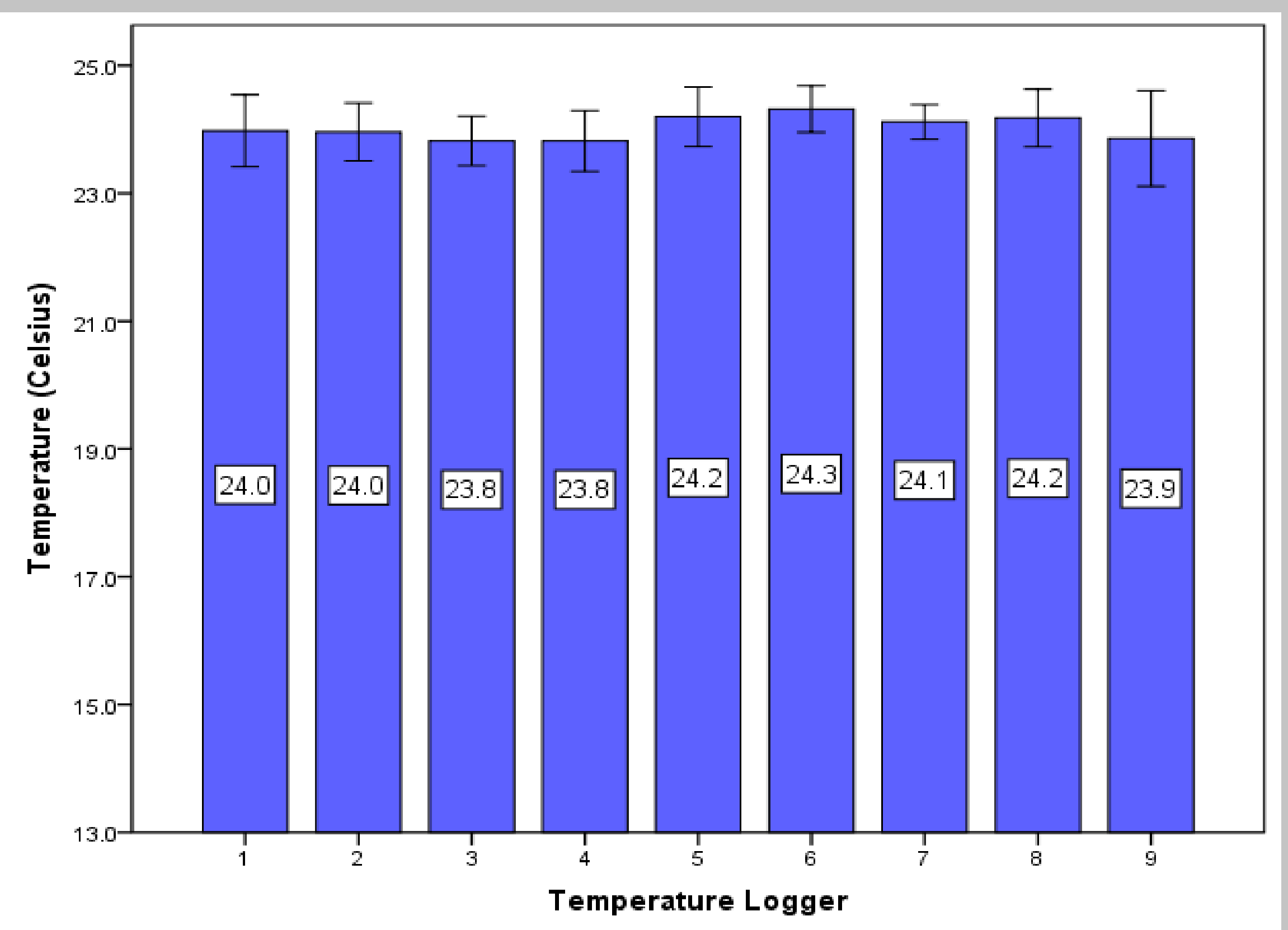


Figure 4: Temperatures (Celsius) recorded by the nine temperature loggers in August

- The One-Way ANOVA test was used to compare the mean temperature between different temperature loggers and between the different days in August 2011 (p-value = 0.377 and 0.117 respectively).

Conclusion

Training is a key ingredient of this system. Changes need to be implemented in the cooling system as the maximum temperatures in August 2011 reached 25°C.

References

- ¹ Hoyle David, ISO 9000 Quality Systems Handbook, third edition, Butterworth-Heinemann Ltd, 16-27 (1998).
- ² Guidelines on Good Distribution Practice of Medicinal Products for Human Use (94/C 63/03), [online], (2003) [cited 2009 October], Available from URL: <http://ec.europa.eu/health/files/eudralex/vol-4/gdpguidelines1.pdf>
- ³ Azzopardi Vanessa, GDP: The Example of a Wholesaler [dissertation]. Msida (Malta): Department of Pharmacy, University of Malta; (2010)