Auditing in a Medicinal Regulatory Framework

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INTRODUCTION

There is perhaps no other area where the relevance of audits influence patients' safety other than the pharmaceutical field.

AIMS

- **To develop an independent and effective audit system at the heart of the Regulatory Authority based on the principles of risk management, governance and internal control.**
- **To analyse the audits findings and recommendations which were carried out in Year 2022.**

METHOD

- **Setting: Malta Medicines Authority**
- **Phase 1: Development of the audit strategy and annual audit programme**

Top management through a consultative forum were asked to identify a suitable and sustainable development of an independent and effective audit system.

- **Phase 2: Analyses of the audits performed in Year 2022**

Enlisting the audit findings and corresponding recommendations for improvement. The internal audits were carried out by internal auditors. Training on ISO 19011:2018 and ISO 9001:2015 was organised internally, to secure a pool of inhouse trained auditors. As part of the training initiative, prior to occupying the role of an internal lead auditor, personnel accompanied experienced lead auditors in various internal audits. Internal auditors designated to perform audits were required to prepare an audit performance report, highlighting the audit outcomes, recommendations for improvement and corrective actions and preventive actions.

RESULTS

Top management, which consisted of eight directors anonymously decided on a risk-based audit approach. The details of the risk-based approach are as follows in Table 1.

	Impact/ Severity to Public Health / Organisation (I)	Likelihood of non-detection (L)	Internal Control (IC)	Risk Score
Processes	(1 -5) (low to high)	(1- 5) (low to high)	(1 - 5) (no – full)	(L x I)/IC

Table 1: Risk Assessment Tool for Audits

Through the analysis of 12 audit reports, a summary of findings and recommendations for improvement had been devised.

Findings	Recommendations for Improvement
Lack of definitions of the abbreviations mentioned in internal documentation	Inclusion of the definitions for the abbreviations used
The appendices referred to in the internal documentation did not tally with the actual reference number of the appendix	Revision of appendices references and omission of appendices which are not in use
No records were found for the training sessions	Revision of the internal document to capture that training and development records shall be
Minute taking was not taken in all occasions as mentioned in the internal documentation	Revision of the internal document to limit minute-taking to management review meetings, ad hoc management/Directors meetings, staff meetings, annual stakeholder meetings
Template for external use presentations are not easily accessible	Inclusion of the presentation template as an appendix for ease of reference

CONCLUSION

An independent internal audit system based on ISO 19011:2018 presents an opportunity to focus attention to detail, which is an integral part of the pharmaceutical operational function, and of exceptional reference to medicinal regulatory sciences.