Volume 3 • Issue 2 • 2021

Review Article

Journal of Biotechnology and Immunology

Standard Operating Procedures for reporting, investigating, and handling Deviations in Healthcare Organizations

Mohamed Refaat[1]*, Marwan ElBagoury[2] and Amy Hutchinson[3]

[1]*Gentium Healthcare, Cairo, Egypt*

[2]*University of South Wales, School of Law, Accounting and Finance, Pontypridd, Wales*

[3]*McMaster University, Hamilton, Canada*

***Corresponding Author:** Mohamed Refaat, Gentium Healthcare, Cairo, Egypt.

Received: July 02, 2021; **Published:** October 12, 2021

Abstract

The purpose of this paper is to provide best practice procedures for the reporting, investigating, and handling of deviations from an organization's defined Standard Operating Procedures (SOPs). These practices ensure transparency, enhancement of Quality Assurance (QA) measures for important procedures, continuous improvement of employee follow through, and a quick response to deviations from procedure [1].

Key words: *SOPs; Reporting; Investigating; Handling Deviations; Healthcare Organizations*

Introduction

This Standard Operating Procedure is applicable to all deviations from procedures related to Patient Oriented Programs (POPs) [2] and/or Patient Support Programs (PSPs) conducted by Healthcare organizations [3]. This Standard Operating Procedure is applicable to deviations spotted or reported by agents, employees, and managers or deviations identified by a source data verification process (SDV) [4]. It is currently being applied to Gentium Healthcare.

Procedures

Deviation Reporting [5, 6]

Deviations should be recorded and immediately reported to the person in charge and the quality management department with explicit explanations and the immediate deviated actions within 24 hours of their observation [7].

The related department manager or Operations Head will suggest the corrective action(s) required to contain the non-conformity [8].

Results

Corrective Actions

The related manager or Operations Head initiates and completes the suggested corrective actions(s). The order of correcting tasks should be done according to vulnerability stemming from the deviation and any pre-agreements made with the Marketing Authorization Holder (MAH).

Discussion

Documenting Corrective Actions [9]

Evidence of the actions taken should be collected and stored. The quality manager should review and evaluate the initiation and

effectiveness of the corrective actions to either approve or send them back for so more information may be gathered [10].

A Quality Assurance representative shall evaluate any effects on quality the deviation had and propose a suitable quality control corrective action based on the nature of the deviation [11]. This Quality Assurance representative will then define the deviation and give it a unique deviation control number under which to store deviation information.

Conclusion

Prevention of Future Deviations

All deviation handling processes will involve root cause analysis and the creation of a Corrective and Preventative Actions (CAPA) plan.

Deviation Reporting Form [12]

Control No. Date:	
Principal Investigator:	
Project Title:	
Project Manager:	
What are you reporting? Regulatory Noncompliance Unplanned Major Deviation	
Date of occurrence:	Date of discovery:
Please describe what occurred (Description of deviation/Query requested):	
What corrective action have you taken to directly address this event? Mentioning the effect on e.g. cost, quality, delivery….etc.	
What have you done to prevent this from reoccurring?	
Signature of Principal Investigator	Date

References

1. Guide to Good Manufacturing Practice for Medicinal Products.
2. Brittenden, J.; Reid, D. (2015). Standard Operating Procedure: Management of Deviations, Breaches and Urgent Safety Measures SOP Number: UoA-NHSG-SOP-045 Version No: 1 Issue Date: 1-4-15 Date Effective: 15-4-15 Review Due Date: 1-4-18.
3. WORLD METEOROLOGICAL ORGANIZATION WMO QUALITY MANAGEMENT FRAMEWORK (QMF) FIRST WMO TECHNICAL REPORT Revised Edition; (2005).
4. THE AUDIT OFFICE: RULES, POLICIES AND PROCEDURES M ANUAL REGULATORY STRUCTURE, SYSTEM S AND OPERATIONS.
5. Liljedahl, A.; Muftic, A. Managing Production Deviations-A Case Study at Scania AB.
6. Deviation Handling and Quality Risk Management A Note for Guidance for the Manufacture of Prequalified Vaccines for Supply to United Nations Agencies; (2013).
7. https://nlp.cs.princeton.edu/CRW/WWC_vocab.txt (accessed May 14, 2020).
8. National Railway Safety Regulator Act (16/2002), as amended » RSR Determination of the format form and content of a safety management system as well as the form, content and manner of submission of a safety management system report https://www.greengazette.co.za/notices/national-railway-safety-regulator-act-16-2002-as-amended-rsr-determination-of-the-format-form-and-content-of-a-safety-management-system-as-well-as-the-form-content-and-manner-of_20180518-GGN-41632-00502.pdf (accessed May 15, 2020).
9. Halifax. Safety Culture Workshop Report; (2012).
10. FINANCE COMMITTEE; (2017).
11. A Scheme and Training Manual on Good Agricultural Practices (GAP) for Fruits and Vegetables.
12. Watt, A. (2014). 4. Framework for Project Management. BCcampus August 14.