

Standard Operating Procedures for the Assessment, Evaluation, Selection and Training of Subcontractors in healthcare organizations

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Abstract

This document outlines how an organization should assess, evaluate, select, and train subcontractors and/or third-party employers to ensure that they meet the same standards as the organization's permanent employees.

This Standard Operating Procedure applies to all subcontractors providing services to an organization. Organization and its subcontractors are bounded to all regulations, laws and guidelines relevant to the client. Organizations should seek the approval of their primary clients, Marketing Authorization Holder (MAH), and/or the project owner before contracting and commencing operations with a sub-contractor who is contacted depending on the nature of the organization's work.

Key words: SOPS; Training; Healthcare; Subcontractors

Abbreviations: NA

Introduction

This document provides written procedures that outline how an organization should assess, evaluate, select, and train subcontractors and/or third party employers to ensure that they meet the same standards as the organization's permanent employees [1]. This Standard Operating Procedure applies to all subcontractors providing services to an organization [2] and for the sake of this paper, the term "subcontractor" also includes third-party service providers and other external services. Organization and its subcontractors are bounded to all regulations, laws and guidelines relevant to the client [3]. Organizations should seek the approval of their primary clients, Marketing Authorization Holder (MAH), and/

or the project owner before contracting and commencing operations with a sub-contractor [4]. Who is contacted depends on the nature of the organization's work [4]. This procedure is currently being applied to Gentium Healthcare.

Procedure

Evaluation of Sub-Contractors

Organizations should evaluate subcontractors based on their history of work in the field, expertise, and recommendations from previous employees. Subcontractors will be asked to provide their credentials, privileges, service providing license, related legal documents, and a detailed description of their company's history and experience [5].

Subcontractors will also be asked to provide signed and updated documents of their company's hierarchy, organizational charts, Curriculum Vitae, and job descriptions of the involved personnel. These documents may be reviewed by the primary client, Marketing Authorization Holder (MAH), or Project owner (if applicable) for guidance and approval, where necessary [6]. Final approval by the Client, Marketing Authorization Holder, and/or Project owner must be granted before commencing operations [7].

Before the subcontractor's operations begin, the subcontractor will sign an agreement to follow and fulfil the regulations and task orders of the Organization and primary Client, and either the Marketing Authorization Holder or project owner. This document will be shared with the Client, Marketing Authorization Holder, or project owner where they will be asked for their relevant guidance (if applicable) and approval before beginning operations [8].

The subcontractor should notify the organization's Managing Director and Quality Assurance manager of any employee changes, or updates to the assigned roles and responsibilities. The Organization's primary client, Marketing Authorization Holder or project owner should also be asked for approval. Organizations should sign contract agreements that states and protects their right to be notified about changes to the subcontractor's business before job commencement or another time, as agreed upon by the project owners [9].

Results

Trainings

The organization will provide the subcontractor with a list of mandatory trainings that must be completed before their employees can undertake certain tasks. The list of mandatory training will be assigned according to the nature of the subcontracted service and as outlined in agreements with the primary client, Marketing Authorization Holder, or project owners who have interest in the subcontracted services. These trainings should be completed within 14 days of the subcontractor's joining date. All trainings required or requested by the client, Marketing Authorization Holder, or project owners will have logs secured, signed, and archived for the duration of the project the subcontractor is involved in and for at least 5 years after its completion. A longer period of retention may be requested by primary clients, Marketing Authorization Holder, or the project owner. These records will be available for audit at any time [10].

Subcontractor Name: Project Name:	Comments
Credentials, privileges, service providing license, company's hierarchy, organizational chart, Curriculum Vitae and Job descriptions	
Relevant mandatory trainings	
Pharmacovigilance and adverse event reporting training	
Completion of trainings and archiving training Logs	
Specific, additional, and requested training by client or Marketing Authorization Holder	
Subcontractor's capacity to continue business processes during staff change, emergency or disaster.	
Client or Marketing Authorization Holder notification and approval	
Quality Assurance manager Name and Approval	
Head of Operations name and approval	

Table legend: Subcontractor Evaluation Checklist [17].

Discussion

Suggested Relevant Trainings List [11, 12]

#	Training
1	Data Security, Privacy and Confidentiality
2	Pharmacovigilance & Adverse Events Reporting
3	Interaction with Medical Professionals
4	Business Continuity Plan
5	Relevant Standard Operating Procedures
6	Anti-bribery Policy

Any additional specific trainings requested by the client or Marketing Authorization Holder will be completed and implemented under their direct supervision [13]. Any subcontractors must undertake pharmacovigilance and adverse event reporting training under the supervision and/or request of the primary client, Marketing Authorization Holder or project owner in order to meet the organization's needs and comply with local regulations [14].

Conclusion

Employee Transition and Emergency

Organizations will assess the subcontractor's capacity to continue business processes during a time of staff change, hand over or integration of a new team member, emergency, or even disaster [15].

If such events occur, a transition plan will be developed in coordination with the client, Marketing Authorization Holder, or project owner.

This plan should cover [16]:

- Project responsibilities and a list of involved stakeholders with their contacts.
- A brief overview of the project's objectives, workflow, KPIs, history and milestones.
- Any specific or required trainings that must be completed under supervision of the Organization's Quality Assurance manager and in coordination with the primary client, Marketing Authorization Holder, or project owner.
- The appropriate transference of all documents and materials.
- A clear business continuity and disaster recovery plan.
- Any other business continuity plans, disaster recovery measures, or requirements requested by the primary client, Marketing Authorization Holder, or project owner.
- A list of mandatory trainings to be performed by any employees/sub-contractors who undertake certain responsibilities. These training will cover important aspects of the organization and technical knowledge. This training list must be approved by the primary client, Marketing Authorization Holder, or project owner.
- Any specific trainings requested by the primary client, project owner, or Marketing Authorization Holder that must be duly carried out. These trainings will be recorded and kept in the subcontractor's employment history and will be made available for audit purposes at any time for up to 5 years after the end of program.

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