SOPs for Supply Chain Capacity Building activities

SOP1: Supply Chain Capacity Gap Analysis

Pharmaceuticals Fund and Supply Agency (PFSA)		
Document Title	Supply Chain Gap Analysis	
Document No	PFSA-HO/SOP-CBOR-001	
Revision	0	**Effective on:** July/2010 E.C

1. Introduction

Supply chain capacity gap analysis refers to the process through which actual capacity of the supply chain system is assessed and the gaps identified to improve its performance. Gap analysis is the basis for designing, developing and implementing interventions to strengthen the supply chain system at all levels. This activity is the entry point for all other supply chain system strengthening activities of the Agency.

2. Purpose

The purpose of this SOP is **to show the steps**that should be followed in identifying supply chain capacity gaps through collecting and analyzing relevant data.

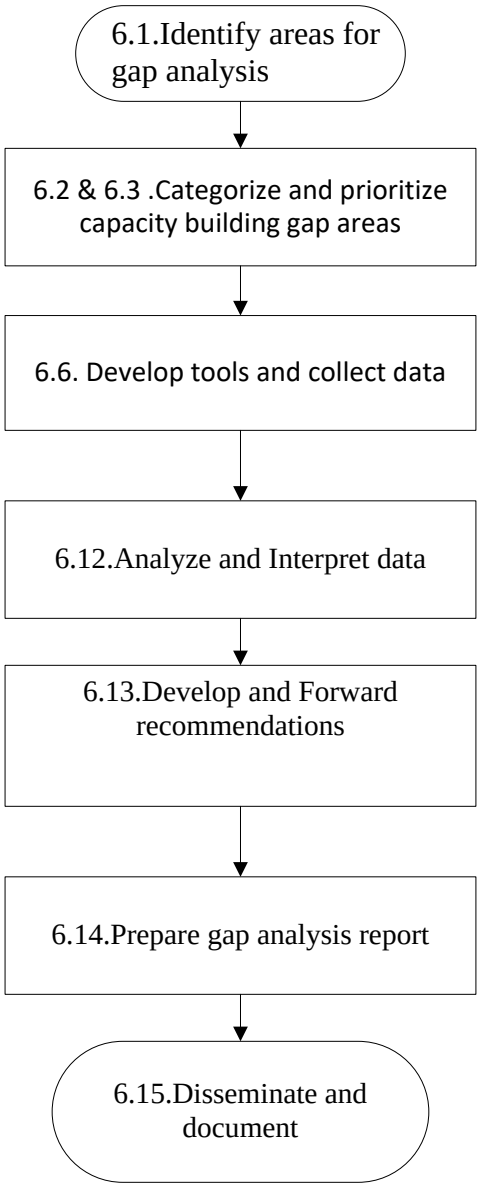
3. Scope

This SOP is applicable for identifying capacity gaps at all levels of the supply chain system.

4. Responsibilities

Title	Responsibility
Capacity Building and Operational Research Team	• Identify areas for gap analysis • Prioritize the identified areas for gap analysis • Plan and collect data • Analyze data and develop recommendations • Prepare report and disseminate to relevant stakeholders

5. Process map/Flowcharts



6. Procedures

6.1. Identify supply chain areas for capacity gap analysis by gathering information from **internal** and **externalstakeholders**. These capacity gap areas can be identified from:

- strategic plans
- performance reports

- assessment reports
- review meeting proceedings
- stakeholder and Customer feedbacks
- Expert opinions from center and branch offices, etc.

6.2. Categorize the identified gap areas into the different supply chain areas; selection, specification, forecasting, supply planning, procurement, contract management, port clearance, storage, inventory management, distribution, medicine use, LMIS, fleet management, installation, grant management, fund management, HR management, general service, etc.

6.3. Prioritize the identified capacity gap areas by considering severity and availability of resources

6.4. Develop plan to undertake the gap analysis in the prioritized areas.

6.5. Secure necessary resources to undertake the gap analysis in the prioritized area

6.6. Develop methods and tools for data collection

6.7. Test the tools developed

6.8. Identify data collectors who have the necessary expertise along the supply chain

6.9. Provide orientation on data collection methods and tools

6.10. Collect necessary data

6.11. Clean and enter the data

6.12. Analyze and interpret the data

6.13. Develop recommendations

6.14. Prepare gap analysis report

6.15. Disseminate and document the gap analysis report

7. Forms

Form No.	Form title

8. Amendment History

Revision:	Effective Date:	Approved By:	Reason
0	July/2010 E.C	Agency Management	Initial release

SOP2: Supply Chain Training Curriculum Development

Pharmaceuticals Fund and Supply Agency (PFSA)		
Document Title	Supply Chain Training Curriculum Development	
Document No	PFSA-HO/SOP-CBOR-002	
Revision	0	**Effective on:** July/2010 E.C

1. Introduction

Training is one of the strategies to fill supply chaingaps. Effective training requires ***properly designed curriculum based on identified gaps***. The process of supply chain curriculum development includes **analysis, *design, development, implementation and evaluation phases***. This activity is used to havestandardized curricula for prioritized supply chain capacity gaps that can be addressed through training.

2. Purpose

The purpose of this SOP is to show the processes that should be followed in analyzing, designing, and developing curricula for supply chain capacity building trainings.

3. Scope

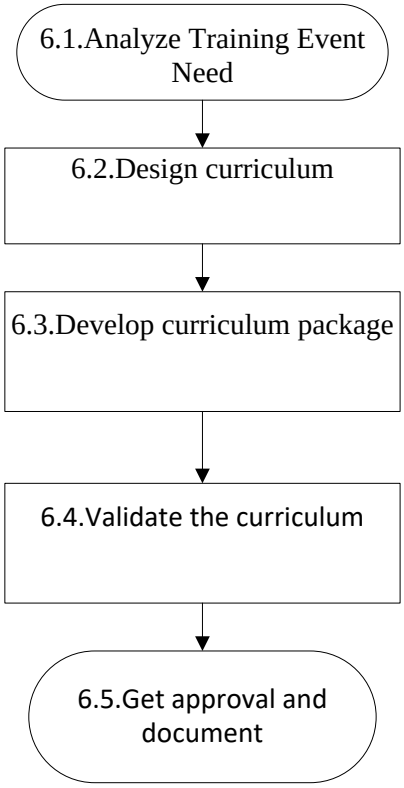
This SOP is applicable for developing curricula for supply chain capacity building trainings carried out by the Agency.

4. Responsibilities

Title	Responsibility
Capacity Building and Operational Research Team/Curriculum development	• Analyze training need • Design and develop curriculum • Validate the curriculum • Get approval

taskforce	

5. Process Map/Flowcharts



6. Procedures

6.1 Procedures in Training Event need analysis (TENA) phase of curriculum development

1. Establish curriculum development taskforce composed of curriculum and subject area experts.
2. Identify supply chain performance gap (see SOP1)
3. Identify target audiences
4. Identify the knowledge, skills and attitude necessary to perform supply chain activities
5. Plan data gathering on target audience's knowledge, skills and attitude
6. Develop data collection tools

7. Collect data
8. Analyze and interpret data
9. Develop recommendations
10. Prepare TENA Report and document

6.2 Procedures for Designing a Curriculum

1. Prepare course description
2. Prepare goal and objectives of the course
3. **Develop training methods and materials**
4. Decide participant and trainer selection criteria
5. Develop methods of course evaluation
6. Decide course duration and suggested class size
7. Develop course outline and schedule
8. Document

6.3 Procedures for Developing supply chain training Curriculum

1. Gather information by reviewing literatures in the area
2. Prepare Participant's Manual based on the course contents
3. Prepare trainer's guide and other relevant material
4. Organize curriculum validation workshop
5. Incorporate comments from the validation workshop and produce final draft document
6. Pilot-test the curriculum
7. Accommodate feedbacks from the pilot trainings
8. Get approval of the final training materials
9. Document soft and hard copies of the materials

7. Forms

Form No.	Form title

9. Amendment History

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SOP3: Conduct Trainings

Pharmaceuticals Fund and Supply Agency (PFSA)		
Document Title	Conducting Trainings	
Document No	PFSA-HO/SOP-CBOR-003	
Revision	0	**Effective on:** July/2010 E.C

1. Introduction

Trainings are provided to improve the knowledge, skill and attitudes of the workforce across the supply chain based on identified gaps.PFSA providesvarious supply chain trainings to capacitate its internal staff and external stakeholders. These trainings are provided in accredited training centers found in different parts of the country. The trainings include***Training of Trainers (TOT) and basic trainings.***

2. Purpose

The purpose of this SOP is to show the steps that should be followed in ***planning, organizing and conducting in-service trainings for internal and external stakeholders*** in the area of supply chain management.

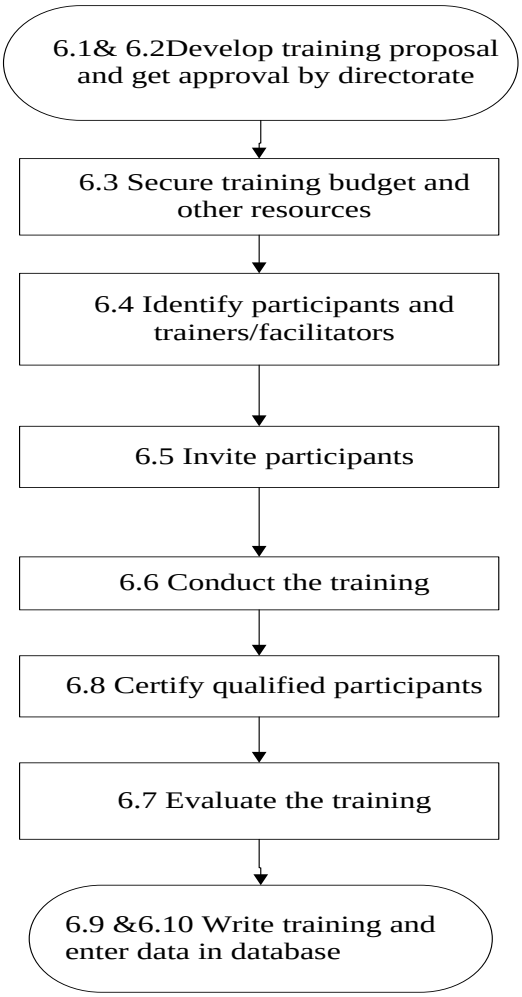
3. Scope

This SOP is applicable for short-term supply chain related in-service training (IPLS, supply chain overview, quantification, Supply Chain M & E, Procurement, Warehouse Operation Management, inventory management, fleet management, supply chain mentoring and supervision, medical supplies and laboratory reagents management, Fund management, HR management, etc.) provided by the Agency.

4. Responsibilities

Title	Responsibility
Capacity Building and Operations Research Team	• Develop training proposal and get approval • Secure training budget and other resources • Identify participants and trainers/facilitators • Invite participants and make a follow-up • Conduct the training • Evaluate the trainings • Write training report and enter the training data in the training database

5. Process map/Flowcharts



6. Procedures

6.1 For each training, prepare training proposal containing resource requirements, participants, trainers, date of training.

6.2 Get proposal approval at Directorate level

6.3 Secure training venue

6.4 Invite participants and facilitators, and make a follow-up

6.5 Make ready the necessary training and stationery materials

6.6 Conduct the training

- Introduce the training course (what the training is about, objectives, contents, methods of evaluation, certification requirements - if any)
- Provide pre-test
- Facilitate the course as per the schedule and TG

6.7 Evaluate the training and participants

- Conduct mid-term evaluation of participants
- Conduct end course evaluation of participants
- Undertake course evaluation
- Post Training evaluation of participants at work

6.8 Certify participants that have met the certification requirements

6.9 Write training report and share to relevant stakeholders

6.10 Enter the training data into the training database

7. Forms

Form No.	Form title

8. Amendment History

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SOP 4: Training evaluation

Pharmaceuticals Fund and Supply Agency (PFSA)		
Document Title	Trainings evaluation	
Document No	PFSA-HO/SOP-CBOR-004	
Revision	0	**Effective on:** July/2010

1. Introduction

Training evaluation is a learning and action-oriented management tool for determining the relevance, effectiveness, and impact of activities in light of their objectives in order to improve both current activities and/or process conducted to determine whether training has met its objectivesand make decisions about the future of the training. For each supply chain management training provided by the Agency, the trainingcurriculumneeds to be evaluated. In addition to the evaluation done during the training, done at specific period of time after the training is conducted so as to determine its outcome.

2. Purpose

The purpose of this SOP is to show the steps that should be followed in evaluating the outcomes of trainings provided by the Agency in the area of supply chain management.

3. Scope

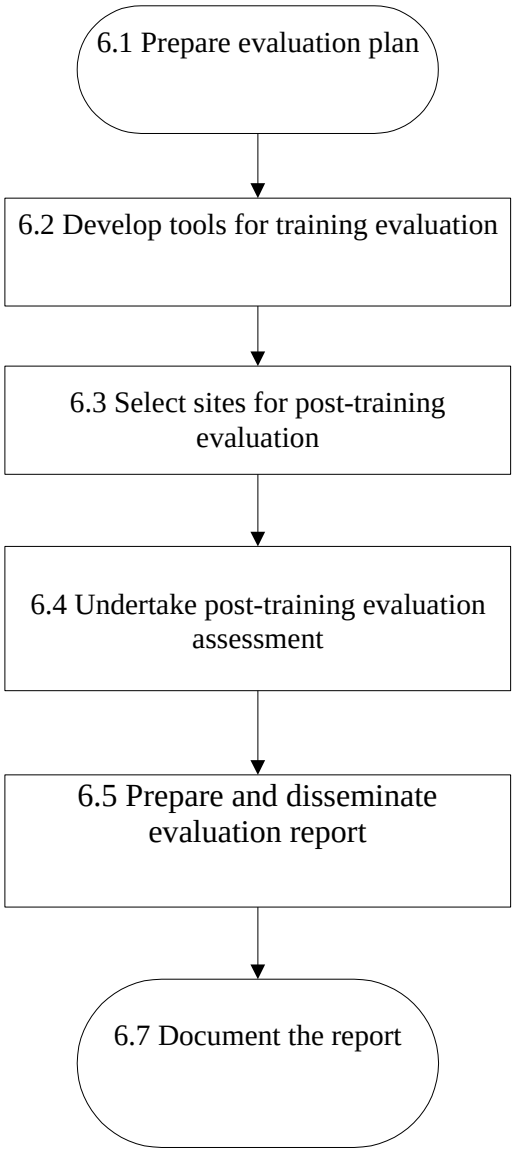
This SOP is applicable for evaluating the outcomes of supply chain trainings provided by the Agency.

4. Responsibilities

Title	Responsibility
Capacity Building and	• Prepare evaluation plan • Develop tools to evaluate the training

Operational Research Team	• Perform post-training evaluation • Prepare and disseminate evaluation report

5. Process map/Flowcharts



6. Procedures

6.1 Prepare plan for training evaluation

6.2 Develop evaluation tools as per pre prepared curriculum

6.3 Make ready the evaluation tools before conducting the training

6.4 Identify sites for post-training evaluation

6.5 Undertake post-training evaluation at site level using the techniques indicated in the curriculum

6.6 Prepare and disseminate evaluation report

6.7 Document the evaluation report

7. Forms

Form No.	Form title

8. Amendment History

Revision:	Effective Date:	Approved By:	Reason
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SOP 5: Organizing an Event

Pharmaceuticals Fund and Supply Agency (PFSA)		
Document Title	Organizing and Event	
Document No	PFSA-HO/SOP-CBOR-005	
Revision	0	**Effective on:** July/2018

1. Introduction

An eventis a special occurrence that is aimed at achieving specific objectives with the ultimate goal of strengthening the supply chain system. Organizing an event involves a series of activities that are undertakenbefore, during and afterthe event. Such events include global and local supply chain annual conferences/summits, workshops, consultative meetings, review meetings, etc. The Agency organizesevents to discuss on various supply chain management issues with its internal and external stakeholders.

2. Purpose

The purpose of this SOP is to show the steps that should be followed in organizing events on supply chain management of pharmaceuticals.

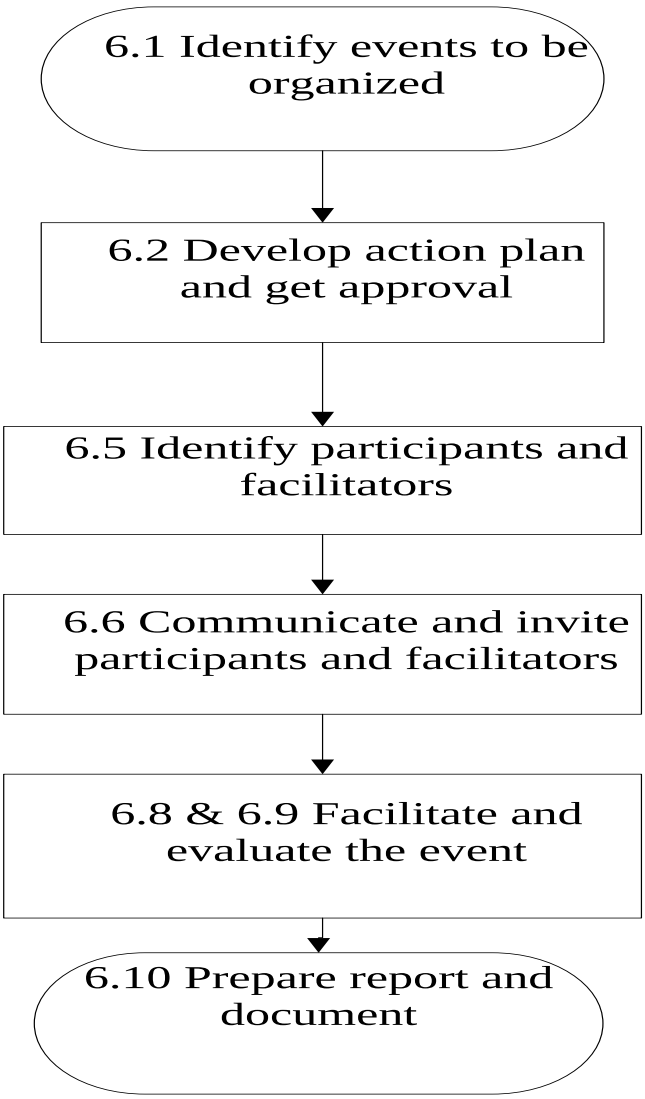
3. Scope

This SOP is applicable to all supply chain management event organizing activities undertaken by the Agency.

4. Responsibilities

Title	Responsibility
Capacity Building and Operational Research Team	• Identify events to be organized • Develop action plan and get approval • Identify facilitators/key note speakers and participants • Communicate and invite facilitators/key note speakers and participants • Arrange necessary logistics • Facilitate the event • Evaluate the event • Prepare report and document

5. Process map/Flowcharts



6. Procedures

6.1 Identify events that need to be organized for internal and external stakeholders

- Communicate with internal and external stakeholders to send their event needs
- Prioritize event needs

6.2 Prepare plan for identified events and get approval

6.3 Communicate with internal and external stakeholders

6.4 Set the date and venue for the event and prepare event schedule

6.5 Identify facilitators/key note speakers and participants

6.6 Invite facilitators/key note speakers and participants, and make a follow-up

6.7 Arrange the necessary logistics for the event

6.8 Facilitate the event as per the schedule

6.9 Evaluate the event

- Evaluate the event during the event (daily participant feedbacks, daily facilitators meetings, etc.)
- Evaluate the event at the end of the event (final feedback from participants)

6.10 Prepare event report/proceedings and communicate to all stakeholders

6.11 Enter the data in event registration database and document the report/proceeding

7. Forms

Form No.	**Form title**

8. Amendment History

Revision:	**Effective Date:**	**Approved By:**	**Reason**
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SOP6: Supportive Supervision

Pharmaceuticals Fund and Supply Agency (PFSA)		
Document Title	Supportive Supervision	
Document No	PFSA-HO/SOP-CBOR-006	
Revision	0	**Effective on:** July/2010 E.C

1. Introduction

*Supportive Supervision (SS)*is the process of guiding, helping and encouraging the supply chain workforce to improve their performance thereby meet the defined standards of their organization.SS is one of the capacity building approaches and is a collaborative effort between the supervisor and a professional staff/worker to help the staff improve their performance and confidence. The supervisor observes the staff practicing at their work places, and provides constructive feedback. The supervisor and the practitioners discuss to identify areas of strength and address any difficulties the professional experiences during the course of their routine works.

2. Purpose

The purpose of this SOP is to provide step-by-step processes on how to providesupportive supervision on supply chain management.

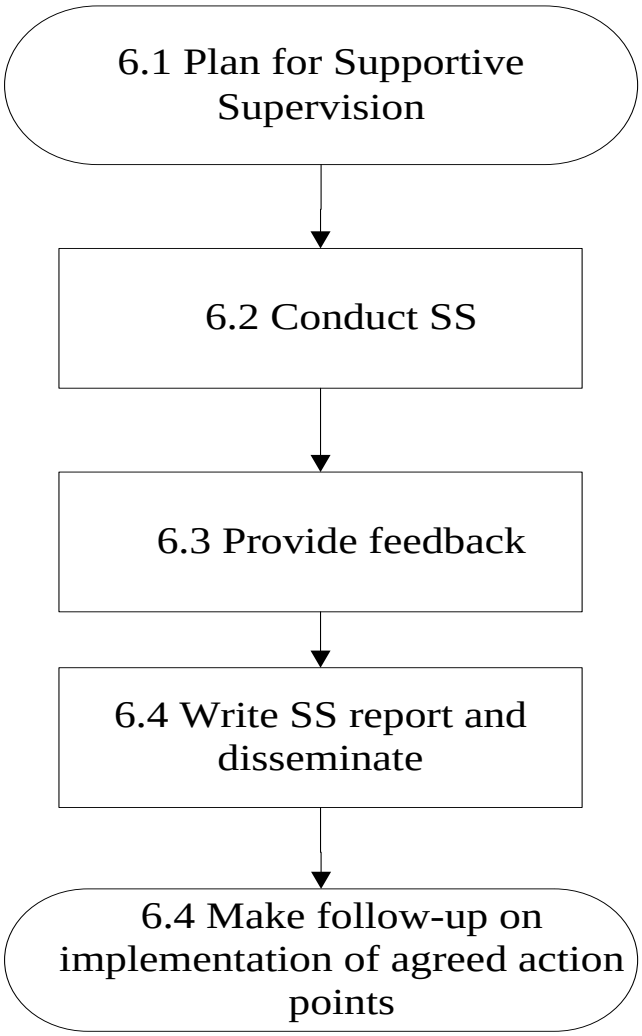
3. Scope

This SOP is applicable for supportive supervision activities provided by the Agency at all levels of the supply chain system.

4. Responsibilities

Title	Responsibility
Capacity Building and Operational Research Team	• Plan for Supportive Supervision • Provide Supportive supervision • Provide feedback • Write SS report • Make follow-up on implementation of agreed action points

5. Process Map/Flowcharts



6. Procedures

6.1 Prepare Plan

- Identify sites/health facilities to be supervised and develop a route plan.
- Develop proposal containing the areas to be supervised, composition of the supervisory team, sites to be supervised, supervision checklist, and supervision schedule.
- Establish a supportive supervision team with members from the relevant stakeholders and partners depending on the area to be supervised
- Secure the resources necessary for the supportive supervision
- Inform the relevant institutions and supervisees on the dates, team composition, time, objectives of the visit and support needed.
- Organize a preparatory team meeting the preceding day.
- Plot a route map of the health facilities to be supervised with regard to the time given for the supervision(where to where… long distances first then shortest ones last, how many facilities per day in accordance with their locations and the likes)

6.2 Provide Supportive Supervision

- Review the previous action points and status of implementation, if any.
- Observe and gather information using the checklist.
- Note their problems and challenges (identify gaps)
- Address and solve problems in positive ways.
- Provide corrective and supportive feedback on performance.(Avoid making promises and be honest)
- In case a procedure is performed incorrectly, demonstrate the correct procedure and ask for re-doing.
- Give on-the-job training on new techniques and approaches if required.

6.3 Provide Feedback

When data collection is completed, the supervisory team should work with health-facility staff as a team, describing each problem in detail and making constructive comments.

- Once the team is done with the supervision, discuss findings and recommendations with the health facility's team, including the management.

- Use positive feedback, when performance is good; and constructive feedback, when performance needs improvement.
- Start with those areas they are doing well followed by those where there are problems.
- Focus on systems and processes, the performance or action, not on the person responsible.
- Provide informational updates on policies or new recommended practices, guidelines and training opportunities;
- Discuss previous action points (if any) which were not implemented and include them in the new action plan.
- Outline areas that need improvement and guide them to come up with corrective actions within a given time line. Listen attentively, with encouragement and open mind believing that everyone has contributions to make. Give a chance to the team and management and to reflect.

6.5 Report writing and follow-up action

After supervision, the supervisor must prepare a supervisory report. This report is vital for planning corrective measures, and also to provide future supervisory visits.

- ✓ Use the report writing format to document the visit including action and follow up plans
- ✓ The supervision report must:
    - identify which facilities were supervised; (by type- Hospital, HC, HP, etc)
    - list of the names, position and responsibilities of persons contacted in the supervised area
    - the amount of fund utilized for the SS and the fund source
    - discuss each item in the supervision checklist in accordance with findings;
    - describe what immediate corrective actions were taken during the visit for areas that need improvement;
    - identify the agreed pointes that needs improvement with the staff members concerned for the next visit (attach if any action plans are developed);
- ✓ Share information at weekly Directorate meeting
- ✓ Disseminate the report to relevant bodies

- ✓ If possible, organize a meeting to discuss the results of the supervisory visits that need special attention and immediate action.
- ✓ Aggregate report at each level and document
- ✓ Follow-up on implementation of agreed upon action points

7. Forms

Form No.	Form title

8. Amendment History

Revision:	Effective Date:	Approved By:	Reason
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SOP7: On-the-Job Training (OJT)

Pharmaceuticals Fund and Supply Agency (PFSA)		
Document Title	On-the-Job Training (OJT)	
Document No	PFSA-HO/SOP-CBOR-007	
Revision	0	**Effective on:** July/2010 E.C

1. Introduction

On-the-Job-Training (OJT) is one of the training approaches whereby a trainer provides training to a trainee on the job. It focuses on developing skill to perform a specific task. Some of the competencies required for the supply chain workforce within PFSA and other supply chain actors can be addressed through this approach.

2. Purpose

The purpose of this SOP is to show the steps that should be followed in capacitating the supply chain workforce through OJT.

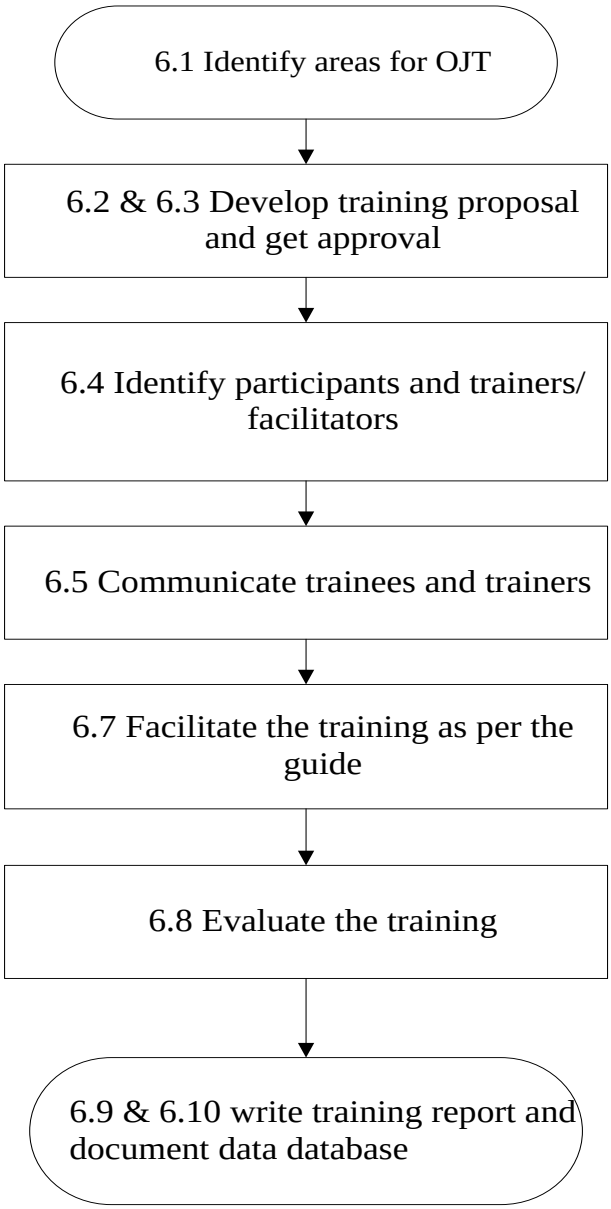
3. Scope

This SOP is applicable for the provision of OJT in supply chain management by the Agency.

4. Responsibilities

Title	Responsibility
Capacity Building and Operational Research Team	• Identify areas for OJT from the gap analysis • Develop proposal and get approval • Identify trainees and trainers • Facilitate the OJT • Evaluate the training • Write report and enter the training data in the database

5. Process Map/Flowcharts



6. Procedures

6.1 Identify areas for OJT from the gap analysis (see SOP1)

6.2 Develop proposal (area of training, resource requirement, site of training and trainees, trainers, date of training).

6.3 Get approval from the Directorate

6.4 Develop guide for OJT

6.5 Communicate the identified participants, institutions and trainers

6.6 Make ready the necessary training and stationery materials

6.7 Provide the OJT as per the guide

- self-introduce
- state objectives of the OJT
- introduce the course schedule
- Facilitate the OJT as per the schedule and TG

6.8 Evaluate the training (see SOPs 3 & 4)

6.9 Write training report and share to relevant stakeholders

6.10 Enter the training data into the training database

7. Forms

Form No.	Form title

8. Amendment History

Revision:	Effective Date:	Approved By:	Reason
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SOP 8: Mentoring in Supply chain Management

Pharmaceuticals Fund and Supply Agency (PFSA)		
Document Title	**Mentoring in supply chain**	
Document No	PFSA-HO/SOP-CBOR-008	
Revision	0	**Effective on:** July/2010 E.C

1. Introduction

Mentoring is a system of practical training and consultation that fosters ongoing professional development with the ultimate goal of providing quality service. In a mentoring system, a more knowledgeable, skillful and experienced person is paired with another individual soasto help the later develop his/her professional knowledge, skills and attitudes. Mentoring is one of the strategies that can enhance supply chain workforce's knowledge, skill and attitude toimprove the job performance, satisfaction and retention.

2. Purpose

The purpose of this SOP is to show the steps that should be followed in providing mentorship for the supply chain workforce at all levels.

3. Scope

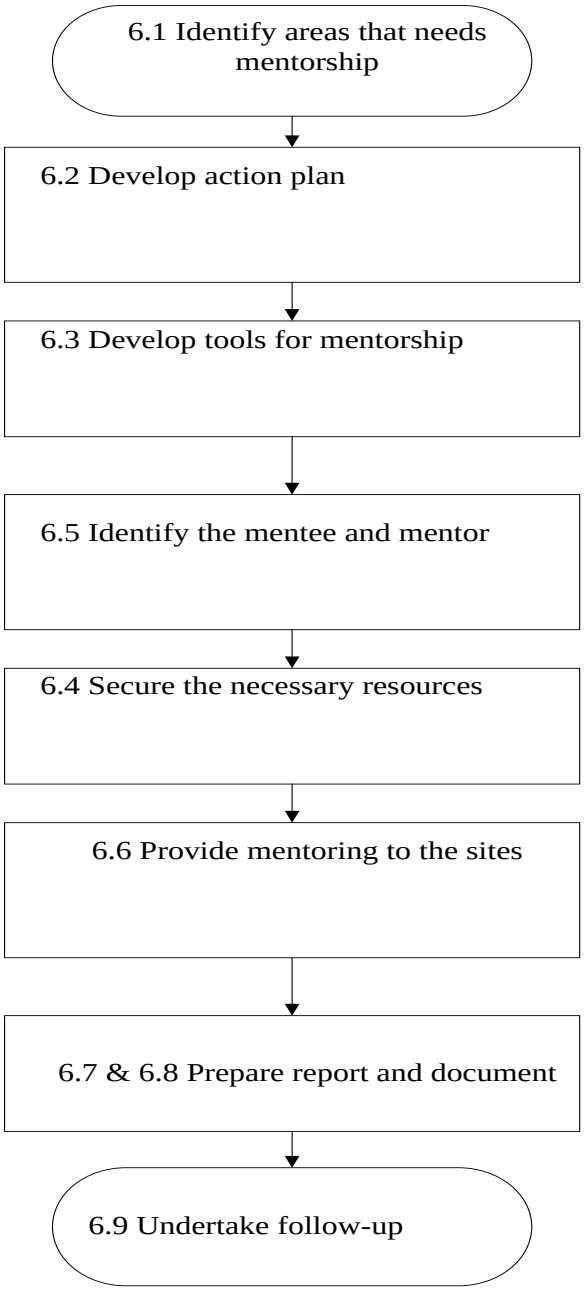
This SOP is applicable for providing mentoring activities across the supply chain system by the Agency.

4. Responsibilities

Title	Responsibility
Capacity Building and Operational Research Team	• Identify areas that needs mentorship • Develop action plan • Develop tools for mentorship • Identify the mentee and mentor • Secure the necessary resources

	• Provide mentoring to the identified sites • Prepare mentorship report • Undertake follow-up

5. Processmap/Flowchart



6. Procedures

6.1 Based on gap analysis of supply chain, identify areas and sites that needs mentorship

6.2 Develop mentorship proposal containing identified areas, sites that needs mentorship, objectives, mentees, mentors, duration/schedule and budget requirement, and get approval by the management

6.3 Develop required mentoring tools(checklist and mentoring guide)

6.4 Secure required resources

6.5 Communicate the selected sites, mentees and mentors

6.6 Deliver the mentorship as per the mentoring guide and checklist

6.7 Write report and communicate

6.8 Document the mentorship report

6.9 Follow-up progress of the mentee

7. Forms

Form No.	**Form title**

8. Amendment History

Revision:	**Effective Date:**	**Approved By:**	**Reason**
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SOP9: Material support for Supply chain Activities

Pharmaceuticals Fund and Supply Agency (PFSA)		
Document Title	**Material support for Supply chain Activities**	
Document No	PFSA-HO/SOP-CBOR-009	
Revision	0	**Effective on:** July/2010 E.C

1. Introduction

Strong Supply chain requires the availability of adequate quantity of quality materials to undergo supply chain operations. The materials include warehouse handling materials, (shelf, palate, trolley, Ventilator, ladder, Job aids, warehouse guidelines, locators, sign and symbols, posters, shelves, pallets, trolley), recording and reporting vouchers and formats (Computers, IFRR, RRF, HPMRR, BIN card, stock card, vouchers (Model 19, model 22, sales tickets, registers, pad registers etc),Reference materials etc. Material support is provided to health facilities and other supply chain institutions based on identified gaps.

2. Purpose

The purpose of this SOP is to show the procedures that should be followed during material support by the Agency to relevant supply chain institutions.

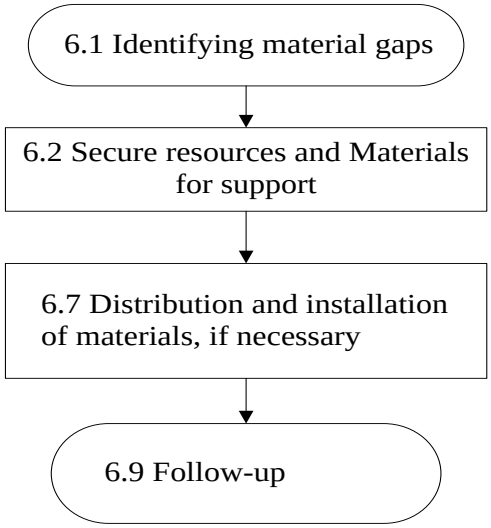
3. Scope

This SOP is applicable for the provision of Supply chain support Materials from the Agency to relevant supply chain institutions.

4. Responsibilities

Title	Responsibility
Capacity Building and Operational Research Team	• Identify material support needs • Secure resources and Material for support • Prepare material distribution breakdown • Handover the materials to General Service and Property Administration Directorate for distribution • Make follow-up on distribution of materials
General service and Property Administration Directorate	• Distribute the materials as per the breakdown • Facilitate installation of the materials, if necessary • Follow-up on distribution of the materials

5. Process Map/Flowcharts



6. Procedures

6.1 Identify materialsgaps (See SOP 1)

6.2 Secure materials/resources for procurement of material

6.3 Develop specifications of Materials

6.4 Send to procurement unit

6.5 Follow-up the procurement status

6.6Prepare and send distribution plan to General Service and Property Administration Directorate.

6.7 Distribute the materials as per the distribution plan

6.8Facilitate installation of materials, if any

6.9Follow-up the distribution status and installation

7. Forms

Form No.	Form title

8. Amendment History

Revision:	Effective Date:	Approved By:	Reason
0	July/2010 E.C	Agency Management	Initial release

SOP10: Document preparation

Pharmaceuticals Fund and Supply Agency (PFSA)		
Document Title	**Supply chain documents Preparation**	
Document No.	PFSA-HO/SOP-CBOR-010	
Revision	0	**Effective on:** July/2010 E.C

5. Introduction

Documents like training materials (PG and TG), SOPs, manuals and guides are very important for operation of the supply chain system. The preparation of these documents should be based on identified gaps and follow standardized approach.

2. Purpose

The purpose of this SOP is to show the steps that should be followed in the preparation of supply chain documents.

3. Scope

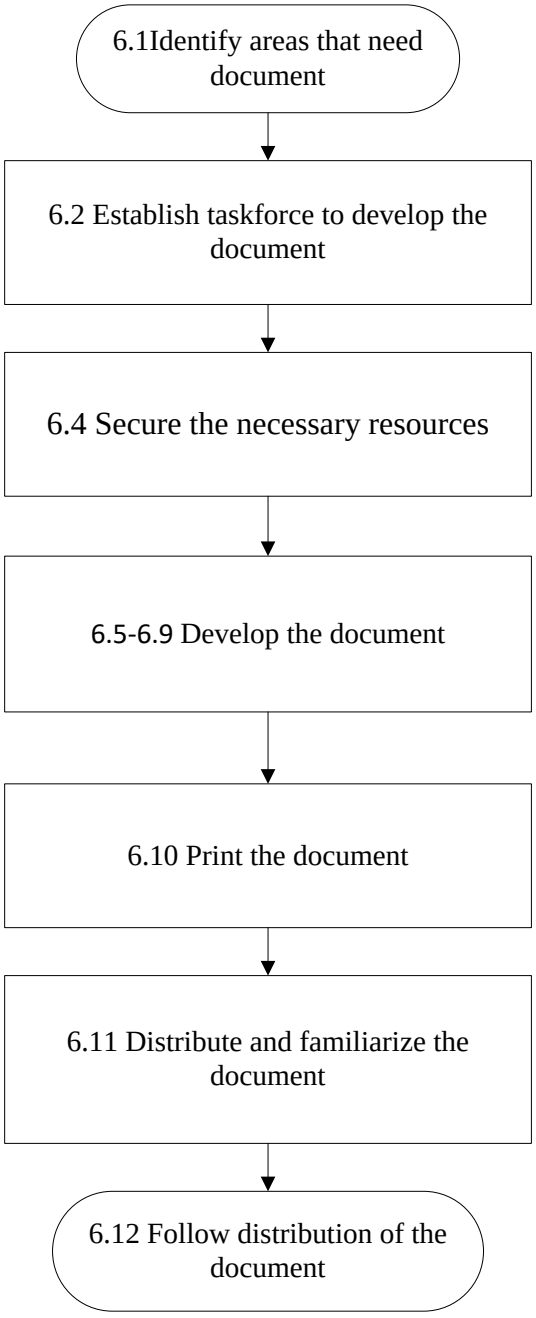
This SOP is applicable for the preparation of standardized documents in the area of supply chain management.

4. Responsibilities

Title	Responsibility
Capacity Building and Operational Research Team	• Identifying Areas which need document preparation • Establish taskforce for document development • Secure necessary resources for document preparation • Develop the document • Print the document • Follow-up on distribution status • Familiarize the documents to users

General Service and Property Administration Directorate	• Receive and distribute the document • Follow-up on distribution status

5. Process Map/Flowcharts



6. Procedures

6.1 Identify supply chain operations that require document preparation (See SOP 1)

6.2 Establish taskforce including subject matter experts and curriculum writers.

6.3 Collect relevant literatures

6.4 Secure necessary budget for the document preparation

6.5 Design contents of the document

6.6 Produce draft document based on the content

6.7 Circulate the document for review by relevant experts

6.8Incorporate comments forwarded by the experts

6.9 Organize mini-workshop to validate the document(s)

6.10 Finalize and print the document

6.11 Distribute and familiarize the document to users

6.12 Follow-up distribution status of the document

7. Amendment History

Revision:	**Effective Date:**	**Approved By:**	**Reason**
0	July/2010 E.C	Agency Management	Initial release

SOP 11: Conduct Operational Research/Assessment

Pharmaceuticals Fund and Supply Agency (PFSA)		
Document Title	**Operations Research**	
Document No	PFSA-HO/SOP-CBOR-011	
Revision	0	**Effective on:** Initial release

1. Introduction

Operational research is a means to search for knowledge and interventions, strategies or tools that can enhance the quality and effectiveness of supply chain operations at all levels. The Agency undertakes such research on identified supply chain management areas so as to improve the system. Findings of such studies serve as input for the development of strategies and action plans at all levels.

2. Purpose

The purpose of this SOP is to show the steps that should be followed in planning and undertaking operational research on supply management of pharmaceuticals.

3. Scope

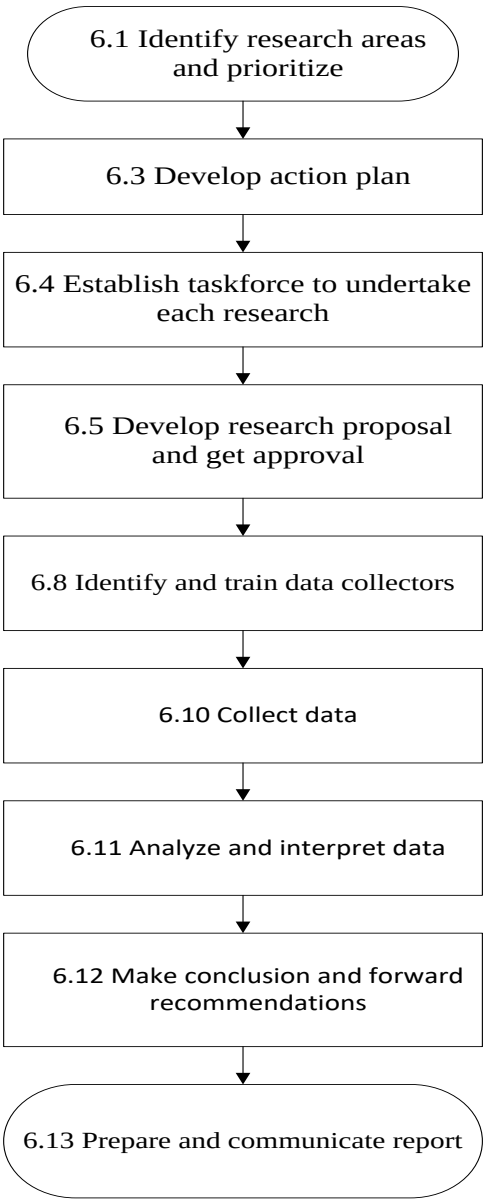
This SOP is applicable to all operational research activities undertaken by the Agency.

4. Responsibilities

Title	Responsibility
Capacity Building and Operational Research Team	• Identify research areas and prioritize • Develop action plan for research • Establish taskforce to undertake the research • Develop research proposal and get approval • Secure fund • Identify and train data collectors

	• Collect data • Analyze and interpret data • Make conclusion and forward recommendation • Prepare and disseminate the report • Publish and document the report

5. Process map/Flowcharts



6. Procedures

6.1 Identify areas that require operational research/assessment

6.2 Prioritize the identified research areas

6.3 Develop action plan

6.4 Establish taskforce to undertake the research

6.5 Develop research proposal and get approval

- Write proposal (brief background, objectives, methodology, budget breakdown, research plan, data collection tools)
- Get feedback from staff
- Finalize and get approval from management/research committee

6.6 Communicate the proposal to internal and external stakeholders

6.7 Secure fund

6.8 Identify and train data collectors

6.9 Test the data collection tools (pilot test)

- Select site/population for pilot test
- Collect data using the tools
- Check appropriateness of the data collection tools
- Make the necessary modification on the tools

6.10 Collect data

6.11 Analyze and interpret data

6.12 Make conclusion and forward recommendations

6.13 Write research report and communicate to all stakeholders

6.14 Disseminate the findings through a workshop

6.15 Publish and disseminate the report

6.16 Document the report

7. Amendment History

Revision:	Effective Date:	Approved By:	Reason
0	July/2010 E.C	Agency Management	Initial release