

Implementing an ISO 17025 Accreditation Action Plan at Senegal's National Quality Control Laboratory

Dakar, Senegal
October 8-17, 2012

Trip Report

Latifa El-Hadri, Ph.D.
Program Manager

Donnell Charles, Ph.D.
Manager, Laboratory Quality Management Services

Promoting the Quality of Medicines

Implemented by U.S. Pharmacopeia
12601 Twinbrook Parkway
Rockville, MD 20852 USA
Tel: (+1-301-816-8239)
Email: pqm@usp.org and lwe@usp.org

Cooperative Agreement # GHS-A-00-09-00003-00

Sponsoring USAID Missions: USAID/Senegal, through the President's Malaria Initiative

Grantee: Promoting the Quality of Medicines (PQM) Program

Author(s) Name: Latifa El-Hadri & Donnell Charles

Language: English and French

Date of Publication: December 23, 2012



USAID
FROM THE AMERICAN PEOPLE



PROMOTING THE QUALITY OF MEDICINES

This report is made possible by the generous support of the American people through the United States Agency for International Development (USAID), under Cooperative Agreement No. GHS-A-00-09-00003-00, and the President's Malaria Initiative (PMI). The contents are the responsibility of the Promoting the Quality of Medicines Program, implemented by the U. S. Pharmacopeia, and do not necessarily reflect the views of USAID, PMI, or the United States Government.

Executive Summary

PQM staff traveled to Senegal in October 2012 to review the progress of the National Quality Control Laboratory (LNCM) towards implementing corrective and preventive actions (CAPAs) based on the non-conformities identified during a previous PQM visit. During the trip, PQM helped LNCM establish an implementation roadmap and action plan that will be used to guide and monitor the progress of LNCM toward its accreditation.

In a meeting held at the Ministry of Health (MOH) cabinet, PQM presented to major stakeholders the ISO 17025 roadmap and gave an overview of the lab's needs. One of the goals of this meeting was to have the country's major health programs embrace the accreditation activities as one of the pillars of strengthening health systems in Senegal.

In addition to these activities, Dr. El Hadri conducted monitoring and evaluation visits to two sentinel sites that were added to the Medicine Quality Monitoring (MQM) program last year. These visits were conducted with representatives from the National Malaria Program (PNLP), National Tuberculosis Program (PNT), Direction of Pharmacies and Medicines (DPM), and LNCM. The visits revealed poor storage conditions in public facilities, expired anti-tuberculosis medicines, recalled antibiotics, and an insufficient stock of antimalarials for infants. PQM shared the findings with the Chief Doctors (MCR) of each visited site and followed up with DPM for regulatory action.

TABLE OF CONTENTS

| | |
|--|----|
| <u>Acknowledgements</u> | 4 |
| <u>Acronyms</u> | 5 |
| <u>Background</u> | 6 |
| <u>Purpose of Trip</u> | 6 |
| <u>Source of Funding</u> | 6 |
| <u>Overview of Activities</u> | 6 |
| <u>Conclusions</u> | 11 |
| <u>Next Steps</u> | 11 |
| Annex 1: Training Agenda | 12 |
| Annex 2: Participant List: Training | 16 |
| Annex 3: List of Equipment Needed | 17 |
| Annex 4: Participant List: Meeting | 18 |
| Annex 5: ISO Background Information | 19 |
| Annex 6: Participants' Training Evaluations | 24 |
| Annex 7: Site Visits (in French) | 26 |

About PQM

The Promoting the Quality of Medicines (PQM) program, funded by the U.S. Agency for International Development (USAID), is the successor of the Drug Quality and Information (DQI) program implemented by the United States Pharmacopeia (USP). PQM is USAID's response to the growing challenge posed by the proliferation of counterfeit and substandard medicines. By providing technical assistance to developing countries, PQM helps build local capacity in medicine quality assurance systems, increase the supply of quality medicines to priority USAID health programs, and ensure the quality and safety of medicines globally. This document does not necessarily represent the views or opinions of USAID or the United States Government. It may be reproduced if credit is given to PQM and USP.

ACKNOWLEDGEMENTS

The authors would like to thank:

- USAID/Senegal for their support and valuable input
- Special gratitude to the PMI advisor for his high level of interest and feedback
- Special thanks to the General Director of Health and LNCM lab chief for facilitating the meeting at the MOH cabinet
- Representatives from PNL, PNT, DPM, and LNCM for participating in the sentinel site visits
- LNCM staff for their motivation and commitment to implementing the ISO 17025 accreditation action plan
- PQM administrative staff and editors for their assistance with logistical arrangements and for editing the trip report
- Mr. Anthony Boni and Dr. Maria Miralles at USAID/Washington for their support and advice

ACRONYMS

| | |
|-------|---|
| CAPA | Corrective and Preventative Action |
| DPL | Direction de la Pharmacie et Laboratoires (Department of Pharmacies and Laboratories) |
| DQI | Drug Quality and Information Program |
| DSR | Division de la Santé de la Reproduction (Division of Reproductive Health) |
| HPLC | High Performance Liquid Chromatography |
| IEC | International Electrotechnical Commission |
| ILC | Inter-Laboratory Comparison |
| ISO | International Organization for Standardization |
| LNCM | Laboratoire National de Contrôle des Médicaments (National Quality Control Lab) |
| LOD | Loss on Drying |
| MOH | Ministry of Health |
| MQM | Medicines Quality Monitoring |
| PMI | President's Malaria Initiative |
| PNA | Pharmacie nationale d'approvisionnement (central medical store) |
| PQM | Promoting the Quality of Medicines Program |
| PT | Proficiency Testing |
| QA | Quality Assurance |
| QC | Quality Control |
| QMS | Quality Management System |
| SOP | Standard Operating Procedure |
| TA | Technical Assistance |
| TB | Tuberculosis |
| USAID | United States Agency for International Development |
| USP | United States Pharmacopeia |
| UV | Ultraviolet Absorption |

Background

Since 2002, USAID and USP have been providing technical assistance to Senegal to strengthen their medicine quality assurance (QA) programs and quality control (QC) systems. In the 2012 work plan, a critical component of PQM's technical assistance (TA) has been to strengthen the national quality control laboratory's (Laboratoire National de Contrôle des Médicaments or "LNCM") compliance with international quality management system (QMS) standards. The ultimate goal for LNCM is to obtain ISO/IEC 17025:2005 accreditation.

In addition to helping the lab, PQM has been providing assistance since 2004 to help strengthen the medicines quality monitoring (MQM) program. This program covers nine sentinel sites and includes major health programs in Senegal.

Purpose of Trip

The primary objective of the trip was to review LNCM's progress in implementing corrective actions suggested by PQM during a previous QMS audit and lab inspection. The secondary objectives include monitoring and evaluation visits to two sentinel sites and a presentation to relevant stakeholders of the ISO 17025 accreditation process and laboratory needs related to equipment and training.

Source of Funding

This trip was funded by USAID/Senegal through the President's Malaria Initiative (PMI).

Overview of Activities

Lab activities

| Item | Description |
|-----------------------|--|
| Specific Objectives | <ul style="list-style-type: none">• Present ISO 17025 roadmap for accreditation to LNCM staff• Review missing and revised standard operating procedures (SOPs)• Follow up on corrective and preventative actions (CAPAs) and opportunities for improvement (OFIs) following an LNCM presentation• Review backup software and equipment and Control of Data Procedure• Monitor testing in High Performance Liquid Chromatography (HPLC), Dissolution, Karl Fischer (KF), Loss on Drying (LOD), pH, Viscosity, and Ultraviolet Absorption (UV/VIS)• Follow up on lab equipment calibration and certification• Plan the next steps for ISO 17 025 accreditation |
| Agenda | See Agenda in <i>Annex 1</i> for detailed information |
| Venue/Location | LNCM |
| Organizers | LNCM and PQM |
| Trainers/Facilitators | Donnell Charles and Latifa El- Hadri |
| Trainees | 10 staff from LNCM; See <i>Annex 2</i> for complete participant list |
| Conclusion | <ul style="list-style-type: none">• LNCM has made improvements regarding their CAPAs, and some have been corrected; however, not all have been implemented.• With PQM guidance, LNCM has decided to change their internal |

| | |
|------------|--|
| | <p>audit process to comply with ISO 17025 management requirements</p> <ul style="list-style-type: none"> • Internal audit training revealed that LNCM needs to improve its internal audit frequency to ensure implementation of SOPs, particularly since this step still remains a critical challenge • Management review training revealed that the report presented by LNCM staff needs to be more detailed which will help the LNCM director to identify areas of improvement • PQM advised the lab to schedule at least two management reviews per year. • PQM recommends skill strengthening on techniques for the scope of accreditation, especially internal auditing, UV, Dissolution, LOD, and HPLC through participation in Inter-Laboratory Comparison (ILC). |
| Next Steps | <p>The lab managers need to conduct the following:</p> <ol style="list-style-type: none"> 1. Finalize and prioritize all documents related to the scope of accreditation <ol style="list-style-type: none"> a. Ensure that QC checks are added to all quantitative procedures b. Ensure that QC are trended on a periodic basis c. Ensure that internal and external documents are controlled d. Ensure that Good Documentation Practices process is in place 2. Participate in the ILC as necessary 3. Participate in a Proficiency Testing (PT) as necessary, and ensure that there is a 5 year PT plan for all methods in the scope of accreditation 4. Update all training and authorization records related to the scope of accreditation 5. Select an accredited organization to start calibrating equipment that will be under the scope of accreditation and begin this process <ol style="list-style-type: none"> a. Two analysts should monitor or participate in the calibration process to ensure all equipment records are updated b. Ensure that the electronic data is backed-up on a scheduled basis and that there are personnel to accomplish this c. Ensure that uncertainty has been documented for the quantitative process pertaining to equipment 6. Conduct and document internal audits <ol style="list-style-type: none"> a. Conduct document training for auditors 7. Conduct and document management review 8. Ensure that environment and access controls are in place |

| | |
|--|---|
| | <p>The laboratory will also need to review:</p> <ol style="list-style-type: none"> 1. The training records of staff operating the equipment 2. The calibration and certification of the equipment 3. The staff trained to do in-house laboratory performance checks (PQM provided a performance checklist) 4. Laboratory notebooks related to equipment maintenance 5. Electronic data related to the assay and data retrieval 6. The SOPs pertaining to the equipment 7. The ILC or PT used with the equipment, if applicable <p>The laboratory will need to procure equipment to perform critical tests this upcoming fiscal year (see <i>Annex 3</i> for a complete list)</p> |
|--|---|

Training of LNCM staff, October 8-12, 2012

During the first week of the visit, PQM conducted the following activities:

1. Present ISO 17025 roadmap for accreditation to LNCM staff

PQM presented the action plan for the roadmap that includes all the steps that the lab staff needs to implement during the accreditation process. PQM worked closely with the lab staff to update the action plan and provide them with guidance on completing certain activities in the action plan.

2. Review the missing and revised SOPs

To finalize SOPs that are pertinent to the lab's scope of accreditation, PQM staff reviewed the SOPs drafted by LNCM and provided suggestions on how to improve them. PQM provided 20 new SOP templates to LNCM and will assist the lab staff to finalize them. After the review sessions, PQM emphasized the importance of lab staff complying with all SOPs pertinent to the scope of accreditation.

3. Follow up on CAPAs and OFIs following an LNCM presentation

LNCM presented several corrective actions to PQM. PQM analyzed the root cause of the lab non-conformities and proposed an action plan with dates for the CAPA review. LNCM QA and laboratory staff accepted the proposed dates, and QA staff stated that they would follow up on the actions.

4. Review backup software and equipment and Control of Data Procedure

PQM was able to examine the server and check the laboratory's backup process. PQM also interviewed Dr. Omar Sarr, Manager of Physical Chemistry, and the IT support staff that conducted the scheduled backup. There is sufficient control of data, but the processes need to be better documented and permanent staff needs to be identified.

5. Monitor testing in major lab areas

To determine the senior staff's level of proficiency, PQM observed them during their use of major lab equipment. The major observations identified are:

- The HPLC poses a challenge to the analysts as both the instrument and the software required manual adjustments several times during the testing.
- Method consistency among analysts was not acceptable.
- Need to use proper reagents and solvents of high quality, especially HPLC grade solvents

The staff appears consistent and proficient during dissolution and pH determination. PQM emphasized the importance of not reusing the same filter for different samples, as that may cause cross-contamination and non-conforming work. The analysts explained that the lab does not have a budget for disposable supplies, which pushes the technicians to reuse the filters. There is a need for a sufficient supply of lab consumables and disposables.

Dr. Charles helped the staff perform two different LOD tests; both were successful. For the UV follow-up, the technicians took turns, as with the HPLC, and performed assays according to USP monographs.



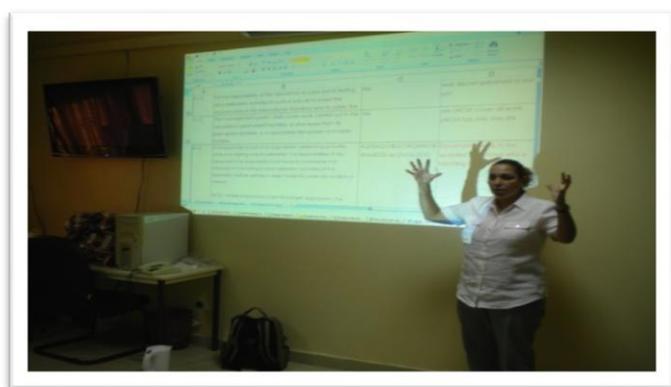
LNCM performing LOD and dissolution testing under the supervision of PQM staff

6. Follow up on lab equipment calibration and certification

PQM suggested two calibration organizations (Egyptian Accreditation Council or Uganda National Bureau of Standards) that can generate the required certificates for ISO 17025 approval.

7. Plan the next steps for ISO 17025 accreditation

As a requirement of ISO 17025 accreditation, the lab needs to have a five-year ISO 17025 implementation plan. PQM provided guidance on how to establish the plan and discussed strategic planning that the lab can adopt during the plan's implementation. The lab will need to finalize the scope of accreditation (with possible expansions to be decided upon in the future), the accrediting body, and an accredited proficiency provider.



Dr. El-Hadri presenting the ISO 17025 roadmap action plan

Meeting with the major stakeholders and discussions on the laboratory's ISO 17025 accreditation

To present the lab's ISO accreditation processes and the benefits of being accredited, PQM facilitated a meeting with relevant partners (see *Annex 4*) for a complete list of participants). The meeting was held at the Ministry of Health (MOH) cabinet, as requested by Papa Amadou Diack, General Director of Health.

Before the meeting, all attendees received background information (See *Annex 5*). PQM presented on staff LNCM ISO 17025 accreditation processes, and the LNCM director presented on LNCM's needs and justifications in terms of lab equipment, training, and testing. Both presentations can be obtained by contacting Dr. El Hadri at USP lwe@usp.org.

Following the presentations, the attendees discussed the importance of lab accreditation and how the major partners can contribute to financing this activity. The main outcomes of these discussions were:

- ISO 17025 accreditation would result in international recognition and the assurance of high quality services for the lab's clients and good quality medicines for consumers.
- LNCM's accreditation activities should be considered as part of the MOH framework of health priorities, which will contribute to strengthening health systems in Senegal.
- Decision makers should embrace LNCM accreditation, as it pertains to quality issues, and should include it in the framework of the national health workplan.
- Since the MOH is a client of the LNCM, there is a need to join efforts and reinforce this activity
- LNCM will prepare a document for pledges of financial contributions from various partners
- LNCM should share the roadmap for ISO 17025 accreditation with the partners.



Training of LNCM staff, October 13-17, 2012

During the second week of the visit, PQM trained the lab staff on how to enter information into the roadmap and helped finalize deadlines for submitting reviewed documentation, completing the CAPA review, and finalizing internal audits and management reviews through 2014. At the end of the week, PQM asked LNCM staff to complete an evaluation of the training. (See *Annex 6*)

Other Activities

Monitoring and evaluation visits

Dr. El Hadri and representatives from DPM, PLNP, PNT, and LNCM visited two sentinel sites (Louga and Zinguichor). These sites were added to MQM activities in 2011. Four personnel from these two sites had been trained by Dr. Adama Diehdihiou, the focal point of MQM activities, on sampling strategies, the use of Minilab[®] basic tests, and reporting data. The main findings of these visits include:

- Oxapen, an antibiotic that was banned by DPM in June 2011, was found
- Public medicines outlets had poor storage conditions. For example, oxytocin, used to induce

labor in difficult pregnancies, was stored improperly in a refrigerator up to 23°C (should be stored at 2-8°C)

- Expired anti-tuberculosis medicines were found
- There was an insufficient stock of antimalarials for infants, and some were to expire by the end of the month

These findings were shared with the respective Chief Doctor (MCR) of each visited site, and PQM followed up with concerned health programs for action to be taken in regards to the expired, banned, and insufficient stocks of medicines. See *Annex 7* for more information on the site visits.

Meeting with USAID/Senegal

PQM staff met with USAID/Senegal PMI advisors, Dr. Lamine Diouf and Mrs. Debbie Gueye, to debrief them on the outcomes of the site visits, progress that the lab has made toward ISO 17025 accreditation, the meeting at the MOH, and next steps.

Dr. Diouf gave an overview of the MOH meeting, since he was one of the attendees, and underlined the need to have the MOH include the lab accreditation activities as one of their priorities. He also emphasized the need to join efforts with other partners in financing these activities.

At the end of the meeting, PQM and Mrs. Gueye discussed the upcoming year's workplan. PQM agreed to send the draft for USAID review by the end October 2012.

Conclusions

PQM concludes that the current progress of LNCM is adequate. If lab management and staff maintain their motivation in the lab accreditation process, significant improvements can be achieved. LNCM needs to improve their technical capacity and lab equipment, designate and train more staff for each scope of accreditation, and hire more IT support staff. PQM is enthusiastic to continue working with LNCM to increase their proficiency. PQM recommends that senior management increase their commitment to and provide more resources for the laboratory in order for it to become ISO 17025 accredited.

Next Steps

By the end of October 2013, PQM will:

- Follow up with LNCM on the progress of the lab staff training, the roadmap, ISO implementation, and strategic laboratory planning
- Monitor and guide the lab staff in accordance to the ISO 17025 action plan
- Review SOPs and assist in finalizing them
- Assist in selecting the accrediting and the calibration bodies and the proficiency testing provider
- Follow up with DPM in taking actions regarding the findings of the site visits

In addition, if the laboratory plans to be accredited by 2014, PQM recommends that all activities related to documentation, CAPAs, equipment repairs and services, training, and proficiency should be completed by December 2013. This will allow the laboratory time to prepare for pre-assessment and subsequent accreditation before December 2014. These suggested dates are contingent upon the amount of resources and effort provided by the LNCM laboratory.

Agenda for Trip

USP/PQM Visit: Dr. Latifa El-Hadri and Donnell Charles

Venue: LNCM – Dakar Sénégal

Date: October 8-17, 2012

LNCM ISO 17025 ACCREDITATION: FOLLOW-UP PQM SEPTEMBER VISIT 2012

| Date | DAY 1-Morning Activity | Responsible Parties | Comments |
|------------------------------|--|--|---|
| 08OCT 12 | | | |
| 08:30- 10:30 | <ul style="list-style-type: none"> Overview of Action Plan from PQM previous visit: Accomplishments/Ongoing/Planned Activities | <ul style="list-style-type: none"> LNCM | <ul style="list-style-type: none"> LNCM will designate the presenter |
| 10:30- 12:00 | <ul style="list-style-type: none"> Presentation of ISO 17025 road map for accreditation to LNCM staff | <ul style="list-style-type: none"> PQM | |
| 12:00- 13:00 | Lunch | | |
| 13:00- 15:00 | <ul style="list-style-type: none"> Review the missing SOPs (15) and the revised ones. | <ul style="list-style-type: none"> LNCM/PQM | <ul style="list-style-type: none"> LNCM will present the new and revised SOP's |
| 15:00- 17:00 | <ul style="list-style-type: none"> Review the missing SOPs and the revised ones (continued). | <ul style="list-style-type: none"> PQM | |
| Date 09OCT 12 | DAY 2-Morning Activity | | |
| 08:30- 12:00 | <ul style="list-style-type: none"> Presentation by LNCM of corrective actions requested from PQM | <ul style="list-style-type: none"> LNCM | <ul style="list-style-type: none"> LNCM will designate the presenter |
| 12:00- 13:00 | Lunch | | |
| 13:00- 15:00 | <ul style="list-style-type: none"> Follow-up on Corrective and Preventative Actions (CAPA), on LNCM deficiencies following PQM QMS. Discuss Management Review of September 2011. | <ul style="list-style-type: none"> LNCM | <ul style="list-style-type: none"> LNCM will designate the presenter |
| 15:00- 17:00 | <ul style="list-style-type: none"> Follow-up on Opportunities for Improvements (OFIs) and other on LNCM deficiencies following PQM QMS. Discuss and schedule next Internal Lab Audit | <ul style="list-style-type: none"> LNCM | <ul style="list-style-type: none"> LNCM will designate the presenter |
| Date10O CT 12 | DAY 3-Morning Activity | | |

| | | | |
|----------------------------|--|--|---|
| 08:30-12:00 | <ul style="list-style-type: none"> Management Review October 2012 | <ul style="list-style-type: none"> LNCM | <ul style="list-style-type: none"> LNCM will designate personnel in-charge of the test to be accredited. |
| 12:00-13:00 | Lunch | | |
| 13:00-15:00 | <ul style="list-style-type: none"> Monitor testing in the following areas <ul style="list-style-type: none"> a. UV/VIS <851> b. pH <791> | <ul style="list-style-type: none"> PQM | <ul style="list-style-type: none"> LNCM will designate personnel in-charge of the test to be accredited. |
| 15:00-17:00 | <ul style="list-style-type: none"> Monitor testing in the following areas <ul style="list-style-type: none"> c. KF <921> d. LOD <731> e. Viscosity <911> | <ul style="list-style-type: none"> PQM | <ul style="list-style-type: none"> LNCM will designate personnel in-charge of the test to be accredited. |
| Date 11OCT 12 | DAY 4-Morning Activity | | |
| 08:30-12:00 | <ul style="list-style-type: none"> Monitor testing in the following areas <ul style="list-style-type: none"> f. HPLC <621> g. Dissolution <711> h. Uniformity of Dosage <905> | <ul style="list-style-type: none"> PQM | <ul style="list-style-type: none"> LNCM will designate personnel in-charge of the test to be accredited. |
| 12:00-13:00 | Lunch | | |
| 13:00-15:00 | <ul style="list-style-type: none"> Review back-up software and equipment and Control of Data Procedure Retrieve data from previous testing using back-up software, from the last year | <ul style="list-style-type: none"> LNCM | <ul style="list-style-type: none"> LNCM will present the data. |
| 15:00-17:00 | <ul style="list-style-type: none"> Mock Management Review | <ul style="list-style-type: none"> LNCM | <ul style="list-style-type: none"> LNCM will present the MR plan. |
| Date 12OCT 12 | DAY 5-Morning Activity | | |
| 08:30-12:00 | <ul style="list-style-type: none"> Follow up on lab equipment calibration and certification | <ul style="list-style-type: none"> PQM/LNCM | <ul style="list-style-type: none"> LNCM will present the data. |
| 12:00-13:00 | Lunch | | |
| 13:00-15:00 | <ul style="list-style-type: none"> Planning the next steps of ISO 17025 accreditation | <ul style="list-style-type: none"> PQM/LNCM | <ul style="list-style-type: none"> As needed |

| | | | |
|---------------------|---|--|--|
| 15:00-17:00 | <ul style="list-style-type: none"> • Wrap up and closing | <ul style="list-style-type: none"> • PQM | <ul style="list-style-type: none"> • PQM |
| Date 15OCT 12 | DAY6-Morning Activity | | |
| 08:30-6:00 | <ul style="list-style-type: none"> • Meeting with LNCM and Health Ministry | <ul style="list-style-type: none"> • PQM/LNCM | <ul style="list-style-type: none"> • LNCM will present the data. |
| Date 16OCT 12 | DAY7- Morning Activity | | |
| 08:30-6:00 | <ul style="list-style-type: none"> • Planning | <ul style="list-style-type: none"> • PQM/LNCM | <ul style="list-style-type: none"> • LNCM TASK |
| 16 OCT | <ul style="list-style-type: none"> • Planning | PQM Task | <ul style="list-style-type: none"> • Calibration Chose <ul style="list-style-type: none"> ○ Calibration Company 30NOV2012 ○ Shipping References (TBD) • Sampling <ul style="list-style-type: none"> ○ Scheduling two Inventory Report before MR JUN2013 • Calibration reports and Review (TBD) • Equipment Staff Training 30NOV2012 |

ROUND TABLE MEETING AT DPM

| Date | DAY 1- Activity | Participants | Comment |
|--------|---|---|---|
| 11 OCT | Conduct round table meeting (See Purpose: 1. Present the process of LNCM ISO 17025 accreditation 2. Present the lab's needs in terms of lab equipment, training, and testing(see the attached table), 3. Present the rational / justification behind the lab 's needs , and how partners can contribute in financing LNCM accreditation. 4. Others. | DPM, LNCM, major health programs, rep of the MOH cabinet, rep of the board of pharmacists, PNA, USAID, and other relevant partners. | Pr Yerim is in charge of coordinating this meeting with DPM. Invite will be sent by DPM to all participants |

MEDICINE QUALITY MONITORING (MQM) PROGRAM ACTIVITY

| Date | DAY 1- Activity | Participants | Comment |
|-------------------------|---|--|--|
| 09 OCT 2 All DAY | <ul style="list-style-type: none"> • Travel to Louga Sentinel Site | Madicke (DPM) Ibrahima (PNLP) Adama (LNCM) Latifa (PQM) | <ul style="list-style-type: none"> • Conduct M&E visit • Meet with MCR • Validate Minilab results |

| | | | |
|--|--|--|--|
| 11-12 October, 2 days | <ul style="list-style-type: none"> • Travel to Zinguichor | Madicke (DPM) Ibrahima (PNLP) Adama (LNCM) Latifa (PQM) | <ul style="list-style-type: none"> • Conduct M&E visit • Meet with MCR • Validate Minilab results |
| 15 OCT | <ul style="list-style-type: none"> • Complete planned activities at LNCM • Validate minilab samples to be confirmed by LNCM • Meet with PNLP, DPM, LCNM, HIV, TB, DSR, PNA and discuss FY13 activities • Discuss sampling logistics and source of collection for FY 13 round | <ul style="list-style-type: none"> • PQM | Venue :LNCM and DPM |
| 16 OCT | <ul style="list-style-type: none"> • Meet with DPM director and finalize the workshop planning for Customs and DPM • Debrief the Mission | <ul style="list-style-type: none"> • | <ul style="list-style-type: none"> • |

List of LNCM Staff
Post Audit Evaluation- Training

| Participant | Institution | Title |
|---------------------|--------------------|--------------------------------------|
| Assane Dieng | LNCM | Logistic Specialist |
| Djibril Fall | LNCM | QA Manager |
| Antoinette A Dioh | LNCM | Administrator QA Support |
| Fatou Ndiaye | LNCM | Microbiology Specialist |
| Niang Mouhamadou | LNCM | Microbiology Manager |
| Mame Ndack Ndiaye | LNCM | Sr. Physical Chemistry Specialist |
| Ngom Mamadou | LNCM | Microbiology Specialist |
| Sergne Omar Sarr | LNCM | Physical Chemistry Manager |
| Sokhra Astou G Diop | LNCM | Sr. Physical Chemistry Specialist |
| Yerim Diop | LNCM | Director |

List of equipment needed by LNCM

| Equipment & Materials Needed | | |
|---|-------|------------------|
| Type | Model | Estimated Cost |
| Dissolution system (one additional) | TBD | \$25,000 |
| GC columns | TBD | \$10,000 |
| HPLC (at least 2 more - Waters) | TBD | \$130,000 |
| HPLC columns | TBD | \$10,000 |
| KF Titrator | TBD | \$15,000 |
| KF Titrator parts/consumables | TBD | \$4,000 |
| Large Hood (with exhaust) | TBD | \$6,000 |
| Large Sonnicators (bath combo) | TBD | \$2,000 |
| Laundry machine/Dryer combo (washing lab coats) | TBD | \$5,000 |
| PC/Monitor/software - Waters | TBD | \$3,500 |
| pH Meter | TBD | \$1,500 |
| Refrigerator and Freezer combo | TBD | \$10,000 |
| Safety Shower combo | TBD | \$5,000 |
| Security Door | TBD | \$2,000 |
| Storage cabinets - various sizes | TBD | \$4,000 |
| Storage cabinets -for lab consumables | TBD | \$2,000 |
| UPS systems (4-6) | TBD | \$60,000 |
| UV lamp (short and long) | TBD | \$2,000 |
| UV-Vis system | TBD | \$45,000 |
| Various Lab reagents/solvents | TBD | \$10,000 |
| Viscometer | TBD | \$10,000 |
| Vortex | TBD | \$600 |
| Washing Machine (Glassware) | TBD | \$11,000 |
| Washing machine consumables | TBD | \$3,000 |
| Waste drums | TBD | \$2,000 |
| Total (not including overhead) | | \$378,600 |
| + Shipping/freight (40% of total) | | \$152,640 |
| Sum Total | | \$531,240 |

Meeting with Major Stakeholders

Presentation of the ISO 17025 roadmap and lab needs
October 15, 2012 Dakar, Senegal

| Participants | Name | Organization |
|--------------|-------------------|---------------|
| 1 | Mame.B. Diouf | USAID/Senegal |
| 2 | Matar Camara | USAID/Senegal |
| 3 | Mady BA | PNLP/MSAS |
| 4 | Birome Drame | DPM/MSAS |
| 5 | Fatou Ndioye | PNA |
| 6 | Ndeye Fatoune | DSRE |
| 7 | Yerim Diop | LNCM |
| 8 | Adama Diedhiou | LNCM |
| 9 | Serigne Omar Sarr | LNCM |
| 10 | Jean Prerira | LNCM |
| 11 | Latifa El Hadri | USP/ PQM |
| 12 | Donnell Charles | USP/PQM |

Non-Scientific Background

Follow-up on QMS & Internal Audit conducted by USP/ PQM Team

Dakar, Senegal
September, 2012

This table summarizes the main activities that the laboratory needs in order to comply with ISO 17025:2005 Accreditation and requirements

This table identifies only the needed items pertaining to Equipment, General Supplies and Internal and External Training

The Table identifies areas where contributing Partners can support the laboratory financially and distribute the cost to help toward ISO 17025:2005 Accreditation.

| ISO 17025 Requirement | Laboratory Actives /Requirement for ISO 17025:2005 Accreditation | Rational /Justification |
|--|---|--|
| ISO 17025 Administrative Requirements | | |
| 1 | <p>Accreditation Body (Location)</p> <p>An accreditation body is a group of international organizations that maintain the international standards and that regulates and supports testing and calibration laboratories in becoming accredited at their specific national sites.</p> | <p>To become an ISO 17025 accredited laboratory, the laboratory site must be assessed by an ILAC approved accreditation body. This accreditation will be recognized globally allowing the laboratory to accept business within and outside of Africa.</p> <p>The Cost for assessment = US\$; 9,500</p> |
| 2 | <p>Accredit Calibration Provider (Equipment)</p> <p>A Calibration Provider is part of an accredited meteorology networks that calibrate, certify and verify equipment that generates data and results.</p> | <p>Prior to becoming an ISO 17025 accredited laboratory, the laboratory must select an ISO 17025 Accredited Calibration provider. This provider will calibrate equipment related to their scope of accreditation certify that the equipment is operational, functioning as designed and meets the specification or qualification of the vendor and the laboratory. The laboratory will be provided documentation by the ISO 17025 Accredited</p> |

| | | |
|---|---|---|
| | <p>Once the data has been reviewed the Provider submits a report to the testing laboratory of their equipment.</p> <p>The Provider keeps a record of the work done and provides an official certificate for services provided on each piece of equipment or kit.</p> | <p>Calibration provider as proof of activity.</p> <p>The Cost for calibration = US\$; TBD</p> |
| 3 | <p>Accredited PT Provider (Personnel)</p> <p>A PT Provider is part of an accredited network that prepares and issues samples for assay to be tested laboratories.</p> <p>The results are generated and sent back to the PT provider for review and approval.</p> <p>Once the data has been reviewed the PT provider submits a report to the testing laboratory of there data.</p> <p>The PT provider keeps a record of laboratories and staff that have successfully completed the Proficiency Testing.</p> | <p>Prior to becoming an ISO 17025 accredited laboratory, the laboratory must select an ISO 17025 Accredited Proficiency Test provider. This provider will provide test and samples related to the laboratory’s future scope of accreditation. Successful completion of the proficiency testing certifies the staff has the correct procedures, can operate the equipment as designed and generates data that meets specification or qualification of the sample provided.</p> <p>The laboratory will be provided documentation by the ISO 17025 Proficiency Provider as proof of activity. The information will also be registered with the PT provider and readily available to the public upon request.</p> <p>The Cost for PT Provider = US\$; TBD</p> |
| 4 | <p>ISO 17025:2005 Standard (2) EN/FR (Documentation)</p> <p>This is the official international standard used as a guidance for ISO 17025:2005</p> | <p>The Laboratory need to purchase their own approved copy of the ISO 17025:2005 standard as the official reference source for the lab. This will allow the laboratory to provide internal communication and guidance using the standard to training the staff.</p> <p>The Cost for standard = US\$; 120 Total Cost (1) =US\$ 120</p> |

| EQUIPMENT | | |
|-----------|--|---|
| 1 | HPLC (2) | The Laboratory only has one function Varian™ HPLC. |
| | An HPLC is used to detect, separate and calculate the amount of active pharmaceutical ingredients or impurities in drugs and other products. | <p>The Laboratory needs two HPLCs preferably of the same Agilent™ brands w/ auto sampler. For the Laboratory to add this to their scope of accreditation there must be evidence of at least one working instrument. Providing two instruments will ensure if one fails the laboratory is still capable of performing the activities on the other.</p> <p>The Cost for one unit = US\$; 70,000 The Cost for Qualification=US\$; 10,000 The Cost for Service Contract= US\$; 20,000 Total Cost (2) =US\$ 200,000</p> |
| 2 | Karl Fisher (2) | The Laboratory only has one functioning Karl Fisher Unit. |
| | A Karl Fisher unit is used to detect, separate and calculate the amount of water in drugs and other products. | <p>The Laboratory needs two KF units preferably of the same brand. For the Laboratory to add this to their scope of accreditation there must be evidence of at least one working instrument. Providing two instruments will ensure if one fails the laboratory is still capable of performing the activities on the other.</p> <p>The Cost for one unit = US\$; 800 The Cost for Qualification=US\$; 100 The Cost for Service Contract= US\$; 100 Total Cost (2) =US\$ 2,000</p> |
| 3 | Refrigerator (1) | The Laboratory only has one functioning refrigerator which cycles |
| | A Refrigerator is used to store samples, standards and reagents at a constant refrigerated environment 5°C ± 3°C temperature. | <p>The Laboratory needs one, for the Laboratory to add this to their scope of accreditation there must be evidence of at least one working instrument. The laboratory must show they can store sample, standards and reagents in a controlled refrigerated environment 5°C ± 3°C.</p> <p>Total Cost (1) =US\$ 1,500</p> |
| 4 | Freezer (1) | The Laboratory does not have a freezer in their immediate area. |
| | A Freezer is used to store | The Laboratory needs one, for the Laboratory to add this to their scope of accreditation there |

| | | |
|---|---|---|
| | samples, standards and reagents at a constant frozen environment $-20^{\circ}\text{C} \pm 10^{\circ}\text{C}$ temperature. | must be evidence of at least one working instrument. The laboratory must show they can store sample, standards and reagents in a controlled refrigerated environment $-20^{\circ}\text{C} \pm 10^{\circ}\text{C}$. Total Cost (1) =US\$ 1,500 |
| 5 | pH (2) | The Laboratory only has one functioning pH meter which is currently not maintained |
| | A pH meter is used to measure the activity of hydrogen ions of aqueous solution at 25°C / RT. | The Laboratory needs two for the Laboratory to add this to their scope of accreditation there must be evidence of at least one working instrument. The laboratory must show they can test the pH of samples at a range between 2, 4,7,10 and 14. The Cost for one unit = US\$; 750 The Cost for Qualification=US\$; 500 Total Cost (2) =US\$ 2,500 |
| 6 | Oven w/ Vacuum (1) | The Laboratory only has one oven |
| | A laboratory oven is used to dry or ignite a liquid or solid material at a constant time and temperature with or without pressure. | The Laboratory needs another oven w/ pressure for the Laboratory to add this to their scope of accreditation there must be evidence of at least one working instrument. The laboratory must show they reach temperatures of at least 250°C under vacuum. The Cost for one unit = US\$; 2,000 The Cost for Qualification=US\$; 500 Total Cost (1) =US\$ 2,500 |
| 7 | Dissolution Calibration kit (1) | The Laboratory only has two dissolution apparatus |
| | A dissolution unit is used to measure the rate a solid material dissolves under vortex in an aqueous solution at a set temperature. | The Laboratory needs a certified calibration kit for the Laboratory to add this to their scope of accreditation there must be evidence of at least one working instrument. The laboratory must show they can perform this calibration using this equipment. The Cost for Calibration kit = US\$; 1,400 The Cost for Qualification=US\$; 1,000 Total Cost (1) =US\$ 2,400-2,500 |
| 8 | References Standards (2) | The Laboratory only has one set of reference weights and reference thermometer |
| | A reference standard allows | The Laboratory needs two reference standards of each preferably of the same brand. For the |

| | | |
|--------------------------|---|--|
| | the user to ensure the instruments are verified against a device that has been properly calibrated and certified by an approved Calibration Provider recognized by an ILAC accredited organization. | Laboratory to add this to their scope of accreditation there must be evidence of at least one reference standard instrument. Providing two instruments will ensure if one fails the laboratory is still capable of performing the activities on the other. The Cost for Calibration = US\$; 3,000 The Cost for Qualification=US\$; 1,000 Total Cost (2) =US\$ 3,000-4,000 |
| 9 | Viscometer (1) | The Laboratory only has one viscometer in the laboratory. |
| | A viscosity meter is used to measure the thickness or resistance of a fluid which is being manipulated by sheer or stress while stirring. | The Laboratory needs two viscometers of each preferably of the same brand. For the Laboratory to add this to their scope of accreditation there must be evidence of at least one viscometer instrument. Providing two instruments will ensure if one fails the laboratory is still capable of performing the activities on the other. The Cost for one unit = US\$; 4,000 The Cost for Qualification=US\$; 500 Total Cost (1) =US\$ 4,500 |
| GENERAL EQUIPMENT | | |
| 1 | Chemical Hood and Filters (if applicable) | The Cost for Material = US\$; 12,500 |
| 2 | Desiccate for KF | The Cost for Material = US\$; 300 |
| 3 | GC Columns | The Cost for Material = US\$; 900 |
| 4 | HPLC Columns and Guards | The Cost for Material = US\$; 1200 per kit |
| 5 | KF solutions/reagents | The Cost for Material = US\$; 450 |
| 6 | Millipore filters | The Cost for Material = US\$; 200 per 50 |
| 7 | pH Buffer Solutions | The Cost for Material = US\$; 100/L |
| 8 | PPE (glasses, gloves, mask etc.) | The Cost for Material = US\$; 200+/Quarterly |
| 9 | USP Reference Reagents | The Cost for Material = US\$; TBD |
| 10 | USP Reference Standards | The Cost for Material = US\$; TBD |
| 11 | UV/VIS cuvetts | The Cost for Material = US\$; 250 |
| 12 | Viscometer Apparatus | The Cost for Material = US\$; 1000 |
| 13 | Working Thermometers | The Cost for Material =US\$; 150-200 |

Summary of Evaluation by Participants

PQM QMS ISO 17025 Training

Follow-up training of ISO 17025 Section 4- Managerial and Section 5- Technical Training

Dakar, Senegal ♦ October 8-17, 2012

Participants: 9

| Indicator | Exceed Expectations | Met Expectations | Met Some Expectations | Unsatisfactory | Total |
|--|---------------------|------------------|-----------------------|----------------|-------|
| 1. General: ISO 17025 Section 4 | | 9 | - | | 9 |
| 2. General: ISO 17025 Section 5 | | 8* | | | 8 |
| 3. General ISO Roadmap and Continual Review | 1 | 8 | | | 9 |
| 4. ISO 17025 Section 4.3 Document Control- Template | | 8 | | | |
| 5. ISO 17025 Section 4.10 Improvement Review | | 7 | 1 | | 8 |
| 6. ISO 17025 Section 4.13 Record Control | 1 | 7 | | | 8 |
| 7. ISO 17025 Section 4.14 Internal and External Audit Review | 1 | 7 | 1 | | 9 |
| 8. ISO 17025 Section 4.15 Management Review | 2 | 6 | | 1 | 9 |
| 9. Management 5 Year Planning | 1 | 7 | | 1 | 9 |
| 10. Discussion and Review on Accreditation Body <ul style="list-style-type: none"> • Accreditation body • Proficiency body • Calibration body | | 8* | | | 8 |
| 11. ISO 17025 Section 5 (5.5) | | 8* | | | 8 |
| 12. Discussion and Observation of ISO 17025 scope <ul style="list-style-type: none"> • UV/VIS <851> • pH <791> • LOD <731> • Dissolution <711> • HPLC <621> | 1 | 7* | | | 8 |
| 13. Course objectives were relevant to my needs | 2 | 7 | | | 9 |
| 14. I was able to understand the content of the materials presented | 1 | 8 | - | | 9 |
| 15. Overall the course was useful and will help me do my job better | 2 | 7 | - | | 9 |
| 16. There were enough practical exercises to facilitate understanding of the course | 1 | 8 | - | | 9 |
| 17. The pacing of sessions was appropriate for my understanding of course materials | 2 | 7 | - | | 9 |
| 18. The instructors were knowledgeable on the subject | 4 | 5 | - | | 9 |
| 19. The instructors allowed an appropriate level of participation in the class | 3 | 6 | - | | 9 |

**Represents omission of question by staff.*

Any other comments/suggestions:

1. What did you like best about the course?
 - The templates provided by PQM

2. What did you least like about the course?
 - More QMS practice
 - More practice time for all training,
 - More than 2 weeks to fully assess our progress

3. What are your recommendations/suggestions for improvement of the course?
 - Increase length of training time
 - Increase training in records management
 - Conduct lab training in French

The participant evaluations and experiences of the facilitators during the course will be used to update the training materials at a later date.

**Visites de sites sentinelles de Louga et Ziguinchor
SUPERVISION LOUGA**

Date le 09/10/2012

Equipe de supervision constituée par

- Dr Ndèye DOME FALL : DPM
- Dr Latifa El HADRI : USP/PQM
- Dr Talla DIOP : PNT
- Dr Ibrahima DIALLO : PNLP
- Dr Adama DIEDHIOU : LNCM
-

PRA de LOUGA

Personne rencontrée Dr Waly Coly DIOUF (Pharmacien Responsable de la PRA de Louga depuis une dizaine de jours)

Constats

- Locaux étroits pour la gestion des stocks des médicaments (nouveaux locaux sont en construction)
- Pas d'étagères, médicaments déposés en vrac à même le sol, de même que les formes injectables
- Conditions de stockage (température et humidité élevées)

Points soulevés

- Suite à plusieurs notifications, il a été signalé des problèmes rencontrés avec des médicaments à base de Bipuvacaine : échantillons envoyés au LNCM pour un contrôle de qualité (Contacter Dr Serigne Omar SARR LNCM pour la suite qui a été réservée à ce cas)
- Résultats d'analyse d'échantillons de Metronidazole non conformes au LNCM ; le fabricant a envoyé des échantillons pour une contre-expertise en France.
- Discussion sur les Guidelines et SOP à mettre en place pour un plan de contrôle de la réception jusqu'à l'utilisation par le patient, des médicaments des programmes (avec formation du personnel LNCM/DPM/PNA/Programmes sur la collecte et le transfert des échantillons au LNCM/USP)

Centre de Santé de Louga

Constat

Conditions conservation des médicaments non-conformes

- Température ambiante supérieure à 35°C entre 12h et 15h),
- Echantillons d'Oxytocine conservés dans le réfrigérateur à l'intérieur duquel le thermomètre indiquait 23°C (alors que les conditions de conservation requises sont comprises entre 2 et 8°C)
- Dr Ibrahima DIALLO a aidé le responsable à remplir la maquette de commande pour le renouvellement du stock afin de remplacer les échantillons qui doivent périmer en fin octobre 2012.

- En effet, le team leader (Dr Jean Louis PREIRA) avait informé Dr DIALLO de la péremption très proche de ces médicaments antipaludiques ;

Hôpital régional de Louga

Personnes rencontrées

Dr Ramatoulaye GUEYE : Pharmacienne responsable de la Pharmacie Hospitalière

Constats

Conditions de stockage des médicaments non-conformes (température ambiante supérieure à 35°C au moment de la visite, le climatiseur est en panne)

Présence d'échantillons d'ACT nourrisson qui périssent en fin octobre 2012

Présence dans le stock d'échantillons d'OXAPEN (cloxacilline) retiré du marché depuis décembre 2011.

Note de rappel à envoyer par la DPM pour le retrait effectif et prise en compte de ce point lors des prochaines missions d'inspection

Analystes Minilab

Maîtrise des techniques de base

Recommandations formulées par l'équipe de supervision pour l'amélioration de l'organisation pratique du travail

REGION MEDICALE DE LOUGA

Personne rencontrée

Dr Babacar NDOYE Médecin Chef adjoint de la Région Médicale

Constats

Implication du pharmacien de la PRA dans les supervisions de la Région

Problèmes d'allocation des fonds dotés aux districts et faiblesse de supervision par l'équipe cadre des districts

Points sur la Pharmacovigilance lors des réunions de réunions de coordination

Prise d'action immédiate

Lettre de correspondance du MCR sera envoyée au Directeur de l'Hôpital Régional pour le retrait effectif des échantillons d'OXAPEN

Une présentation des activités minilab a été faite à tous les niveaux (PRA, Hôpital Régional et Centre de Santé de Louga) et les rapports de 2008 à 2011 ainsi que le Protocole d'Accord signé en 2010, ont été remis au Médecin Chef Adjoint de la Région Médicale.

Le constat de la sous notification a été fait à tous les niveaux, cependant quelques exemplaires des outils de Pharmacovigilance ont été remis aux acteurs lors de la mission.

SUPERVISION ZIGUINCHOR

Date : du 10 au 12 octobre 2012

Equipe constituée par

Dr Ibrahima DIALLO : PNLN ; Dr Birame DRAME : DPM ; Dr Latifa El HADRI : USP/PQM ;

Dr Adama DIEDHIOU : LNCM

REGION MEDICALE DE ZIGUINCHOR

Personne rencontrée

Mamadou THIAM : Planificateur régional (thiamzo@yahoo.fr, 776472519), qui s', qui s'est chargé de nous accueillir dans son bureau en absence du Médecin Chef de la RM (en réunion au niveau de la Gouvernance de Ziguinchor). L'entretien avec lui a porté sur les points suivants :

Remerciements adressés à la DPM pour ses missions d'inspection qui ont contribué au retrait de certains médicaments douteux ou défectueux au niveau de certains districts.

Présentation des activités minilab (contrôle de la qualité des médicaments AP, ATB, ARV et Contraceptifs oraux, et sensibilisation sur la Pharmacovigilance)

Sur la question concernant l'éventuelle présence de médicaments de contrebande dans certains postes de santé frontaliers avec la Guinée, il a été proposé de faciliter l'accès des analystes à ces zones (par le biais de la Croix Rouge Internationale qui y a accès). Néanmoins, la Région Médicale effectue deux missions de supervision par an au niveau de ces zones, des actions immédiates de retraits de médicaments suspects sont prises et des recommandations sont régulièrement formulées. Et cela aboutit souvent à des changements de comportement du personnel.

Il leur a été proposé de prélever ce type de médicaments à chaque fois lors de ces missions de supervision menées par la Région Médicale

Par rapport à la sous notification, il a été proposé de procéder à des sessions de formation sur site au lieu d'organiser à chaque fois des ateliers à Dakar qui ne sont destinés qu'aux MCR et MCD. Cela permettra d'atteindre les personnes clés qui doivent faire la notification ou qui seront chargées de coordonner la collecte et la transmission des fiches de notification.

Hôpital Régional de Ziguinchor

Analyste minilab rencontré : M. Mbaye BADIANE, suppléant de Dr Ngor DIAGNE au niveau de la Pharmacie Hospitalière

Constat

Formation à renforcer par rapport aux techniques de base et à l'interprétation des résultats minilab et surtout pour les team-leaders.

Les conditions de conservation des médicaments sont conformes au niveau de la Pharmacie hospitalière (climatisation, étagères adaptés), étiquetages des rayons, ...

CENTRE DE SANTE DE ZIGUINCHOR (HOPITAL « SILENCE »)

Personnes rencontrées

Dr (Médecin Chef de District) ; M. Gagna DIEDHIOU (Superviseur SSP)

Constats

Conditions de conservation des médicaments non-conformes (toiture en zinc, température supérieure à 35°C

Cependant il y a un réfrigérateur adapté et fonctionnel pour les produits très sensibles à conserver entre 2 et 8°C

Les rayons sont bien étiquetés aussi comme à l'Hôpital Régional.

Rencontre avec le Médecin Chef de la Région Médicale : Dr Maodo Malick DIOP

- Présentation des activités minilab (objectifs, et partage des résultats antérieurs, ...)
- Echange sur la pharmacovigilance et remise des outils de pharmacovigilance notamment des fiches de notification (une centaine) et des manuels et guides de pharmacovigilance (une quarantaine)
- Formulation de recommandation sur l'intégration des activités Minilab lors des réunions de coordination de la RM, et des missions de supervision au niveau des sites difficiles d'accès.
- Présentation d'une vidéo sur le minilab (comment l'utiliser dans le contrôle de qualité des médicaments avec l'approche screening)