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Report of SCMS support to the Head of the National Drug Quality Control Laboratory under US Government-funded Technical Assistance

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SCMS Providing quality medicines for people living with and affected by HIV and AIDS

PEPFAR Implementing Partner

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<Thursday, July 31, 2014>

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About SCMS

The Supply Chain Management System (SCMS) was established to enable the unprecedented scale-up of HIV/AIDS prevention, care and treatment programs in the developing world. SCMS procures and distributes essential medicines and health supplies, works to strengthen existing supply chains in the field, and facilitates collaboration and the exchange of information among key donors and other service providers. SCMS is an international team of 16 organizations funded by the US President's Emergency Plan for AIDS Relief (PEPFAR). The project is managed by the US Agency for International Development.

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Acronyms

AIDS	Acquired immunodeficiency syndrome
ALT	Adult Learning Theory
CHE	Chemistry Module
CMS	Central Medical Stores
DRU	Drug Regulatory Unit
DT	Dissolution Testing
dt	Disintegration Testing
EDTA	Ethylenediaminetetraacetic acid
FDA	Food and Drug Administration
FTIR	Fourier Transform Infrared spectroscopy
GC	Gas chromatography
HIV	Human immunodeficiency virus
HPLC	High-performance liquid chromatography
IR	Infrared spectroscopy
JSI	John Snow Inc.
MoH	Ministry of Health
MS	Mass Spectrometry
NDQCL	National Drug Quality Control Laboratory
NIR	Near Infrared spectroscopy
PEPFAR	President's Emergency Plan for AIDS Relief
PQA	Pharmaceutical Quality Analysis
SCMS	Supply Chain Management System
TLC	Thin-layer chromatography
TOT	Training of Trainers
UB	University of Botswana
US	United States
USAID	US Agency for International Development
UV-Vis	Ultraviolet/visible spectroscopy
WV	Weight variation

GPHF	Global Pharma Health Minilab

Executive Summary

Background

The purpose of this Technical Assistance effort was to build the capacity of the University of Botswana by SCMS to provide sustainable in-country training and mentorship to NDQCL staff and to produce a consistent flow of appropriately trained skilled staff resources in order to support the drug testing and registration process as well as contribute to analytical cost reduction

This is a report on the assignment that the consultant has undertaken for the SCMS Country office, Gaborone, Botswana from March 10 to 15 June October 2013 and March 6-14, 2014..

This is an overall technical report covering the three major tasks in the assignment i.e. pre-visit needs assessment, development of instructional materials and finally training of TOTs. The report gives an outline of the tasks performed and proposes a list of further priority activities and recommendations for the UB/NDQC lab collaboration to enable generate competent analysts.

1 Background

1.1 Introduction

This is overall all technical report concerning a consultation visits to Gaborone Botswana, First in March 10th -15th 2013-to conduct existing capacity assessment and establish to needs for the training. Secondly to develop training curriculum , training material and lecture guide and finally to conduct TOT orientation workshop of UB lecturers and selected staff from National Drug Quality Control Laboratory, Ministry of Health, Gaborone, Botswana 3rd -14th June 2013 and 6-14 march 2014.

As part of the US President's Emergency Plan for AIDS Relief (PEPFAR), the Supply Chain Management System (SCMS) has been strengthening the supply chain of antiretroviral (ARV) medicines and laboratory commodities in Botswana through technical support to the country's Central Medical Stores (CMS), Drug Regulatory Unit (DRU) and the National Drug Quality Control Laboratory (NDQCL).

The National Drug Quality Control Laboratory (NDQCL) is responsible for testing all medicines and related medical products imported, distributed and used in the country for safety, efficacy and quality

Inability by the NDQCL to adequately test samples from new medicine registration applicants threatens the success of the National ARV Program rollout and the quality of drugs in the National Health Service.

In 2008 SCMS facilitated a quality system assessment followed by development and implementation plan for a quality system for the NDQCL by Dr Tom Layloff and Dr Marius Brits[1]. They found that there were insufficient numbers of skilled analysts equipped with chemical analysis and microbiology

[1] Brits, M. and Layloff, T. 2008. "An Assessment of the Botswana National Drug Quality Control Laboratory Quality System Needs." Submitted to the US Agency for International Development by the Supply Chain Management System (SCMS).

techniques and they recommended that a training programme be developed to cover NDQCL staff training through resources at the University of Botswana (UB).

Despite previous SCMS support with specialized training on performance of monograph testing procedures and microbiology testing capacity, the NDQCL has continued to lose trained staff.

During late 2009 SCMS in collaboration with NDQCL and the DRU established a working relationship with the University of Botswana Chemistry department to explore the feasibility of developing a sustainable collaborative programme to build in-country capacity to support the NDQCL. Although the University of Botswana Chemistry Department has the human resources and some equipment required for this activity, further strengthening in the area of Pharmaceutical Analysis will be required.

During 2011, NDQL continued to rely on expensive external training in which a consultant was hired to give hand-on training on various techniques of analysis[2]

On this basis it was necessary to develop a training module within the UB chemistry department undergraduate program curriculum whereby final year students will be trained on pharmaceutical analysis in order to produce an in-country pool of skilled human resources who will be required by NDQCL. For this to happen, a module comprising various courses to meet the needs of NDQCL must be developed, and UB lecturers must be trained to deliver the module beyond the life of SCMS.

[2] E. Kaale, Provision of Services for Training in various Areas in Pharmaceutical Analysis to the National Drug Quality Control Laboratory, 2011 Report submitted to NDQCL , Ministry of Health, Gaborone, Botswana

2 Methodology

2.1 Review of the FDA Training materials and UB Chemistry Curriculum

Both UB Chemistry Curriculum and FDA training materials for analyst were reviewed with the aim to consolidate a common add-on module to be established at the University of Botswana as a sustainable program for training of analyst to support pharmaceutical quality testing at the National Quality Control Laboratory in Gaborone, Botswana. In the long run the faculty will devise a mechanism to incorporate the module in the pre-services so as to produce competent analysts to meet domestic needs for such skills in NDQCL and pharm sector at large

- Documents reviewed
  - Department of Chemistry Handbook, 2010-2011
  - Undergraduate Chemistry curriculum, 2010-2011
  - Analyst Training and Certification Program FDA/Division of Drug Analysis
  - Training Modules to Develop Analytical Proficiency for Pharmaceutical Chemists

2.2 Pre-training assessment visits

Prior to design and development of the training modules a pre-assessment consultation with key stakeholder was made involving the following.

- Meeting with NDQCL staff and assessing status of NDQCL lab

  –A stakeholder consultation discussion with a cross-section selected technical and management staff and assessing status of NDQCL lab using a structured checklist see attached annex1.

- Meeting with UB staff and assessing status of UB lab

  –A stakeholder consultation discussions with a cross-section selected technical and faculty staff and then had a tour in their labs to assess the technologies available and status of UB equipment and suitability for use to support medicines analytical testing at the NDQCL lab using a structured checklist see attached annex 2.

- Facilitate stakeholder meeting to initiate development of module training materials

–a stakeholder workshop first to share the findings of the two assessments and two, to seek more input and understanding of their needs and approach to follow in the course of the development of the training materials

2.3 Develop complete training module curriculum for incorporation into curriculum, including TOT curriculum

The design and development heavenly borrowed from FDA Training materials with incorporation of the local context gathered from the pre-training assessments.

2.4 TOT Orientation workshop

A two week competence based TOT orientation workshop was conducted focusing on two main domains:

- A six TOT module
  - Session 2: Experiential Learning Cycle
  - Session 3: Traditional Teaching Style vs Adult Learning Theory (ALT)
  - Session 4: Training, Presenting, and Facilitating
  - Session 6: Following a Prepared Curriculum
  - Session 7: Art and Science of Effective Feedback
  - Session 8: Practice Sessions
- An eight Pharmaceutical Quality Analysis Modules
  - Module 1: Introduction to pharmaceutical dosage forms, analytical weighing and preparation of samples and standards
  - Module 2 Physical tests (disintegration, friability, weight variation)
  - Module 3 Ultraviolet/visible spectroscopy training module
  - Module 4: Infrared spectroscopy training module

- Module 5 Thin-layer chromatography training module
- Module 6 High-performance liquid chromatography
- Module 7 Gas chromatography training module
- Module 8 Dissolution Testing module

2.5 TOT Orientation workshop for minilab

- Preparatory Session 1:
- Preparatory Session 2:
- Lab Session 1: Introducing the mini lab inventory
- Lab Session 2: TLC Screening of paracetamol 500mg Tablets
- Lab Session 2: TLC Screening of paracetamol 500mg Tablets
- Lab Session 3 TLC Screening of Co-trimoxazole 480 mg Tablets
- Lab Session 4 TLC Screening for an Antibiotic Ciprofloxacin 250 mg Tablets
- Lab Session 5 TLC Screening for an Anthelminthic Albendazole 400mg Tablets
- Lab Session 6TLC Screening for an Antimalarial quinine 300 mg Tablets
- Lab Session 7 TLC Screening for a Lamivudine /Zidovudine combination ARV
- Lab Session 8 TLC Screening for an Anti-Tb Rifampicin 150 mg Tablets
- Lab Session 9 -Practice session ALU
- Lab Session 10 Qualification of analysts by a Proficiency Test Nevirapine

2.6 Workshop self-assessment

A pre and post assessments tools were administered before and after training using a structured questionnaire with Likert scales rating participant's level against the technical modules learning outcomes in measuring attitude. The Tool is appended as annex 3 (a) and (b), (c), and (d).

3 Key Findings

3.1 Review of the FDA Training materials and UB Chemistry Curriculum

3.1.1 Highlight of the FDA materials strengths

A desk review of the materials revealed that the FDA materials were competence based and:

- Recognized that most University curriculum do not provide adequate skills required for FDA proficiency Testing level,
- In-house Materials designed to fill the skills gap from pre-service
- Focus to enhance the skill on technologies to perform a typical Pharmacopeia Monograph
- Comprehensive and stand alone
- Certification of analysts

3.1.2 UB Chemistry Curriculum Highlights

Review of the current UB curriculum showed that the curriculum covers the basic materials in a very comprehensive way for all technologies that are typically required by analyst to perform their day to day routine.

UB Chemistry Curriculum Highlights

Strengths

- The basic and advanced courses in Chemistry are comprehensively taught during undergraduate pre-service training
- This is a good foundation to pursue an add on module on pharmaceutical quality testing
- Excellent Laboratory infrastructure availability
- Availability of qualified personnel both academic and certified technical service personnel

Existing gap

- Specialized modules on pharmaceutical testing such as dissolution release, disintegration as an extension of the application of the techniques

Salient points in the existing curriculum

CHE101 General Chemistry

- Theoretical basics Basic chemistry with laboratory component where the various concepts of wet chemistry experiments

CHE211 Introduction to Analytical Chemistry and CHE213 Analytical Chemistry Lab I

- Basic concepts of scientific experiments with focus on titrimetric reactions like, acid base, redox, EDTA, etc

CHE311 Separation techniques and CHE314 Analytical Chemistry Lab II

- Principles of separation sciences are taught –major ones , TLC, LC, GC, and Electrophoresis

CHE411 Instrumental analysis and CHE412 Advanced Analytical Chemistry

- Principles of separation sciences are taught –major ones , TLC, LC, GC, and Electrophoresis

3.2 Visit at the NDQCL

First a brainstorming meeting was held with a cross section of staff followed by capacity assessment with the use of a structured checklist. The main findings are summarized below.

Strength Highlights

- Laboratory equipment
- Started working on Quality Management system
- Analysts willingness to upgrade their skills
- NDQCL Management readiness to collaborate with UB and BOBS

- Joint training
- Testing
- Skill exchange

- MoH supports to the current intervention

Table 1 Summary of the existing infrastructure at UB and NDQCL laboratory

TECHNOLOGY	NQDCL[3]	UB[4]
Liquid Chromatography(LC)	√	√
Gas Chromatography (GC)	x	√
Thin-Layer Chromatography (TLC, HPTLC)	√	√
Ultraviolet-Visible Spectrometry (UV)	√	√
Infrared Spectrometry (IR)	√	√
Dissolution Apparatus	√	x
Disintegration Apparatus	√	x
pH meter.	√	√
Friability Tester	√	x
Hardness tester	√	x
Karl Fischer	√	x
Heavy metals AAS	x	√
Analytical Balance	√	√
Polarimeter	√	√
Melting point	√	√
LC-MS,	√	√
GC-MS	x	√
NMR	x	√

Key √= technology was available X= technology was missing

3.3 Stakeholder consultation workshop

A consultation workshop was held to first share the findings of the two assessments and two, to seek more input and understanding of their needs and approach to follow in the course of the development of the materials and implementation of the intervention to address a sustainable in-country production of competent analysts yielded the following consensus approach:

Two approaches toward training were identified:

[3] For more details see attachment in annex 4
[4] For more details see attachment in annex 5

- Pre-service students: Add on pharmaceutical testing in the respective courses in particular the lab sessions plus a consideration of experiential field placement in the industry for the undergraduate students.

- In-service training for staff working in the field (NDQCL. DRU etc.) this will be offered as a stand-alone module to be prepared by adapting the FDA material for training of analysis to suit the needs of Botswana

3.4 Training module curriculum for incorporation into curriculum, including TOT curriculum

Though a very consultative approach the following documents were developed and availed for training:

- PQA Technical Module lectures guide. See attachment in annex 6
- PQA Technical Module participant's materials. See attachment in annex 7
- PowerPoint presentations for the eight modules. See attachment in annex 8 (a)-(h)

3.5 TOT Orientation workshop

A total of 15 TOT (13 from UB and 2 from NDQCL) participated in the TOT orientation workshop.

The workshop was conducted in line with the prior recommendation from the stakeholder consultation meeting conducted in March, 2013. Annex 8 give an outline of the two weeks training program.

Two domains of competences the focus of the training:

- TOT modules where by trainee were acquitted with theories and principles of adult learning and practiced on how they can be applied in delivering adult training.

- The PQA technical modules were covered over the following topics Module 1: Introduction to pharmaceutical dosage forms, analytical weighing and preparation of samples and standards, Module 2 Physical tests (disintegration, friability, weight variation), Module 3 Ultraviolet/visible spectroscopy training module, Module 4:

Infrared spectroscopy training module, Module 5 Thin-layer chromatography training module, Module 6 High-performance liquid chromatography, Module 7 Gas chromatography training module, and Module 8 Dissolution Testing module

- The unique thing about this training is that it was designed with about 75% of the training being hands-on. The availability of adequate laboratory infrastructure is a critical requirement for the success of future training s.

3.6 Pre and post Workshop self-assessment

The results from pre workshop assessments with respect of TOT modules revealed that participant had an average of score of 59.8% (range 38.9-88.9%). A similar assessment administered post training hand indicated a significant transformation now with average scores rising to 92% (range 77-100%). See Tables 2 and 3 below. With respect of the pharmaceutical quality assessment modules a similar trend of transformation was also noted. The results from pre workshop assessments with respect of TOT modules revealed that participant had an average of score of 63.8% (range 42.7-88.7%) Similar assessment administered post training had indicated a significant transformation in terms of knowledge and skills acquired during the just ended. The group average scores had raised form 59.8% to 89.6% (range 79.3-100%). See Tables 2 and 3 below.

Table 2: Pre and post training assessment per Individual participants

TOT Modules																								
Participant	1		2		3		3		5		6		7		8		9		10		11		12	
	PRE	POST	PRE	POST	PRE	POST	PRE	POST	PRE	POST	PRE	POST	PRE	POST	PRE	POST	PRE	POST	PRE	POST	PRE	POST	PRE	POST
Average scores	1.7	2.3	2.4	3.0	1.5	2.5	1.3	2.7	1.8		2.7	3.0	1.3		2.2	3.0	1.2	3.0	1.7		1.8	2.7	2.0	2.7
average % scores	55.6	77.8	80.0	100.0	50.0	83.3	44.4	88.9	61.1		88.9	100.0	44.4		72.2	100.0	38.9	100.0	55.6		60.0	88.9	66.7	88.9
PQA Technical Modules																								
Average scores	1.4	2.5	1.7	2.5	1.3	2.6	1.6	2.9	2.3		2.2	3.0	2.6		2.4	3.0	1.4	2.6	1.7		1.7	2.4	2.6	2.8
average % scores	47.0	83.8	58.1	82.1	42.7	86.3	52.5	95.7	75.7		74.4	99.1	87.7		80.7	100.0	45.4	85.4	57.3		55.6	79.3	86.3	94.6

Table 3 Overall group average score Pre and post training assessment

Participant	Overall group score	
TOT Modules	PRE	POST
Average scores	1.8	2.8
average % scores	59.8	92.0
Range	38.9-88.9	77-100
PQA Technical Modules		
Average scores	1.9	2.7
average % scores	63.6	89.6
Range	42.7-88.7	79.3-100

Table 4: Pre and post training assessment per Individual participants

Participant	1		2		3		4		5		6		7		8		9		10		11	
Assessment	PRE	POST	PRE	POST	PRE	POST	PRE	POST	PRE	POST	PRE	POST	PRE	POST	PRE	POST	PRE	POST	PRE	POST	PRE	POST
Average score	2.3	2.7	2.5	3.0	2.8	3.0	2.3	2.9	2.6	2.7	2.7	3.0	3.0	3.0	2.8	3.0	2.4	2.6	3.0	3.0	2.6	0.0
% average score	77.8	88.9	83.3	100.0	91.7	100.0	77.8	97.2	86.1	88.9	88.9	100.0	100.0	100.0	91.7	100.0	80.6	86.1	100.0	100.0	86.1	0.0

3.7 GPHF Mini lab kit TOT Orientation workshop

Prior to the hands-on orientation on GPHF Mini lab kit the following milestones were achieved:

- Training of Trainers (TOT) guide was updated to incorporate the GPHF instructional materials See annex 6
- A debrief meeting with SCMS including verification of the training materials (GPHF Mini lab kit and supplies)
- Visit to the proposed training room/lab and confirmation of the suitability for the training
- Setting up of the training stations

Training

- A total of 10 TOT participated in the orientation training and two NDQCL lab supervisors: These had the following background: Five (5) – from UB Chemistry department out of which 3 were academic and 2 were technical staff. And five (5)-analysts from NDQCL and two (2) – supervisors also coming from NDQCL.

- The GPHF Mini lab kit hands-on training covered the following sessions Lab Session 1: Introducing the mini lab inventory , Lab Session 2: TLC Screening of paracetamol 500mg Tablets, Lab Session 2: TLC Screening of paracetamol 500mg Tablets, Lab Session 3 TLC Screening of Co-trimoxazole 480 mg Tablets, Lab Session 4 TLC Screening for an Antibiotic Ciprofloxacin 250 mg Tablets, Lab Session 5 TLC Screening for an Anthelminthic Albendazole 400mg Tablets, Lab Session 6TLC Screening for an Antimalarial quinine 300 mg Tablets, Lab Session 7 TLC Screening for a Lamivudine /Zidovudine combination ARV, Lab Session 8 TLC Screening for an Anti-Tb Rifampicin 150 mg Tablets, Lab Session 9 - Practice session ALU and Lab Session 10 Qualification of analysts by a Proficiency Test Nevirapine
- The unique thing about this training is that it was designed with about 100% of the training being hands-on.

3.8 Pre and post Workshop self-assessment of GPHF Mini lab kit TOT Orientation workshop

The results from pre workshop assessments with respect of TOT modules revealed that participant had an average of score of 87% (range 77-100%). A similar assessment administered post training hand indicated a significant transformation in terms of knowledge and skills acquired during the just ended TOT on GPHF mini lab with average scores rising to 96% (range 86-100%). See Tables 4 and 5 below.

Table 5 Overall group average score Pre and post training assessment

Participant	Overall group score	
TOT Modules	PRE	POST
average % scores	87	96.0
Range	77-100	87-100

3.9 Evaluation of qualification test results

- Friday morning the TOT participants engaged on the qualification exercise. We prepared possible poor quality products which could be found from the marked. 4 scenario were depicted
    - Nevirapine good quality product
    - Nevirapine with 50% content –grossly substandard
    - Counterfeit wit ciprofloxacin- wrong drug
    - Counterfeit with chalk –No drug
- This sample tablets were prepared and coded an distributed to participant for assessment
    - 11 TOT participated in the qualification assignment.

      -All 11/11 could identify the unknown substance as shown under the four categories

      -3/3 (100%) TOTs could correctly identify and estimated the content of Nevirapine as good quality product

      -3/3 (100%) TOTs could correctly identify but only 1/3(33.33%) could estimate the content of Nevirapine was below 80% content – meaning it was substandard

      -3/3 (100%) TOTs could correctly identify the Counterfeit as it was ciprofloxacin instead of Nevirapine - wrong drug content estimation was not applicable

      -2/2 (100%)TOTs could correctly identify the Counterfeit as it was just chalk instead of Nevirapine Counterfeit with chalk –No drug content estimation was not applicable

-Overall proficiency was 9/11 (82%) and was considered very well.

3.10 Workshop evaluation

At the end of training an overall workshop evaluation tool see annex was given to the TOTs to evaluation the conduction of the workshop on how the following criteria were met: objectives of the course, organization of the sessions, use of visual aids, handouts/trainer guide/mini lab manual, organization of the training stations, adequacy of the training materials[reference, samples and consumable, glassware, training room arrangements, pace of the sessions, length of the course, course administration, and the overall organization of the course

The results from this evaluation revealed that TOT participant had an overall score of 96% with average of score ranging from 80-98%. The results are summarized in Table 6

Table 6. The overall workshop evaluation

Evaluation Criteria		
	average score	**% Score**
Objectives of the course	4.2	84.0
Organization of the sessions	4.6	91.1
Use of Visual Aids	4.4	88.9
Handouts/Trainer guide/Mini lab manual	4.8	96.0
Organization of the Training stations	4.9	98.0
Adequacy of the training materials[reference, samples and consumable, glassware]	4.7	94.0
Training room arrangements	4.7	94.0
Pace of the sessions	4.4	88.0
Length of the course	4.0	80.0
Course administration	4.7	94.0
Overall organization of the course	4.8	96.0

4 Identified challenges and recommendations

Challenge 1

- At NDQCL there were limited resources mostly human which manifested in inadequate number of skilled analyst who can perform to the FDA proficiency level. Huge sample backlogs, risk of product samples moving into supply chain without

being tested, in the recent past the SCMS has facilitated external consultants visit for training and also several Lab staff sent abroad like Zimbabwe, Kenya, etc for specialized training. As such the external trainings are by far very costly and unsustainable

Recommended solution 1-1

Risk based testing approach in which the least resources available are directed to deal with the major risk.

Two Tier Testing

- Tier I →Rapid screening of all product by Minilab testing to identify suspicious one
- Tier two II→Full monograph testing at the central laboratory

Metrics: ↑ number of product tested

↓ Number counterfeit and substandard medicines

Recommended solution 1-2

Establish in-country training capacity for analyst to improve testing skills to FDA performance level at UB

- Conduct TOT both for UB faculty and NDQCL
- Support training of 2 Cohorts of analysts (2x5)

Metrics:

- ♯ TOT trained; and ♯ analyst trained to FDA level
- Cost reduction,
- ↑ coverage of analyst training to include other organs like DRU

Challenge 2

Lack of experiential field placement for the in-service UB students at an industrial based institution. Experiential learning is a program that formally integrates a student's academic studies with work experience in participating employer organizations. In this regard NDQCL would indeed be an ideal place for such training.

Recommended Solution 2-1

- Discussed it with UB and agreed to conduct internal discussions to re-introduce the field placement for its undergraduate students.
- Proposed an interim measure to support of up to 3 student placement at NDQCL per cohort

Metrics:

♯ Undergraduate students supported for field placement at NDQCL

Recommended solution 2-2

- Opportunity for joint post graduate research training in areas of method development and Validation.

Metrics:

- ♯ research students jointly supervised

Challenge 3

- Inadequate skilled technical to support maintenance and repair of lab equipment to certification level

  Recommendation

  - Strengthen in-country equipment maintenance capacity by support training of a maintenance technician from UB to a certification level for 3 major equipment maker [Agilent, Shimadzu and Waters]

  – Metrics:

    - Improved In-country equipment maintenance capacity
    - ↓ Costly foreign dependence for maintenance,
    - ↓ restoration turnaround time
    - Technician trained to certification level

Challenge 4

- Inadequate availability of lab supplies and non-qualified lab equipment

  Recommendation

  - Based on the field experiences we underwent I recommend future training by UB should consider a preparatory session ahead of any planned training to avoid surprise failures during training. In this preparatory instructor with work with technician to

establish that all anticipated laboratory experiment can be done. This means countercheck the equipment status in this case I would even recommend some aspects of OQ/PQ qualification can be looked at.

– The inventory of the lab supplies such as reagents and other consumables. In some case also method failure was attributed by non-availability of all required supplies in the specifications recommended, I recommend future planning all critical supplies should be provided like HPLC and GC columns.

5 Immediate follow up activities

5.1 From the June 2013 Training

It is my opinion that for the UB/NDQCL to keep moving forward with the milestones achieved so far the following follow up actions will have to be considered

- Follow up hands on training 3-5 days for the GPHF Mini Lab kit
- UB to conduct a brainstorming meeting to plan implementation of the trainings at UB
- UB instructors conducts training
- UB to incorporation of some pharmaceutical quality testing modules into the Chemistry Curriculum
- UB to consider inclusion into postgraduate training program
- UB to re-introduce experiential field placement at NDQCL
- MoH to consider implementing a model Drug QA Program with Minilab screening at Ports of Entries and full monograph testing at the central lab.
- SCMS Country office convenes a technical working group from DRU/NDQCL/UB to map modules into short courses to address their training needs.
- NDQCL establishes a maintenance contract with U BW for selected equipment items.
- DRU to consider consulting UB experts on further developing the methods library for use by the hand held NIR unit.

5.2 From GPHF Mini lab kit TOT Orientation workshop

- Procurement to refill the consumables depleted during training
- Official hand over of the GPHF Mini lab kit to UB
- Procurement of a GPHF Mini lab kit for NDQCL to be deployed at CMS and immediately start screening
- Incorporation of some pharmaceutical quality testing modules into the Chemistry Curriculum
- Benchmarking in country where the program has been successfully implemented

- Stakeholder planning meetings involving MoH/NDQCL/DRU/ UB/CMS and SCMS FBO, and CDC to design implementation of the GPHF Mini lab kit program in Botswana. MoH should take the lead The meeting should consider the following :

  -The identify the key stakeholder, their roles and contributions

  -To examine their strength /weakness in terms of resources: both human, finances and infrastructure and agree on contribution to the success of the program

  -Agree on time line and possible source of funding to launch the program

- Set short course training schedule for Mini lab for FY 2014/15
- SCMS to explore possibility to have UB trained on the Micro Phazir needs.
- Need to set up Technical working group on Pharmaceutical quality Testing at the ministry level

6 List of Annexes 1

Annex 1.	UB Technology assessment checklist
Annex 2	UB Technology assessment checklists
Annex 3 a	Training of Trainer Self-Assessment PRE
Annex 3 b	Training of Trainer Self-Assessment POST
Annex 3 c	Training of Trainer Self-Assessment PRE
Annex 3 d	Training of Trainer Self-Assessment POST
Annex 3 e	Training of Trainer Self-Assessment POST
Annex 4	NDQCL Technology and skills needs assessment Report
Annex 5	UB Technology assessments Report
Annex 6	Updated Lecture guide
Annex 7	Participants materials
Annex 8	Training Programme two weeks
Annex 8 a	Training Programme one week

7 References

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