

Republic of Namibia



**Ministry of Health and
Social Services**

Medicine Dossier Evaluation, Good Manufacturing Practices, Quality Control, and Good Distribution Practices Training, Namibia

May 2014



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SIAPS 

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About SIAPS

The goal of the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program is to assure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes. Toward this end, the SIAPS result areas include improving governance, building capacity for pharmaceutical management and services, addressing information needed for decision-making in the pharmaceutical sector, strengthening financing strategies and mechanisms to improve access to medicines, and increasing quality pharmaceutical services.

Recommended Citation

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Key Words

Good Manufacturing Practices, GMP, Good Distribution Practices, GDP, Good Review Practices, GRevP, Namibia Medicines Regulatory Council, NMRC

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ACRONYMS AND ABBREVIATIONS

CTD	Common Technical Document
GDP	Good Distribution Practices
GMP	Good Manufacturing Practices
GRevP	Good Review Practices
GRP	Good Regulatory Practices
MoHSS	Ministry of Health and Social Services
MRF	Medicine Registration Form
MSH	Management Sciences for Health
NMRC	Namibia Medicines Regulatory Council
PC&I	Pharmaceutical Control and Inspection
QC	Quality Control
SIAPS	Systems for Improved Access to Pharmaceuticals and Services
TRS	Technical Report Series
UNAM	University of Namibia
USAID	United States Agency for International Development
WHO	World Health Organization

ACKNOWLEDGMENTS

We, the authors of this report, express our gratitude to the Ministry of Health and Social Services (MoHSS) for making it possible for this work to be carried out in their departments.

We are also grateful to the Registrar of Medicines, Mr. Johannes Gaeseb, and the staff of the Namibia Medicines Regulatory Council (NMRC) secretariat for the time and support provided throughout the preparations for and implementation of this training.

We also owe a great debt of gratitude to the participants for their interest, active participation, and commitment throughout the workshop.

We acknowledge the administration and staff of SIAPS Namibia for the logistical and administrative support in preparation for and implementation of this training.

BACKGROUND

The Namibia Medicines Regulatory Council (NMRC) is mandated by the Namibian Medicines and Related Substances and Control Act of 2003 to regulate and ensure access to medical products and protect public health. Currently, in the Ministry of Health and Social Services (MoHSS), the Pharmaceutical Control and Inspection (PC&I) office is the secretariat of the NMRC. PC&I is a subdivision of the Pharmaceutical Services Division, which is under the Tertiary Health Care and Clinical Support Services Directorate.

Through technical assistance from the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program funded by the US Agency for International Development (USAID) to improve and strengthen regulatory systems in Namibia, a gap analysis of the NMRC operations was conducted in January 2014. The analysis determined that NMRC had a chronic deficiency of funds and human resources to efficiently and effectively perform its mandated functions and defined the following training needs:

- Provide staff with technical knowledge about how to perform their functions of dossier review and inspection of manufacturers and distributors within and outside Namibia
- Faced with a severe backlog of work (over 700 medicines registration dossiers had been backlogged with NMRC for up to five years), provide NMRC and its staff with (a) training to organize their operations and (b) strategies to work more efficiently to minimize, if not entirely eliminate, the medicines dossier registration backlog

The topics of this workshop had been previously agreed upon with NMRC management and were presented in interactive lectures, discussions, and practical dossier reviews during the week of May 12–16, 2014 at the Roof of Africa Hotel in Windhoek, Namibia. (Annexes A–C provide the invitation letter sent to participants, the attendance list, and the training program schedule.)

GOAL AND OBJECTIVES OF THE WORKSHOP

Goal

The goal of the workshop was to build capacity and enlarge the pool of technical personnel—including NMRC technical staff, MoHSS pharmacists, lecturers at the University of Namibia (UNAM) School of Pharmacy, and pharmacists from the private sector—who have expertise in medicine dossier review practices including the globally accepted common technical documents (CTD) format and other regulatory aspects of Good Manufacturing Practices (GMP) and Good Distribution Practices (GDP) to ensure patient safety of medicines approved for sale in Namibia.

Specific Objectives

- To provide NMRC technical staff and other pharmacy personnel from MoHSS and the private sector with detailed training in GDP, GMP, and Good Review Practices (GRevP)
- To provide NMRC staff and other pharmacy personnel from MoHSS and the private sector with an understanding of their role in enforcing compliance to GDP, GMP, and GRevP
- To provide non-NMRC staff (e.g., MoHSS regional pharmacists and pharmacists from the UNAM School of Pharmacy and the private sector) with training in medicines dossier review in the event that they might be called upon to assist NMRC in dossier review and approval

SUMMARY OF TRAINING AND WORKSHOP PROCEEDINGS

Methods of Presentation

The training involved lectures using PowerPoint presentations and small group discussions for participants to analyze key issues raised during the lecture and to derive potential solutions. These potential problems and solutions were then evaluated by the trainer and all workshop participants (including NMRC management).

A key element of the training was for participants to review actual medicines registration dossiers that had been submitted to NMRC to determine where they might be deficient.

General Summary

The workshop objectives were successfully achieved. Forty-two pharmaceutical personnel including NMRC staff, UNAM School of Pharmacy lecturers, MoHSS pharmacists, private pharmacists, and representatives of importers and distributors were trained to enlarge the pool of dossier reviewers in the country. The trainees were also exposed to other aspects of medicine regulations including GDP and GMP.

As reflected in the pre- and post-training test scores (annex D), the training enhanced the knowledge and skills of the participants in the various areas of medicine regulation. The median, average, minimum, and maximum scores increased significantly for the pre- and post-training test by the participants.

The participants' evaluations of the training and a group picture are presented in annexes E and F, respectively.

Detailed Summary of the Training Sessions

Day 1—Good Distribution Practices (half-day session)

The participants were exposed to the global approaches to GDP and quality management for distribution systems. The major concerns of GDP were elaborated with practical examples including the following:

- Counterfeit measures—regulations and technologies
- Temperature degradation—cold chain monitoring
- Theft and tampering
- Stock rotation and sanitation
- Record-keeping
- Vendor, supplier, and contractor auditing

Several references and guidelines for GDP were highlighted: WHO's *Good Distribution Practices for Pharmaceutical Products* (TRS No. 957, 2010),¹ US FDA–CFR–21², the European Union's commission directive for GDP transport and storage (Directive 2003/94/EC),³ Canada's *Guidelines for Temperature Control of Drug Products during Storage and Transportation (GUI 0069)*,⁴ and USP standards 1079 and 1083.⁵

Day 1—Good Manufacturing Practices (half-day session)

The training involved GMP principles and philosophies including the ICH⁶ quality initiatives. The types of GMP inspections and inspection pragmatics were explained. To perform effective GMP inspections, participants were given an overview of the inspection preparation activities, the processes to be inspected (e.g., qualifications and validations, water systems, sterilization technologies, and powder-blending technologies) and the inspection performance activities (e.g., techniques of asking questions and concluding inspections). This portion of the training was concluded with case studies that we discussed by the participants and the facilitator.

Day 2—Managing the Quality Surveillance Laboratory in a GMP-Compliant Manner

The training focused on managing analytical chemistry laboratories in a GMP-compliant manner, and the facilitator highlighted the importance of the following:

- Training laboratory personnel on GMP, calculations and mathematics of results, and documentation
- Equipment calibration
- Record keeping including electronic records and the requirements of the US Food and Drug Administration's guidance, *Part 11, Electronic Signatures—Scope and Application*,⁷ and the European Union's *Good Manufacturing Practice Medicinal Products for Human and Veterinary Use* (vol. 4), annex 11 "Computerised Systems."⁸
- Chemical reference standards
- Analytical method validation and transfer

The training also included case studies and question-and-answer sessions.

¹ http://www.who.int/medicines/areas/quality_safety/quality_assurance/distribution/en/

² <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=11>

³ http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000154.jsp;

http://ec.europa.eu/health/files/eudralex/vol-1/dir_2003_94/dir_2003_94_en.pdf

⁴ <http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/docs/gui-0069-eng.php>

⁵ United States Pharmacopeia—<https://mc.usp.org/sites/default/files/documents/GeneralChapterPDFs/c1079%20USP36.pdf> and

http://www.usp.org/sites/default/files/usp_pdf/EN/USPNF/revisions/c1083.pdf

⁶ International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use

⁷ <http://www.fda.gov/regulatoryinformation/guidances/ucm125067.htm>

⁸ http://ec.europa.eu/health/files/eudralex/vol-4/annex11_01-2011_en.pdf

Days 3 and 4—Good Review Practices

In this session, the principles of Good Regulatory Practices (GRP) and GRevP were explained and illustrated. Participants were taken through the medicines development process in line with the ICH guidelines. The components of the globally accepted CTD format for medicine dossier presentation were highlighted, and information expected in each module was discussed in detail, specifically as it applied to the registration of generic medicines.

The following modules are required for CTD format:

- Module 1—Regional information
- Module 2—Summaries of quality, pharmacology, toxicology, and efficacy of the product
- Module 3—Quality
 - Assay method development
 - Drug substance characterization
 - Batch records
 - Product stability and expiration dating
 - Bioavailability and bioequivalence
- Module 4—Nonclinical data
- Module 5—Clinical data

Participants had an opportunity to study a mock quality overall summary of Sakura tablets prepared for purposes of training. Case studies and open discussions were also undertaken.

Day 5—Good Review Practices

Day 5 was dedicated to practical sessions in which each participant was given the opportunity to conduct a technical evaluation of two pharmaceutical dossiers and to write satisfactory reports as a way of demonstrating the knowledge and skills acquired during the training.



Figure 1. Participants during a dossier review hands-on session.
(Photo by SIAPS Namibia)

NEXT STEP: POST-IMPLEMENTATION ACTION PLAN

Table 1 shows the post-training implementation plan and the expected outcomes.

Table 1. Purpose of the Post-Training Action Plan

No.	Activity description	Location	Person responsible	Timeline	Method of verification of completion	Potential barriers
1	Plan, organize, and conduct two dossier evaluation retreats.	Namibia	SIAPS and NMRC	December 2014	<ul style="list-style-type: none">• Number of trained personnel participating in dossier retreats• Number of dossiers evaluated during the retreats	Availability of resources (funds and personnel)

ANNEX A. PARTICIPANT INVITATION LETTER

9 - 0/0001



REPUBLIC OF NAMIBIA

Ministry of Health and Social Services

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Ministerial Building
Harvey Street
Windhoek

Telephone: (061) 203 2403
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OFFICE OF THE PERMANENT SECRETARY

Ref. No. : 10/1
Enquiries: Johannes Gaeseb

Date: 09 April 2014

TO: ALL REGIONAL DIRECTORS

RE: INVITATION OF ALL REGIONAL PHARMACISTS TO THE TRAINING ON REGISTRATION APPLICATION DOSSIER EVALUATION, CURRENT GOOD MANUFACTURING PRACTICES (cGMP) AND GOOD DISTRIBUTION PRACTICES (GDP), WINDHOEK, 12 – 16 MAY 2014.

In collaboration with the MoHSS's development partner MSH/SIAPS, the Namibia Medicines Regulatory Council (NMRC) is organising training on the topics mentioned below. Essentially the training will be on how to submit medicines registration applications in the Common Technical Document (CTD) format and the review of these registration application dossiers. This is another effort to build capacity in this area which is essential to ensure availability of quality medicines in the country.

The training schedule is as follows:

Session one - CTD Format:	12 – 14 May 2014
Session two - cGMP:	15 May 2014
Session three - GDP:	16 May 2014

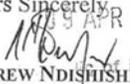
"Health for All"

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Training, Namibia*

I wish to request you to release your regional pharmacist to attend the training detailed above. The expenses for accommodation and meals will be covered and you are only requested to provide transport.

Please submit your nominations before or on 25th April 2014 preferably by e-mail to: Ms. Saren Kauhondamua, e-mail: drugreg@nmrc.com.na, Tel: 061 2032402, Fax: 061 225 048.

Yours Sincerely,


ANDREW NDISHISHI (MR)
PERMANENT SECRETARY



ANNEX B. ATTENDANCE LIST^a

Name	Gender	Designation	Duty Station
Facilitators			
Michael H. Anisfeld	M	SIAPS Consultant	TDY—Windhoek
Pascal Rite	M	Registration Pharmacist	NMRC—Windhoek
Nasser Mbaziira	M	Senior Technical Advisor	SIAPS—Windhoek
Trainees			
Mr. Nelson Olabanji	M	Regional pharmacist	Swakopmund Health Directorate
Mr. Msafiri F Kweba	M	Regional pharmacist	Oshakati
Mrs. Grace Adeniy	F	Regional pharmacist	Katima Mulilo
Mr. Norbert Marealle	M	Regional pharmacist	Okahandja
Mr. Ahmad Zaman	M	Regional pharmacist	Opuwo Hospital
Mrs. Girlie Madyara	F	Pharmacist	St. Mary Rehoboth Hospital
Mr. Augustine Odo	M	Regional pharmacist	Outapi
Mr. Tafadzwa Marimo	M	Pharmacist	Keetmanshoop
Mrs. Hilka Udjombala	F	Pharmacist	NMRC
Dr. Diethardt Rodenwoldt	M	Veterinarian	Swakopmund Veterinary Clinic
Ms. Rosemary Ehiemua	F	Pharmacist	Ohangwena Hospital
Mr. Louis Prins	M	Pharmacist	Nampharm
Ms. Erlene Van Aerde	F	Pharmacist	Medi Park Pharmaceutical
Mr. Paulus Mwandingi	M	Pharmacist	Private consultant
Mr. Qamar Niaz	M	Pharmacist	NMPC
Mr. Evans Sagwa	M	Pharmacist	SIAPS
Mr. Alemayehu Wolde	M	Pharmacist	SIAPS
Mrs. Harriet Kagoya	F	Other health worker	SIAPS
Ms. Fiona Mbai	F	Pharmacist	Blue Shark
Mr. Johannes Gaeseb	M	Pharmacist	NMRC—Secretariat
Mr. Gilbert Habimana	M	Pharmacist	NMRC—Secretariat
Mr. Ruigi Njiriri	M	Pharmacist	NMRC—Secretariat
Ms. Saren Kauhondamwa	F	Pharmacist	NMRC—Secretariat
Mr. Howard Masiyachengo	M	Pharmacist	NMRC—QSL
Mrs. Laydia Hamalwa	F	Other health worker	NMRC—QSL
Mr. Zedekias Tjiho	M	Other health worker	NMRC—QSL
Mr. Ulrich Ritter	M	Pharmacist	NMRC
Mr. Albie Jordan	M	Pharmacist	Fabupharm
Ms. Ronelda Dewitt	F	Other health worker	Fabupharm
Mr. Fanie Badenhart	M	Pharmacist	Fabupharm
Mr. Benjamin Ongeru	M	Other health worker	SIAPS

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Training, Namibia*

Name	Gender	Designation	Duty Station
Ms. Mariza Titus	F	Other health worker	Intrahealth
Ms. Elizabeth Ohandi	F	Other health worker	Abt Associates
Mr. Seth Nowaseb	M	Pharmacologist	UNAM School of Pharmacy
Dr. Michael Knott	M	Pharmacist	UNAM School of Pharmacy
Mrs. Ester Naikaku	F	Pharmacist	UNAM School of Pharmacy
Mr. Dann Kibuule	M	Pharmacist	UNAM School of Pharmacy
Mr. Anthony Ishola	M	Other health worker	UNAM School of Pharmacy
Ms. Klaudia Amakali	F	Other health worker	UNAM School of Pharmacy
Mr. Bonifasius Singu	M	Pharmacist	UNAM School of Pharmacy
Ms. Helena Ndakolonkoshi	F	Pharmacist	Central Medical Store
Ms. Ester N.Mvula	F	Pharmacist	Central Medical Store
Ms. Rakel Mbango	F	Pharmacist	Central Medical Store
Ms. S Nakamhela	F	Pharmacist	Central Medical Store
Ms. Elina Veigo	F	Pharmacist	Erongo MED
Ms. Sandra Kapinuga	F	Other health worker	Erongo MED
Ms. Kudakwashe Chikomwe	F	Pharmacist assistant	Erongo MED
Ms. Coetzee Bernadia	F	Pharmacist	Pharmaceutical Society of Namibia
Mr. Cosma Mukaratrua	M	Pharmacist	Erongo MED
Ms. Marreli Fourie	M	Pharmacist	NMRC

a = List reflects names of participants who signed attendance sheets; not all participants completed course.

ANNEX C. TRAINING PROGRAM

Namibian Medicines Regulatory Council
 Dossier Evaluation and Good Regulatory Practice Training Workshop
 May 12–16, 2014, Roof of Africa Hotel, Windhoek

Time	Session/Activity	Responsibility
Monday, May 12, 2014		
08:00-08:50	Registration, Welcoming Remarks, and Official Opening	Gisella Gowases, Evans Sagwa, and Johannes Gaeseb
08:50-09:00	Pre-training Evaluation	Nasser Mbaziira
Good Distribution Practices		
09:00–09:20	Understanding the Supply Chain and Global Approaches to GDP and Good Storage Practices	Michael Anisfeld
09:20–09:40	Quality Management Systems	
09:40–10:10	Counterfeit Measures—Regulations/Technologies	
10:10–10:30	Questions and Answers	All
10:30–11:00	Tea Break and Group Photo	
11:00–11:20	Assessment of Transportation of Cold Chain Laboratory Commodities in Namibia	Alemayehu Wolde
11:20–11:40	Temperature Degradation—Cold Chain Monitoring	Michael Anisfeld
11:40–12:00	Questions and Answers	All
12:00–12:20	Vendor/Supplier and Contractor Auditing	Michael Anisfeld
12:20–12:50	Theft/Tampering, Stock Rotation, Sanitation, and Record-Keeping	
12:50–13:00	Questions and Answers	All
13:00–14:00	Lunch	
Overview of GMP Inspection Process		
14:00–14:20	GMP Principles and Philosophy	Michael Anisfeld
14:20–14:40	Types of GMP Inspections	
14:40–15:00	Questions and Answers	All
15:00–15:40	Preparation for Inspection and GMP Technologies	Michael Anisfeld
15:40–16:00	Questions and Answers	All
16:00–16:20	Tea Break	
16:20–17:00	GMP Case Studies—Group work	Michael Anisfeld

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Time	Session/Activity	Responsibility
Tuesday, May 13, 2014		
08:00–08:30	Registration	All
GMPs for Quality Control (QC) Laboratories		
08:30–09:15	Key Areas of QC Personnel Training	Michael Anisfeld
09:15–09:30	Questions and Answers	All
09:30–10:15	Qualification and Calibration of Laboratory Equipment	Michael Anisfeld
10:15–10:30	Questions and Answers	All
10:30–11:00	Tea Break	
11:00–11:45	Record-Keeping in the QC Laboratory	Michael Anisfeld
11:45–12:00	Questions and Answers	All
12:00–12:30	Reference Standards.	Michael Anisfeld
12:30–13:00	Questions and Answers	All
13:00–14:00	Lunch	
14:00–14:45	Analytical Method Validation and Transfer	Michael Anisfeld
14:45–15:15	Questions and Answers	All
15:15–16:00	IntraHealth Presentation	Maritza Titus
16:00–16:20	Tea Break	
16:20–17:00	IntraHealth Presentation	Maritza Titus
Wednesday, May 14, 2014		
08:00–08:30	Registration	All
Evaluation of Dossiers for Generic Products		
08:30–09:00	General Considerations of Good Regulatory and Review Practices	Michael Anisfeld
09:00–09:30	Quality Management Systems for NMRA	
09:30–09:45	Questions and Answers	All
09:45–10:15	Pharmaceutical Development Process and Overview of ICH Guidelines	Michael Anisfeld
10:15–10:30	Questions and Answers	All
10:30–11:00	Tea Break	
11:00–11:45	CTD—Module 1 and Module 2	Michael Anisfeld
11:45–12:00	Questions and Answers	All
12:00–12:45	Quality Assessment for API; CTD—Module 3	Michael Anisfeld
12:45–13:00	Questions and Answers	All
13:00–14:00	Lunch	
14:00–14:45	Quality Assessment for FPP; CTD—Module 3	Michael Anisfeld
14:45–15:00	Questions and Answers	All
15:00–15:45	Analytical Method Development and Validation	Michael Anisfeld
16:00–16:20	Tea Break	
16:20–16:50	Review of Batch Records	Michael Anisfeld
16:50–17:00	Questions and Answers	All

*Medicine Dossier Evaluation, Good Manufacturing Practices, Quality Control, and Good Distribution Practices
Training, Namibia*

Time	Session/Activity	Responsibility
Thursday, May 15, 2014		
08:00–08:30	Registration	All
Evaluation of Dossiers for Generic Products		
08:30–09:00	Stability Studies for FPP	Michael Anisfeld
09:00–09:15	Questions and Answers	All
09:15–09:45	Overview of Bioequivalence Studies	Michael Anisfeld
09:45–10:00	Questions and Answers	All
10:00–10:30	Tea Break	
10:30–11:00	Overview of Nonclinical and Clinical Studies—Modules 3 and 4 of the CTD Format	Michael Anisfeld
11:00–11:15	Questions and Answers	All
11:15–11:45	Demonstration—“Amokinol QOS”	Michael Anisfeld
11:45–12:30	Demonstration of Dossier Evaluation—MRF Review Checklist	Pascal Rite
12:30–13:00	Questions and Answers	All
13:00–14:00	Lunch	
14:00–16:00	Dossier Evaluation Case Studies Using MRF—Part I	Michael Anisfeld and Pascal Rite
16:00–16:30	Tea Break	
16:30–17:00	Questions and Answers	All
Friday, May 16, 2014		
08:00–08:30	Registration	All
Evaluation of Dossiers for Generic Products		
08:00–10:00	Dossier Evaluation Case Studies Using MRF—Part II	Michael Anisfeld and Pascal Rite
10:00–10:30	Questions and Answers	All
10:30–11:00	Tea Break	
11:00–13:00	Dossier Evaluation Case Studies Using MRF—Part III	Michael Anisfeld and Pascal Rite
14:00–16:00	Dossier Evaluation Case Studies Using MRF—Part IV	Michael Anisfeld and Pascal Rite
16:20–17:00	Post–Training Evaluation and Plan of Action; Closing Remarks	All; Evans Sagwa and Johannes Gaeseb

ANNEX D. PRE- AND POST-TEST SCORES PER PARTICIPANT AND SUMMARY

The pre- and post-training tests were designed to evaluate the participants' level of knowledge before and after the training on the topics covered during the training. Both tests had the same questions, but the number of each question was deliberately changed. The tests included 20 multiple choice questions on medicine dossier evaluation, GMP, GDP, and quality control of medicines.

The median scores for the pre- and post-training tests were 55% and 68%, respectively. The pre-test had minimum and maximum scores of 40% and 85%, respectively. A minimum score of 50% and maximum score of 98% were registered in the post-training test. The scores show a significant improvement in the knowledge of participants in the pharmaceutical regulatory aspects of dossier evaluation, GMP, GDP and QC. (See table D1 and figures D1 and D2 for details.)

Table D1. Summary of Pre- and Post-Training Test Results^b

Participant Code No.	Pre-Training Result	Post-Training Result
1	70%	75%
3	50%	68%
4	45%	68%
5	70%	68%
6	45%	60%
7	65%	73%
8	55%	80%
10	65%	75%
13	70%	70%
14	40%	60%
15	50%	55%
16	55%	68%
17	70%	68%
18	55%	98%
19	55%	68%
21	40%	68%
22	70%	55%
23	45%	53%
24	65%	50%
26	55%	63%
29	85%	65%
30	55%	65%
34	65%	68%
41	60%	60%

b = Missing numbers due to some participants not taking both pre- and post-tests.

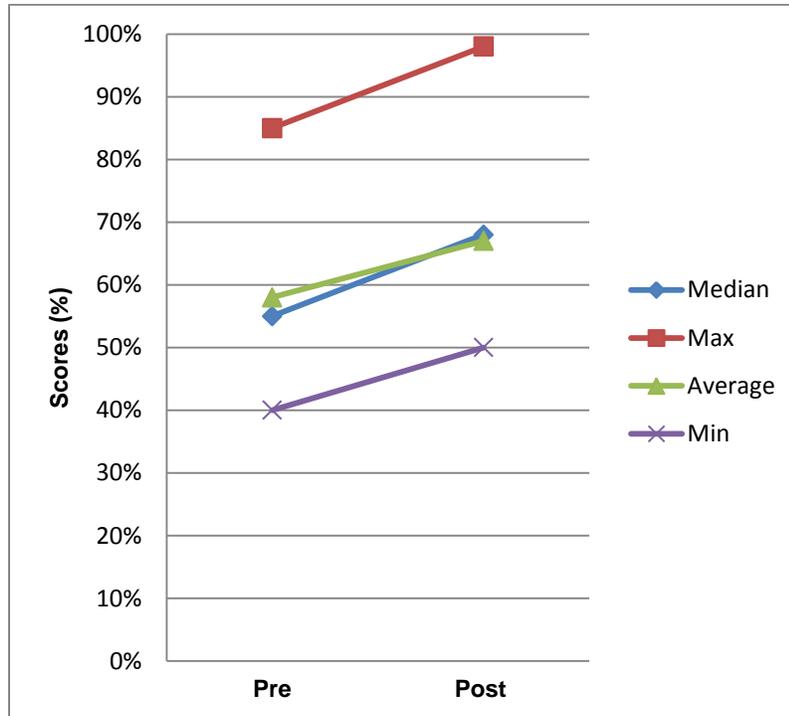


Figure D1. Pre- and post-training test performance

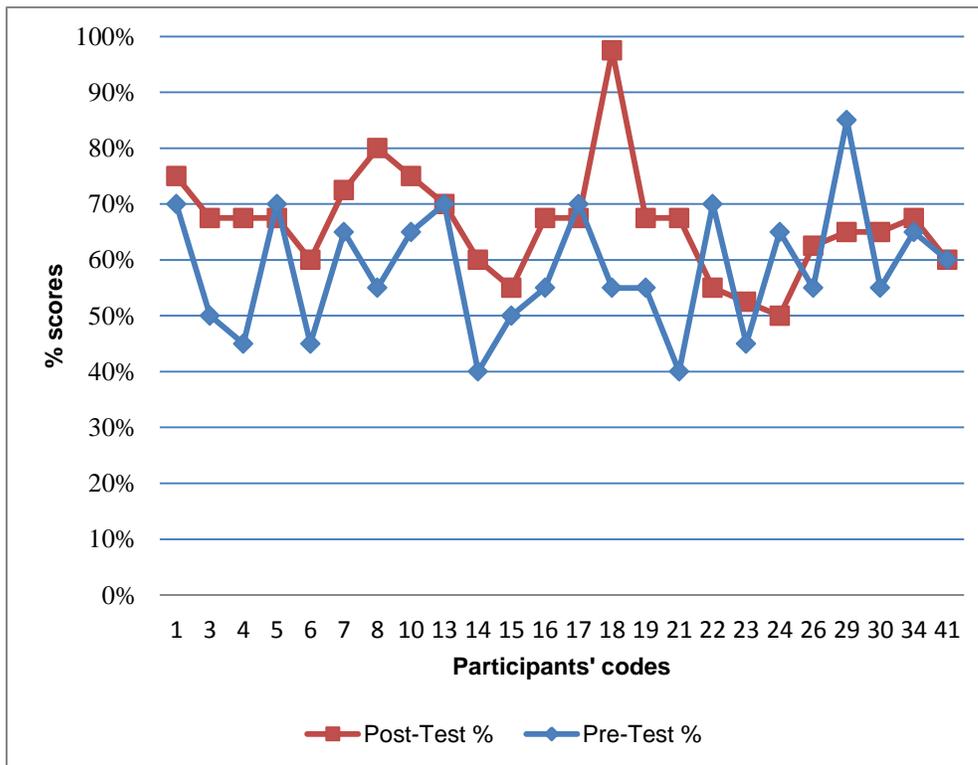


Figure D2. Individual pre- and post-training test score trends

ANNEX E. TRAINING WORKSHOP EVALUATION

Table E1. Evaluation, Part I

Evaluation Parameters	Strongly Agree	Agree	Disagree	Strongly Disagree
The information in this course will be helpful in my work.	69%	31%	0%	0%
The objectives were clearly defined at the beginning of the training course.	68%	32%	0%	0%
The amount of material covered in five days was appropriate.	40%	54%	6%	0%
The defined objectives were achieved by the end of the training course.	45%	55%	0%	0%
The depth of coverage of the material in the training course was appropriate.	40%	60%	0%	0%
Overall, I would say the quality of the instruction was good.	74%	26%	0%	0%
Overall, the workshop met my expectations.	57%	43%	0%	0%

Evaluation Parameters	Very Good	Good	Satisfactory	Poor
Organization of the workshop	45.7%	31.4%	20.0%	2.9%
Communication of information to participants before the workshop	28.6%	42.9%	22.9%	5.7%
The mode of running the workshop	51.4%	42.9%	5.7%	0.0%
Overall satisfaction with the workshop materials and visual aids	54.3%	42.9%	2.9%	0.0%
Overall satisfaction with the length of the workshop	32.4%	38.2%	20.6%	8.8%
Overall satisfaction with the pace of the workshop	34.3%	45.7%	14.3%	5.7%
Overall satisfaction with the style and format of the sessions	47.1%	52.9%	0.0%	0.0%
Overall satisfaction with the workshop facilities	28.6%	40.0%	22.9%	8.6%
Meals	34.3%	48.6%	11.4%	5.7%

Participants' recommendations and comments

Recommendations

- 1 The venue was too small and congested.
- 2 Program should be sent to participants in advance.
- 3 Practical training in the form of hands-on exercises should be organized for dossier reviewers to practice what they have learned.
- 4 Increase the period of holding the workshop.
- 5 It is important to provide materials to read before the workshop.

General Comments

- 1 Very informative workshop, well presented by knowledgeable and experienced presenters. Excellent work. Thank you, SIAPS, NMRC.
- 2 A very good and well-structured medium for first-time evaluators like me.
- 3 Such workshops should be done on a yearly basis.
- 4 The workshop was excellent; I learned new things.
- 5 Thanks for the continuing professional development points.
- 6 Very well organized, great logistical arrangements, and administrative support.

ANNEX F. PARTICIPANT GROUP PHOTO



Last row left: Mr. Johannes Gaeseb (Registrar, NMRC) and participants who attended the dossier evaluation training workshop, May 12–16, 2014, at the Roof of Africa Hotel, Windhoek. The lecturer Mr. Michael Anisfeld is in the second row, center.

(Photo by SIAPS staff, Namibia)