

Evaluating the Quality Management System of Panama's Official Medicine Control Laboratory

**Panama City, Panama
May 3-7, 2010**

Trip Report

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Promoting the Quality of Medicines Program

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Cooperative Agreement # GHS-A-00-09-00003-00
Sponsoring USAID Missions: USAID Bureau for Latin America and the Caribbean
Health Program Element: AMI Program
Grantee: Promoting the Quality of Medicines (PQM) Program
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Language: English (Relevant sections will be disseminated separately to country partners in Spanish.)
Date of Publication: June 02, 2010



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 number GHS-A-00-09-00003-00. 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 or the United States Government.

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 leadership 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.

Abstract *

PQM staff travelled to Panama City, Panama with a representative from the Centro Nacional de Control de Calidad (CNCC), Peru's Official Medicine Control Laboratory (OMCL), to evaluate the Quality Management System (QMS) of the Instituto Especializado de Análisis (IEA), Panama's OMCL, May 3-7, 2010. PQM and CNCC made recommendations for improvements that will enable IEA to meet international quality standards. This report is an abbreviated audit findings. A full report with the citations and recommendations for improvement will be sent following this report.

Recommended Citation*

Barojas, A, and Villalva, O; 2010. *Evaluating the Quality Management System of Panama's Official Medicine Control Laboratory*. Panama City, Panama; May 3-7, 2010. Submitted to the U.S. Agency for International Development by the Promoting the Quality of Medicines Program. Rockville, Maryland: United States Pharmacopeia.

Key Words*

Panama, quality management system, WHO, prequalification, ISO/IEC 17025:2005, quality assurance, quality control, AMI, RAVREDA, OMCL, malaria, IEA, CNCC, PQM, USP

* This section will be translated into Spanish and disseminated separately to country partners.

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ACKNOWLEDGEMENTS*

The authors would like to thank:

- The staff at IEA, in particular, Dr. Nilka Guerrero, whose efforts and logistical help made the trip successful
- CNCC, in particular, Dr. Ruben Tabuchi, for continuous assistance to PQM-sponsored activities
- The PQM administrative staff and editors for their assistance with logistical arrangements and for editing the trip report
- The USAID/Panama Mission
- The USAID Bureau for Latin America and the Caribbean, in particular Dr. Peg Marshal and Dr. Jaime Chang
- Mr. Anthony Boni and Ms. Veerle Coigneux at USAID/Washington for their support and advice

* This section will be translated into Spanish and disseminated separately to country partners.

ACRONYMS

ACCLASS	Assured Calibration and Laboratory Accreditation Select Services
AMI	Amazon Malaria Initiative
CA	Central America
CAPA	Corrective and Preventive Action
CNCC	Centro Nacional de Control de Calidad
DCS	Document Control System
DNFD	Dirección Nacional de Farmacia y Drogas
DQI	Drug Quality and Information
EA	European Cooperation for Accreditation
ENAC	Entidad Nacional de Acreditación
GLP	Good Laboratory Practices
GNPCL	Good Practices for National Pharmaceutical Control Laboratories
HSS/MT	Health Systems based on Primary Health Care / Medicines and Health Technologies
IEA	Instituto Especializado de Análisis
IEC	International Electrotechnical Commission
ILAC	International Laboratory Accreditation Cooperation
INS	Instituto Nacional de Salud
ISO	International Organization for Standardization
LAC	Latin America and Caribbean
MRA	Medicine Regulatory Authority
OMCL	Official Medicines Control Laboratory
PAHO	Pan American Health Organization
PQ	Prequalification
PQM	Promoting the Quality of Medicines
QA	Quality Assurance
QC	Quality Control
QM	Quality Manual
QMS	Quality Management System
QP	Quality Policy
RAVREDA	Red Amazónica de Vigilancia de la Resistencia de los Antimaláricos
SOP	Standard Operating Procedure
UP	Universidad de Panamá
USAID	United States Agency for International Development
USP	United States Pharmacopeia
WHO	World Health Organization

Background*

Since 2002, the U.S. Agency for International Development (USAID) has supported U.S. Pharmacopeia (USP) participation—first through the Drug Quality and Information program and, currently, through the Promoting the Quality of Medicines (PQM) program[#]—in the Amazon Malaria Initiative (AMI). Within the context of AMI, PQM has collaborated with the Pan American Health Organization (PAHO) Area of Health Systems based on Primary Health Care/Medicines and Health Technologies (HSS/MT) to improve the technical capacity of the Official Medicine Control Laboratories (OMCLs) in the Americas.

Recently, AMI has expanded its programs to countries in Central America (CA) and the Caribbean, and as a result PAHO and PQM decided to target selected OMCLs in CA to improve their quality management systems (QMS) in an effort to increase compliance with international quality standards.

In the Americas, there are substantial differences in the capacity of OMCLs to adequately perform QC analysis according to international quality standards. To improve regional capabilities and establish sustainable South-South collaborations, PQM and PAHO decided to leverage laboratories with more advanced capacity in order to establish one or more reference laboratories for the region.

On this visit, PQM was accompanied by staff from the Centro Nacional de Control de Calidad (CNCC) of the Instituto Nacional de Salud (INS) from Peru. Since 2009, CNCC has been proactively assuming the role of a reference laboratory and has made substantial contributions to the region's OMCLs. Of particular importance is CNCC's willingness to share with other OMCLs their expertise in compliance with international quality standards. Currently, CNCC has been granted International Organization for Standardization/ International Electrotechnical Commission (ISO/IEC) 17025:2005 accreditation by an internationally recognized accrediting agency, Assured Calibration and Laboratory Accreditation Select Services (ACLASS).. Based on these credentials, CNCC will assist PQM and PAHO in evaluating the QMS of the region's OMCLs and provide recommended corrective actions to ensure compliance with international quality standards.

Purpose of Trip*

This primary objective of the trip was to evaluate the QMS of the Instituto Especializado de Análisis (IEA) in Panama.

Source of Funding*

This trip was supported with funds from the USAID Bureau for Latin America and the Caribbean for AMI Program.

* This section will be translated into Spanish and disseminated separately to country partners.

The Promoting the Quality of Medicines (PQM) program is the successor of the Drug Quality and Information (DQI) program. To avoid confusion, the program will be referred to as PQM throughout this report.

Overview of Activities

May 3-7, 2010

See [Annex 1](#) for a detailed agenda and [Annex 2](#) for a full list of participants. For details of additional meetings with in-country partners, please see [Annex 3](#). For the participants' evaluations (in Spanish) of the visit, please see [Annex 4](#).

The intent of this visit was to evaluate IEA's QMS by performing a mock assessment (similar to an audit), utilizing the following standards:

- New revision of WHO Good Practices for National Pharmaceutical Control Laboratories (GPNPCL) (also referred to as WHO Good Laboratory Practices or "GLP") (Published September 2009); and,
- ISO/IEC 17025:2005 Standards.

The evaluation was performed by staff from PQM and CNCC.

The ultimate goal is for IEA to become a WHO-prequalified quality control (QC) lab and subsequently apply for ISO/IEC 17025:2005 accreditation. Attaining working conditions that conform to these stringent standards will provide Panama's Ministry of Health, especially the Dirección Nacional de Farmacia y Drogas (DNFD)—Panama's medicine regulatory authority (MRA)—with a QC lab capable of producing trustworthy and valid results, while assuring that IEA's QMS, administrative, and technical operations are functioning at the highest internationally recognized standards.

The evaluation focused on the following areas:

- Improve management and staff understanding of WHO GPNPCL and ISO/IEC 17025:2005 standards
- Build capacity in internal auditing procedures (process, facility and method audits)
- Review laboratory infrastructure
- Review components of the QMS:
 - Key documents, specifically the Quality Manual (QM) and critical Standard Operating Procedures (SOPs)
 - Document Control System (DCS)
 - Staff training records
 - Laboratory notebooks
 - Equipment maintenance and calibration program
 - Equipment records and logbooks
 - Corrective Action and Preventive Action (CAPA) Program
 - Review recent audits and corresponding CAPAs
 - Internal, including recent management review
 - External, particularly the most recent APPLUS+ ISO 9001:2008 audit
- Review safety procedures
- Identify areas to streamline work processes

Key Findings

It is evident that IEA dedicates substantial resources to ensuring the lab's results are valid and trustworthy. The following are some noteworthy characteristics of the current QMS and IEA's commitment to quality:

- The technical capacity of the laboratory is excellent and the staff clearly displays a willingness to identify their deficiencies and improve the quality of their services.
- The laboratory has all of the necessary equipment to effectively perform QC analysis according to compendial methods.
- While there are some deficiencies in the lab infrastructure (discussed below), the overall infrastructure is adequate to perform QC analysis according to international quality standards.
- The organizational set-up of IEA allows the Quality Assurance (QA) department to operate in an autonomous manner and has the necessary mandate to establish a stringent QMS across all IEA departments.
- Currently, the lab has been granted ISO 9011:2008 certification by APPLUS+.
 - APPLUS+ is an independent entity who is accredited by the Entidad Nacional de Acreditación (ENAC).
 - ENAC is a signatory to mutual recognition agreements with both the European Cooperation for Accreditation (EA) and the International Laboratory Accreditation Cooperation (ILAC).
- While the number of staff in the QA department could be increased, staff from each respective unit (microbiology, medicines, etc.) provides assistance to QA, particularly during internal audits.
- IEA has a well developed QMS, which includes:
 - QM with the following components:
 - Well defined Quality Policy (QP)
 - High-level management commitment to implement the QP
 - Clearly defined scope for the QMS that covers all IEA departments and operations
 - QMS with well-defined objectives and structure
 - DCS that is controlled and managed by the QA department. The DCS includes:
 - Procedures for the creation, revision, release, and distribution of all the documents
 - A master list of controlled documents, including SOPs
 - Staff functions and requirements
 - Equipment requirements, including validation and calibration program
 - Sample handling procedures
 - Record control procedures
 - Internal audit procedures
 - CAPA procedures
- Safety protocols, which include processes for waste disposal.

The presence and characteristics of these components are indicative of the significant financial and human resources that have been committed to improving the quality of IEA's services. It is

important to acknowledge these achievements as they demonstrate consistent managerial support and proper execution by QA and key lab staff.

Nonetheless, the evaluation did identify significant nonconformities with both WHO GPNPCL and ISO/IEC 17025:2005 standards. The following are the most significant observations identified during the evaluation:

- Documentation:
 - Certain procedures are being performed without a corresponding SOP. As a result there is a lack of standardization among analysts and a lack of objective evidence for staff training on internal procedures.
 - Certain procedures are inadequately described in their respective SOPs and do not reflect or contradict the actual process being carried out in the lab. These SOPs will need to be revised and staff should be trained prior to implementing the revised SOPs.
 - SOPs are not always accessible to staff, and staff are often not aware of current SOPs revisions. As a result, staff could be performing activities that are inconsistent with internal SOPs.
- Control of records:
 - The laboratory has systematic deficiencies in controlling, retaining and providing adequate records. As a result there is a paucity of metrological traceability and the integrity and accuracy of the data emitted by the lab may be compromised. Deficiencies were identified with three types of records:
 - Equipment:
 - There is a lack of evidence for equipment qualification (DQ/IQ/OQ/PQ) and/or a history of use of the equipment (date of entry to lab, maintenance performed on equipment, out of service occurrences, etc.).
 - Equipment logbooks do not provide traceable data to the medicine being analyzed or the notebook which contains the original data.
 - Out of service equipment are not adequately marked.
 - Staff training:
 - There is a lack of evidence to prove lab analysts have been trained on internal SOPs prior to testing samples.
 - Technical:
 - Staff is not recording all of the original data/observations that are necessary to repeat the test under conditions as close as possible to the original test.
 - Staff is recording original data in documents that are not controlled.
 - Systematic presence of solutions, reagents, and secondary standards with insufficient information on the label to identify the container's contents and/or suitability of use of contents for testing.

- Microbiology lab infrastructure:
 - One of the rooms in the microbiology lab, which is intended to be a sterile area with a laminar flow hood, is not being utilized due to a hole in the ceiling. The ceiling has caved in twice in this location due to high humidity exposure. As a result the roof has not been permanently repaired and the room (including the hood) is not being used.
 - Currently, the lab has not established a sterile area. While this may be related to the previous point, the area that is used for sterility tests can result in contamination of the samples and poses potential health risks to staff. Staff must ensure entrances to sterile areas are controlled and appropriate clothing is used to protect samples and staff.
- Safety procedures:
 - Staff were observed working in testing areas with the following deviations from their internal safety procedures:
 - No eye protection
 - No use of lab coats
 - Open toed shoes
 - Exposed legs
 - Drinks inside testing areas
 - No use of gloves
 - Staff was observed eating with their lab coats.
 - Several staff lab coats were dirty and needed washing; however, there is no established process for washing the lab coats within IEA. Currently, staff takes home their lab coats to wash them. This can potentially expose individuals outside of IEA to the contents of the dirty lab coats.
- Compliance with a client's request:
 - In certain circumstances, staff is emitting results that are inconsistent with the client request. Of particular concern is IEA's application of improper methods for some medicines. As a result there is the possibility of emitting false positives which could potentially lead to registration and utilization of medicines that pose a risk to the public's health.

Note: Subsequent to this report, PQM and CNCC will provide a detailed report for all of the identified nonconformities with references to the specific ISO/GPNCL clauses, severity of observation, description and objective evidence of the observation, recommended corrective actions, and suggested timeline for implementation.

Additionally, it is relevant to note that in the last seven months, IEA has focused a significant portion of its resources on testing a large backlog of products (approximately 700 products) from their primary client (DNFD). Currently, this problem has been mostly resolved and only a relatively small fraction (46 products) of the original backlog remains. It is important to acknowledge this achievement as DNFD is IEA's primary client and a key component of ISO 17025 is to ensure client satisfaction.

Conclusions

PQM and CNCC were pleased with the dedication of IEA staff and the outcome of the evaluation. Additionally, IEA staff is very eager to identify their deficiencies and improve their QMS to ensure compliance with both ISO/IEC 17025:2005 and WHO GPNPCL. It is evident that IEA has all of the necessary components to comply with international quality standards and places a high priority on ensuring the quality of their services.

Nonetheless, the current QMS is based on ISO 9001 standards, and significant improvements need to be implemented to ensure compliance with both WHO GPNPCL and ISO/IEC 17025:2005. For IEA to successfully become a WHO prequalified QC lab and obtain ISO/IEC 17025:2005 accreditation, it is essential to remediate the identified nonconformities. Addressing them will require substantial commitment in time and effort from IEA; however, if appropriate resources are dedicated, PQM and CNCC are confident that IEA is capable of introducing the necessary corrections to their QMS in a timely manner.

If IEA commits to implementing a QMS compliant with ISO/IEC 17025:2005 and WHO GPNPCL, PQM, CNCC and PAHO will work together to provide the necessary support and guidance to remediate the QMS deficiencies.

Next Steps

- PQM and CNCC will send a detailed report to IEA for all of the identified nonconformities with references to the specific ISO/GPNCL clauses, severity of observation, description, objective evidence, recommended corrective action, and suggested time line for implementation.
- PQM and CNCC will send an outline to IEA of a strategic plan aimed at addressing the observations identified during the evaluation and the necessary steps to comply with both ISO/IEC 17025:2005 and WHO GPNPCL.
 - The plan will be structured in phases to ensure priority is placed on the most critical observations.
 - PQM and CNCC will develop the outline and IEA should modify and finalize the document as necessary.
 - After the plan is finalized and IEA begins implementing the plan, PQM will sponsor CNCC staff to perform a follow-up visit to assess the implementation process and/or modify the plan accordingly.
- IEA should communicate with PQM, PAHO, and CNCC regarding any specific requests for technical assistance.

IEA QMS Evaluation: Agenda

Panama City, Panama

May 3 - 7, 2010

Monday, May 3:

- Tour of IEA Installations
- Presentation: Introduction and Objective of Evaluation
- Presentation: International Quality Standards & OMCL Situation in Americas

Tuesday, May 4:

- Presentation: CNCC Experiences
- Presentation: Implementing a Rigorous Quality Management System
- Presentation: Expectations of External Audits & Recommended Auditee Behavior
- Presentation: Simulated Method Audit
- Begin Facility Inspection (Performed by Ofelia Villalva – CNCC)
- Begin Process Audit (Performed by Adrian Barojas – PQM)

Wednesday, May 5:

- Continue PQM Facility inspection
- Continue Process Audit
- Meeting with IEA Director

Thursday, May 6:

- Finish PQM Facility inspection
- Finish Process Audit
- Meeting with University of Panama Dean
- Meeting with USAID/Panama

Friday, May 7:

- Presentation: Evaluation Findings, Recommendations, and Next Steps
- USP/NF Question and Answer Session

PQM Meetings: Lists of Participants

Panama City, Panama

May 3-7, 2010

May 3, 4 & 7, 2010 – IEA Presentations

Participant	Institution
Aizprua, Jorge	IEA
Arosemena Elena (de)	IEA
Castillo, Juan Manuel	IEA
Chen, Marisol de	IEA
Cedeño, Jorge	IEA
Cortéz, Edgardo	IEA
Del Cid, Octaviza	IEA
De León, Gisela	IEA
De León, Leticia	IEA
De Trinidad. Lissette	IEA
Franco, Damaso L.	IEA
Dutary, Antonio E.	IEA
Gálvez, Blanca	IEA
González, Lina	IEA
Gordon Mario	IEA
Jones, Jacqueline	IEA
Guerrero, Nilka	IEA
Lasso, José	IEA
Noriega, Yariela de	IEA
Núñez, Flor	IEA
Núñez. Leticia de	IEA
Rivera Andres	IEA
Saavedra, Garisel de	IEA
Sarmiento, Galia	IEA
Soler, Sabina	IEA
Villalva, Ofelia	CNCC-INS
Barojas, Adrian	PQM

May 3-7, 2010 – IEA QMS Evaluation

Participant	Institution
De León, Leticia	IEA
Jones, Jacqueline	IEA
Guerrero, Nilka	IEA
Noriega, Yariela de	IEA
Saavedra, Garisel de	IEA
Soler, Sabina	IEA
Villalva, Ofelia	CNCC-INS
Barojas, Adrian	PQM

May 5, 2010 – Meeting with IEA Director

Participant	Institution
Arosemena, Gustavo	IEA - Director
Jones, Jacqueline	IEA
Guerrero, Nilka	IEA
Noriega, Yariela de	IEA
Villalva, Ofelia	CNCC-INS
Barojas, Adrian	PQM

May 6, 2010 – Meeting with University of Panama (UP) Dean

Participant	Institution
Arosemena, Gustavo	IEA – Director
Cuevas, Adrian	UP – Director of Administrative Services
Garcia de Paredes, Gustavo	UP - Dean
Guerrero, Nilka	IEA
Molinar, Eldis Barnes	UP – Vice Dean
Soler, Sabina	IEA
Villalva, Ofelia	CNCC-INS
Barojas, Adrian	PQM

May 6, 2010 – Meeting with USAID/Panama

Participant	Institution
Drost, Cristina	USAID/Panama
Varela, Nilka	USAID/Panama
Barojas, Adrian	PQM

IEA Visit: Additional Meetings*

Meeting with Gustavo Arosemena, IEA Director

May 5, 2010

Participants: See [Annex 2](#) for a complete list of participants.

Meeting Proceedings and Conclusions:

PQM discussed the objectives and main findings of the current trip with the IEA director, particularly the need for his continuous commitment to improve the QMS. The IEA director committed to providing his staff with the necessary support to implement a QMS that is compliant with both WHO GPNPCL and ISO/IEC.

Additionally, PQM and CNCC expressed their willingness to provide technical assistance and perform follow-up visits as necessary to assist IEA in improving their QMS.

Next Steps

- PQM and CNCC will work with IEA to address the observations identified during the evaluation (See *Next Steps* in *Overview of Activities* section).

Meeting with Gustavo Garcia de Paredes, University of Panama Dean

May 6, 2010

Participants: See [Annex 2](#) for a complete list of participants.

Meeting Proceedings and Conclusions:

PQM discussed the objectives and main findings of the current trip with the UP dean, particularly as related to the benefits of obtaining WHO PQ and ISO/IEC 17025:2005 accreditation. Since IEA is part of the UP, PQM and CNCC emphasized the need for high level administrative support to ensure IEA can implement adequate actions to remediate the observations identified during the evaluation.

Additionally, PQM and CNCC expressed their willingness to provide technical assistance and perform follow-up visits as necessary to assist IEA in improving their QMS.

The UP dean committed to providing IEA with the necessary support to implement a QMS that is compliant with both WHO GPNPCL and ISO/IEC. The UP dean also asked for assistance from PQM regarding potential changes to the national medicine legislation. PQM agreed to provide assistance and will respond according to requests by UP and IEA.

Next Steps

- UP and IEA will request assistance from PQM regarding the national medicine legislation. PQM will respond accordingly and if necessary consult with other potential stakeholders (PAHO, FDA, etc.).

* This section will be translated into Spanish and disseminated separately to country partners.

- PQM recommends that IEA establish monthly or bi-monthly meetings with the UP dean to update him on improvements to the QMS.

Meeting with USAID/Panama

May 6, 2010

Participants: See [Annex 2](#) for a complete list of participants.

Meeting Proceedings and Conclusions:

PQM discussed the objectives and main findings of the current trip with USAID/Panama.

USAID/Panama does not have a bilateral health department, but requested PQM to keep the Mission updated on any USAID-funded initiatives.

Next Steps

- PQM will update USAID/Panama as activities continue to develop.

Evaluación por los Participantes

Fecha de Evaluación: 3-7 de Mayo del 2010

Se les dará la forma de evaluación a los participantes al concluir la evaluación y se pedirá que califiquen el material educativo y sus actividades asociadas. Se les pedirá a los participantes que califiquen todas las categorías que apliquen.

[Esto debe completarse y regresarse al instructor/facilitador al final de la evaluación]

Indicador	Coincido rotundamente	Coincido	Estoy un tanto en desacuerdo
1. Los objetivos del curso fueron relevantes a mis actividades	22		
2. El curso abarco a mis expectativas	17	5	
3. Fui capaz de entender el contenido del material presentado	19	3	
4. El curso completo fue de utilidad y me ayudará a hacer mejor mi trabajo	21	1	
5. Hubo ejercicios prácticos suficientes que facilitaron el entendimiento de la evaluación	13	9	
6. El ritmo de las sesiones fue apropiado para que entendiera los materiales de la evaluación	15	7	
7. Los instructores tenían conocimiento del tema	20	2	
8. Los instructores permitieron un buen nivel de participación en las clases	20	2	

Otros comentarios/Sugerencias:

1. ¿Cuáles tópico(s) o aspectos no deberían de incluirse en la evaluación en un futuro?

- La gran mayoría de los participantes indicaron satisfacción con los diferentes aspectos de la evaluación

2. ¿Cuáles son sus recomendaciones/sugerencias para mejorar la evaluación?

- Incrementar el tiempo de la evaluación (6)
- Incorporar a personal del área administrativa para que dichas personas entiendan de qué modo sus funciones impactan en el sistema de gestión de calidad (5)
- Encontrar un balance adecuado en el tiempo dedicado a acumular evidencia en una no conformidad específica y el tiempo dedicado a evaluar otras no conformidades potenciales (2)
- Incrementar la rigurosidad de la evaluación en el área de seguridad (2)
- Incrementar la frecuencia de visitas de PQM y CNCC (1)

3. ¿Qué es lo que más le gusta de la evaluación?

- El conocimiento de los instructores (9)
- El apoyo en mejorar deficiencias del sistema y en dar sugerencias inmediatas para remediar no-conformidades (6)
- El enfoque de evaluación en ISO 17025 y BPL de la OMS (4)
- La oportunidad de realizar preguntas y tener interacción con los instructores (4)
- La disponibilidad de instructores en dar seguimiento al IEA (1)
- El nivel de detalle con que la evaluación enfoca el trabajo puntual del analista (1)
- Las charlas teóricas al principio de la semana (1)

4. Describa que temas o actividades le gustaría recibir apoyo en el futuro de los facilitadores:

- Oportunidades de pasantías en laboratorios acreditados/precalificados (5)
- Interpretación de capítulos generales, advertencias generales y monografías de la USP (4)
- Seguimiento por PQM y CNCC a las no-conformidades observadas durante la evaluación (4)
- Capacitaciones analíticas prácticas para el personal del laboratorio (4)
- Incorporar actividades que ayuden a incrementar la motivación del personal (3)
- Apoyo a otras áreas, tales como alimentos, suplementos dietéticos y productos diversos (3)
- Validación/verificación de métodos analíticos (2)
- Apoyar en desarrollar procedimientos internos para verificar/asegurar que reactivos son adecuados para utilizar en las pruebas analíticas (1)
- Historia, evolución y expectativas futuras de la USP (1)
- Cursos a distancia, vía internet, sobre temas técnicos e interpretación de datos (1)
- Apoyo en cómo evaluar las especificaciones del expediente (dossier) para medicamentos que no están en la farmacopea (1)
- Apoyo para enfocar la acreditación ISO 17025 con vistas a un alcance amplio, orientándose a metodologías y no monografías (1)
- Apoyar a implementar mecanismos para aumentar la productividad sin descuidar la calidad de los resultados (1)
- Apoyar en mejorar almacenamiento de reactivos (1)