

Evaluation of Laboratory Quality Management Systems: Rostov-on-Don and St. Petersburg Roszdravnadzor Regional Medicine Quality Control Laboratories

Rostov-on-Don, Russian Federation
July 16-19, 2012

St. Petersburg, Russian Federation
July 23-27, 2012

Trip Report

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Promoting the Quality of Medicines

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Executive Summary

The PQM team traveled to Russia to observe ACLASS, an internationally recognized accrediting body, during their planning visit at the Rostov-on-Don Quality Control (QC) lab. ACLASS interviewed the staff, evaluated their proficiency in conducting the tests for the scope of accreditation, and conducted training on Measurement Uncertainty.

After this activity was complete, PQM evaluated the Quality Management System (QMS) of Roszdravnadzor Regional Medicine Quality Control Laboratory in St. Petersburg and inspected their facility.

The goal for Rostov-on-Don and St. Petersburg Roszdravnadzor Regional Medicine QC Laboratories is to obtain ISO/IEC 17025:2005 accreditation and, at a later stage, be incorporated into the list of World Health Organization (WHO) Prequalified (PQ) medicine QC laboratories.

PQM will work with the laboratories on implementing effective corrective actions and continue to provide technical assistance to strengthen their QMS. PQM will work with ACLASS to perform the assessment audit of the Rostov-on-Don lab within three months and will conduct a follow-up visit to the St. Petersburg lab within twelve months to confirm that the labs have effectively resolved the nonconformities that were identified during this trip.

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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.

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- PQM administrative staff and editors for their assistance with logistical arrangements and for editing the trip report.

ACRONYMS

CAPA	Corrective and Preventative Action
CNCC	Centro Nacional de Control de Calidad
DQI	Drug Quality and Information Program
GLP	Good Laboratory Practices
GPPQCL	Good Practices for Pharmaceutical Quality Control Laboratories
IEC	International Electrotechnical Commission
IMCESACMP	Information and Methodological Center for Expertise, Stocktaking and Analysis of Circulation of Medical Products of Roszdravnadzor
INS	Instituto Nacional de Salud de Peru
ISO	International Organization for Standardization
PQ	Prequalification
PQM	Promoting the Quality of Medicines Program
QC	Quality Control
QMS	Quality Management System
SOP	Standard Operating Procedure
USAID	United States Agency for International Development
USP	United States Pharmacopeia
WHO	World Health Organization

Background

Since 2010, PQM has received funding from USAID/Russia to assist Roszdravnadzor in improving their Regional Medicine Quality Control (QC) Laboratories' compliance with international quality management system (QMS) standards. Roszdravnadzor's goal is to have all of their Regional Medicine QC Laboratories obtain International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025:2005 accreditation, and subsequently, be incorporated into the list of World Health Organization (WHO) Prequalified (PQ) medicine QC laboratories. Roszdravnadzor identified the regional medicine QC labs located in Rostov-on-Don and Kazan as priority labs and asked PQM for assistance in evaluating their QMS. The first audit of the Rostov-on-Don lab was conducted in September 2011, and a follow-up audit was conducted in April 2012.

Purpose of Trip

The purposes of this trip were to:

- Accompany ACLASS, an internationally recognized accrediting organization, during their planning visit at the Rostov-on-Don QC lab
 - ACLASS will interview the staff and evaluate their proficiency in conducting the tests for the scope of accreditation
 - ACLASS will conduct a training on Measurement Uncertainty
- PQM will evaluate the QMS of Roszdravnadzor Regional Medicine Quality Control Laboratory in St. Petersburg and inspect the facility

Source of Funding

These activities were funded by USAID/Russia.

Overview of Activities

The goal for Rostov-on-Don and St. Petersburg Roszdravnadzor Regional Medicine QC Laboratories is to obtain ISO/IEC 17025:2005 accreditation and, at a later stage, be incorporated into the list of WHO PQ medicine QC laboratories. Attaining working conditions that conform to these stringent standards will assure that the administrative and technical operations of the two laboratories are functioning at the highest internationally recognized standards and will provide Roszdravnadzor with QC laboratories capable of producing accurate and valid results in accordance with international standards.

Rostov

Item	Description
Institution Evaluated	Rostov-on-Don Roszdravnadzor Regional Medicine QC Laboratory
Specific Objectives/ Expected Outcomes	ACLASS will: <ul style="list-style-type: none">• Evaluate the proficiency of the staff to perform the tests identified for the scope of accreditation• Improve the capacity of the lab staff to perform rigorous internal auditing procedures• Conduct a training on measurement uncertainty• Determine when the lab will be ready for an assessment audit
Partners	Roszdravnadzor, PQM, and ACLASS
Evaluators	Bill Hirt, ACLASS

Areas Evaluated	<ul style="list-style-type: none"> • QMS Documents, focusing on critical Standard Operating Procedures (SOPs) • Observation of the proficiency of the tests chosen for the scope of accreditation • Accommodations (or “premises”) • Handling of test items • Document and record control • Equipment • Staff training • Test methods • Reporting & evaluation of test results • Safety & good housekeeping • Internal audit • Corrective and preventive actions (CAPAs)
Participants	The list of participants included in <i>Annex 1</i>
Agenda	The agenda is included in <i>Annex 2</i>
Key Findings	<p>The laboratory has made substantial progress in relation to nonconformities found in April 2012. The laboratory staff have demonstrated commitment to their tasks and shown their proficiency in all the tests chosen for the scope of accreditation. They have also made substantial progress in implementing internal procedures as part of the QMS based on ISO/IEC 17025:2005 and WHO GPPQCL.</p> <p>Details of the findings will be provided in a separate confidential report that will be delivered directly to Roszdravnadzor.</p>
Next Steps	PQM will work with ACLASS to perform an assessment of the Rostov-on-Don lab within 2-3 months.
Conclusion	PQM staff is very pleased with the lab’s progress; the lab should be ready for an ISO/IEC 17025:2005 audit by October 2012.

St. Petersburg

Item	Description
Institution Evaluated	St. Petersburg Roszdravnadzor Regional Medicine QC Laboratory
Specific Objectives/ Expected Outcomes	<p>Evaluate the QMS of the Saint Petersburg Roszdravnadzor Regional Medicine QC Laboratory utilizing the following standards:</p> <ul style="list-style-type: none"> • WHO Good Practices for National Pharmaceutical Control Laboratories (GPPQCL) (Technical Report Series, No. 957, 2010, 44th Report, Annex 1, also referred to as WHO Good Laboratory Practices or “GLP”) • ISO/IEC 17025:2005 Standards <p>Improve the capacity of laboratory staff to perform rigorous internal auditing procedures.</p>

Partners	Roszdraznadzor, PQM
Evaluators	Ofelia del Rosario Villalva Rojas, CNCC-INS; Regina Okafor, Kirill Burimski, and Oksana Dmitrenok, PQM
Areas Evaluated	<ul style="list-style-type: none"> • QMS Documents, focusing on critical SOPs • Observation of the proficiency of the tests chosen for the scope of accreditation • Accommodations (or “premises”) • Handling of test items • Document and record control • Equipment • Staff training • Test methods • Reporting & evaluation of test results • Safety & good housekeeping • Internal audit • CAPAs
Participants	The list of participants is included in <i>Annex 3</i>
Agenda	The agenda is included in <i>Annex 4</i>
Key Findings	<p>The laboratory has made substantial progress in implementing internal procedures as part of the QMS based on ISO/IEC 17025:2005 and WHO GPPQCL.</p> <p>Details of the findings will be provided in a separate confidential report that will be delivered directly to St. Petersburg.</p>
Next Steps	<ul style="list-style-type: none"> • PQM will work with the laboratory on implementing effective corrective actions and continue to provide technical assistance to strengthen the QMS. • PQM will perform a follow-up visit within 12 months to confirm the lab has effectively resolved the nonconformances that were identified. • Depending on the results of the follow-up visit, a recommendation will be made regarding formal application for ISO 17025 accreditation and/or WHO PQ
Conclusion	The lab will need an additional 18 months until it is ready for a formal ISO/IEC 17025:2005 assessment or WHO inspection.

PQM Trip: List of Participants

Rostov-on-Don, Russian Federation ♦ July 16-20, 2012

Key Personnel – participants in the audit

No.	Name	Position
1	Anna Grigorieva	Acting Director of Rostov Laboratory
2	Egor Kurbatov	Quality Service Manager
3	Elena Avdeeva	Head of Microbiology Laboratory
4	Ekaterina Fedotova	Senior Pharmaceutical Chemist (Acting Head of Analytical Laboratory)
5	Larisa Kurbatova	Head of Administrative Department
6	Olga Popova	HR Manger
7	Irina Efimova	Head of Pharmacological Laboratory

Other Participants

Victoria Belanova	Federal State Budgetary Institution IMCESACMP (Information and Methodological Center for Expertise, Stocktaking and Analysis of Circulation of Medical Products of Roszdravnadzor), Moscow
Gulnara Nuriyazdanova	Kazan Laboratory



ANSI-ASQ National Accreditation Board/AClass

AClass Accreditation Assessment Schedule

FSBI - Rostov ISO/IEC 17025

<u>Time/Date</u>	<u>Activity</u>	<u>Assessors</u>
	Day 1 – Monday, July 16, 2012	
9:00 am	Opening Meeting and Lab Tour	All
10:00 to noon	Witness of pH and Weight methods	HIRT
Noon to 1:00	Lunch	
1:00 to 4 pm	Witness of HPLC method(s)	HIRT
4 to 4:30 pm	Daily wrap-up	All
	Day 2 – Tuesday, July 17, 2012	
9:00 to noon	Witness of Dissolution method	HIRT
Noon to 1:00	Lunch	
1:00 to 4 pm	Witness of UV-Vis and TLC methods	HIRT
4 to 4:30 pm	Daily wrap-up	All
	Day 3 – Wednesday, July 18, 2012	
9:00 to noon	Review of 17025 elements 5.1 thru 5.10	HIRT
Noon to 1:00	Lunch	
1:00 to 4 pm	Review of 17025 elements 4.1 thru 4.15	HIRT
4 to 4:30 pm	Daily wrap-up	All
	Day 4 – Thursday, July 19, 2012	
9:00 am – noon	Uncertainty / Proficiency Testing review (Training if warranted)	HIRT
Noon to 1:00	Lunch	
1:00 to 4 pm	Final method review and report preparation	HIRT
4 to 5 pm	Closing Meeting	All

PQM Trip: List of Participants

St. Petersburg, Russian Federation ♦ July 23-27, 2012

**Key Personnel – participants in the evaluation,
Saint Petersburg Lab**

1	Kosenko, Juri	Director
2	Strelkova, Lyubov	Deputy
3	Tikhonenko, Anna	Head of Administrative Department
4	Trusov, Sergey	Head of Analytical Lab
5	Mametyeva, Anna	Head of Microbiological Lab
6	Bogdanova, Irina	Head of Pharmacological Lab
7	Batrysheva, Julia	Analyst

**PQM Visit to Evaluate Quality Management System (QMS) of
Saint Petersburg Regional Medicine QC Laboratory:**

Saint Petersburg, Russia
July 23 - 27, 2012

DAY	ACTIVITY
Monday	<ul style="list-style-type: none"> • Meeting with Lab Director or similar • Opening meeting <ul style="list-style-type: none"> ○ Update on current situation in lab ○ Discuss objectives, roles of each evaluator and expectations of visit ○ Adjust agenda as necessary • Identification of the responsible persons to guide the audit (at least two) • Process audit: Regina Okafor • Facility inspection: Physicochemical areas: Ofelia Villalva <ul style="list-style-type: none"> ○ SOPs, analyst worksheet, records, verification of analytical methods ○ Maintenance and Calibration Program ○ Training Program: Personnel files
Tuesday to Friday	<p>Regina Okafor:</p> <ul style="list-style-type: none"> • Document evaluation of Quality Management System <ul style="list-style-type: none"> ○ Internal Audit Program ○ CAPA ○ Quality assurance area ○ Proficiency test ○ Review of Non-conforming work ○ Complaints <p>Ofelia Villalva:</p> <ul style="list-style-type: none"> • Facility Inspection: Microbiological and Pharmacological areas: SOPs, analyst worksheet, records • OOS • Metrology area
	<ul style="list-style-type: none"> • COA: Regina Okafor • Reference Standards, Reagents: Ofelia Villalva • Acquisitions: Ofelia Villalva • Presentation: Findings, • Experiences and recommendation, and Next Steps • Closing meeting