

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

Rostov-on-Don, Russian Federation
April 16-18, 2012

Kazan, Russian Federation
April 23-27, 2012

Trip Report

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Executive Summary

The PQM team traveled to Russia to:

- Follow up on the QMS audit of the Rostov-on-Don Roszdravnadzor Regional Medicine QC Laboratory, carried out by PQM and CNCC in September 2011
 - Evaluate the implementation and effectiveness of Corrective and Preventive Actions (CAPAs) for the nonconformities previously identified
 - Inspect the facilities
 - Interview the staff
- Evaluate the QMS of Roszdravnadzor Regional Medicine Quality Control Laboratories in Kazan.

The evaluations were performed using the following internationally recognized standards:

- World Health Organization (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”) and,
- The International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025:2005 Standards

The goal for Rostov-on-Don and Kazan 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 Prequalified medicine QC laboratories.

PQM will work with the laboratories on implementing effective corrective actions and continue to provide technical assistance to strengthen their Quality Management Systems (QMS). PQM will work with ACLASS or another accrediting body to perform a pre-audit of the Rostov-on-Don lab within 3-4 months. Depending on the results of the pre-audit, a recommendation will be made regarding formal application for ISO 17025 accreditation and/or WHO prequalification. PQM will conduct a follow-up visit of the Kazan lab within 18 months to confirm the lab has effectively resolved the nonconformities that were identified.

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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 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.

Purpose of Trip

The purposes of this trip were to:

- Follow up on the QMS audit of the Rostov-on-Don Roszdravnadzor Regional Medicine QC Laboratory, carried out by PQM and CNCC in September 2011
 - Evaluate the implementation and effectiveness of Corrective and Preventive Actions (CAPAs) for the nonconformities previously identified
 - Inspect the facilities
 - Interview the staff
- Evaluate the QMS of Roszdravnadzor Regional Medicine Quality Control Laboratories in Kazan.

Source of Funding

These activities were funded by USAID/Russia.

Overview of Activities

The goal for Rostov-on-Don and Kazan 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 Prequalified 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 | <ul style="list-style-type: none">• Evaluate the QMS of the Rostov-on-Don Roszdravnadzor Regional Medicine QC Laboratory utilizing the following standards:<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”) and,○ The International Organization for |

| | |
|-----------------|--|
| | <p>Standardization/International Electrotechnical Commission (ISO/IEC) 17025:2005 Standards</p> <ul style="list-style-type: none"> • Improve capacity of laboratory staff to perform rigorous internal auditing procedures. |
| Partners | Roszdraznador, PQM, & CNCC-INS |
| Evaluators | Ofelia del Rosario Villalva Rojas, CNCC-INS & Kirill Burimski, PQM |
| Areas Evaluated | <ul style="list-style-type: none"> • QMS Documents, focusing on critical Standard Operating Procedures (SOPs) • 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) |
| Key Findings | <ul style="list-style-type: none"> • The laboratory has made substantial progress in relation to nonconformities found in September 2011 • Laboratory staff has demonstrated commitment to their tasks and are willing to improve their activities and procedures • The laboratory staff has made substantial progress in implementing internal procedures as part of the QMS based on ISO/IEC 17025:2005 and WHO GPPQCL. <p>Details will be provided in a separate confidential report that will be delivered directly to Roszdraznador.</p> |
| Next Steps | PQM will work with ACLASS or another accrediting body to perform a pre-audit of the Rostov-on-Don lab within 3-4 months and audit within 7-9 months. |
| Conclusion | PQM staff is very pleased with the lab’s progress; the lab should be ready for ISO/IEC 17025:2005 audit by the end of 2012. |

Kazan

| Item | Description |
|-----------------------|--|
| Institution Evaluated | Kazan Roszdraznador Regional Medicine QC Laboratory |
| Specific Objectives | <ul style="list-style-type: none"> • Evaluate the QMS of the Kazan Roszdraznador Regional Medicine QC Laboratory utilizing the following standards: <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 |

| | |
|-----------------|---|
| | <p>Practices or “GLP”) and,</p> <ul style="list-style-type: none"> ○ The International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025:2005 Standards ● Improve capacity of laboratory staff to perform rigorous internal auditing procedures. |
| Partners | Roszdravnadzor, PQM, & CNCC-INS |
| Evaluators | Ofelia del Rosario Villalva Rojas, CNCC-INS; David Andrews, USP; & Kirill Burimski, PQM |
| Areas Evaluated | <ul style="list-style-type: none"> ● QMS Documents, focusing on critical Standard Operating Procedures (SOPs) ● 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) |
| Key Findings | <ul style="list-style-type: none"> ● The lab has made significant progress in implementing a QMS that is potentially in compliance with ISO/IEC 17025:2005 and WHO GPPQCL. Nonetheless, the evaluation did identify nonconformities with ISO/IEC 17025:2005 and WHO GPPQCL standards. <p>Details will be provided in a separate confidential report that will be delivered directly to Roszdravnadzor.</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 their 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 prequalification. |
| 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 ♦ April 16-18, 2012

| Participant | Institution |
|--------------------|--------------------------|
| Anna Grigorieva | Rostov-on-Don Laboratory |
| Vladimir Sorokin | Rostov-on-Don Laboratory |
| Egor Kurbatov | Rostov-on-Don Laboratory |
| Elena Avdeeva | Rostov-on-Don Laboratory |
| Irina Efimova | Rostov-on-Don Laboratory |
| Larisa Kurbatova | Rostov-on-Don Laboratory |
| Victoria Belanova | IMCESACMP |
| Ofelia Villalva | CNCC-INS |
| Kirill Burimski | PQM |

**PQM Follow-up Visit to Evaluate Quality Management System (QMS) of
Roszdravnadzor Regional Medicine QC Laboratory**
Rostov-on-Don, Russia ♦ April 16 - 18, 2012

Standards utilized during the Evaluation

- World Health Organization (WHO) Good Practices for Pharmaceutical Quality Control Laboratories (GPPQCL)
- International Organization for Standardization/ International Electrotechnical Commission (ISO/IEC) 17025:2005 - General Requirements for the Competence of Testing and Calibration Laboratories

Objectives

- Evaluate the QMS of the laboratory and identify any nonconformities with WHO GPPQCL and ISO/IEC 17025:2005.
- Improve capacity of laboratory staff to perform rigorous internal auditing procedures.

Scope

Focus on areas (administrative and technical) used to test pharmaceutical products with emphasis on areas where nonconformities were found during the September 2011 assessment.

Evaluators

Ofelia del Rosario Villalva Rojas, Executive Director of Laboratories, National Quality Control Center of the National Institute of Health of Peru; Kirill Burimski, Program Manager, USP/PQM

Agenda

| Day | Activities |
|---------------------------|--|
| Monday to Wednesday | <ul style="list-style-type: none"> • Opening meeting: <ul style="list-style-type: none"> ○ Update on current situation in lab ○ Discuss objectives and expectations of visit ○ Adjust agenda as necessary • Facility inspection • Process audit • Review Non conformities in 2011 • Review critical SOPs <ul style="list-style-type: none"> ○ Internal audit program ○ Corrective and Preventive Actions (CAPAs) ○ Review of Non-conforming work • QMS Evaluation - Closing meeting: <ul style="list-style-type: none"> ○ Findings, recommendations and next steps |

PQM Trip: List of Participants

Kazan, Russian Federation ♦ April 23-27, 2012

| Participant | Institution |
|-----------------------|--------------------|
| Kadria Minnekeeva | Kazan Laboratory |
| Zulfia Nigmatzianova | Kazan Laboratory |
| Roman Galeev | Kazan Laboratory |
| Gulnara Nuriyazdanova | Kazan Laboratory |
| Olga Pavlova | Kazan Laboratory |
| Olga Porfirieva | Kazan Laboratory |
| Elena Anisimova | Kazan Laboratory |
| Victoria Belanova | IMCESACMP |
| Ofelia Villalva | CNCC-INS |
| David Andrews | USP |
| Kirill Burimski | USP/PQM |

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

Kazan, Russia ♦ April 23 - 27, 2012

Standards utilized during the Evaluation

- World Health Organization (WHO) Good Practices for Pharmaceutical Quality Control Laboratories (GPPQCL)
- International Organization for Standardization/ International Electrotechnical Commission (ISO/IEC) 17025:2005 - General Requirements for the Competence of Testing and Calibration Laboratories

Visit Objectives

- Evaluate the QMS of the laboratory and identify any nonconformities with WHO GPPQCL and ISO/IEC 17025:2005.
- Improve capacity of laboratory staff to perform rigorous internal auditing procedures.

Evaluators

- Ofelia del Rosario Villalva Rojas, Executive Director of Laboratories, National Quality Control Center of the National Institute of Health of Peru
- David Andrews, USP
- Kirill Burimski, USP/PQM

Agenda

| 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: • Facility inspection: Physicochemical areas: <ul style="list-style-type: none"> ○ SOPs, analyst worksheet, records, verification of analytical methods ○ Maintenance and Calibration Program ○ Training Program: Personnel files |

| | |
|------------------------------|---|
| <p>Tuesday to Friday</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 • Facility Inspection: Microbiological area: SOPs, analyst worksheet, records • Out of Specification (OOS) • Metrology |
| | <ul style="list-style-type: none"> • COA • Reference Standards, Reagents • Acquisitions • Presentation • Findings, Experiences, and Recommendations • Next Steps • Closing |