

**Laboratory Training Courses for the Staff of Roszdravnadzor's National Network
of Medicines Quality Control Laboratories**

Moscow, Russia
October 5, 2012

Saint Petersburg, Russia
October 15-18, 2012

Trip Report

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Promoting the Quality of Medicines Program

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Executive Summary

The Promoting the Quality of Medicines (PQM) Program, United States Pharmacopeia (USP), in collaboration with Roszdravnadzor (RZN, the Food and Drug Administration of the Russian Federation), developed laboratory training courses and trained the staff of Roszdravnadzor's national network of medicines quality control laboratories in Saint Petersburg, Russia October 15-18, 2012.

Three training courses on microbiological aspects of medicines quality control, disinfectants and antiseptics, and pyrogen testing were developed to suit the needs of the Roszdravnadzor staff and translated into Russian by experts in relevant fields. Fourteen individuals representing eight regional/federal district labs participated in the training courses, which were held at Roszdravnadzor's Saint Petersburg Medicines Quality Control Laboratory.

By the end of the training, participants gained competency in basic and advanced microbiological methods of quality control, including identification of antimicrobial effectiveness, determination of microorganism quantities, testing for specific microorganisms, sterility and pyrogen testing, and identification of microorganisms and their properties.

During this trip, staff also met with former USAID/Russia Office of Health staff to discuss PQM close-out activities and logistics.

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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 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.

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- The staff of Saint Petersburg Medicines Quality Control Laboratory, for hosting the workshop—particularly Mr. Jury Kosenko and Dr. Lyubov Strelkova—for their high level of interest and feedback
- Dr. A.V. Titova, Roszdravnadzor’s Federal State Budgetary Institution Information and Methodological Center for Expertise, Stocktaking and Analysis of Circulation of Medical Products, for her assistance in preparing the training
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ACRONYMS

DQI	Drug Quality and Information Program
IMCESACMP	Information and Methodological Center for Expertise, Stocktaking and Analysis of Circulation of Medical Products (the Federal State Budgetary Institution)
LAL	Limulus amebocyte lysate
MOU	Memorandum of Understanding
MQCL	Medicines Quality Control Laboratory
PQM	Promoting the Quality of Medicines program
QC	Quality Control
RS	Reference Standards
RZN	Rosdravnadzor, the Federal Service on Surveillance in Healthcare and Social Development of Russian Federation
USAID	United States Agency for International Development
USP	United States Pharmacopeia

Background

In April 2009, the United States Pharmacopeia (USP) and Roszdravnadzor (RZN) signed a Memorandum of Understanding (MOU). In one of the provisions, the two organizations agreed “to explore joint and mutually beneficial education and training programs on compendial and allied topics, including proficiency testing, execution of compendial procedures, good laboratory practices, testing to conform to Good Manufacturing Practices, marketplace surveillance, and execution of approaches to combat counterfeit and substandard medicines.”

In the early months of 2010, RZN began to establish regional and federal district medicine quality control laboratories (MQCLs). RZN asked USP to provide training courses for the newly hired staff of the laboratories, as well as for the staff of the existing lab in Moscow.

In 2010-2012, twenty-four training courses on topics ranging from good laboratory practices to the theory and practical application of advanced analytical test methods were conducted at RZN’s Scientific Centre for Expertise of Medical Products in Moscow and at MQCLs in Rostov-on-Don and Saint Petersburg. During the courses, laboratory testing of anti-tuberculosis medicines was conducted, whenever possible. Responses from the participants’ evaluation questionnaires showed their great interest and enthusiasm for attending other courses, including courses on microbiological issues. In letters to the U.S. Agency for International Development/Russia (USAID/Russia) and USP, Dr. Telnova, Acting Director of RZN, expressed appreciation for the training and conveyed the agency’s wish to collaborate on additional trainings in the future. RZN requested three training courses on microbiological aspects of medicines quality to be conducted at Saint Petersburg MQCL for the microbiologists of the recently established regional quality control laboratories.

USP developed the presentations and lab practices on microbiological methods and had them translated into Russian by experts in relevant fields. The USP and RZN staffs jointly refined the presentations, tailoring them to suit the needs of the RZN staff. PQM conducted the training as part of USAID close-out activities.

Purpose of Trip

- Conduct trainings for the staff of RZN’s national network of MQCLs
- Meet USAID/Russia Office of Health staff to discuss close-out activities

Source of Funding

This trip was supported by USAID/Russia. To minimize costs, RZN covered expenses for its participants, including travel and accommodations, and provided the training venue.

Overview of Activities

Item	Description
Titles of Trainings	<ul style="list-style-type: none"> • Microbiological aspects of medicines quality control • Disinfectants and antiseptics • Pyrogen testing and bacterial endotoxins
Specific Objectives/ Expected Outcomes	After USP/PQM staff conduct the trainings, the participants will be able to understand the importance of appropriate pyrogen testing and other microbiological methods in medicines quality control
Venue/Location	Saint Petersburg Medicines Quality Control Laboratory
Organizers/Sponsors	PQM, USAID Russia, RZN, Information and Methodological Center for Expertise, Stocktaking and Analysis of Circulation of Medical Products (IMCESACMP), and Saint Petersburg MQCL
Trainers	Dr. Radhakrishna Tirumalai and Mr. Pradeep Ganganala
Trainees	14 individuals from 8 regional/federal district MQCLs participated. See Participant List in <i>Annex 1</i> for detailed information.
Agenda	See <i>Annex 2</i> for detailed information
Closing Ceremony	Dr. Radhakrishna Tirumalai, Mr. Pradeep Ganganala, and Dr. Kirill Burimski spoke during closing ceremonies. Certificates were provided to the participants.
Equipment Provided	<ul style="list-style-type: none"> • Ready Depyrogenated 10 x 75 mm borosilicate glass test tubes • Ready Depyrogenated 13 x 100 mm borosilicate glass tubes • USP reference standards
Training Evaluations	The participants agreed that the course materials were relevant to their jobs and that the new skills would help them in their daily work. See participant evaluations in <i>Annexes 3-5</i> for details.
Outcomes/Conclusion	The training courses were successful and met the intended objectives. The participants were dedicated and showed great interest in learning all the aspects of the training program.
Next Steps	<ul style="list-style-type: none"> • Electronic versions of the course materials were disseminated to the training participants and other interested specialists. • RZN requested that USP continue offering training courses in 2013. In collaboration with RZN, USP will develop a list of training courses for the staff of regional MQCLs.

Training course: Microbiological aspects of medicines quality control

This course module covered topics such as antimicrobial efficacy testing, microbial limits, sterility tests, validation of microbial recovery methods, and microbial identification. 14 participants attended the course; 12 participants evaluated the course (see *Annex 3*).

Training course: Disinfectants and antiseptics

This course module covered topics such as the need for use of disinfectants, related regulations, methods of selection, efficacy testing, and cleaning validation. 14 participants attended the course; 12 participants evaluated the course (see *Annex 4*).

Training course: Pyrogen tests and bacterial endotoxins

This course covered pyrogen testing and bacterial endotoxin testing—including limulus amoebocyte lysate (LAL) reagent sensitivity determination, inhibition/enhancement testing, gel clot limit tests, and photometric tests with examples on calculation of endotoxin limits and maximum valid dilution. In addition, a laboratory exercise of bacterial endotoxin testing (sensitivity of LAL reagent) and a gel clot limit test on actual injection products was conducted. 14 participants attended; 12 participants evaluated the course (see *Annex 5*).

Other Activities

Meeting at former USAID/Russia office Moscow, October 5, 2012

Kirill Burimski and Oksana Dmitrenok had a meeting at the former office of USAID/Russia with Bill Slater, Susanne Hoza, Nikita Afanasiev, and Marina Kulikova (all former USAID/Russia Office of Health staff).

According to the Russian government's requirement, all of USAID/Russia's activities ceased on October 1, 2012. Close-out activities and other related topics were discussed. PQM staff was informed that all USAID programs must be terminated by December 31, 2012. The time between October 1 and December 31 may be used only for close-out activities. Close-out activities include final report development, audits, getting rid of equipment, etc. If a particular activity was 80-90% done as of October 1, the time between October 1 and December 31 might be used to fully complete it, but this should clearly be part of close-out activities.

List of Participants

Employees of MQCLs participating in the PE training courses on October 15-18, 2012

Last name, First name	Position
Yekaterinburg MQCL	
1. Pavlova, Elena	Head of Microbiological lab
Gudermes MQCL	
2. Bidirova, Zulpa	Senior Microbiologist
Kazan MQCL	
3. Kirillova, Julia	Head of Microbiological lab
Khabarovsk MQCL	
4. Rokush, Svetlana	Head of Microbiological lab
Krasnoyarsk MQCL	
5. Sharikov, Andrey	Microbiologist
Kursk MQCL	
6. Malykhina, Elena	Pharmacist-analyst of microbiological department
Saint Petersburg MQCL	
7. Kosenko, Juri	Director
8. Strelkova, Lyubov	Deputy
9. Mametyeva, Anna	Head of Microbiology
10. Rasulova, Larisa	Microbiologist
11. Razukrantova, Nadezhda	Microbiologist
12. Tereshkina, Irina	Microbiologist
13. Lobynceva, Tatiana	Microbiologist
Stavropol MQCL	
14. Bullit, Natalia	Pharmacist-analyst

Training Program Schedule

Microbiological Aspects of Medicines QC

Series of Training Seminars
RZN's North West Region MQCL, Saint Petersburg, Russia
October 15 – 18, 2012

Seminar	Dates	Trainers
1. Microbiologic aspects of medicines QC <ul style="list-style-type: none"> • Basics of microbiology. • Identification of antimicrobial effectiveness. • Non-sterile products: <ul style="list-style-type: none"> - Determination of microorganism quantities - Testing for specific microorganisms • Pharmaceuticals and substances: Criteria for pharmaceutical use • Sterility testing • Identification of microorganisms and their properties – USP General Chapter <1113> • Characteristics of the nutrient media and acceptable methods for pharmacopeial microbiological testing 	Monday-Tuesday, October 15-16	Dr. Radhakrishna Tirumalai
2. Disinfectants and antiseptics: USP General Chapter <1072>	Wednesday, October 17	Dr. Radhakrishna Tirumalai
3. Pyrogen tests and bacterial endotoxin (theory and practice)	Wednesday-Thursday, October 17-18	Dr. Radhakrishna Tirumalai Mr. G. Pradeep
Seminar closing		

Schedule of classes

09:00 – 18:00

Lunch

13:00 – 14:00

Coffee breaks

11:00 – 11:15 and 16:00 – 16:15

Microbiological aspects of medicines quality control

Evaluations by Participants

Participants are given evaluation forms at the beginning of the course. Participants are asked to rate its educational materials and associated activities. Participants are asked to rate all categories that apply and return the completed form to the instructor.

12 participants returned the forms.

Indicator	Strongly Agree	Agree	Disagree Somewhat	Strongly Disagree
1. Course objectives were relevant to my needs	7	5		
2. I was able to understand the content of the materials presented	7	5		
3. In general the course was useful and will help me do my job better	8	4		
4. The flow of the course was consistent with my understanding of the materials presented	6	6		
5. The instructors were knowledgeable on the subject	10	2		
6. The instructors allowed an appropriate level of participation in the class	9	3		

Any other comments/suggestions:

- Thank you. (2)
- The course was interesting for me. It was pleasure to participate in the course.(1)
- Special thanks to Elena Frolova, Russian interpreter, for excellent high professional translation. (1)
- There were a few mistakes in Russian translation of slides. (1)

Disinfectants and antiseptics

Evaluations by Participants

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12 participants returned the forms.

Indicator	Strongly Agree	Agree	Disagree Somewhat	Strongly Disagree
1. Course objectives were relevant to my needs	8	4		
2. I was able to understand the content of the materials presented	8	4		
3. In general the course was useful and will help me do my job better	9	3		
4. The flow of the course was consistent with my understanding of the materials presented	10	2		
5. The instructors were knowledgeable on the subject	9	3		
6. The instructors allowed an appropriate level of participation in the class	9	3		

Any other comments/suggestions:

- Thank you! (1)

Pyrogen testing and bacterial endotoxin

Evaluations by Participants

Participants are given evaluation forms at the beginning of the course. Participants are asked to rate its educational materials and associated activities. Participants are asked to rate all categories that apply and return the completed form to the instructor.

12 participants returned the forms.

Indicator	Strongly Agree	Agree	Disagree Somewhat	Strongly Disagree
1. Course objectives were relevant to my needs	9	3		
2. I was able to understand the content of the materials presented	8	4		
3. In general the course was useful and will help me do my job better	10	2		
4. The flow of the course was consistent with my understanding of the materials presented	9	2	1	
5. The instructors were knowledgeable on the subject	10	2		
6. The instructors allowed an appropriate level of participation in the class	9	3		

Any other comments/suggestions:

- Thank you very much. (2)
- The course material was presented clearly. (1)
- Two days are not enough for this module. (1)