

Rosdravnadzor's International Conference on the Quality of Medicines and Medical Devices: The Modern Requirements and Approaches

Moscow, Russia
April 19-20 and 25, 2012

Trip Report

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Promoting the Quality of Medicines

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Executive Summary

In April 2012, the Promoting the Quality of Medicines (PQM) Program, funded by the United States Agency for International Development (USAID) and implemented by the United States Pharmacopeia (USP), delivered three presentations covering different aspects of medicines quality control at Roszdraznadzor's International Conference on the Quality of Medicines and Medical Devices: The Modern Requirements and Approaches. The presentations addressed rapid tests of medicines quality, the ISO 17025 accreditation and WHO Prequalification Programme for Medicines Quality Control Laboratories (MQCLs), and PQM technical assistance to manufacturers of second-line anti-tuberculosis medicines pursuing WHO prequalification. The Conference was held April 19-20, 2012, in Moscow.

During the workshop, the PQM team also attended a high-level meeting with Roszdraznadzor to discuss future collaborations, including the next steps for implementing the use of Raman spectroscopy in the MQCLs.

PQM staff met with representatives of the Russian manufacturer Sintez, which expressed interest in receiving technical assistance from PQM in preparing for WHO prequalification status, and the company Enhanced Spectrometry, Inc., Russian vendor of the Enspectr[®] Raman spectrometer and other devices.

The PQM team later met with the staff of USAID/Russia, Office of Health, and discussed PQM's progress to date and future plans.

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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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- Mr. Anthony Boni and Dr. Maria Miralles at USAID/Headquarters for their collaboration and support
- Dr. Fred Long and Ms. Ofelia Villalva Rojas for their presentations at the Conference and as PQM consultants
- Drs. E.A. Telnova and Valentina Kosenko, and Mr. Belanov of Roszdraznadzor for their support
- Our USP colleagues for their support and editorial and administrative assistance, as well as Ms. Helen Kharab and Dr. Patrick Lukulay

ACRONYMS

DQI	Drug Quality and Information Program
FDC	Fixed Dose Combinations
GF	Global Fund
GMP	Good Manufacturing Practices
MOH	Ministry of Health
MQCL	Medicines Quality Control Laboratory
PQ	Prequalification through the WHO Prequalification Programme
PQM	Promoting the Quality of Medicines Program
QA	Quality Assurance
QC	Quality Control
RZN	Roszdraznadzor— Federal Service on Surveillance in Healthcare and Social Development of the Russian Federation
SOP	Standard Operating Procedure
TB	Tuberculosis
USAID	United States Agency for International Development
USP	United States Pharmacopeia
WHO	World Health Organization

Background

The U.S. Agency for International Development (USAID) and U.S. Pharmacopeia (USP) have been providing technical assistance to Russia since 1994, first through the Rational Pharmaceutical Management project, then through the USP Drug Quality and Information program and, currently, through the Promoting the Quality of Medicines (PQM) program. Most recently, activities have focused on strengthening the technical capacity of Roszdraznador (RZN) to effectively control the quality of anti-tuberculosis (TB) medicines; increasing access to WHO-prequalified second-line anti-TB (SL-ATB) medicines and promoting demand for participation in the WHO Prequalification Programme; and reducing the prevalence of substandard and counterfeit anti-TB medicines in the country.

In April 2009, USP and RZN signed a Memorandum of Understanding. In one of the provisions, the two organizations agreed “to explore joint and mutually beneficial education and training programs” Thus, PQM has been providing training and guidance on the quality assurance of medicines, working with RZN’s network of new medicines quality control laboratories (MQCLs) in the federal districts of Russia to establish medicines quality monitoring and compendial analysis to test for substandard or counterfeit medicines.

In 2010, RZN started collecting near-infrared (NIR) spectra for various medicines to be used for medicines analysis. So far, RZN has equipped three MQCLs with mobile express laboratories including NIR spectrometers, and intends to do the same with all of its MQCLs. RZN has also expressed interest in Raman spectroscopy, an emerging diagnostic method that enables rapid non-invasive volumetric analysis of pharmaceutical formulations that may provide results when traditional NIR cannot provide reliable data. Recently the agency asked PQM to facilitate discussions with international experts on Raman spectroscopy and to provide them technical assistance toward establishing a spectral database for anti-TB medicines. PQM arranged for Dr. Frederick H. Long, President, Spectroscopic Solutions LLC, to meet with Roszdraznador officials to discuss the next steps for implementing Raman spectroscopy at the MQCLs.

In 2011 PQM conducted an audit of the Rostov-on-Don MQCL to begin preparing it for the ISO 17025 accreditation /WHO prequalification—examining staff training, equipment qualification, quality systems management, management structure, and documentation as well as inspecting its facilities. The accreditation of the Roszdraznador lab would not only benefit health systems in Russia, it could qualify them to perform quality control tests for medicines procured using resources of The Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) and offer its services to other countries in the region.

Purpose of Trip

- Deliver presentations at RZN’s International conference Quality of Medicines and Medical Devices. The Modern Requirements and Approaches.
- Meet with staff of RZN and RZN MQCLs to discuss next steps for implementing Raman spectroscopy into general practice at MQCLs.
- Meet with USAID/Russia, Office of Health, staff to discuss PQM progress and plans.

Overview of Activities

Roszdraznador's International Conference on the Quality of Medicines and Medical Devices: The Modern Requirements and Approaches

April 19-20, 2012

Item	Description
Specific Objectives/ Expected Outcomes	<ul style="list-style-type: none"> • PQM staff will make three presentations at the Conference • PQM staff will meet with USAID/Russia and Roszdraznador to discuss PQM activities and future plans
Venue/Location	Holiday Inn Moscow Sokolniki (24 Rusakovskaya str., Moscow)
Organizers and Sponsors	<ul style="list-style-type: none"> • PQM Program • Roszdraznador • USAID/Russia Mission and USAID/Core TB Program • USP
Audience	More than 600 people attended the Conference comprising specialists from pharmaceutical manufacturers and distributors of pharmaceutical products, Russian pharmaceutical professional and public organizations and associations, RZN staff, the State Budget Institution's Information and Methodological Center for Expertise, Stocktaking and Analysis of Circulation of Medical Products (Moscow), staff from regional and federal district MQCLs, representatives of WHO and European Directorate for the Quality of Medicines and Health, National Institute for the Control Pharmaceutical and Biological Products of China, and medicines regulatory authorities of Ukraine, Belarus, and Kazakhstan.
Agenda	See Agenda (Annex 1) for detailed information.
Opening Ceremony	<ul style="list-style-type: none"> • Dr. Tatyana Golikova, Minister of Health and Social Development sent greetings to participants • Dr. E. A. Telnova, Acting Head of RZN, welcomed participants and gave a short address focused on the importance of this conference to the quality control of medicines in Russia. Dr. Telnova also thanked international experts, including USP PQM representatives, for participating in the conference and expressed RZN's interest in further cooperation in this area.
Presentations	<ul style="list-style-type: none"> • "Raman spectroscopy for pharmaceutical applications" Frederick H. Long, Ph.D., President, Spectroscopic Solutions LLC • "Requirements to the quality assurance system of MQCL: Systemic incompliance detected during audit" Ofelia del Rosario Villalva Rojas, QF, LA-IRCA, PQM consultant • "PQM Technical Assistance in Good Manufacturing Practices" Kennedy M. Chibwe, Ph.D., MBA, Senior Program Advisor, PQM

	
Outcomes/Conclusion	<ul style="list-style-type: none"> • Dr. Kosenko thanked USP PQM for participating in the workshop and mentioned that the participants liked the presentations • RZN expressed an interest in publishing the USP PQM presentations on their website
Next Steps	<ul style="list-style-type: none"> • PQM will facilitate discussions with experts on Raman spectroscopy and provide technical assistance to RZN on the establishment of a spectral database for anti-TB medicines by June 2012. • PQM will conduct its first audit of the Kazan MQCL in April 2012 and will continue to provide technical assistance to the Rostov-on-Don MQCL as it works toward ISO 17025 accreditation and WHO prequalification.

Other Meetings

Meeting with Sintez LLC, April 19, 2012

Participants: Ms. Lyubov Pshenichnikova, Quality Control Director, Sintez
 Ms. Madina Sottaeva, Chief of GMP and Quality Department, JSC "Pharm-Sintez"
 Drs. Kennedy Chibwe, Kirill Burimski, Oksana Dmitrenok, and Ms. Natalia Morozova, PQM

PQM met with the Sintez staff and discussed the current status of the dossier on the company's product, Kanamycin 1.0 g, powder for injections. Sintez submitted to PQM results of the previous three months of stability studies (both long-term and accelerated) which had started in January 2012. Apart from the stability study, PQM Consultant Natalia Morozova pointed out some missing data that Sintez should add into the dossier for Kanamycin; then, the dossier should be converted to common technical document (CTD) format.

Next steps:

1. The stability study should be continued and the data sent to PQM on a regular basis.
2. PQM will provide Sintez with the list of missing data.
3. Sintez will send to PQM the data, required for compilation of the dossier in CTD format, in parallel with the stability study.
4. Ms. Morozova will visit Sintez in May.

Meeting with Roszdrazhnadzor, April 20, 2012

Participants: Dr. E.A. Telnova, Acting Head, RZN
 Dr. Kosenko, Head, Division of State Quality Control of Medical Products

Mr. Belanov, Head, International Cooperation Department
Ms. Anastasia Nikitina, Chief Specialist-Expert, International Cooperation Department
Mr. Andrey Koroteev, Chief Executive Officer, Federal State Budget Institution (FSI) "Informational and Methodological Center for Expertise, Stocktaking and Analysis of Circulation of Medical Products"
Dr. Anna Titova, Deputy Head, Department of Organization of Medicines Quality Control, FSI "Information and Methodological Center for Expertise, Stocktaking and Analysis of Circulation of Medical Products"
Ms. Anna Grigorieva, Deputy, Rostov-on-Don MQCL
Drs. Kennedy Chibwe, Kirill Burimski, and Oksana Dmitrenok, and Ms. Natalia Morozova, PQM

RZN reiterated its thanks for USP PQM's participation in the conference, and the group discussed future collaborative work, including:

- Results of second audit of Rostov-on-Don MQCL (conducted a week prior to the Conference): Ms. Ofelia Villalva Rojas and Dr. Burimski agreed that, generally, the Rostov-on-Don lab is ready for ISO accreditation for seven–eight tests. RZN would like ACLASS to conduct the official audit and provide the ISO accreditation to Rostov-on-Don MQCL.
- Implementing Raman spectroscopy in MQCLs and the test equipment.
- Visit of RZN delegation to USP Headquarters in June 2012.

Next steps:

1. RZN will determine the scope of tests that the Rostov-on-Don MQCL will submit for accreditation.
2. PQM will contact ACLASS to perform the accreditation audit on Rostov-on-Don MQCL.
3. PQM will conduct the first audit of the Kazan MQCL in April 2012.
4. PQM will facilitate discussions with Raman spectroscopy experts and provide technical assistance to RZN on establishing a spectral database for anti-TB medicines.

Meeting with Enhanced Spectrometry, Inc., April 20, 2012

Participants: Mr. Alexey Steblev, Vice President Business Development, Enhanced Spectrometry, Inc.

Dr. Frederick H. Long, President, Spectroscopic Solutions LLC, PQM Consultant
Drs. Kennedy Chibwe, Kirill Burimski, and Oksana Dmitrenok, and Ms. Natalia Morozova, PQM

Alexey Steblyev made a brief presentation about his company, Enhanced Spectrometry, Inc., and the Enspectr[®] products they sell. The company, located in Chernogolovka (Moscow region), was formed in 2009 as a joint venture comprising leading scientists from the Institute of Solid State Physics of the Russian Academy of Sciences and business development managers from InQubit.

Among other devices and software, Enhanced Spectrometry, Inc., sells the EnSpectr[®] R532, a portable Raman analyzer.

Next steps:

1. PQM will further evaluate Enhanced Spectrometry, Inc., and make a firm recommendation on the EnSpectr analyzer by June 2012.

Meeting with USAID/Russia, Office of Health, April 25, 2012

Participants: Mr. William Slater, Director, Office of Health (OH) USAID/Russia
Ms. Suzanne Hoza, Project Officer, OH, USAID/Russia
Dr. Marina Kulikova, Project Management Specialist, TB Control Program, OH, USAID/Russia
Drs. Kennedy Chibwe and Oksana Dmitrenok, and Ms. Natalia Morozova, PQM

PQM staff met with staff of the USAID/Russia Office of Health to discuss the purpose of this trip, updated them on the progress of PQM activities in Russia, and discussed future projects. The following summaries the discussions:

- Dr. Chibwe acknowledged and thanked Mr. Slater and his staff for the continued support for PQM and expressed that he looked forward to continued support.
- Mr. Slater stated that he was happy with PQM's activities in Russia. He also mentioned that the positive relationship that USP has with RZN and the Russia Ministry of Health was appreciated.
- Dr. Chibwe highlighted the current activities conducted on this particular trip ([Annex 2](#)).
- In conclusion, Dr. Chibwe requested support for Akrikhin Company, as they may need some assistance on bioavailability/bioequivalence studies, to which Mr. Slater responded that he would gladly look into it.

Conclusion

The Conference was a successful one that saw USP present on three different topics. The Conference also highlighted the determination that RZN has on moving forward in adopting and implementing internationally acknowledged systems for pharmaceutical industry in Russia.



International Conference

Quality of Medicines and Medical Devices

The Modern Requirements and Approaches

PROGRAMME

Moscow

April 19-20, 2012

Organizational Issues

<i>Place</i>	<i>Holiday Inn Moscow Sokolniki (24 Rusakovskaya str., Moscow)</i>
<i>Registration</i>	The hall of the hotel <i>Holiday Inn Moscow Sokolniki</i> April 19 8.30 - 9.15
<i>Coffee-break</i>	April 19: 15.00 – 15.30 April 20: 11.00 – 11.15 15.30 – 15.45
<i>Lunch</i>	April 19: 12.00 – 13.00 April 20: 13.00 – 14.00
<i>Interpretation</i>	Simultaneous English and Russian interpretation <i>Please, hand in headphones upon completion of each conference day</i>
<i>Press-conference</i>	April 19: 11.45 Hall «Sokolniki»

April 19	Hall «Sokolniki»	
Plenary session		
Chairpersons	Prof. Elena Telnova, acting head of Roszdraznadzor Dr. Diana Mikhailova, director of the Department of the development of pharmaceutical market and medical techniques market, Ministry of healthcare and social development Dr. Susanne Keitel, director of EDQM	
9:15	Welcome address Results of regulatory supervision and control over circulation of medicinal products in 2011. Long term objectives	Prof. Elena Telnova, acting head of the Federal Service on Surveillance in Healthcare and Social Development
9:40	Regulation of medical devices circulation in the view of new legislation of the Russian Federation	Dr. Diana Mikhailova, director of the Department of the development of pharmaceutical market and medical techniques market, Ministry of healthcare and social development
10:05	New regulatory aspects in the sphere of medicines circulation. Council of Europe's activities in combating counterfeit medical products.	Dr. Susanne Keitel, director of EDQM
10:30	Regulation of circulation of medicines in the Republic of Kazakhstan	Larisa Pak, deputy chairperson of the committee of medical and pharmaceutical activities control, Ministry of healthcare of the Republic of Kazakhstan
10:55	Regulation of circulation of medicines in Ukraine	A. Solovyev, State administration of Ukraine on medicinal products
11:20	Regulation of circulation of medicines in the Republic of Belarus	Ludmila Reutskaya, head of the department of pharmaceutical inspection and medicines supply, Ministry of healthcare of the Republic of Belarus
11:45 – 12:00	Press-conference, Hall «Sokolniki»	
12:00 – 13:00	Lunch	
Hall «Sokolniki 1»		
Breakout session Actual Methodology of Drug Quality Control. Part I. Methods of Rapid Testing of Medicines		
Chairperson	Valentina Kosenko, Head of the Division of State Quality Control of Medical Products, Roszdraznadzor, Russia	

13.00	Introduction of NIR-spectrometry into the state medicines quality control system of the Russian Federation	Valentina Kosenko, Head of the Division of State Quality Control of Medical Products, Roszdraznadzor, Russia
13.25	Raman spectroscopy for pharmaceutical applications	Frederick H. Long, Ph.D. President, Spectroscopic Solutions LLC, USP consultant
13.50	Modern spectrum technologies and solutions for rapid analysis in pharmaceutical industry	Irina Merker, Bruker Optik GmbH, Germany
14.15	State quality control system of medicines in the People's Republic of China. Experience of rapid diagnosis methods implementation	Jin Shaohong, National Institute for the Control of Pharmaceuticals and Biological Products (NICPBP), P.R. China.
14.40	The application of NIR-spectroscopy in the production of medicines in Russia	Svetlana Skorik, Polisan Ltd
15.00-15.30	Coffee-break	
Panel discussion		
API and Excipients Quality Assurance System in the Russian Federation		
Chairpersons	Valentina Kosenko, Head of the Division of State Quality Control of Medical Products, Roszdraznadzor, Russia Dr. Susanne Keitel, Director of EDQM Li Yunlong, general director of the National Institute for the Control of Pharmaceuticals and Biological Products (NICPBP), P.R. China	
15.30	World API market. Prospects for the development of API manufacture in Russia	Maria Denisova, IMS HEALTH Russia
15.50	State regulation of API and excipients quality control in the Russian Federation	Alla Trapkova, deputy head of the Division of State Quality Control of Medical Products, Roszdraznadzor
16.10	The system of API and excipients approval for use in the manufacture of medicines in EU countries	Dr. Susanne Keitel, Director of EDQM
16.40	Quality control of API manufacture in China	Li Yunlong, general director of the National Institute for the Control of Pharmaceuticals and Biological Products (NICPBP), P.R. China
17.00	Compliance of API manufacture and quality control in the factories of the Russian Federation to the GMP guidelines	M. Grigoriev, director on the development, JSC Pharmcenter
17.20	Issues for discussion: 1. Quality of APIs used in production of medicines in the Russian Federation. Outstanding Issues. 2. Principal challenges and difficulties of API introduction into the foreign markets. Russian manufacturers' opinion	
Hall «Sokolniki 2»		

Breakout session Assurance of safe application of generic medicines in post-registration period		
Chairpersons	Sergey Glagolev, Chief of the department for monitoring of safety and effectiveness of medicines, Roszdraznador Jeremy Labadie, Uppsala Monitoring Centre, WHO	
13.00	Regulatory aspects of medicines safety monitoring in the Russian Federation	Sergey Glagolev, Chief of the department for monitoring of safety and effectiveness of medicines, Roszdraznador
13.30	Organization of Pharmacovigilance service at a pharmaceutical company-manufacturer of generics	Dr. F. Klein, medical director, authorized on pharmacovigilance STADA AG; G.N. Aleeva, regulatory affairs director, STADA CIS
14.30	Running a pharmacovigilance system in international pharmaceutical company	Irena Orel, head of the department of clinical trials and pharmacovigilance, KRKA
15.00-15.30	Coffee-break	
15.30	Issues of generic's safety: the tactics of detection and prevention	Jeremy Labadie, working group safety data analysis, Uppsala Monitoring Centre, WHO
16.00	Discussion	
Hall «Krymskiy Val»		
Breakout session State Quality Control of Medical Devices at Different Stages of their Circulation		
Chairperson	Elena Barmanova, head of the Division of medical devices quality control, Roszdraznador	
13.00	The state registration of medical devices: what's new in the legislation	Elena Barmanova, head of the Division of medical devices quality control, Roszdraznador
13.25	Examination of the efficacy, safety and quality of medical devices as a part of the state registration	O. Romanov, VNIIMT
13.50	Features of medical technology testing	L. Osipov, MOMT
14.15	Licensing of manufacture and technical maintenance of medical devices: problems and solutions	E. Turianskiy, deputy head of the Division of medical devices quality control, Roszdraznador A. Semenov, Association of the organizations of the military-industrial complex of the manufacturers of medical devices and equipment

14.40	Medical devices safety monitoring	V. Zinichenko, VNIIMT
15.05	State quality control of medical devices	A. Astakhova, Division of medical devices quality control Roszdraznadzor
15.30 – 15.45	Coffee-break	
15.45	New legislation in the sphere of medical devices circulation in Russia and its influence on foreign industry	A. Teriakova, International Medical Devices Manufacturers Association IMEDA
16.10	Discussion	
Panel discussion Problems of training of personnel in the field of quality control of medicines		
Chairperson	Maria Denisova, IMS HEALTH Russia	
16.45	The basic needs of the industry (in the sphere of pharmanalysis). Requirements to the applicants.	I. Nadelyaeva, "Olympus of science", co-executor and the organizer of the pharmaceutical contest
17.00	Discussion on problems of training of personnel in the field of quality control of medicines	
April 20	Hall «Sokolniki 1»	
Breakout session Actual Methodology of Drug Quality Control. Part II. Development of Laboratory Methods of Medicines Quality Control		
Chairpersons	Valentina Kosenko, Head of the Division of State Quality Control of Medical Products, Roszdraznadzor, Russia Ian Trussell, head of the inspection of the WHO prequalification of medicines program	
9.00	Principles of new laboratory methods introduction into medicines quality control practices. European experience	Dr. Andrea Lodi, head of the EDQM Laboratory Department.
9.30	USP Monograph modernization to maintain up-to-date standards to prevent economically motivated adulteration of medicines and foods	Natalia Kouznetsova, Ph.D. Applied Compendial Research Separation Sciences Laboratory, scientific associate, USP
10.00	Biosimilars. Focus on the quality control	T. Schreitmuller, Hoffmann-la Roche Ltd.
10.30	Approaches to quality control of biosimilars	Eric R. Pungerkar, head of the Department of research development, Lek pharmaceuticals
11.00-11.15	Coffee-break	
11.15	Development of medicines quality control system in the Russian Federation	Valentina Kosenko, Head of the Division of State Quality Control of Medical Products, Roszdraznadzor, Russia

11.40	Creation and development of laboratory database with regard to medicines quality control in the Russian Federation	Anna Titova, Deputy Head of the Department of Organization of the Medicines Quality Control; FSI «Information and Methodological Center for Expertise, Stocktaking and Analysis of Circulation of Medical Products», Russia
12.05	Prequalification of medicines quality control laboratories in the frames of WHO prequalification of medicines program	Ian Trussell, head of the inspection of the WHO prequalification of medicines program; Olexandr Polishchuk, Division of Health Systems and Public Health WHO Regional Office for Europe
12.45	Requirements to the quality assurance system of QC laboratories. Systemic (general) errors (deficiencies) detected during audit	Ofelia Villalva Rojas CNCC – INS Peru, consultant, USP
13:00 – 14:00	Lunch	
Breakout session System of Quality Assurance of Medicines		
Chairpersons	Valentina Kosenko, Head of the Division of State Quality Control of Medical Products, Roszdraznadzor, Russia Ian Trussell, head of the inspection of the WHO prequalification of medicines program Larisa Pak, deputy chairperson of the committee of medical and pharmaceutical activities control, Ministry of healthcare of the Republic of Kazakhstan	
14:00	Harmonization of requirements to the quality of medicines within the Customs Union	Larisa Pak, deputy chairperson of the committee of medical and pharmaceutical activities control, Ministry of healthcare of the Republic of Kazakhstan
14.30	Principles of WHO prequalification of the manufacturers of finished dosage forms and active pharmaceutical ingredients according to WHO prequalification of medicines program	Ian Trussell, head of the inspection of the WHO prequalification of medicines program; Olexandr Polishchuk, Division of Health Systems and Public Health WHO Regional Office for Europe
15.00	System of inspection of medicines and APIs manufacturers according to WHO prequalification of medicines program	Ian Trussell, head of the inspection of the WHO prequalification of medicines program
15.30-15.45	Coffee-break	
15.45	PQM Technical Assistance in Good Manufacturing Practices	Kennedy M. Chibwe, Ph.D., MBA, Deputy Director, Senior Program Advisor, Promoting the Quality of Medicines Program, USP
16.15	Requirements to system of quality assurance for the control laboratories of manufacturers of medicines	Alla Teterina, quality director, Stada

16.45	Discussion	
Hall «Sokolniki 2»		
Breakout session Wholesale and Retail Sale of Medicines. Topical Issues and Solution Approaches		
Chairperson	Irina Krupnova, head of the department of state control of medicines circulation, Roszdraznadzor	
9:00	Legal regulation in the sphere of turnover of narcotic and psychotropic substances and their precursors, harmonization of normative legal acts of the Russian Federation with the generally recognized principles of international law in the field of countering the illegal drugs and their precursors circulation	N. Nikolaeva, Ministry of health and social development of the Russian Federation
9.40	Features of the prevention and investigation of crimes in the sphere of legal circulation of narcotic drugs and psychotropic substances and their precursors	E.V. Maslovskaya, The Federal drug control service
10.20	Licensing of retail sale of medicines in relation to Federal Law No. 99-Φ3 dated 04/05/2011 "Licensing of particular types of activities". Features of State control over pharmaceutical activities in relation to changes in the legislation	Irina Krupnova, head of the department of state control of medicines circulation, Roszdraznadzor
11.00-11.15	Ceffee-break	
11.15	Legal and ethical mechanisms of retail competition in ensuring the quality of medicines	N. Ignatieva, Executive Director of Russian Association of pharmacy chains
11.50	Peculiarities of state supervision over circulation of medicines. Control of medicines advertising	Irina Krupnova, head of the department of state control of medicines circulation, Roszdraznadzor; E.N. Orikhivskaya, head of the Licensing Department of the Moscow Department of healthcare
12.30	Discussion	
13:00 – 14:00	Lunch	
Breakout session Bioequivalence as one of the factors assuring efficacy and safety of generic medicines		
Chairpersons	Yuriy Afonchikov, Head of Clinical Trials Control Department,	

	Roszdraznavor A.A. Firsov, associate member of the Russian Academy of Medical Sciences, professor, Doctor of Biology, director of G.F. Gause Institute of New Antibiotics Research or V.P. Zherdev, Doctor of Medicine, professor, honoured worker of science of the Russian Federation, head of the pharmacokinetics laboratory, V.V. Zakusov State Foundation Institute of Pharmacology, the Russian Academy of Medical Sciences	
14.00	Modern approaches to the efficacy and safety assessment of generic medicines	Johannes Kramer, AAPS; Phast GmbH, Germany
14.45	Bioequivalence research, comparative dissolution kinetics test, biowaiver procedure in the development of drugs. Practical aspects and application experience	Galina Ramenskaya, professor, director of Research Institute of Pharmacy, Department Chair of Pharmaceutical and toxicological Chemistry, I.M. Sechenov First Moscow State Medical University, Ministry of healthcare and social development; Igor Shokhin, assistant of the Pharmaceutical and Toxicological chemistry department of the I.M. Sechenov First Moscow State Medical University, Ministry of healthcare and social development;
15.15	Research and practice basis for bioequivalence study of medicines: planning of the study	V.P. Zherdev, Doctor of Medicine, professor, honoured worker of science of the Russian Federation, head of the pharmacokinetics laboratory, V.V. Zakusov State Foundation Institute of Pharmacology, the Russian Academy of Medical Sciences
15.45-16.00	Coffee-break	
16.00	Research and practical basis for bioequivalence study of medicines: presentation of the study results	A.A. Firsov, associate member of the Russian Academy of Medical Sciences, professor, Doctor of Biology, director of G.F. Gause Institute of New Antibiotics Research
16.30	Experience of bioequivalence study in the Russian Federation according to the requirements of EMEA	V.V. Pisarev, general director of the science-and-production center PROBIOTECH, Moscow
16.50	Bioequivalence studies: problems and prospects. Experience of the Russian Contract Research Organization	E.V. Peregoedov, director for the North-West Region, JSC Synergy Research Group, Moscow
17.10	Discussion	



ANNEX 2

2012 CIS Activities Report

1. March 19 – 23, Moscow, Russia

PQM training course

Basic tests and selection of samples for monitoring of anti-TB medicines quality using Minilabs® in Russian TB clinics (theory and practice)

Presentations and training:

- *GPHF Minilabs®* by Richard Jähnke
- *Minilab® Training* by Lukas Roth and Sanford Bradby
- *Medicines Quality Monitoring in TB Clinics in Russia and Study Protocol* by Kirill Burimski, Oksana Dmitrenok, and Lukas Roth

2. March – August, Moscow, Russia

Translation of WHO Prequalification materials into Russian

3. April 17 – 18, Rostov-on-Don, Russia

Follow-up visit/Second audit of Roszdraznadzor Medicines Quality Control Laboratory by Ofelia Villalva Rojas and Kirill Burimski

4. April 19 – 20, Moscow, Russia

International Conference on the Quality of Medicines and Medical Devices: The Modern Requirements and Approaches

Presentations:

- *Raman Spectroscopy for Monitoring Medicines Quality* by Fred Long
- *PQM Technical Assistance for Participation in WHO Prequalification Programme* by Kennedy Chibwe (Core TB funding)
- *“Requirements to the quality assurance system of MQCL: Systemic non-compliance detected during audit”* by Ofelia Villalva Rojas
- *Modification of Pharmacopeial Monographs* by Natalia Kouznetsova, USP (USP funds)

5. April 23 – 24, Moscow Region, Russia

WHO Prequalification

Visit to AKRIKHIN Pharmaceuticals Co. in the format of the *Technical Assistant Program* by Kennedy Chibwe, David Vanscoy, Oksana Dmitrenok, and Natalia Morozova (Core TB funding)

- Meeting with Akrikhin management and discussion of issues regarding registration, standards, bioequivalence/bioavailability studies, pharmacovigilance, etc. Visit to the production site (solid finished products)
- Visit to the warehouses and QC lab

6. April 23 – 27, Kazan, Russia

First audit of Roszdraznador Medicines Quality Control Laboratory by Ofelia Villalva Rojas, David Andrews, and Kirill Burimski

7. June 11 – 13, Rockville, MD, USA

Visit of Roszdraznador delegation to USP – not sponsored by USAID

- Acting Director Dr. Elena Telnova
- Seven directors of Roszdraznador regional offices

8. June 25 – 29, Rockville, MD, USA

Visit of six managers of Roszdraznador Medicines Quality Control Laboratories to USP for executive training. Some topics:

- USAID-USP Program Promoting Quality of Medicines Program
- International Quality Standards ISO 17025 and WHO GLP
- Regulation of Compounded Preparations
- Spectral Libraries Database

Tour of USP laboratories

Potential visit to an FDA laboratory

9. July – October, St. Petersburg, Krasnoyarsk, Russia

Pharmacopeial Education courses for Roszdraznador laboratory staff

July, St. Petersburg – Analytical

- Basic approaches to sample preparation
- Validation of analytical methods
- Identification of residual organic solvents by Gas Chromatography
- Atomic absorption spectroscopy in drug tests

September, St. Petersburg – Microbiology

- Definition of bacterial endotoxins in injectables and medicine substances
- Test for microbiological contamination
- Microbiological assay of antibiotics
- Cleaning and disinfection of microbiology laboratory

September – October, Krasnoyarsk – Pharmacology

- Drug toxicity in post-registration Medicines Quality Control; Pharmacopeial and other methods
- Identifying histamine-like and depressor substances in medicines
- Pre-clinical medicines studies

10. July – August, Russia and Ukraine

Tentative PQM visits to manufacturers of second-line anti-tuberculosis medicines