

BIOGRAPHICAL SKETCHES
SABIT STANDARDS GROUP ON MEDICAL EQUIPMENT
February 22 – March 22, 2003

ARMENIA

Vladimir Mkrtumyan

Chief Engineer
Arm-Medservice Ltd.
Yerevan, Armenia

Education

Degree in Electronic Engineering, with a specialization in semiconductor devices. Has attended seminars given by Siemens, TUR and Toshiba on equipment calibration and maintenance of diagnostic equipment.

Background

Chief Engineer for Arm-Service Ltd, a private medical equipment import firm. Arm-Medservice represents the world's leading brands of medical equipment on the Armenian market. Mkrtumyan's work for the firm focuses on calibration, testing and quality control of medical equipment. He previously worked for nine years as Head of the Technical Operations Department at the same company. Arm-Medservice Ltd. was founded in 1992 by Mkrtumyan and a partner, importing primarily equipment for blood analysis and sterilization. The company installs imported equipment using manufacturers' specifications to meet GosStandart Armenia certification.

Interests

Would like to have information on U.S. standards and certification practices to improve his skills and knowledge. Wants to better understand the U.S. regulatory system, legal metrology, quality control, and good manufacturing practices. Hopes to establish lasting business links with U.S. producers of medical equipment, especially x-ray and ultrasound equipment.

English Language Skills: Poor

Gagik Grigoryan

Head of Pharmaceutical Department
Armenian National Institute of Health
Yerevan, Armenia

Education

PhD in Pharmacology. Has taken World Health Organization courses on Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP).

Background

Head of Pharmaceutical Department at the National Institute of Health of Armenia since 1999, and also Head of Pharmaceutical and Medical Technology Inspection at Drug and Medical Technology Agency since 1995. Previously worked as Head of the Radiation Pharmacology Laboratory. Grigoryan has extensive experience in Pharmacology, and supervises a staff of ten specialists. His current work involves the study of international standards and conformity assessment systems for pharmaceuticals, medical devices and medical equipment. In his second job, Grigoryan inspects pharmaceutical technologies and medical equipment, as well as calibrates and checks the quality control of goods imported into Armenia.

Interests

Grigoryan wants to learn the U.S. process of certification. Major problems in Armenia include lack of access to current information, as well as a lack of modern medical equipment and quality control methods. While in the United States, he wants to study the U.S. regulatory system, obtain information on the FDA Regulatory Approval Process, learn more about legal metrology and quality control, study clinical trials for devices, and become acquainted with the latest in bio-medical technology. Hopes to establish contact with the National Institutes of Health (NIH).

English Language Skills: Fair

AZERBAIJAN

Ismail Gafarov

Azerbaijan Medical University
Baku, Azerbaijan

Education

Degree from Academy for Cybernetics. Specialist in math and probability theory.

Background

Works as an instructor and programmer in the Computer Science Department of the Azerbaijan Medical University. Gafarov is also a metrologist for the university, carrying out clinical tests on medical devices and equipment and researching standards and conformity issues.

Interests

Interested in gathering information on the state of the U.S. medical devices field and sharing that knowledge with colleagues. Hopes to return home with recommendations on replacing the old Soviet standards system with internationally compliant system, and wants to make contact with U.S. companies for possible future cooperation.

English Language Skills: Fair

GEORGIA

Andro Atoshvili

Head of Medical Technologies Division
Ministry of Labor, Health and Social Affairs
Tbilisi, Georgia

Education

Degree in biomedical engineering

Background

Works in the Medical Division of the Ministry of Labor, Health and Social Affairs, where he serves as head of the Medical Technology Division. Atoshvili's work involves preparation of directives and normative documents and the creation of new standards, test methods and safety regulations. Prior to accepting this position two years ago, he worked both for the Georgian Technical University as a medical equipment repair engineer and for the Ministry of Health as its expert on medical equipment standards.

Interests

Wants to learn about U.S. safety regulations and the preparation, adoption and applications of standards. Would like to become more familiar with GMP issues and clinical trials, as well as product testing and laboratory accreditation, and then share his knowledge with his colleagues upon returning to Georgia.

English Language Skills: Good

KAZAKSTAN

Kendybay Adiyatov

President
National Center of Accreditation
Astana, Kazakhstan

Education

BA in Engineering.

Background

Mr. Adiyatov has served as president of the National Center of Accreditation since 1992. Appointed by Minister of Industry and Trade, Mr. Adiyatov's work involves overall management of the center, accreditation of certification bodies and test laboratories, standards development, and training courses focusing on standardization, certification, metrology and accreditation. He previously served as Director, Industry & Import

Substitution Department, Ministry of Economy & Trade of Kazakhstan, and also worked at the National Bank of Kazakhstan, and for John Deere.

Interests

Wants to find new ways of overcoming technical barriers to importing U.S. medical equipment to Kazakhstan. Wishes to learn more about internationally accepted procedures for standardization and accreditation. Hopes to make contacts with U.S. companies and create mutually beneficial working relationships.

English Language Skills: Good

Aibek Mirzakhmetov

General Director
Eurasia Pharm Limited
Astana, Kazakhstan

Education

MD, specializing in surgery, PhD (Candidate) in Economics

Background

Dr. Mirzakhmetov is General Director of Eurasia Pharm Limited, a company that sells pharmaceutical products and supplies imported medical equipment to Kazakh enterprises. His work involves management, marketing, strategic planning, negotiations, processing of government-required documents and analysis of industry trends. Dr. Mirzakhmetov previously served as General Manager of the GosOtsenka Republic State Enterprise, and as a surgical intern. He has international sales experience with U.S.-based ABBOTT to supply laboratory equipment to Kazakhstan (through their Moscow representational office.)

Interests

Interested in harmonization of Kazakh and U.S. standards, and in developing a joint venture on assembling Medical Equipment from the U.S.

English Language Skills: Good

KYRGYZSTAN

Ishenbay Moldotashev

Leading Scientific Researcher and Advisor
National Center of Cardiology and Therapy
Bishkek, Kyrgyzstan

Education

MD – Cardiologist. The High Attestation Commission of Russian Cardiology Scientific Center, Moscow, Medical Doctorate Degree, 1986 – 1989; Scientific Research Institute for Cardiology, Yerevan, PhD (Candidate Degree), 1978 – 1981; Kyrgyz Governmental Medical Institute, Physician, 1969 - 1977

Background

Dr. Moldotashev currently fulfills two roles: 1) Senior Scientific Researcher and Advisor to the National Center for Cardiology & Therapy; and 2) Expert for the Medical Equipment Committee of the Medical Equipment & Drug Provision Department. He previously worked as Chairman of the Medical Equipment & Drug Provision Department from 1998 through 2000. His major responsibilities include: 1) scientific & practical supervision of the Center's Department for Chronic Heart Failure; and 2) certification of medical equipment and evaluation of pharmaceuticals, including clinical experiments and testing. Dr. Moldotashev has twenty-five years experience working at the National Center of Cardiology in Kyrgyzstan where he undertakes both research and administrative roles. As an Expert of the Medical Equipment Committee, Dr. Moldotashev also has experience in working with the foreign companies, particularly specializing in ultrasound equipment, including ACCUSON/USA.

Interests

Sees the main problems of the healthcare system of Kyrgyzstan as lack of information about the international medical devices community and insufficient resources. Hopes to learn about the U.S. system of conformity

assessment and apply useful lessons to the Kyrgyz system upon his return home. Interested in tobacco issues and standards.

English Language Skills: Poor

RUSSIA

Igor Dovzhik

Deputy Chief of Laboratory and Research Scientist
Laboratory for Safety Evaluation of Medical Devices
Biomaterials Research Institute of Transplantology and Artificial Organs
Moscow, Russia

Education

Degree in Biology. Has published more than fifteen papers on methods of evaluation of biomaterials, medical devices and tissue/material interactions.

Background

After working as a teacher until 1995 (including three years in Germany), Mr. Dovzhik, an active research scientist, was invited to join the Ophthalmology Institute to conduct certification research. His lab was transferred to the Transplantology Institute, accredited by Russia's GOSSTANDART. Mr. Dovzhik's work focuses on the preparation of protocols related to certification of medical devices.

Interests

ISO 10993, safety evaluation of medical devices.

English Language Skills: Good

Tatyana Doubovik

Group Leader for Product Certification
Russian Research Institute for Medical Engineering
Moscow, Russia

Education

Engineer in biotechnical devices and systems. Expert in product certification.

Background

Ms. Doubovik is a group leader for auditing certified products at the All-Russian Research Institute for Medical Engineering (part of GosStandart and the Ministry of Health.) She participates in the development of state standards for medical devices, harmonizes state standards with IEC standards, controls and inspects products for compliance with standards, analyzes production facilities of manufacturers, and prepares audit results.

Interests

Hopes to learn about newest developments in medical engineering and new technologies, as well as gain a better understanding of conformity assessment procedures in the United States.

English Language Skills: Good knowledge of technical terms

Serguei Logatchev

Head of Department
Ministry of Industry, Science and Technology
Moscow, Russia

Education

Engineer Technologist focusing on cybernetics; diploma in market economy and regulation

Background

Since 1999, Mr. Logatchev has served as head of the department of policy development for medical device production. He is charged with reorganizing the medical device regulatory departments. Mr. Logatchev previously worked as the head of laboratory. He has more than twenty years of experience in medical devices and chemicals and started his career as a professor at the Mendeleev Institute.

Interests

Needs to become acquainted with the organizational, economic and legislative aspects of U.S. policy in the field of medical devices. Also wants to learn about market surveillance, high-technology enterprises and global harmonization activities.

English Language Skills: Fair to Good

Serguei Ivanov

Leading Researcher
Scientific Production Firm "VINAR"
Moscow, Russia

Education

Engineer Technologist. PhD in Chemistry. Additional study on certification, environmental protection, and GMP requirements for the manufacture of pharmaceutical products. Recent courses on English language.

Background

Mr. Ivanov is a researcher at VINAR, a private company engaged in the manufacture of medical test systems and sterilization devices for tests (chemical indicators). In addition to manufacturing medical products, the company sells imported products and sterilization packages. At VINAR, Mr. Ivanov researches and tests new products, tests imported products new to the Russian market, and analyzes markets as well as normative and technical documentation. He has worked in this field since 1977 and previously worked as a senior engineer in a private trading company. Mr. Ivanov is experienced in scientific translations of standard norms. He returned recently from the "Medica" trade fair in Dusseldorf, Germany where he made established contact with two U.S. companies with hopes to acquire sterilization and other devices.

Interests

Interested in information about standards for sterilization and new trading opportunities in the United States. Wants to find ways to overcome regulatory barriers in Russia which are burdensome and ineffective. Hopes to find new products for import into Russia.

English Language Skills: Good

Sergey Shmeliov

Founder/Technical Director
Neurosoft
Ivanovo, Russia

Education

PhD in Technical Sciences, specialized in automatic control systems.

Background

Dr. Shmeliov is the founder of Neurosoft, a private firm producing fourth-generation electroencephalographs and rheographs, electroneuromyographs and the hardware for evoked potentials study. The company also produces magnetic stimulators, miniature third-generation electrocardiographs, and the equipment for psychophysiological testing and complex analysis of autonomous nervous system. Neurosoft holds an internationally granted ISO 9002 certificate. Dr. Shmeliov is in charge of the development, production and certification departments. He ensures that products meet specifications from both GosStandart and the Ministry of Health. His major tasks are to create new medical devices, organize production output, and handle all certification and licensing questions.

Neurosoft, established in 1992, employs one hundred people and is one of the leading manufacturers of diagnostic electrophysiological equipment in Russia. One of their devices (electronic miograph) was considered

one of the best 100 products of the year in Russia. The company currently exports goods to Yugoslavia, Hungary, and Romania.

Interests

Most pressing problem is difficulty in understanding international certification and standardization requirements. Would like to learn about US regulatory system.

English Language Skills: Fair

Serguei Solonnikov

Head of Inspection Control
Center for Certification of Medical Devices
Moscow, Russia

Education

Electrical Engineer (Medical Equipment). Expert in certification of medical devices and quality systems.

Background

Mr. Solonnikov oversees inspection control for the Center, a certification institution within the State Institute of Medical Polymers. The Center is tasked by GosStandart to certify medical devices. Mr. Solonnikov has been the head of the audit group since 1998 and has worked in certification for seven years. His work focuses on the certification of medical devices, determination of frequency of inspection control of certified devices, plant audits, and control of corrective actions in production plans. He previously worked as an expert in the certification of medical devices.

Interests

Needs to gain familiarity with the U.S. regulatory system. Would like to know more about conformity assessment in the United States and other countries.

English Language Skills: Poor

UKRAINE

Yuriy Konstantinov

Founder/Co-Owner
RnK Medical Devices Registration Consulting Bureau
Kiev, Ukraine

Education

M.D. Special knowledge of medical devices, standards and ISO 9000.

Background

Dr. Konstantinov is the founder of RnK, a private firm providing consultative services to clients in the examination, trials, certification and production of medical devices in Ukraine. Dr. Konstantinov has worked in the industry for ten years at a number of different organizations, all focused on standards and certification of medical equipment.

Interests

Interested in learning more about the certification and regulatory process in the United States (and EU) to help develop and improve the system locally in Ukraine. Also interested in meeting U.S. companies looking to enter the Ukrainian medical equipment market.

English Language Skills: Good

Anatoly Komar

Executive Director
TechnoCom
Kiev, Ukraine

Education

Physicist. Specialty in metals.

Background

TechnoCom is a private firm producing medical equipment for wave energy stabilative therapy, diagnostic systems, electro-puncture diagnostics, and potentiometric titration. Mr. Komar has worked for nine years in the medical devices industry and has served as the executive director of TechnoCom for three years. His work focuses on preparation of documentation and reports on technical tests, registration of documents in the state system, and preliminary and clinical tests of medical equipment.

Interests

Main interests are certification and regulations impacting the medical equipment industry. Works a great deal with the certification process in Ukraine and would like to make sure that the equipment produced by his company can be sold worldwide (i.e. must meet EU, US, etc. standards). Interested in laws and regulations in the United States but this information is very difficult to obtain locally in Ukraine. Interested in making contacts with U.S. companies so that their equipment can be sold in Ukraine and his equipment can be sold in the United States.

English Language Skills: Fair

UZBEKISTAN

Rustam Mukhamedov

General Director/Founder

Gentex Service

Tashkent, Uzbekistan

Education

Doctorate in Biochemistry. Post-doctoral degree from Guelph University in Canada in molecular genetics.

Background

Dr. Mukhamedov is the co-founder of Gentex, which imports medical equipment from all over the world for Uzbek clinics and hospitals, provides genetic diagnostics and runs a high-tech medical laboratory. Dr. Mukhamedov has served as the general director for four years. He previously worked as research scientist and director of a molecular genetics laboratory. Dr. Mukhamedov has more than twenty years experience in molecular genetics, as a researcher and scholar.

Interest

Needs to apply to the State Committee of certification before selling U.S. products in the Uzbek market, and wants to better understand the U.S. system of regulation and conformity assessment. Would like to be more knowledgeable about U.S. standards and methods of certification.

English Language Skills: Good