The Tools to Apply International GXP Standards in the Russian Federation: GXP Educational Programs Developed by NP TEMPO in Cooperation with RAPS.

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Noncommercial Partnership "The Center of Modern Medical Technology" (TEMPO) was established in 2002 as a non-profit association engaging advanced research organizations and production enterprises focused on biotechnology and life sciences. TEMPO is an evolving and growing partnership, bringing together 19 governmental, educational and private entities. The partnership activity is aimed at improving the state of healthcare in the Russian Federation, in particular through the consolidation of efforts to apply international GXP standards in healthcare product development and manufacturing.

The gradual introduction of GLP and GMP standards in Russia aimed at creating an environment for the development and production of safe and efficacious drugs begins with the training of laboratory and manufacturing personnel. Working on behalf of its 19 member institutions TEMPO has evolved as the premier Russian training platform for sharing knowledge and experience in international GXP quality standards and regulatory affairs.

In 2004 with financial and intellectual support of the BioIndustry Initiative Program (BII) of the US Department of State, TEMPO successfully launched the first Russian GLP training program in tight cooperation with RAPS. After RAPS' expert auditing both the GLP program and GLP training implementation have been recognized by RAPS as fully correspondent to international educational standards. In 2005 and 2008, TEMPO successfully realized multiple training sessions in GLP for 165 Russian specialists dealing with preclinical investigations of newly developed pharmaceutics, biopreparations and vaccines. Leading Russian experts possessing extensive, hands-on experience in application and maintenance of GLP standards in preclinical safety and toxicological investigations, lectured in the GLP training sessions. Practical training organized by TEMPO using laboratory facilities equipped and maintained as required by GLP, can be considered a significant addition to lectures and seminars.

In 2006 the BII supported TEMPO to launch a GMP training program basing on the GLP project as a successful model for development and implementation of GXP training programs. Again RAPS was engaged by BII to serve as a collaborator

providing needed expertise in the systems of training, education and knowledge resources for pharmacological enterprises staff - GMP compliance specialists. Ten regulatory affairs specialists were selected by RAPS and invited to participate in the International Advisory Committee. The first basic training program in the GMP area was held in 2006 and an advanced program for training GMP auditors in 2007 was developed and implemented, both in cooperation with RAPS experts. Currently nearly 200 specialists of TEMPO member institutions have been trained in these GMP courses. Furthermore, a GMP distance education course has been developed and realized to expand GMP training efforts.

The GLP and GMP programs have been implemented and utilized throughout Moscow Medical Academy to further the advancement of regulatory affairs as a legitimate and vital profession. The current situation in Russia on education and training of specialists working in drug development and manufacturing has been analyzed and widely discussed in several roundtable discussions organized by TEMPO between 2006 and 2008. TEMPO will continue to promote the development of a GXP educational system in Russia and integration of Russian specialists into international regulatory community.