The GMP Inspectorate in Russia:

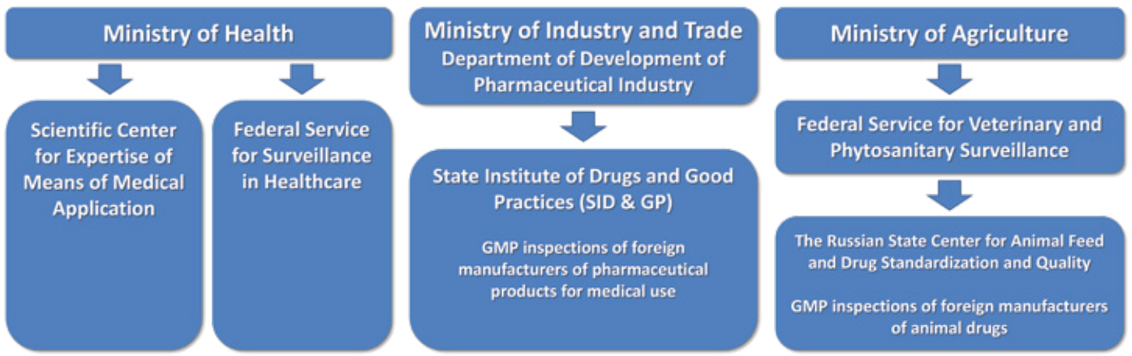
FSI SID & GP is the authority for conducting GMP inspections of foreign medicine manufacturers

5 March 2019

The GMP inspectorate in Russia within the system for regulation of medicines is a quite young structure. Even though the demands on organising production and controlling the quality of finished medicines were formulated back in 1974 and the first ever rules for organising production and quality control of medicines in modern Russia appeared in 1991, the GMP inspectorate was only set up in 2013. At this time, the Ministry for Industry and Trade of the Russian Federation (Minpromtorg) was empowered to approve rules for good production practice and issue conclusions on conformity of manufacturers of medicines for medical application with these rules' requirements. Since then, the Rules for Good Manufacturing Practice (approved by order of the Ministry for Industry and Trade of the Russian Federation No. 916 dated 14.06.2013) have been in effect in Russia. In essence, these are a translation of the GMP EU rules that were effective when the order was drawn up. In 2014, as the expert organisation involved in licensing control over pharma enterprises located in the Russian Federation, FSI State Institute of Drugs and Good Practices (FSI SID & GP) began operating as part of the Minpromtorg commission. Since 2015, FSI SID & GP has been authorised to inspect manufacturers of medicines for medical use produced outside the Russian Federation for conformity with the GMP rules. The purpose of the inspections is to issue conclusions on conformity by medicine manufacturers with the requirements of the rules for good manufacturing practice. SID & GP is thus empowered to conduct inspections of foreign sites operated by medicine manufacturers and the Minpromtorg Department for development of the pharmaceutical and medical industry checks on compliance with the GMP by domestic producers.

As the GMP inspectorate, SID & GP is a structure that appeared only a few years ago but has already earned an excellent reputation among foreign inspectorates and manufacturers.

Apart from ensuring the quality of medicines, the inspectors also promote the GMP rules and make all market players aware of the need to observe



Regulation System of Medicines in Russia

俄罗斯GMP监察机构：

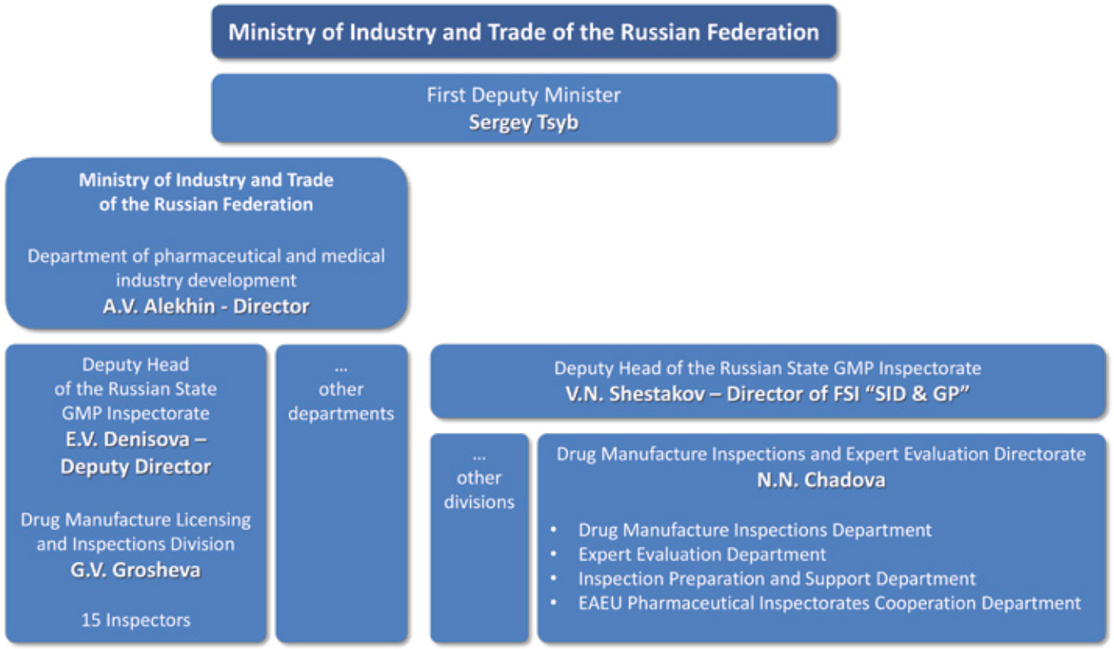
联邦预算机构“国家药物和GP研究院”是授权对国外制药厂进行GMP监察的机构

俄罗斯联邦药品监管系统

俄罗斯药品监管体系中的GMP监察机构是一个很年轻的国家机构。虽然在1974年就已制定成品药生产企业质量控制要求，1991年颁布俄罗斯现代史上首部制药企业质量控制规定，但GMP监察机构成立于2013年。其时由俄罗斯联邦工贸部批准生产质量管理规范及签发医用药品生产企业符合该规范要求的结论。此后俄罗斯境内开始执行药品生产质量管理规范（俄罗斯联邦工贸部2013年6月14日第№916号令批准），这部规范实质是第№916号令制定时欧盟现行的GMP标准的译本。2014年，联邦预算机构“国家药物和GP研究院”作为隶属于俄罗斯工贸部委员会成员的鉴定组织，开始对俄罗斯境内的制药企业进行许可监察。自2015年以来，联邦预算机构“国家药物和GP研究院”授权对俄罗斯联邦境外的医用药品生产企业进行符合GMP标准的检查，为企业签发生产质量管理规范符合性结论。国家药物和GP研究院授权对境外制药企业进行检查，俄罗斯工贸部下属制药和医疗行业发展司则检查本地制造商是否符合GMP要求。

国家药物和GP研究院作为GMP监察机构虽然仅成立几年，但已向国外监察机构和制药企业展现出自身的业务能力。研究院除确保药品质量外，还承担了普及GMP标准的责任，向所有市场参与者贯彻只有遵循这些标准才能生产出高质量药品的意识。GMP标准将“质量”概念提升到全新高度，使其成为评估生产企业工作的最重要标准之一，也是衡量企业竞争力的准绳。

虽然成立不仅，但仅2016年国家药物和GP研究院已对俄罗斯联邦境外的国外药品生产企业的工厂进行了1499次检查。对中国制药企业进行了27次现场检查，并据此签发了14个GMP标准符合性结论。药品监察机构提出的批评意见包括：



GMP Pharmaceutical Inspectorate Structure

these standards in order to manufacture high-quality medicines. It is the GMP rules that raise the "quality" concept to a fundamentally new level and make it one of the crucial criteria for assessing a manufacturer's operation, including from the point of view of competitiveness.

Despite the fact it was created only recently, SID & GP since 2016 has already managed to conduct 1499 inspections of foreign sites where medicines are manufactured outside the Russian Federation. 27 of these were carried out at pharma company sites in China. As a result of these inspections, 14 GMP standards compliance certificates were issued.

Among the critical comments identified by the Russian Inspectorate are the following:

- the procedure for issuing a production permit is ambiguous and not systematic. For example, the same form and the same rules of its execution are used by the authorized person for permission to mark the commercial series of the substance and for permission to issue the commercial series of the substance with the mark. In a series release permit, the authorized person does not record the number of the specification to which the series corresponds. The authorized person does not take into account the correctness of the consumer marking on the packaging of the substance during the issuance of the permit for the series. When a series of substances are shipped from the warehouse, the storekeeper does not make a record confirming the checking of the series status;
- the method of determining impurities in the substance does not comply with the ND RF:
  - the procedure for the analysis of the parameter "Microbiological purity" does not include verification of the correct calculation of the number of colonies by the second microbiologist
  - to control the parameter "Authenticity by IR spectrometry" substance is not set quantitative criteria for compliance between the spectra of the test sample and the standard sample
  - specification of package labelling substance contains conflicting information: "For the production of sterile and non-sterile dosage forms»;
- do not provide a justification for exclusion of continuous monitoring for particulates in the working area of purity class A for critical operations (filling aluminium containers). Monitoring of the concentration of aerosol particles takes place at the beginning and the end of a filling process. There is no justification for the lack of monitoring of aerosol particles concentration in the equipped state for the isolated zones with the unidirectional air flow of class A.

It should be noted that FSI SID & GP not only conducts GMP inspections of foreign pharma manufacturers; it also works to establish mutual relations with foreign colleagues, and international organisations for the purpose of harmonising the legislations and unifying requirements in the sphere of Good Manufacturing Practices. In particular, work is under way and working meetings are held with EDQM and EMA, the regional office of the ISPE for countries of the EAEU and the CIS, the status of a WHO Educational Centre has been obtained for GMP and GDP inspectors, as well as that of a preliminary PIC/S applicant.

INTERNATIONAL COOPERATION

2018 was marked by broader international co-operation and development

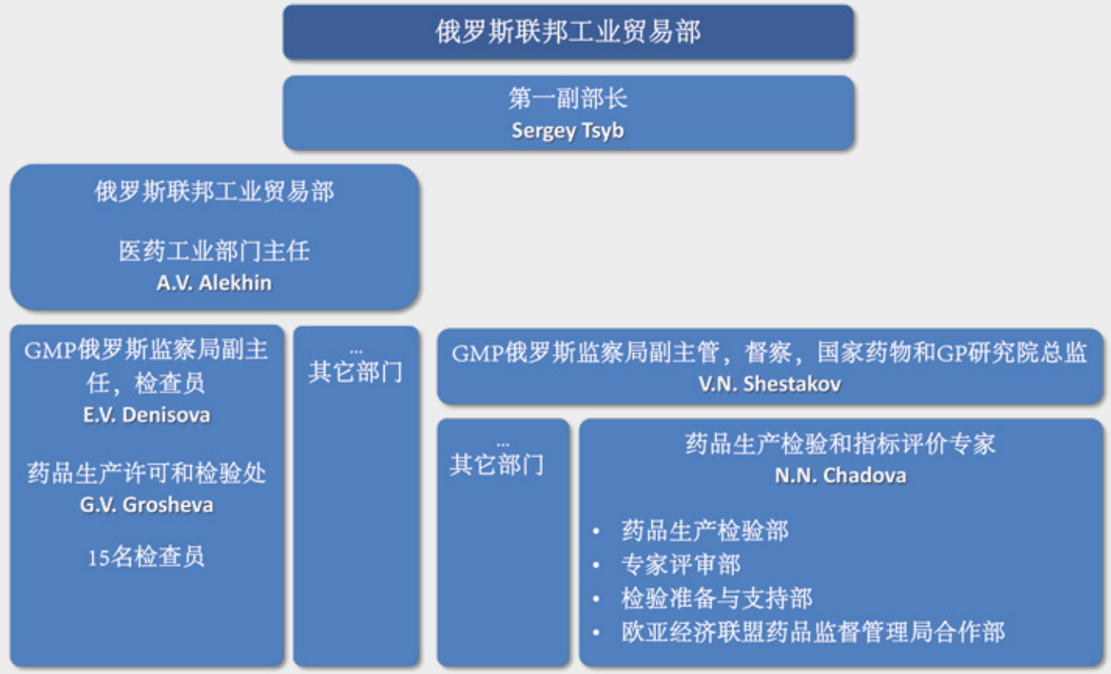
- 颁发生产许可证的程序不系统，不清晰。例如，授权人使用相同的格式和规定办理药品商业系列标志和已有标志药品商用系列的标志许可。授权人未在批量生产许可证中记录系列相对应的规格编号。在办理批量生产许可证期间，授权人并未考虑药品包装上使用消费标志的正确性。从仓库发出药品时仓库管理员未记录药品系列状态检查的情况；
- 确定药品杂质的方法与俄罗斯联邦规范文件不符：
  - 分析参数“微生物纯度”的过程中未检查第二位微生物学家统计的菌落数的准确性；
  - 为控制药品“红外光谱法真实性”参数，检查样品与标准样品光谱间未建立对应的
    定量标准；
  - 药品包装标识有相互矛盾的信息：“用于生产无菌和有菌药剂”；
- 未提出关键工序（填充铝容器）A类清洁工作区未连续监测颗粒的理由。在填充开始和结束时监测气溶胶颗粒的浓度。未提出A类单向气流释放区在填充状态时未监测气溶胶颗粒浓度的理由。

值得一提的是，国家药物和GP研究院在对外国制药企业进行GMP检查的同时，还与外国同行和国际组织建立了合作关系，协调统一药品生产质量管理规范领域的法规和要求。与EDQM和EMA，EAEU和独联体国家的ISPE区域办事处举行工作会议，并取得世界卫生组织GMP和GDP监察教育中心地位及PIC/S初步申请人的资格。

国际合作

2018年着力扩大国际合作，推动与外国同行的合作，签署了多个合作协议。例如，基于与COFEPRIS（墨西哥）和CDSCO（印度）代表b2b会议结果，确立了合作重点。

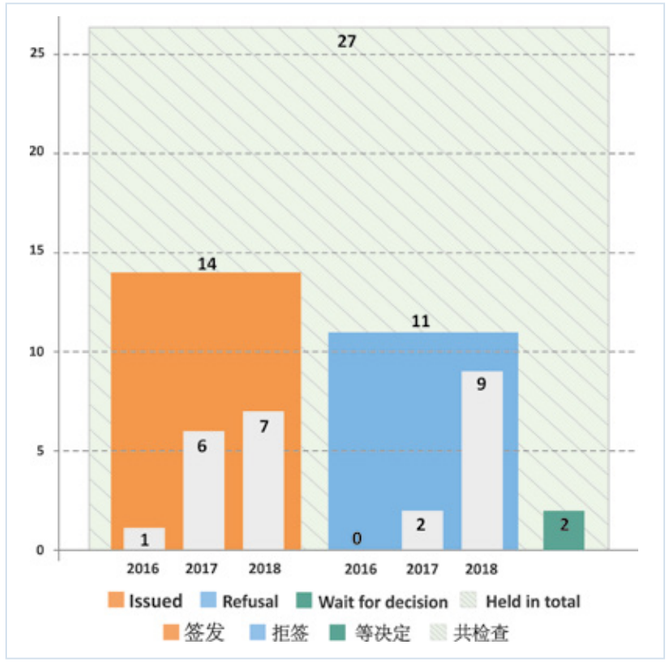
与MHRA（Medicines and Healthcare products Regulatory Agency）举行工作会议，确定合作方向，并于2019年1月29日签署合作备忘录，共同举办培训活动，抵制不合格药品，长期共享信息。在俄罗斯-意大利药品和医药分组第一次会议上探讨了监管机构合作的前景，“国家药物和GMP（生产质量管理



GMP药品监督机构

GMP INSPECTIONS HELD BY RUSSIAN INSPECTORATE IN CHINA

俄罗斯监察机构在中国进行的GMP检查



Data of the Department of Economics and analysis of pharmaceutical and medical industry of FSI SID & GP

联邦预算机构“国家药物和GP研究院”制药和医疗行业经济与分析部数据

The Chinese market is represented on the territory of the Russian Federation by medicines and dietary supplements. According to the results of 2018, it amounted to 1.4 million packages, which is 6.4% less than the volumes in 2017. In value terms, the market fell by 2.9% to RUB 0.9 billion. It is obvious that within the framework of the implementation of state programs on import substitution and support of domestic manufacturers, the presence of Chinese medicines and dietary Supplements in the Russian pharmaceutical market is gradually decreasing. (In 2017, the volume of the market of medicines and dietary supplements from China decreased compared to 2016 by 20% in packages and amounted to 1.5 million units. and by 9.1% in rubles, amounting to 0.9 billion rubles).

If we consider only the market of medicines from China, in 2018 it amounted to 0.7 million units by 0.5 billion rubles, which is less than the volume of the previous year by 29.3% and 13.9%, respectively. In 2017, the volume of the market of medicines amounted to 0.9 million units 0.6 billion RUB, compared to 2016 is less than 16.6%, 6.4% respectively. In general, the share of Chinese medicines in total sales of medicines in the Russian market decreased both in physical and in value terms and amounted to 0.01% (0.02% – 2016-2017) in packages and 0.04% (0.05% – 2016-2017) in rubles.

Generics are mainly supplied to the Russian pharmaceutical market from China. Thus, in 2016 -2018, 29 INNs (30 tons) of Chinese medicines were sold in Russia. 2 INNs of them are original drugs, the volume of which at the end of 2018 was 21 thousand packs by 48.3 million rubles, which is more by 16.6% and 2 times, respectively, when compared with the same period last year. Sales of generic Chinese production (16 INNs) in 2018 declined by 2017, by 13.4% million packs and amounted to 0.4 million packs. At the same time, in value terms, there was an increase of 2.1% – 0.2 billion rubles.

The volume of imported pharmaceutical substances in 2018 amounted to 8.0 million kg, which is 12.4% less than in 2017. But in value terms, the volume increased by 11.5% and amounted to 0.3 billion USD. In 2017, the volume amounted to 9.1 million kg by 0.2 billion USD, which is more than in 2016 by 3.8% and 16.2%, respectively.

The share of imports of Chinese pharmaceutical substances in total imports of substances to Russia in 2016 was 70% in packages and 30% in value terms, in 2018 – 60% in packages and 20% in value terms.

Leaders in imports of INNs are lisinopril, Deoxycholic acid, Doxycycline.

453 INNs in total were imported in the period under review.

of mutual relations with foreign colleagues, sometimes resulting in co-operation agreements being signed. For instance, B2B meetings with representatives of COFEPRIS (Mexico) and CDSCO (India) determined the collaboration targets.

Working meetings were held with MHRA (Medicines and Healthcare products Regulatory Agency), where lines of cooperation were determined, resulting in the signing on 29 January 2019 of a memorandum of cooperation. This provides training events to be held and assistance provided in combating substandard medicines, as well as regular exchange of information. The prospects for collaboration between regulators were discussed at the first meeting of the Russian-Italian subgroup of pharmaceuticals and medicine as part of the discussion between representatives of the FDA, MHRA and SID & GP on Appendix 1 to the European GMP rules. Moreover, this meeting was followed by launch of educational projects for the Russian inspectorate by Fedegari, the leading Italian manufacturer of equipment for the pharma industry.

The first visit to Japanese colleagues was made by representatives of the Russian inspectorate: as part of the professional collaboration on GMP compliance inspections, meetings were organised with the PMDA (Pharmaceuticals and

俄罗斯联邦境内出售中国药品和膳食补充剂。截止2018年底合计达到140万包，比2017年减少6.4%。按价值计市场占比下降2.9%，约9亿卢布。显而易见，受国家进口替代和扶持国内生产企业计划的影响，中国药品和膳食补充剂在俄罗斯医药市场呈逐渐减少趋势（2017年中国药品和膳食补充剂市场销量以包装计较2016年减少20%，为150万包，以卢布计减少9.1%，约为9亿卢布）。如果仅看中国药品的市场，2018年为70万包，5亿卢布，较上一年分别减少了（以包装计）29.3%和（以卢布计）13.9%。2017年药品市场量达到90万包，6亿卢布。比2016年分别减少（以包装计）16.6%和（以卢布计）6.4%。整体来讲，中国药品在俄罗斯药品市场销售总额中的份额（以包装计和以卢布计）都有所下降，以包装计为0.01%（2016年-2017年为0.02%），以卢布计为0.04%（2016年-2017年为0.05%）。中国主要向俄罗斯医药市场出口仿制药。2016-2018年俄罗斯共售出29种INN（国际非专利药品名称）（30种商品名）中国药品。2种INN（国际非专利药品名称）为原研药，2018年其销售数量为2.1万包，4830万卢布，较去年同期相比分别增长16.6%（以包装计），增加了1倍（以卢布计）。

2018年中国生产的仿制药（16种INN（国际非专利药品名称））的销量比2017年减少13.4%，为40万包。同期以价值计增长了2.1%为2亿卢布。2018年进口药品数量达800万公斤，比2017年减少12.4%。同期以价值计总量增长11.5%，达3亿美元。2017年进口总量为910万公斤，2亿美元，分别比2016年增长3.8%（以包装计）和16.2%（以价值计）。

2016年中国向俄罗斯出口药品占俄罗斯进口总量：以包装计为70%，以价值计为30%。2018年中国向俄罗斯出口药品占俄罗斯进口总量：以包装计为60%，以价值计为20%。

进口药品主要INN（国际非专利药品名称）为：赖诺普利，脱氧胆酸，强力霉素。

调查期间共进口453种INN（国际非专利药品名称）。

规范）研究院”参会代表与FDA，MHRA共同讨论了GMP欧洲标准附件1的修订问题。此次会后，意大利制药行业领头的设备制造商Fedegari公司开始着手俄罗斯监察机构的教育项目。

为落实行业间GMP符合性检查的合作，俄罗斯监察机构代表首次访问日本，与PMDA（日本药品医疗器械局）及制药公司代表—日本药品制造商协会成员进行会谈。

还与多个生产质量管理规范监察部门或专业机构签署了合作协议，包括保加利亚监察机构（Bulgarian Drug Agency – 保加利亚卫生部药品管理局）。

联邦预算机构“国家药物和GP研究院”院长弗拉迪斯拉夫·谢斯塔科夫称：“与外国同行建立有效的沟通渠道是协调GMP标准和要求，统一监察方法的方法之一。监管机构对产品的生产要求对于那些不仅在一个国家销售产品的制造商来说非常重要，当然，各国的检查机制和条件不同，不可能完全复制另一个国家的系统，因此交流经验，讨论现有区域的发展和合作是非常必要可行的工作方式。”

去年我们就EAEU和欧盟区域医药市场的问题和发展趋势举行了会议，并展开积极的工作。2018年4月，联邦预算机构“国家药物和GP研究院”院长弗拉迪斯拉夫·谢斯塔科夫在布鲁塞尔参加了欧亚经济委员会工作组、欧亚交流中心、欧洲药品质量管理局(EDQM)、欧洲制药工业协会联合会（EFPIA）和国际药品生产者协会（AIPM）举办的联席会议。会议主题是欧盟和欧亚经济联盟区域医药市场的趋势，先进经验及存在的问题。

“国家药物和GP研究院”继续与EDQM展开合作，并于2019年初在斯特拉斯堡EDQM总部举行了会议，会上除强调遵守国际GMP和GLP标准外，两个监管机构还详细讨论了俄罗斯药品生产商取得合格证书（CEP）的问题。

开始与FIMEA（芬兰社会保障和卫生部下属的

Medical Devices Agency of Japan) and representatives of pharma companies belonging to the Japan Pharmaceuticals Manufacturers Association (JPMA).

The countries with inspectors or relevant agencies handling matters of Good Manufacturing Practices include Bulgaria (Bulgarian Drug Agency of the Ministry of Health of the Republic of Bulgaria).

"Establishment of efficient communications channels with foreign colleagues is a way to harmonise the GMP requirements and standards and unify approaches for conducting inspections. This is important for medicine manufacturers with an active interest in the regulators' opinions regarding the requirements applied to manufacture of output distributed beyond a single country", according to FSI SID & GP's Director **Vladislav Shestakov**. *"The mechanisms and conditions for checks do, of course, differ. The system which is used in another country cannot simply be copied; exchange of experience, discussion of existing zones of development and collaboration are needed."*

Last year saw active work and meetings on problems and trends in the development of the regional pharma markets of the EAEU and the EU. In particular, in April 2018, Vladislav Shestakov, Director of FSI SID & GP, took part in a joint meeting of the working group of the Eurasian Economic Union Commission (EAEC), the Eurasian Communications Centre, the European Directorate for Quality of Medicines (EDQM), the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the Association of International Pharmaceutical Manufacturers (AIPM) in Brussels. At the meeting were discussed the trends, the latest methods and the problems of the regional pharma markets of the European Union and the Eurasian Economic Union.

SID & GP has continued developing co-operation with EDQM and, in early 2019, held more detailed meetings at the EDQM headquarters in Strasbourg. The regulators discussed not only observance of the international GMP and GLP standards, but also the question of Russian manufacturers of pharmaceutical substances obtaining Certificates of Suitability to the monographs of the European Pharmacopoeia (CEP).

With representatives of FIMEA (the Finnish Medicines Agency under the Ministry of Social Security and Health of Finland), work has begun on the possibility of signing a memorandum of co-operation between Finnish and Russian GMP inspectorates.

There has also been collaboration on quality standards, security of regulatory data and best practices in conducting inspections of pharmaceutical manufacturers for compliance with the GMP with regulatory agencies of individual EU countries: FAMHP (Federal Agency for Medicines and Health Products) and AEMPS (Spanish Agency of Medicines and Medical Devices).

The experience of Chinese colleagues from the NMPA (National Medical Products Administration of China) in collaborating with international organisations and associations, such as the WHO, PIC/S, ICH and EMA has also been taken on board. At a meeting in Moscow, Deputy Director General of the Administration for Quality Control of Products and Medicines of Yunnan Province Xing Yawei noted that the given meeting was the first step in establishing professional contacts between representatives of China's NMPA and of the Russian GMP inspectorate.

Experience is being exchanged with colleagues from South-East Asia and SID & GP personnel visited Singapore to discuss proposals for co-operation on joint inspections in order to improve the quality of medicines manufactured in this region and circulating on the Russian market.

The strengthening of mutual trust between the inspectorates of different countries remains relevant to the SID & GP in 2019. Today, cooperation agreements have also been signed with such regulators of the Latin American region as the Center for State Control of Drugs, Equipment and Medical Devices, the National Regulatory Authority of Cuba (CECMED) and the Institute of Public Health of the Republic of Chile, ISP CHILE). In March, an agreement was signed on inspecting pharmaceutical companies for compliance with GMP regulations and helping to fight low-quality, counterfeit drugs with the Spanish Agency for Drugs and Medical Products (AEMPS).

The Russian inspectorate's openness to dialogue and interest in establishing relations of trust with foreign partners responsible for regulating medicine manufacturing, including with respect to compliance by manufacturing sites with the GMP standards, has engendered mutual interest: representatives of FSI SID & GP regularly encourage exchange of experience and tell of the work of the inspectorate in Russia at conferences and roundtables on relevant topics. At the XIII Summit in Spanish Pharmaceutical Inspections, Institute personnel were the only foreign guests. On the ISPE conference in Singapore were discussed topics like joining the PIC/S and mutual recognition of GMP inspections. At the International Conference of Drug Regulatory Authorities (ICDRA) in Dublin, work was performed to strengthen professional collaboration between the Russian GMP inspectorate and the WHO, EMA (European Medicines Agency), PAHO (Pan American Health Organisation), ICMRA (International Coalition of Medicines Regulatory Authorities), regulators from the European Union, Africa, Asia and America. In Riyadh, at the annual conference of the SFDA (Saudi Food and Drug Authority), Vladislav Shestakov was the honoured speaker at the opening of the conference and later, as part of the event, representatives of FSI SID & GP familiarised themselves with their colleagues' experience of the procedure for joining the PIC/S.

At the end of 2018, experts from State Institute of Drugs and Good Practices under Minpromtorg of Russia took part in the Second International Week in Regulatory Science and Good Regulatory Practices in Mexico, organised by the Ministry of Health of Mexico and the Federal Commission for the Protection against Sanitary Risk (COFEPRIS) with the participation of the Centre of Excellence in regulatory science and effective regulatory practices (CoE) and in cooperation with the National College of Biological Pharmaceutical Chemists of Mexico AC (CNQFBM). Here the SID & GP experts acquainted participants on the Latin American market with the specifics of how Russian and EAEU inspectors work and with the consequences of transferring to a unified medicine market within the EAEU.

Let us note that, in turn, SID & GP also invites colleagues to events held with the Institute's support: the GxP summit and the GMP conference. In 2018, the latter was attended by colleagues from Spain, Japan, Cuba, Kazakhstan, the USA, Croatia, Bulgaria, Mexico and the UK. ■

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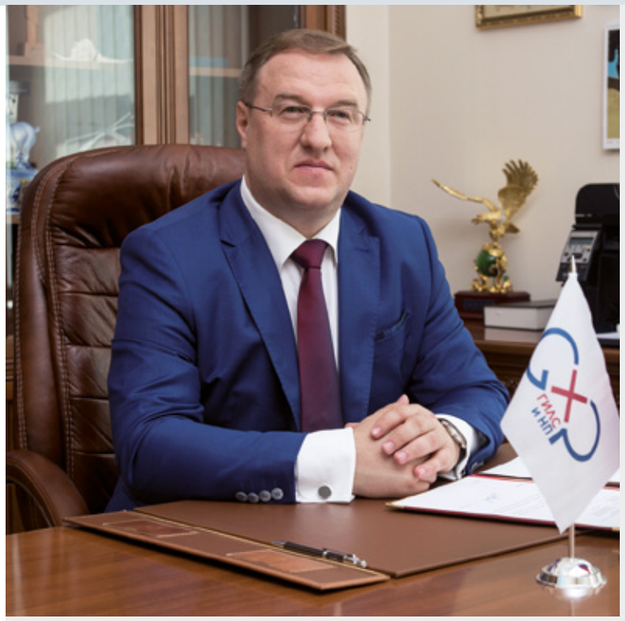

Vladislav Shestakov
the director of FSI SID & GP

弗拉迪斯拉夫•谢斯塔科夫称
国家药物和GP研究院总监

芬兰药品管理局）代表讨论芬兰和俄罗斯GMP监察机构之间签署合作备忘录的工作。

与欧盟各成员国监察机构，如FAMHP（比利时药品与保健食品联邦局）和AEMPS（西班牙药品监督局）就制药企业进行GMP符合性监察时，质量标准、保护监管数据及维护最佳作业规范等问题的合作。

与NMPA（国家药品监督管理局）中国同行分享与世界卫生组织，PIC/S，ICH，EMA等国际组织和协会的工作经验。云南省食品药品监督管理局副局长邢亚伟在莫斯科会议时指出，此次会面是中国NMPA代表与俄罗斯GMP代表建立业务联系的第一步。

“国家药物和GP研究院”的工作人员访问新加坡，与东南亚同行交流经验，双方讨论了联合监察领域的合作建议，以提高该地区生产药品的质量，这些药品将在俄罗斯市场销售。

加强与不同国家监察机构之间的相互信任仍然是“国家药物和GP研究院”2019年的首要任务。目前已与古巴国家监管局（CECMED）药品、设备及医疗器械国家管理中心、智利共和国公共卫生研究院（Institute of Public Health of the Republic of Chile, ISP CHILE）等拉丁美洲地区监察机构签署了合作协议。3月份，与西班牙药品监督局（AEMPS）签署协议，旨在检查制药企业与GMP标准的符合性，携手打击低劣质假冒药品。

俄罗斯监察机构对对话合作持开放态度，对技术平台符合GMP标准、及与国外药品生产监管机构建立信任的合作伙伴关系有着浓厚兴趣，这是大家共同的利益：“国家药物和GP研究院”的代表们经常被邀请参加各类会议和专题圆桌会议，分享并讨论俄罗斯监察机构的工作情况。在西班牙举行的第十三届药品监察峰会上，研究院的工作人员是唯一的外国嘉宾。新加坡ISPE会议上讨论了加入PIC/S及与GMP监察结果相互承认的问题。在都柏林举行的药物流通领域监管机构国际会议（ICDRA）上讨论了加强俄罗斯GMP监察机构与世界卫生组织、EMA（欧洲医疗管理处）、PAHO（泛美卫生组织）、ICMRA（药品监管国际联盟）、欧盟、非洲、亚洲和美洲监察机构的互动和合作。在利雅得SFDA（沙特阿拉伯食品药品管理总局）年会上，弗拉迪斯拉夫·谢斯塔科夫作为会议开幕的名誉发言人，联邦预算机构“国家药物和GP研究院”的代表们在活动中学习了同行们加入PIC/S的经验。

2018年底，俄罗斯工贸部下属“国家药物和GP研究院”的专家参加了由墨西哥卫生部、墨西哥联邦抗癌保健委员会（COFEPRIS）组织的在墨西哥举办的第二届国际监管科学和生产质量管理实践周，监管科学和生产质量管理领域先进经验中心（CoE）与墨西哥国家化学家、药剂师和生物学家学院A.C.（CNQFBM）联合出席会议。会上“国家药物和GP研究院”的专家向拉丁美洲的同行们介绍了俄罗斯和EAEU监察机构的工作特点，以及向EAEU药物流通单一市场过渡的成果。

联邦预算机构“国家药物和GP研究院”也多次邀请同行们参加研究院举办的多项活动：GxP峰会，GMP会议。2018年西班牙、日本、古巴、哈萨克斯坦、美国、克罗地亚、保加利亚、墨西哥及英国的同行们都曾到访研究院。 ■

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