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Localization of foreign medicinal products manufacturing in Russia

Foreign pharmaceutical companies tend to increasingly involve localization of manufacturing plans in their scenarios for business development in Russia. Arguments for this option became clear years ago, when the national program Pharma-2020 was created and announced by the Russian president. In line with the goals of this program the (majority of imported medicines should be substituted) with local products by 2020. To achieve the goal set by the president, different measures were determined for gradual implementation (support of local medicinal products development, amendments to legislation in registration, pricing and circulation of pharmaceuticals and so on). As a result of Pharma-2020's progress over the years, local medicinal products manufacturers have been able to secure certain benefits, such as easier access to state programs and auctions organized for healthcare system supply. This is how localization of pharmaceutical manufacturing started its development approximately 10 years ago: From secondary packaging to full cycle, as the definition of localization has been changing over the years. Now, in 2016, many foreign companies possess valid experience, having either built their own plants in Russia or engaged in cooperation with domestic producers. There are many stories of successful localization; however, there are certain regulatory/technological challenges, which should be taken into account, when a company is at the point of considering localization in Russia. A company's decision to either opt for any kind of localization or to continue import should be made on the basis of thorough consideration of internal and external factors.

Biography

Jelena Gankina has extensive experience in the pharmaceutical industry. Having graduated as a Pharmacist in Moscow, she started her professional career as a scientist in R&D (Scientific Research Institute of Pharmacology, Moscow) and obtained her PhD in Molecular Pharmacology. She has presented her scientific results during professional events and in scientific press in Russia and abroad. Since 1994, she has been working in the regulatory field, where she has gathered experience in generic (LEK Pharmaceuticals, PLIVA Hrvatska d. o. o., Polpharma), innovative (Bristol-Myers Squibb) and Russian domestic companies (Akrikhin) in Russia, CIS and the EU in different areas: registration (APIs, medicinal products, medical devices, para-pharmaceuticals), quality, pharmacovigilance and clinical operations.

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