



International Projects

Belarus: Enabling official medicine laboratories to meet internationally recognized standards of quality control

The starting-point

In February 2019 BSI completed a 36-month EU-funded (€1.4m) project to strengthen Belarus's pharmaceutical inspection system and upgrade the capacity of four official medicine quality-control laboratories.

The project was designed to support the Belarus government's efforts to advance the national healthcare system and public welfare of its 9.5m citizens, by improving the quality, effectiveness and safety of medicines and pharmaceuticals. The project also sought to increase international recognition of Belarus and to foster more international collaboration, with the aim of stimulating a higher volume of imports and exports of medicines between Belarus and EU countries.

Wider recognition

Volodymyr Yakubov, Business Development Director, International Projects, who was the Project Director and the counterpart of the Belarusian Deputy Minister of Health explains "The project's key aim was to ensure compliance between Belarus's national medicine quality control system and international standards – more specifically, ISO/IEC 17025. This would lead to recognition by the European Directorate for the Quality of Medicines [EDQM], which has official oversight of quality control of medicines. The international projects team at BSI helped to prepare four official testing laboratories for integration with GEON, the network of official medicines control laboratories in Europe under EDQM, so that their quality control would be more widely recognized by regulatory authorities beyond Belarus."



BSI worked closely with official laboratory managers and staff of the Ministry of Health in Belarus, advising them on investing in facilities, hardware and software that would help them to meet internationally recognized standards of quality control.

As well as consulting on aligning test methods with European and international standards, we provided training and made arrangements for Belarusian staff to attend important networking events.

In addition, BSI trained 12 control laboratories and other stakeholders in compliance with major changes brought by the new ISO/IEC 17025 standard.

Increasing competence

BSI advised on integrating the Belarusian regulatory system of distributing medicines into the common European system.

This included the Belarus Ministry of Health's Pharmaceutical Inspectorate joining the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S). This is a cooperative arrangement between regulatory authorities in support of Good Manufacturing Practice (GMP), which is a standard for making medicinal products.

"We achieved this by assessing the Inspectorate, identifying gaps and recommending how to bridge them to enable application for PIC/S membership. We also helped with preparing application documents," Volodymyr explains. "And to increase the competence of Belarusian GMP inspectors, we organized study tours. Crucially, we also supported the development and implementation of the Inspectorate's new quality management system."

BSI provided further support during the project, where we identified additional needs. This included, for example, more in-house training for Inspectorate staff and more detailed instructions on legislative changes.



Results

We successfully achieved the four main objectives of the project:

- Raised the competences of inspectors in line with PIC/S requirements.
- Established and implemented Pharmaceutical Inspection's QMS in line with PIC/S requirements.
- Developed a draft proposal for legislative changes based on MEMO1 & MEMO2, to facilitate the gradual aligning of national legislation with PIC/S (EU) requirements.
- Established and updated the communication system with PIC/S, working with four lists of relevant contacts.

Further achievements

- All four of the official testing laboratories we worked with achieved international recognition for accreditation, through international recognition of the Belarusian State Centre for Accreditation in 2018.
- In addition, two of the control laboratories and other stakeholder laboratories we trained went on to apply for GEON network membership.

Vyacheslav Shilo, Deputy Minister of Health for the Republic of Belarus, commented that: "As a result of the project, Belarus now has a significantly stronger system for controlling its biological medicines, while our medicines inspection system is aligned with PIC/S. Both are essential for safe and effective use of present-day medicines."

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Sergey Marchanko, Director of the Belarus Ministry of Health's Center for Examinations and Tests, added: “The Ministry's links to European and international medicine control networks have been strengthened significantly.

And our knowledge of international standards in medicine and pharmaceutical control has increased considerably, strengthening the platform for international collaboration. We're very grateful for the work BSI did.”

Why BSI?

BSI is a global thought leader championing business excellence, innovation and best practice – whether by developing agile standards or offering quality management advisory services. BSI's International Projects team works with developing countries and transition economies to improve their quality infrastructure, trade and investment flows and market access, with the goal of boosting economic growth and prosperity.

Our aim

BSI's International Projects (IP) division was formed with a specific mission – to help governments improve their trade policy-making processes, unlock prosperity and boost private sector competitiveness.

For over 20 years, we've been providing regular best-in-class expertise on trade promotion, regulatory compliance and export readiness on a range of aid-funded programmes in more than 100 countries.

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