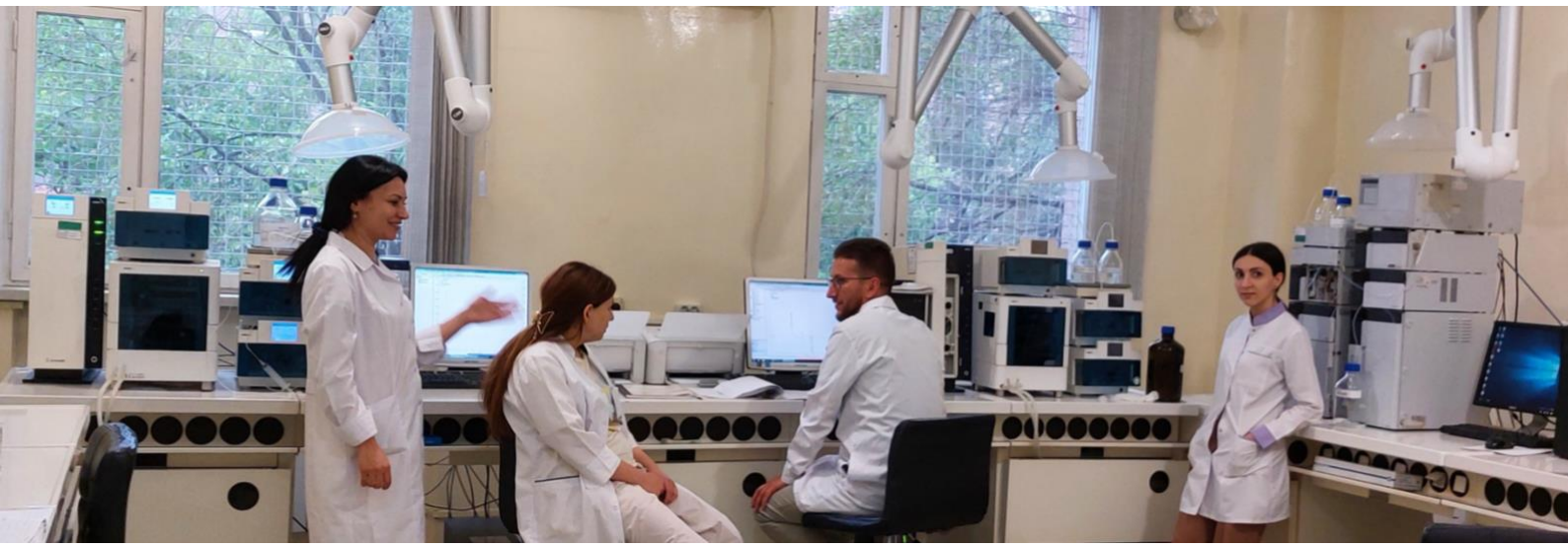
Calidena Process in the Project “Quality Standards for Increased Trade in the Eastern Partnership Countries”

Value Chain: Pharmaceutical Sector (Armenia)



Pharmacists in the Laboratory of Medicines Quality Control. Photo: Dr. Christina Foerg-Wimmer

Context and rationale for the selection of the pharmaceuticals value chain in Armenia

The pharmaceutical sector in Armenia can be characterized as steadily developing. According to government statistics, the export volume roughly doubled in the last 10 years while there was a 179% increase in pharma manufacturing between 2011 and 2021 (cf.: The Government will create new development opportunities for the pharmaceutical industry).

The selection of the pharmaceutical value chain for the Calidena process is aligned with its recent identification as a priority sector for Armenia. In May 2023 the government adopted a 5-year strategic plan for its further development (Ibid.). According to it, the diversification of export markets and an increase in production capacities and volumes are among its strategic objectives. To support their accomplishment, the strategy is underpinned by a 2.5 billion AMD package allocated for various actions, among which are efforts to improve the medicines registration process, establishment of a Biotech Center, bioequivalence study co-financing for manufacturers, promotion and awareness raising on the quality and availability of domestically produced pharmaceutical products, and various training and educational programmes.

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Identified gaps

A kickoff workshop was organized in Yerevan on 31 May -2 June 2023 and attended by representatives of the private sector (value chain representatives) and QI institutions. The workshop participants identified the following main gaps in QI as they relate to the pharmaceutical VC:

Participants at the kick-off workshop in Yerevan, Armenia

- QMS implementation / Quality documentation;
- Weak capacities in the area of biological products, sterile products; Bioequivalence Testing; Good Practices (in particular GCP and GcLP);
- Lack of proficiency testing (PT) provider (ISO 17043 accredited);
- A shortage of qualified staff in the areas of microbiology, chemistry, pharmacy, and engineering;
- Weak supplier qualification (Active Pharmaceutical Ingredients and excipients) and availability of respective quality documentation (due to low volumes that Armenian manufacturers procure);
- No toxicology lab to perform tests.

Calidena activities

A draft action plan with activities to address some of the identified gaps was developed as a result of the kick-off workshop. The main activities include:

- Support to the regulatory authority in QMS implementation and review of quality documentation;
- Quality systems training for quality control laboratories (ISO 17025 training series);
- GMP tailor-made training modules for producers and regulators on topics of interest such as data integrity, cleaning validation, and quality risk management;
- GMP mock audits at Armenian producers to help assess their compliance with the implementation of international requirements;
- Support for quality control laboratories to participate in international proficiency testing schemes organized by an ISO 17043 accredited PT provider.

Expected outcomes

The primary outcomes expected from the Calidena process in Armenia include:

- Greater awareness of the importance of QI for the pharmaceutical sector;
- Improved laboratory quality systems for private and public actors in the pharmaceutical sector;
- Improvements in the implementation of international Good Practices (in particular GMP) by regulators and pharmaceutical manufacturers;
- Improved implementation of QMS and quality documentation and advances toward WHO Global Benchmarking Tool GBT assessment for the Armenian regulatory authority.

Leading Organisations

Host: Scientific Centre Drug and Medical Technology Expertise

Co-host: Association of Manufacturers of Pharmaceuticals (ArPharMa)

Links to Green Transformation

The pharmaceutical sector contributes to CO_2 emissions and in many countries reduces water quality. For example, release into the environment of wastewater, containing active pharmaceutical ingredients (APIs), could lead to knock-on effects such as antimicrobial resistance, further posing a serious threat to human and animal health. However, opportunities exist for a transition to a green pharmaceutical sector. They include steps to integrate environmental goals into good manufacturing practices (e.g., implement advanced wastewater treatment systems) and consciously involve trade associations and consumers. In the countries of the Eastern Partnership, efforts can be made to systematically introduce environmental management systems in accordance with IS0 14001 in the pharmaceutical sector and to convert the energy supply to renewable sources in order to contribute to the green transformation of that sector.

Contacts

Stefan Wallerath, PTB Project Coordinator: stefan.wallerath@ptb.de

Dr. Christina Foerg-Wimmer, Facilitator: c.foerg@gmx.de

Lusine Safaryan, Facilitator: l.safaryan@yahoo.com

What is Calidena?

Calidena is a participatory approach developed and applied by the Physikalisch-Technische Bundesanstalt (PTB) to stimulate quality in value chains. Its toolset can be used in cooperation projects that aim to strengthen the user orientation of the Quality Infrastructure (QI) of partner countries and in value chain initiatives that aim at closing quality-related gaps. For more information on the Calidena process, visit the Calidena website.

Calidena in the Eastern Partnership (EaP) countries

In 2022, a Calidena process was launched in each of the five partner counties participating in the PTB project "Quality Standards for Increased Trade in the Eastern Partnership Countries." A different value chain was selected for each EaP country depending on local circumstances and needs to be identified based on a "QI market potential rapid assessment" study conducted in the framework of the EaP project.