

QUALITY AND INFORMATION SECURITY POLICY

The executive management of the **BULGARIAN DRUG AGENCY** (BDA) undertakes the responsibility to constantly improve its Integrated Quality Management and Information Security System, thereby insuring the accomplishment of the mission of the Agency related to provision of high-quality services in the regulation of medicinal products, medical devices and blood transfusion in the territory of the Republic of Bulgaria, through effective implementation of the available resources and through collaboration with its partners, all the while preserving the confidentiality, integrity and availability of the information related to its customers and partners.

The executive management represented by the Executive Director hereby declares officially its **QUALITY AND INFORMATION SECURITY SYSTEM**, fully convinced that the prosperity and future of the Bulgarian Drug Agency depend on the trust and satisfaction of the public and businesses with its work.

THE QUALITY AND INFORMATION SECURITY POLICY IS DEVOTED TO THE SATISFACTION OF THE NEEDS THAT THE PUBLIC AND THE BUSINESSES HAVE IN RELATION TO RECEIVING HIGH-QUALITY AND SECURE SERVICES IN THE FIELD OF MEDICINAL REGULATION, CONTROL OF MEDICINAL PRODUCTS, ANALYSIS OF MEDICINAL PRODUCTS, CONTROL OF MEDICINAL USE, CONTROL OF MEDICAL DEVICES AND BLOOD TRANSFUSION SERVICES, TO PRESERVING AND IMPROVING THE QUALITY OF THE PROVIDED SERVICES AND TO TRAINING COMPETENT, AMBITIOUS AND COMPETITIVE SPECIALISTS, IMPLEMENTING THE NATIONAL AND INTERNATIONAL STANDARDS IN THIS FIELD.

The executive management undertakes to implement the **QUALITY AND INFORMATION SECURITY POLICY** in the following strategic areas:

- Protection of public health in the territory of the Republic of Bulgaria
- Provision of professional, independent and scientifically justified services for assessment of the quality, safety, and efficacy of medicinal products by implementing the national and EU legislation and standards in the field of medicinal regulation and blood transfusion control;

- Development of best practices for assessment and control of the manufacturing and marketing of medicinal products and medical devices and their use in the territory of the Republic of Bulgaria, and cooperation in the harmonization of the EU regulatory standards and the national legislation of the Republic of Bulgaria;
- Publication of impartial and comprehensible information about the medicines and their use;
- Support of businesses in their scientific studies and innovations related to the manufacturing of medicinal products and medical devices;
- Continuous improvement of the processes, services, and procedures;
- Open and transparent communication with all partners and third parties;
- Promotion of the prosperity, motivation and professional development of all employees and experts working at BDA;
- Continuous improvement of the professional qualification, communication skills and the professional ethics of the employees and experts working at BDA;
- Training and information exchange with EU regulatory bodies, on medicines and blood transfusion control aiming to improve the effectiveness of BDA's work and of the competence and responsibility of all employees and experts in relation to the provision of high-quality and secure services;
- Monitoring and management of the processes carried out at BDA for the optimization and effective management of resources;
- Insuring the confidentiality, integrity and proper access to all physical and electronic information assets of BDA, through planning, selection, integration and maintenance of adequate organizational and technical measures for their protection on the basis of periodic risk analysis and implementation of the relevant standards and contract requirements;
- Review and updating of the measures for information security (IS) protection following an objective and competent system assessment and revaluation of their effectiveness;
- Monitoring of emerging threats for the information assets and implementation of adequate mechanisms and protection controls;

- Provision of adequate training for all BDA employees on IS issues and systematic maintenance of a high level of awareness among the employees in relation to their personal contribution to this maintenance;
- Provision of adequate checks and investigation procedures related to detected or suspected information security breaches in BDA;
- Establishment of requirements for third parties concerning quality and information security;
- Planning and undertaking of adequate actions for insuring the continuity of BDA's operations, through development, maintenance and verification of action plans for emergency situations.

For the effective and efficient work in the strategic areas listed above, a Management Board has been set up at the **BULGARIAN DRUG AGENCY** with clearly defined rights and obligations, duly recorded and communicated throughout the Agency, related to the insurance of the quality and information security in the operations of the Agency.

The quality and information security policy is communicated to all BDA employees and third parties, and is regularly reviewed and updated.

With regard to that, the executive management of BDA will require from all managers and employees from all departments of the Agency to demonstrate in their daily work high level of professionalism, discipline and responsibility, to be familiar with and strictly adhere to the requirements set forth in the documents of the integrated quality and information security system, and to contribute actively to its development.

The executive management of the BULGARIAN DRUG AGENCY hereby guarantees that the integration, maintenance and continuous improvement of the integrated quality management and information security system conforming to the international standards BS EN ISO 9001:2008 and BS ISO/IEC 27001:2006 insures and guarantees the successful accomplishment of the mission and goals of the Agency.

**AS EXECUTIVE DIRECTOR OF THE BULGARIAN DRUG AGENCY, I HEREBY
DECLARE MY PERSONAL PARTICIPATION AND RESPONSIBILITY FOR THE
IMPLEMENTATION OF THE COMMUNICATED QUALITY AND INFORMATION
SECURITY SYSTEM.**

12 December 2013

Executive Director:

(Assoc. Prof. Kiril Nenov, MD, PhD)