

"Current achievements and future perspectives in medical and biomedical research"

SCIENTIFIC PROGRAM November 24, 2015 - Stip

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Macedonian agency of drug and medical devices, Director

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Republic of Macedonia

Step forward of Macedonian agency for medicines and medical devices, establishment and

strategic plan for development

Assoc. Prof. Zorica Arsovska Sarafinovska

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Prof. Biljana GjorgjeskaUniversity Goce Delcev Stip

Republic of Macedonia

Use of disinfectants and antiseptics in the health institution in Republic of Macedonia

Assoc. Prof. Bistra AngelovskaUniversity Goce Delcev Stip

President of Pharmaceutical Chamber of Macedonia. Republic of Macedonia

Code of Ethics for Pharmacists – Pharmaceutical Chamber of Macedonia

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Co-chair: Ass. Prof. Darinka Gjorgieva Ackova

Prof. Neven Zarkovic

Rudjer Boskovic Institute, Croatia

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Goce Delcev Stip Republic of Macedonia

Nicotinamide adenine dinucleotide biosynthesis and consumption in dysfunctional white adipocytes

Prof. Rubin Gulaboski University

Goce Delcev Stip Republic of Macedonia

New insights into the chemistry and functions of Coenzyme Q

Assoc. Prof. Darko Bosnakovski

University Goce Delcev Stip

Republic of Macedonia

Genetically modified systems to study muscular dystrophies

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Prof. Lia Rimondini

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del Flemonte Offentale, Onto dentai materiali.

Prof. Elizabeta Zisovska

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University Goce Delcev Stip Republic of Macedonia The cytokinesis-blocked micronucleus assay: Good choice for detection and evaluation of genotoxity in human cells

Prof. Lence Miloseva University Goce Delcev Stip

Republic of Macedonia

Multiple predictive model for clinical and subclinical depression in adolescence

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Poster presentation

SESSION 4

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Prof. Adriano Duatti

University of Ferrara, Ferrara, Italy

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Accreditation of the Laboratory of Radiopharmacy – requested requirements or need of challenge

<u>Apostolova Paulina</u>, Delipetreva Katarina, Smilkov Katarina, Gjorgieva Ackova Darinka, Sterjova Marija, Janevik Ivanovska Emilija

Faculty of Medical Sciences, Goce Delcev University - Štip, Republic of Macedonia

Abstract

Laboratory of Radiopharmacy is a part the Faculty of Medical Sciences, Department of Pharmacy in the Goce Delcev University in Stip and was granted by the Government of Republic of Macedonia as a part of the project for improvement of the laboratories in the country. The main field in which the Laboratory of Radiopharmacy has focused after the establishment in 2011 is to introduce a new molecules as a potential radiofarmaceuticals, labeling with radioactive and not radioactive isotopes, defining their structure and especially chemical and radiochemical identification of potential impurities. In the same timecarefully implementing radiation safety program for controlling laboratory environment. The Laboratory is deeply involved in the educational program in all cycles of academic degrees following a few international and local research projects. The laboratory staff is educated and trained in the national and international programs in the field of Radiopharmacy and Radiochemistry, as well included in the training coursesdedicated to the implementation the standards and quality assurance providing additional effectivenessin the work.

All that activities including the requested requirements from the Ministry of Education and Sciences were enough strong reason to start the process of accreditation of the Laboratory of Radiopharmacy and to focus on that all our activities in the next period. The aim of our study is to introduce, to validate and to accreditate the procedures for quality control of radiopharmaceuticals for clinical and research purpose according regulatory standards. At that stage we have in progress the process of Accreditation with implementation of Standard MKC EN ISO/IEC 17025 - General requirements for the competence of testing and calibration laboratories. International Standard ISO/IEC 17025 specifies the general requirements for the competence of testing and calibration laboratories if they wish to demonstrate that they operate a quality system, are technically competent and are able to generate technically and scientifically valid results. The compliance these requirements enables the acceptance of testing and calibration results also between laboratories and countries.

Our Laboratory of Radiopharmacy currently is in the phase of implementation of the General requirements for the competence of testing and calibration laboratories of the Standard MKC EN ISO/IEC 17025. This standard holds five clauses, two annexes, and one bibliography section, out of which, the most important are Clause 4, that specifies the management requirements, and Clause 5, that specifies the requirements for technical competence for the type of tests the laboratory undertakes.

In the same time we are preparing the first method that will be applied to as ISO recognized. The process of accreditation is a longprocess of implementation of the standards and require continuous engagement of all staff and persons included in whole activities of the Laboratory.

After the establishment in the current location and have sufficient and competent staff that was necessary required we started with the initiative of accreditation. We are expecting that the implementation of ISO/IEC 17025 as part of laboratory quality initiatives will provide both, recognized laboratory in a medical and clinical application including professional benefits, and have important rule in the research and educational field, have an access to more agreements for testingand improvednational and global reputation. In the same time constantly to expand data quality and laboratory effectiveness. This will also permit to reach the agreement of thetrends of implementation good laboratory under umbrella of international standards like ISO 17025 in radiopharmaceutical and radiochemical laboratoriesexplained as a need of expandingof "good scientific practice".

The accreditation process of the laboratories according Standard MKC EN ISO/IEC 17025 is also applied for Radiopharmacy and Radiochemistry. We are expecting that our Laboratory of Radiopharmacy will finish the first step of accreditation until June 2016 and be able to continue on the same road of good recognized work following already accepted standards and to have full access and confidentiality to the national and international research and clinical activities.

Keywords

Accreditation, Laboratory of Radiopharmacy, MKC EN ISO/IEC 17025.