# Reflection on 5th RoEQALM Symposium

## Adaptation to EC standards is advisable

Contributed by Manole Cojocaru MD, PhD
RoEQALM President

*How can we improve and guarantee the medical laboratory services? What are the differences between Romania and other countries from EU? What is the best way for learning from the European experience? How should quality assurance programmes be organized? How should quality assurance be undertaken? What should quality assurance programmes accomplish?*

The 5th edition of the successful series of Quality Assurance in Laboratory Medicine Symposia was organized by the Romanian Society for External Quality Assurance in Laboratory Medicine (RoEQALM) in Sibiu (European Cultural Capital in 2007) between 11-13 May 2007.

RoEQALM is a non profit foundation owned by Romanian Society of Laboratory Medicine and National Commission of Laboratory Medicine of Minstry of Health. RoEQALM is notified by Minstry of Health for organizing of external quality assessment schemes (EQAS). RoEQALM grants special importance to organization of programmes for education and specialization in the field of quality control. RoEQALM aims to draw up theoretical materials necessary for ensuring quality in the field of medical laboratory. Experts of the working groups were trained in the INSTAND-WHO Training Course (IWTC) on Quality Management and Quality Assurance in Medical Laboratories. RoEQALM is a member of European Committee for External Quality assurance Programmes in Laboratory Medicine (EQALM). RoEQALM collaborates with Institute for Standardization and Documentation in Medical Laboratories (INSTAND e.v)

This meeting was organized under auspices IFCC, with participation of INSTAND-WHO Collaborating Center for Quality Assurance and Standardization in Laboratory Medicine, Germany.

An exciting programme of plenary lectures and workshops has been arranged on main topic „European regulations and standardization on internal and external quality control in laboratory medicine" The purpose of this symposium was to explain the principles and significance of the EQA schemes. From abroad presented lecture were following: Hans Reinauer, Duesseldorf, Germany "Acceptability Criteria in EQAS-accuracy and precision", Patricia Kaiser, Berlin, Germany "HbA1c and diabetes monitoring-the reference measurement procedure and standardization", Hans-Peter Grunert, Berlin, Germany "Internal quality control for virus diagnostics based on the INSTAND external quality assessment schemes", Sebastian Suerbaum, Hannover, Germany " Internal quality control in bacteriology", Klaus Janitschke, Berlin, Germany "Internal quality control in parazitology", Claus Heuck, Duesseldorf, Germany "Performance targets in laboratory medicine", Heinz Zeichhardt, Berlin, Germany "Waived tests for virus diagnostics", Folker Spitzenberger, Bonn, Germany "The role of EQAS in the European vigilence system for in vitro diagnostic devices", Michael Spannagl, Munchen, Germany, "Recommendations for testing in haemostasis and blood transfusion", Alexander Halliassos from Dade Behring with "External quality control in internet era".

There was also the opportunity for presenting the RoEQALM recommendations and EQAS organized, and for Romanian colleagues to display their findings through plenary presentations.

"RoEQALM Recommendations concerning the Internal Quality Control in Bacteriology" was presented by Olga Mihaela Dorobat; "RoEQALM Recommendations concerning the Internal Quality Control in Parasitology" was presented by Suzana Cilievici; "RoEQALM Recommendations concerning the internal Quality Control in Clinical Chemistry" was presented by Crezante Lazar; "RoEQALM Recommendations on Internal Quality Control for Immunological Quantitative Test"s was presented by Manole Cojocaru.

Crezante Lazar presented "Results of the EQA schemes organized by RoEQALM in Clinical Chemistry in 2006-2007 years".

Ioana Culea presented "European Regulation on Medical Education and Training in Blood Transfusion"; Maria Enea presented "Quality Assurance Using RANDOX 24/7 internet QC"; Iurian Sabina presented "The Evaluation of Standards Utility for Antimicrobial Susceptibility Tests in Clinical Laboratory of Microbiology"; Alina Dobrota presented "Quality Requirements for Ensuring Blood Safety in Hospitals"; Mariana Patiu presented "The Blood Smear in Automated Analysers Era"; Mihai Aldica presented "Education, Training and Development of Professionals in Laboratory Medicine"; Ioana Culea presented "Presentation of CLSI Guideline H54-A, 2005 – Procedures for Validation of INR and Local Calibration of PT/INR Systems"; Camelia Grigore presented "The External Quality Control in Immunology – the French Model"; Simona Avram presented "Presentation of NCCLS (CLSI) Guideline H47-A 1996 – One stage Prothrombine Time (PT) and Activated Partial Throboplastine Time (APTT) Tests".

During symposium there were organized by RoEQALM two workshops: Internal Quality Control of Pre-analytical Phase and Internal Quality Control of Post-analitycal Phase.

Total quality management means that every variable that could possibly affect the quality of the test results has been controlled. RoEQALM promotes efficient and effective quality assurance. Quality assurance is simply a method to determine whether a system is organized, working, and producing to its optimum level. The concept of quality in laboratory medicine contains many facets ranging from housekeeping and waste disposal to safety and management. Clinical laboratory investigations have considerably progressed during the last decade with the use of high-quality instruments and reagents.

Many laboratories have instituted measures to assure quality of their results by integrating essential internal quality control steps in their day to day working and also participating in appropriate external quality assessment schemes.

The main objective of quality assurance is to provide reliable laboratory data in all health care activities and to ensure interlaboratory comparability of results. An effective quality assurance programme should cover all aspects of the laboratory. The basic aim of quality assurance is to generate the confidence of the user in the final report. This can happen only if both the product and the laboratory personnel have performed in accordance with good laboratory practices and approved standards, and tests or analyses have been validated.

In conclusion, an effective quality assurance programme should cover all aspects of the laboratory. Internal and external quality control need to be developed. For Romania, the European experience of quality assurance is highly relevant, and therefore an appreciation and understanding of the background is essential.

I take the chance of thanking for INSTAND cooperation that will contribute to the realization of a great progress in Romania.