KEEPING UP WITH THE NUGEN™ LAB: ITS JOURNEY TOWARDS BECOMING A COMPETENT MOLECULAR BIOLOGY TESTING LABORATORY


Background:
DOST-FNRI has always been active in fighting malnutrition with accurate data, correct information, and innovative technologies. One of the innovations undertaken was in Nutritional Genomics. To support this endeavor, DOST-FNRI capitalized on establishing its own molecular laboratory. The NuGen™ Lab instigated quality in its management system by adhering to the requirements for competence and positioning the laboratory towards ISO/IEC 17025:2005 accreditation.

Objective:
The project aimed to establish and implement a QMS in compliance to the requirements of ISO/IEC 17025:2005 at the NuGen™ Lab.

Methods:
Members of the Quality Assurance Committee (QAC) documented its Quality Management System (QMS) in accordance to the Philippine National Standards, ISO/IEC 17025:2005 Standard and Guidance Documents from the Philippine Accreditation Bureau (PAB). The implementation of the QMS commenced with controlling all of its documents and records. Analytical methods were subjected to validation in terms of accuracy, precision, and robustness prior to use. Quality assurance and quality control measures were set in place in all testing areas to assure the quality of test results.

Results and Findings:
The NuGen™ Lab was able to document its QMS in accordance to the standard and requirements set forth by PAB. The management system of the laboratory was driven by its quality objectives and was monitored by means of key performance indicators. The conduct of internal audit and management review enabled NuGen™ Lab to come up with ways to continuously improve its QMS. On the other hand, quality assurance was implemented in all aspects of its technical operations. Its personnel were found to be competent in performing genotyping. The equipment and methods used to genotype target genes were found to be fit for its intended use. Lastly, the results generated by NuGen™ Lab were found to be comparable to other molecular laboratories abroad that are already ISO/IEC 17025:2005 accredited. Accomplishing all the requirements needed, the NuGen™ Lab submitted its application for ISO/IEC accreditation to PAB.

Conclusion:
A quality management system was established and implemented. It is with high hope that the NuGen Lab will be a premier ISO/IEC 17025:2005 accredited molecular laboratory in the Philippines; providing its customers with InDEPTH (Innovative, Dedicated, Excellent, Proficient, Timely and Holistic) analyses and quality results.