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Pharmacogenetic: Regulatory considerations, Cuban guidance

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The science of pharmacogenomics has advanced significantly in the last five years. The Pharmacogenomics helps identify inter-individual variability in drug response (both toxicity and effectiveness). This information will make it possible to individualize therapy with the intent of maximizing effectiveness and minimizing risk. This discipline is a big challenge for regulatory authorities. The aim of this work is to present the bases of pharmacogenetic, the state of art and implications of this discipline for Latin-American countries and to show the Cuban Guidance for Industry. International literature was reviewed about the existing regulations, guidance, concept paper, scientific articles and the national regulations related with the topic. The results showed that there are several normative and guidance related with pharmacogenomic; the increase of biological product registration and authorized clinical trials in Cuba and the necessity for carrying out pharmacogenetic studies during the clinical phases of our products. We will show the main biomarkers for pharmacogenetics studies and a Cuban general guidance for submission of this type of research. It is divided mainly in four sections: Introduction, objectives and scope, terms and definition and regulatory recommendations (reception, codification and sample storage biomarkers, and ethical considerations). This Cuban guidance will be considered the first guidance related with pharmacogenomic in Latin America. Pharmacogenetic has several advantages in order to get rational use of drugs but still there are many challenges. The hope for the future is that through personalized medicine, doctors and patients will be able to make better-informed choices about treatment.

Biography

Diadelis Remirez Figueredo has received her BA in Biochemistry from Havana University, Cuba and both her MSc in Biomedicine and PhD in Pharmaceutical Sciences from National Center for Scientific Research in Havana and most of the results were done in the Department of Toxicology at the Free University in Amsterdam. Her Postdoctoral training in Molecular Toxicology and Pharmacology was completed at the Faculty of Pharmacy in Toronto, Canada. She has been a Referee of scientific journals. She has been the recipient of National Award of Pharmacology twice from the Cuban Pharmacology Society. She has worked as an Expert for the evaluation of preclinical platform in South Africa (CSIR). She is currently the Vice President of Cuban Pharmacology Society. Presently she works in the Cuba Regulatory Agency and she is one of the Reviewers for authorization of clinical trials. She is the Project Leader about Pharmacogenetic guideline. She belongs to Iberoamerican Pharmacogenetic Network (RIBEF) since 2008 and recently obtained Master degree in Clinical Trials. Her research is described in over 30 published research reports.

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