

MEETING REPORT

On May 6-10, 2009 the Cuban Society of Pharmacology organized the First International Congress on Pharmacology of Vaccines (VACCIPHARMA 2009), held at Sirenis La Salina Hotel, in Varadero beach, Cuba. The main topics of the Congress included Potency and Safety tests and alternative methods for the evaluation of vaccines, Clinical Trials for preventive vaccines and Therapeutic vaccines.



Dr. Concepción Campa, Dr. Rafael Pérez Cristiá, Dr. René Delgado, Dr. Agustín Lage and Dr. Mario Landys Chovel.

The Congress was opened by the speeches given by Dr. Mario Landys Chovel, President of the Organizing Committee of VacciPharma 2009 and Dr. Rafael Pérez Cristiá, Director of the Centre for State Control of the Quality of Drugs (Cuban National Regulatory Authority, NRA). The Opening Lectures were delivered by Dr. Coenraad Hendriksen (NVI, The Netherlands) who spoke on the current status and the new trends in developing alternatives methods for quality control of vaccines and Dr. Agustín Lage (CIM, Cuba) who gave an updated overview on therapeutic vaccines and the change of the dominant paradigm in cancer therapy.



The Opening Lectures by Dr. Coenraad Hendriksen

VACCIPHARMA 2009 offered an outstanding scientific program with 57 Lectures distributed in 3 Workshops and 110 Posters. It is noteworthy to mention that there was an active contribution of 65 delegates from countries such as Argentina, Brazil, Canada, Germany, The Netherlands, Norway, France, United Kingdom, United States, Ecuador, New Zeland, Belgium, Chile, Indonesia and China. Furthermore, we would like to stress the participation of more than 120 Cuban researchers from the most important local institutions devoted to the development and evaluation of vaccines. Hence, the Congress was a suitable framework for exchanging experiences, the presentation of results and discussions on the above mentioned topics.



Dr. Agustín Lage who gave an updated overview on therapeutic vaccines and the change of the dominant paradigm in cancer therapy.

The Workshop “Current potency and safety tests and alternatives for the quality control for the evaluation of vaccines” was organized by Dr. Mario Landys Chovel and had two notable sessions: the first was focused on the regulatory and international perspectives for 3Rs methods, particularly from the European Pharmacopoeia viewpoint, the current status of the Potency tests and also the experiences of different laboratories and organizations in the development and validation of alternative methods for Potency testing of human viral (Rabies, Hepatitis A and B) and bacterial vaccines (D, T, Hib), as well as novel approaches for the characterisation of vaccines.

The second session addressed the updating on the current safety tests and the need for alternatives that include new methods for determining the toxicity of Pertussis toxin, the safety test for acellular Pertussis vaccine and alternatives for *in vitro* pyrogen test based on peripheral blood mononuclear cells. Moreover, results were observed on the application of the consistency approach as well as on the development of serological tests for D and T according to FDA approach. This Workshop also included an interesting session on veterinary vaccines, focused on new advances and experiences in the application of this kind of products.



Dr. Thea Sesardic from the National Institute for Biological Standards and Control (NIBSC).

It's was a pleasure and a unique opportunity to be able to get together with the most relevant scientists working on 3Rs worldwide: Emmanuelle Charton from European Pharmacopoeia, Coenraad Hendriksen, Gideon Kersten and Bernard Metz of the Netherlands Vaccine Institute (NVI), Thea Sesardic and Roland Fleck from the National Institute for Biological Standards and Control (NIBSC), Thomas Montag-Lessing and Christina Bache from Paul Ehrlich Institute (PEI), Roland Dobbelaer and Randi Winsnes, all of which are leaders in their respective fields.

They formed a fantastic range of speakers, contributing enormously to our first purpose, i.e. updating the Cuban scientific community specialised in regulatory and technical aspects related with alternative methods. At the same time, Cuban scientists could make good use of their experience and show the progress we have made on certain alternatives as well as the strategies used to introduce and validate new methods.



Dr. Rolando Ochoa and Dr. Deybis Orta in the Session of the Workshop “Clinical Trials of Preventive Vaccines and Health Policies”

The Workshop “Clinical Trials of Preventive Vaccines and Health Policies” was organized by Dr. Rolando Ochoa and Dr. Deybis Orta. The first session of this Workshop was devoted to the health policies and immunization programs and the second session was addressed to the current status and new trends for the design of clinical trials. The challenges and new approaches for the development of new vaccines against whooping cough, pneumococcal disease, cholera and TB were extensively discussed and the Cuban experience was commented. A new strategy to prevent polio by inactivated poliovirus vaccine administered intradermally was also analyzed.

Two lectures were focused on the analysis of the safety, immunogenicity and effectiveness of the first synthetic vaccine –Quimi-Hib– against *Haemophilus influenzae* type b. The new trends for the clinical evaluation of combination vaccines and the assessment of vaccine efficacy by non-inferiority clinical trials based on immune response were thoroughly studied. The Organizing Committee wants to thank especially to Dr Barry Walker (UK) and Dr Marcel Thalen (The Netherlands) for their active participation.

The main goal of the “Therapeutic vaccines” Workshop, organized by Dr., Greta Garrido, was to promote a strong discussion on how to implement therapeutic vaccines in different fields. The first session was focused on adjuvants and delivery systems as key elements of effective vaccines. Relevant researchers discussed several types of immune-potentiators (e.g. bacterial compounds, toxins and lipids). Also, the use of nanoparticles as delivery systems was an important topic of discussion, as well as safety limitations for the use of new adjuvant systems for human vaccines. Others sessions showed pre-clinical and clinical results of therapeutic vaccines. Different vaccines technologies were presented such as peptides, recombinant proteins and viral vectors. Evidences on allergy and infectious diseases in experimental or clinical setting were shown. At the same time, Cuban scientists shared their experiences in cancer vaccines. The participants were able to observe the results of active immunotherapy against several tumor targets (e.g. EGF, EGFR, VEGF, gonadotropine and gangliosides). The rational design of therapeutic combinations was also introduced. The scientific community has faced the

dissociation between the accumulation of pre-clinical results and the capacity to make predictions and to guide interventions in the clinical setting.



However, this meeting allowed integrating knowledge to deal with a rational, rather than empirical, implementation of combinations. The chronic vaccination for cancer patients in the context of immunosuppression was also a hot point in this workshop.

Participants in the “Therapeutic vaccines” Workshop



Closing ceremony

It was also carried out the Regional Workshop “Development, Production and Quality Control of Combined Vaccine Based on Diphtheria-Tetanus-Pertussis, Hepatitis B and Haemophilus influenzae type b”, organized by the Centre for Genetic Engineering and Biotechnology (CIGB, Cuba), with presentations from manufacturers and National Control Authorities and Laboratories from Argentina, Ecuador, Brazil and Cuba on their experiences with the manufacturing and quality control of combined vaccines. At the same time, Satellite Symposia were organized and held by Cuban NRA, Finlay Institute and several Researching Centers about regulatory issues, new trends in quality assurance and manufacturing and new research projects for the development of vaccines in Cuba, respectively.

VACCIPHARMA 2009 was an exceptional opportunity to enhance the knowledge, scientific exchange and on-going collaboration among professionals devoting their daily activity to the development of vaccines.



Other activities organized in the Congress: Poster sessions, exhibitions and festivals on the beach .

The Organizing Committee would like to thank very much to all persons who helped us during the organization of the Congress. First of all, we would like to thank the relevant scientists from Europe, Asia and America as well as from our country for their scientific contribution. However, we are also very grateful for the support given by organizations and companies such as the Panamerican Health Organization (PAHO), Glaxo Smith Kline (GSK), Sanofi Pasteur, SEPPIC, The Universities Federation for Animal Welfare (UFAW), the Organization for Global Cancer Control (UICC), Copa Airlines, Los Portales and of course for the support of our national scientific centres such as Finlay Institute, The Centre for Molecular Immunology, The Centre for Genetic Engineering and Biotechnology, the Cuban NRA, the National Centre for Animal Sanitary, among others. We would especially like to thank Dr. Dorothea Sesardic and Dr. Coenraad Hendriksen for their support with the original idea and their help in the scientific program.

Dr. Mario Landys Chovel Cuervo
President of the Organizing Committee
VACCIPHARMA 2009
Cuban Society of Pharmacology
<http://www.scf.sld.cu>

Moments



Welcome cocktail



Days of the inauguration.



Dr. Barry Walker from the National Institute for Biological Standards and Control (NIBSC)



The Workshop "Combined Vaccine".



Symposium organized by the Cuban National Agency for Vaccine and Drugs on Regulations for Vaccines.