INSTITUTIONAL PROFILE

Part I – Description of the collaborating centre

1. Name of the Centre:

MOGAM BIOTECHNOLOGY RESEARCH INSTITUTE
341 Pojung-Ri, Koosung-Eup, Yongin-Si, Kyonggi-Do
449- 913 Republic of Korea.
Tel) 82- 31- 260- 9800, 82- 31- 260- 9861 Fax) 82- 31 -260 -9808
E-mail) mhpark@mogam.re.kr

2. Brief history of the Centre:

- The Centre was founded and duly registered as an independent non-profit research organization in the Ministry of Science and Technology, Korea, in 1984.
- The Centre has succeeded in developing the diagnostic kits for Hepatitis B virus, Human immunodeficiency virus 1 and 2, Hepatitis C virus, Hantaan virus and *Helicobacter pylori*.
- The Centre has succeeded in developing the prophylactic vaccines for Hepatitis B virus, Cloth plasma derived and recombinant Hantaan virus(Hemorrhagic fever), Varricella Zoster virus(Chicken pox) and *Orientia tsutsugamushi* (former name; *Rickettsia tsutsugamushi*)
- The Centre has published more than 100 papers in international scientific journals and filed or registered about 250 patents domestically and internationally in last 10 years.
- The Centre was first designated as a WHO collaborating centre in 1989 for Research and Development of Vaccines and Diagnostic Reagents and subsequently extended for the second period that ended in January of 1999.
- The status has been pending since then for the redesignation

3. Title of the WHO collaborating centre

WHO collaborating centre for Research and Development of Vaccines and Diagnostic Reagents

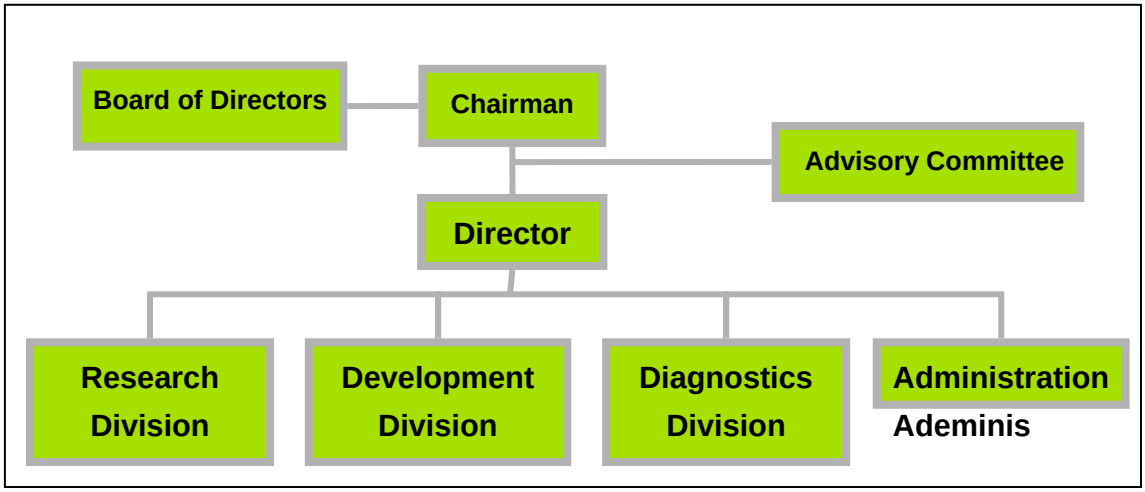
4. Name of the Director of the Centre

Doo-Hong Park, Ph.D.

5. Name of the Head of the Centre

Dr. Young-Sup Huh, Chairman, B. D.

6. Organizational chart of the Centre



Part II – Work plan for 2004 -2008

MOGAM Biotechnology Research Institute will continue to carry out R&D activities during 2004- 2008 by the terms of reference of the WHO collaborating centre.

(1) ***To participate in collaborative studies with WHO on the research and development of new vaccine and diagnostic reagents***

- Development of prophylactic DNA/protein vaccine against Hepatitis C virus
- Development of epitope-based therapeutic vaccines against chronic viral Hepatitis B and C
- Development of viral DNA assay system for Hepatitis B virus
- Development of viral RNA assay system for Human immunodeficiency viruses
- Development of viral RNA assay system for Hepatitis C virus
- Development of animal models for efficacy evaluation of Vaccines and therapeutics against HBV and HCV infectious.

(2) ***To provide consulting services on the development and quality control of vaccine and diagnostic reagents***

- Consulting Green Cross Life Science Co., Korea to establish and develop the Polymerase

chain reaction (PCR)- based molecular diagnostic reagents for HBV, HIV 1&2 and HCV

- Consulting Berna Vaccine Co, Korea, to develop new vaccines for viral hepatitis and emerging infectious diseases

(3) ***To provide training for fellows who are developing vaccine and diagnostic reagents***

- Training research fellows of Green Cross Life Science Co. for the development of molecular diagnostics
- Training research fellows from Hepatology clinics of several hospitals in Korea and other countries how to monitor the immune responses during the course of antiviral therapies for viral hepatitis

(4) ***To provide reference for vaccine and diagnostic reagents***

- Providing reference for vaccine and diagnostic reagents whenever requested from several institutions such as Korean Center for Disease Control, Korean Food and Drug Administration, Korean Red Cross and other institutions that might be arranged by WHO

(5) ***To collect and disseminate information on the development of vaccine and diagnostic reagents***

- Collecting information on the development of new vaccine from International Vaccine Institute(IVI) in Korea
- Disseminating information on the development of new diagnostic reagents to Korean Red Cross and equivant organization abroad
- Sharing information on the development of vaccine and diagnostic reagents with other WHO collaborating centre such as Asan Institute for Life Science (WHO Collaborating Centre for Virus Reference and Research) and Catholic Medical Service Institute, Catholic University (WHO Collaborating Centre for Reference and Research on Viral Hepatitis), and others.

Part III – Description of the activities

(1) Research and development of new diagnostic reagents

- Development of HBV DNA assay kit
(PI : Hae-Jun Park. Ph.D., Research period: 2004-2006)

The course of acute and chronic infection with hepatitis B virus(HBV) is extremely variable. Serological maker for viral activity such as hepatitis B surface antigen (HBsAg) and hepatitis B e antigen (HBeAg) are useful for diagnosis, but HBsAg-negative and HBeAg-negative courses have been identified. The concentration of HBV particles in serum or plasma is a better indicator of viral replication and is significant for the initiation and monitoring of interferon therapy. Assay of the HBV pare self is most conveniently achieved by detection of its DNA. We will develop the HBV DNA assay kit using the polymerase chain reaction(PCR), DNA chip and Lab-on-a-chip technology, which detect the HBV particles in the blood stream.

- Development of HCV RNA assay kit
(PI: Hae-Jun Park, Ph.D., Research period: 2005-2007)

Hepatitis C virus(HCV) is a major etiological agent of post-transfusion and community-acquired hepatitis. Detection of circulating HCV antibody(anti-HCV) and PCR of HCV RNA are the two major techniques used to diagnose HCV infection. Since HCV RNA detection with reverse transcription(RT)-PCR is more direct and sensitive than anti-HCV testing, it has become one of the diagnostic standards for HCV infection. Presently, RT-PCR is the only reliable method that allows early detection of HCV infection. We will develop the HCV RNA assay kit using the RT-PCR, DNA chip and Lab-on-a-chip technology, which detect the HCV RNA in the blood stream

- Development of HIV RNA assay kit
(PI: Hae-Jun Park, Ph.D., Research period: 2005-2007)

Quantification of human immunodeficiency virus(HIV) RNA has been shown to be important in prediction the rate of disease progression and in monitoring anti-retroviral treatment. We will develop the HIV RNA assay kit using the RT-PCR, DNA chip and Lab-on-a-chip technology, which detect the HIV RNA in the blood stream.

- We will also try to develop the diagnostic reagents for several infectious diseases such as Mycobacterium tuberculosis, Human Papillomavirus, Chlamydia trachomatis etc.

(2) Research and development of new vaccines

- Development of prophylactic vaccine against Hepatitis C virus.
(PI: Mahnhoon Park, Ph. D., Research period: 2000-2008)

The hepatitis C virus is the etiological agent of non-A non-B hepatitis, the leading cause of chronic liver infections. Chronic HCV infection is correlated with the risk of developing liver cirrhosis and hepatocellular carcinoma. It is estimated that there are more than 170 million chronic carriers worldwide. To date, there is neither a prophylactic vaccine nor a satisfactory therapeutic treatment. The development of an HCV vaccines has been problematic due to there is no tissue culture system available for HCV and furthermore due to the lack of small animal model system except chimpanzees. In order to develop the prophylactic vaccine against HCV in these circumstances, the Centre decided to use modified HCV glycoprotein gene as DNA vaccine in order to induce strong cellular immune response in addition to use HCV glycoprotein fusion proteins produced in yeast in order to induce humoral immune responses. In animal study, we confirmed that both DNA and fusion protein could induce the humoral and cellular immune response against HCV, and we are now in the process of testing the protective immunogenecity of these candidate vaccines using the surrogate challenge systems.

- Development of CTL-based therapeutic vaccine for chronic hepatitis B and C
(PI: Mahnhoon Park, Ph. D., Research period: 2003-2008)

Our approach to therapeutic vaccine against chronic viral hepatitis B and C is to rationally improve the CTL-based immunotherapy capable of eliciting a strong cellular immune response. The basic concept is to identify the specialized novel epitopes capable of both binding to broad MHC molecules and inducing their specific CTL response *in vivo*. The goal of this approach is to expand the applicability of the epitope-based immunotherapy independent of MHC restriction. Practically, the potent epitopes derived from HCV and HBV were identified and their effectiveness is being examined in *ex vivo* using the patients PBMCs. We already have screened and selected the several novel epitopes with more than

100 patient's PBMCs, and we are validating the selected epitopes using animal model systems.

(3) Providing consulting/training services on the development of vaccine and diagnostic reagents

- The Centre will provide consulting services to Green Cross Life Science Co., Korea to establish the Polymerase chain reaction (PCR)- based molecular diagnostic reagents for HBV, HIV 1&2 and HCV , and will also train the research fellows of Green Cross Life Science Co. for the development of molecular diagnostics by the provision of Dr. Hae-Jun Park and Dr. Young-Ju Ha.

- The Centre will consult with Dr. S.J. Ahn of Berna Vaccine Co, Korea, in order to develop new vaccines for viral hepatitis and the emerging infectious diseases by the provision of Dr. Mahnhoon Park.

- The centre will provide training of research fellows from Hepatology clinics of several hospitals in Korea such as Yonsei Medical school(Dr. K.H. Han) and Asan Hospitals how to monitor the immune responses during the course of antiviral therapies for viral hepatitis using ELISPOT assay by the provision of Dr. Mahnhoon Park.

- The centre will provide consulting services to developing countries in Asia where such services are requested and will accept scientist to provide them with the guidance and training of the quality control and basic production methods of vaccine and diagnostic reagents.

(4) Collecting and disseminating information on the development of vaccines and diagnostic reagents

- The Centre will collaborate with International Vaccine Institute (IVI) in Korea by sharing the information in order to develop vaccines for the emerging infectious diseases.
- The Centre will provide the information of new diagnostic reagents for infectious diseases to such a institution as Korean Red Cross in order to improve the safety of blood supply.
- The Centre will actively exchange information on the development of vaccine and diagnostic reagents with other WHO collaborating centre such as Asan Institute for Life

Science (WHO Collaborating Centre for Virus Reference and Research) and Catholic Medical Service Institute, Catholic University (WHO Collaborating Centre for Reference and Research on Viral Hepatitis) and other institutes in order to contribute to the mission of WHO more efficiently as a team.

- The Centre will actively participate in the program for the research and development of Vaccines and diagnostics reagents that might be internationally arranged by WHO