

Overview of the Laboratory of Respiratory Viruses

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Lab Chief

Laboratory of Pediatric and Respiratory Virus Diseases

CBER/OVRR/DVP

Site Visit

January 31, 2018

Organization of Laboratory of Respiratory Virus Viruses

Research Teams

Influenza Virus Molecular Biology Team
Zhiping Ye, M.D., Ph.D.,

Antigenic Structure and Function Team
Judy Beeler, M.D.,

Influenza Pathogenesis and Immunity Team
*Maryna Eichelberger, Ph.D., left OVRR to take a
position in OCBQ in November, 2017*

Regulatory Review Responsibilities

- Product review for viral vaccines
 - Influenza virus vaccines
 - *Respiratory syncytial virus*
 - *Parainfluenza virus types 1, 2 & 3*
 - *Human metapneumoviruses*
 - *Measles, mumps and rubella*
- Clinical and pre-clinical review for viral vaccines
- Vaccine lot release (protocol review)
- Manufacturers inspections (pre- & post-licensure)
- Participate and make presentations to the Vaccines Advisory Committee on influenza product issues and vaccine strain selection

Regulatory Review Workload



10 scientists in LRVD have regulatory review responsibilities (From Aug. 2013-Jan. 31 2018)

Pre-Investigational New Drugs	24
INDs & amendments	730
Biologics License Applications & supplements	152



Other Regulatory and Public Health Responsibilities of the Laboratory

- Preparation of potency reagents for testing candidate pandemic influenza vaccines
- Selection and recommendation of strains for seasonal influenza vaccines
 - 1 of 4 WHO Essential Regulatory Laboratories
 - Serological analysis of vaccine responses for NH and SH vaccine selection
- Participation and preparation of WHO guidelines on Influenza and RSV vaccines

Influenza Virus Molecular Biology

Personnel

Zhiping Ye, M.D., Ph.D.

Hang Xie, Ph.D.

Ewan Plant, Ph.D.

Xing Li, Ph.D.

Olga Zoueva, Ph.D.

Hongquan Wan, DVM, PhD.*

Jin Gao, M.S.*

Major Regulatory Responsibilities

Influenza virus vaccines

Areas of Research

Molecular & genetic approaches to improving influenza vaccine candidates and vaccine potency reagents

Molecular mechanisms of influenza virus attenuation & virulence

Previous Site Visit – 08/2013

Influenza Virus Molecular Biology Research Update

1. Evaluating antigenicity and immune responses of influenza viruses-*to identify issues and make improvement in strain selection (Dr. Hang Xie)*
2. Identifying NA antigenic epitopes and studying antigenic drift of influenza viruses-*to improve candidate vaccine virus (CVV) selection (Dr. Hongquan Wan and Ms. Jin Gao)*
3. Developing and evaluating influenza CVV and related vaccine potency reagents-*to have potency reagents ready before a pandemic (Dr. Xing Li)*
4. Optimizing influenza CVV with high protein yield potential-*to enhance vaccine production (Drs. Ewan Plant and Xing Li)*

Antigenic Structure and Function

Personnel

Judy Beeler, M.D.

Lynne Crim, B.S.

Susette Audet, B.S.

Major Regulatory Responsibilities

RSV, and other respiratory virus vaccines

Measles virus vaccines

Areas of Research

Serological correlates of infection and protection of RSV and Measles viruses

Previous Site Visit – 08/2013

Antigenic Structure and Function Research Update-RSV

Project 1. Characterization of a human immunoglobulin to be used as a reference standard for RSV neutralization assays

Project 2. Antibody profiling by immunoprecipitation of luciferase-tagged proteins to detect anti-RSV IgG responses

Antigenic Structure and Function Research Update – Measles virus vaccines

Project 3. Development of a high-throughput assay to measure neutralizing antibodies against measles virus using a qPCR readout

Project 4: Collaborative clinical studies to support measles elimination efforts

Thank You