

# Overview of the Laboratory of Respiratory Viruses

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

**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**