

# Laboratory of Pediatric and Respiratory Viruses (LPRVD) Organization

**Zhiping Ye, Ph.D.**

Lab Chief

CBER/OVRR/DVP/LPRVD

VRBPAC

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# LPRVD

## Research Teams

Influenza Virus Molecular Biology

*Zhiping Ye, Ph.D.,*

Influenza neuraminidase antigenicity and efficacy in vaccines

*Robert Daniels, Ph.D.,*

Respiratory Syncytial Virus Antigen Structure and Function

*Judy Beeler, M.D., will retire in 2024 after 35 years at the FDA and was not reviewed during this SV.*

# Influenza Virus Molecular Biology Team

## Personnel (Full-time equivalent, FTE)

Zhiping Ye, Ph.D.

Ewan Plant, Ph.D.

Xing Li, Ph.D.

Olga Zoueva, Ph.D.

Martina Kosikova, Ph.D.

Hang Xie, Ph.D.\*

## Major Regulatory Responsibilities

Influenza virus vaccines

## Areas of Research

Molecular & genetic approaches to improving influenza vaccine production

Previous Site Visit – 01/2018

# Influenza Neuraminidase (NA) Antigenicity and Efficacy in Vaccines Team

## Personnel (FTE)

Robert Daniels, Ph.D. (Joined LPRVD in 2019)

Tahir Malik, Ph.D.

Jin Gao, M.S.

Mira R Martinez, Ph.D.

Hyeog Kang, Ph.D.

Laura Klenow, M.S.\*

Hongquan Wan, Ph.D.\*

## Major Regulatory Responsibilities

Influenza virus vaccines

COVID-19 vaccines

## Areas of Research

Improvement of influenza vaccines by establishing mechanisms to include additional antigens like NA, which can potentially be applied to vaccines against other enveloped viruses that primarily rely on one antigen.

Previous Site Visit – none

# RSV Antigen Structure and Function Team



## Personnel (FTE)

Judy Beeler, MD

Christian Sauder, Ph.D. (joined lab in 2019)

Roberta Lynne Crim, B.S.

Susette Audet, B.S.

## Major Regulatory Responsibilities

Respiratory syncytial virus vaccines

Parainfluenza virus 1,2,3, vaccines

Human metapneumoviruses vaccines

## Areas of Research

Development of serology tests to measure correlates of protection against virus respiratory infection.

**Previous Site Visit – 2018 (Not be reviewed)**

# LPRVD Regulatory Review Workload



Lab:	Ye	Daniels	Beeler
Pre-INDs	3	14	10
IND Original submissions	24	14	23
IND amendments	274	277	1248
BLAs	5	0	8
BLA supplements	99	64	21
Consult Reviews	2	2	2

# Regulatory Review Responsibilities

- Product review for viral vaccines
  - **Influenza virus vaccines**
  - **Respiratory syncytial vaccines**
  - **COVID-19 vaccines**
  - Parainfluenza virus 1,2,3 vaccines
  - Human metapneumoviruses vaccines
  - Measles mumps and rubella vaccines
- Vaccine lot release
- Manufacturers inspections (pre- & post-licensure)
- Participating the Vaccines Advisory Committee on influenza product issues and vaccine strain selection

# Other Regulatory and Public Health Responsibilities of the Laboratory



- 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
  - Neuraminidase antigenic drift
- Preparation of potency reagents for testing candidate pandemic influenza vaccines
- WHO vaccine related guidelines



# Influenza Virus Molecular Biology Team

## Research Update



Research aims:

1. Develop high yield pandemic candidate vaccine viruses (CVVs) and prepare related potency reagents, including those for current H5N1 virus in the US.
2. Evaluate immunogenicity of field isolates and vaccine candidate viruses to support seasonal or pandemic vaccine antigen updates
3. Develop COVID-19 standards for assessing protective antibodies in pre-clinical and clinical samples

# Influenza NA antigenicity and efficacy in vaccines *Team-New July 2019*

## Research aims:

- 1) Establish a strain selection framework and improved assays for identifying NA antigens for seasonal vaccines
- 2) Develop manufacturing approaches to produce new and existing influenza vaccines that elicit improved anti-NA antibody responses
- 3) Evaluate the potential protective benefits of the M and E surface proteins from SARS-CoV-2

**Thank You**