

Office of Vaccines Research and Review

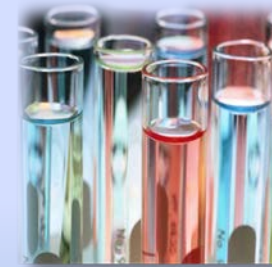
Jay E Slater, MD
LMPCI Site Visit
25 October 2017

OVRB Regulates

- Vaccines
- Allergenic products
- Live biotherapeutic products (probiotics, FMT)
- Phage

OVRP Mission

- To protect and enhance public health by assuring the availability of safe and effective vaccines, allergenic extracts, and other related products
- **The OVRP Research Program** is designed to complement and support the regulatory mission by focusing on issues related to the development of safe and effective products.



OVRR Core Activities



Review, evaluate, and take appropriate actions on INDs, BLAs, amendments, and supplements for vaccines and related biological products and participation in inspections

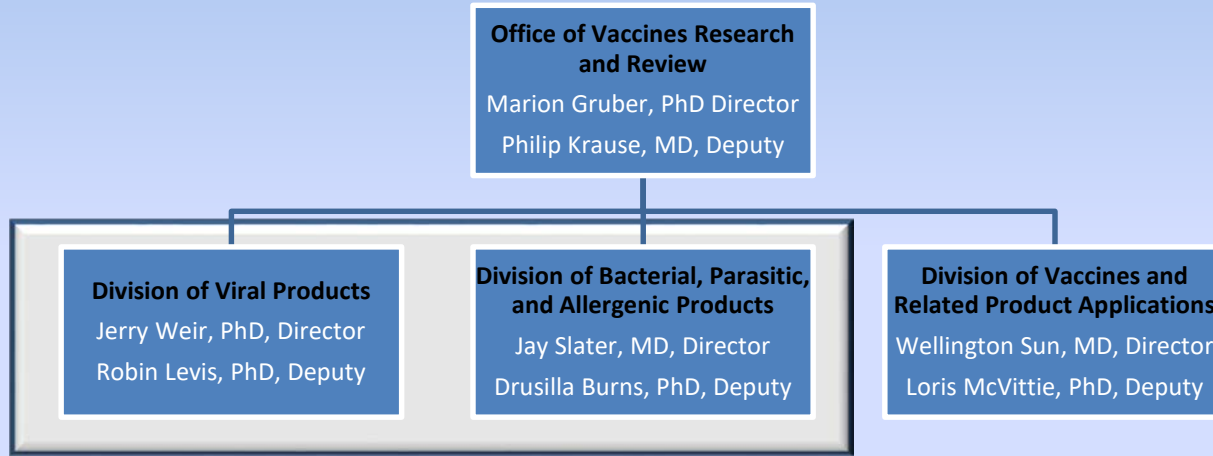


Develop policies and procedures governing the pre-market review of regulated products



Conduct research related to the development, manufacture, and evaluation of vaccines and related products

OVRP Organizational Chart



Research Divisions

OVRP Research Mission



The OVRP Research Program is designed to complement and support the regulatory mission by focusing on issues related to the development of safe and effective products.

OVRP Research Goals

Research Goal 1: **Safety**

- Enhance the safety of preventive vaccines and related biological products through the development of models, methods and reagents needed in the manufacture and evaluation of these products

Research Goal 2: **Efficacy**

- Improve the effectiveness of vaccines and related biological products through the development of models, methods and reagents needed to measure and predict the effectiveness of these products

Research Goal 3: **Availability**

- To develop and study approaches to enhance the availability of vaccines and related biological products

Importance of Research In Regulation of Vaccines and other Products

Emphasis on Safety

- Products for mass use (often universal)
- Recipients are healthy individuals, often children

Keeping pace with technology

- New manufacturing technologies are rapidly evolving

High level of Scrutiny by Public

- Regulatory decisions must be based on science
- Increasing number of anti-vaccine organization and groups

Responding to Public Health Threats

- Antibiotic resistance
- Clostridium difficile
- Emerging adventitious agents

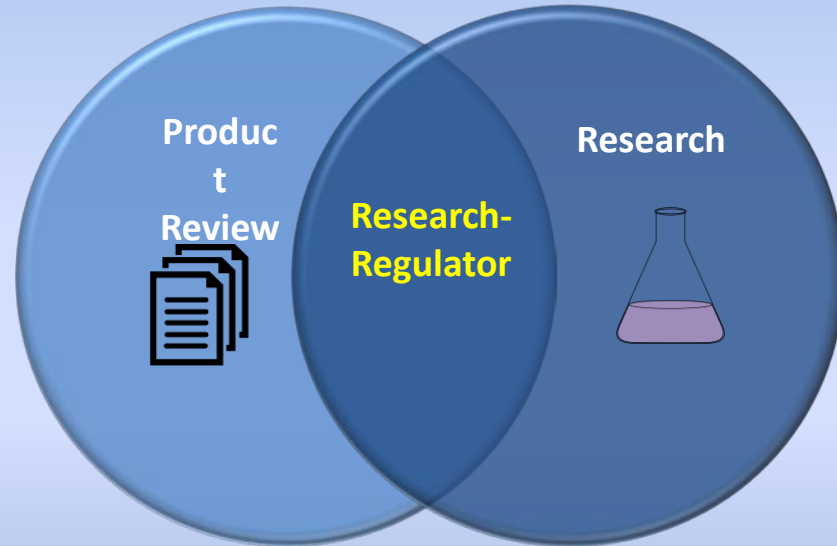
OVRR's Research Is



Research-Regulator Model

Integration of Regulation and Science

- The research-regulator model integrates regulatory review responsibilities with mission-directed research.
- Research-regulators review IND and BLA applications, participate as product-related subject matter experts in inspections, and perform research relevant to evaluation of specific product safety, efficacy, or manufacturing issues.



Division of Bacterial, Parasitic and Allergenic Products

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Division of Bacterial, Parasitic and Allergenic Products



Immediate Office of the Director

Jay E. Slater, MD – Director

Drusilla Burns, PhD – Deputy Director

Laboratory of Bacterial Polysaccharides

Willie Vann, PhD – Chief

Mustafa Akkoyunlu, PhD

Margaret Bash, MD

John Cipollo, PhD

Daron Freedberg, PhD

Laboratory of Respiratory and Special Pathogens

Michael Schmitt, PhD – Chief

Drusilla Burns, PhD

Tod Merkel, PhD

Laboratory of Immunobiochemistry

Ron Rabin, MD – Chief

Jay E. Slater, MD

Laboratory of Mucosal Pathogens & Cellular Immunology

Scott Stibitz, PhD – Chief

Paul Carlson, PhD

Siobhán Cowley, PhD

Karen Elkins, PhD

DBPAP regulatory/research portfolio

Non-invasive, toxin producers

- *Bacillus anthracis*
- *Bordetella pertussis*
- *Clostridium botulinum*
- *Clostridium tetani*
- *Corynebacterium diphtheriae*
- *Clostridium difficile*

Invasive, protective responses to polysaccharides

- *Haemophilus influenzae*
- *Neisseria meningitidis*
- *Streptococcus pneumoniae*

Intracellular

- *Francisella tularensis*
- *Mycobacterium tuberculosis*
- *Mycobacterium bovis*

Enteric

- *Campylobacter jejuni*
- *Salmonella Typhi*
- *Salmonella Typhimurium*
- *Shigella dysenteriae*

Parasite

- *Plasmodium spp*

Other/emerging

- *Staphylococcus aureus*
- Allergenic products
- Live biotherapeutic products (probiotics)
- Phage
- Microbiome-related products

DBPAP regulatory/research portfolio

Bacterial Polysaccharides (LBP)

Non-invasive, toxin producers

- *Bacillus anthracis*
- *Bordetella pertussis*
- *Clostridium botulinum*
- *Clostridium tetani*
- *Corynebacterium diphtheriae*
- *Clostridium difficile*

Invasive, protective responses to polysaccharides

- [*Haemophilus influenzae*](#)
- [*Neisseria meningitidis*](#)
- [*Streptococcus pneumoniae*](#)

Intracellular

- *Francisella tularensis*
- *Mycobacterium tuberculosis*
- *Mycobacterium bovis*

Enteric

- *Campylobacter jejuni*
- [*Salmonella Typhi*](#)
- *Salmonella Typhimurium*
- *Shigella dysenteriae*

Parasite

- *Plasmodium spp*

Other/emerging

- *Staphylococcus aureus*
- Allergenic products
- Live biotherapeutic products (probiotics)
- Phage
- Microbiome-related products

DBPAP regulatory/research portfolio

Immunobiochemistry (LIB)

Non-invasive, toxin producers

- *Bacillus anthracis*
- *Bordetella pertussis*
- *Clostridium botulinum*
- *Clostridium tetani*
- *Corynebacterium diphtheriae*
- *Clostridium difficile*

Invasive, protective responses to polysaccharides

- *Haemophilus influenzae*
- *Neisseria meningitidis*
- *Streptococcus pneumoniae*

Intracellular

- *Francisella tularensis*
- *Mycobacterium tuberculosis*
- *Mycobacterium bovis*

Enteric

- *Campylobacter jejuni*
- *Salmonella Typhi*
- *Salmonella Typhimurium*
- *Shigella dysenteriae*

Parasite

- *Plasmodium spp*

Other/emerging

- *Staphylococcus aureus*
- [Allergenic products](#)
- Live biotherapeutic products (probiotics)
- Phage
- Microbiome-related products

DBPAP regulatory/research portfolio

Respiratory and Special Pathogens (LRSP)

Non-invasive, toxin producers

- [*Bacillus anthracis*](#)
- [*Bordetella pertussis*](#)
- [*Clostridium botulinum*](#)
- [*Clostridium tetani*](#)
- [*Corynebacterium diphtheriae*](#)
- *Clostridium difficile*

Invasive, protective responses to polysaccharides

- *Haemophilus influenzae*
- *Neisseria meningitidis*
- *Streptococcus pneumoniae*

Intracellular

- *Francisella tularensis*
- *Mycobacterium tuberculosis*
- *Mycobacterium bovis*

Enteric

- *Campylobacter jejuni*
- *Salmonella Typhi*
- *Salmonella Typhimurium*
- *Shigella dysenteriae*

Parasite

- *Plasmodium spp*

Other/emerging

- [*Staphylococcus aureus*](#)
- Allergenic products
- Live biotherapeutic products (probiotics)
- Phage
- Microbiome-related products

DBPAP regulatory/research portfolio

Mucosal Pathogens and Cellular Immunology (LMPCI)

Non-invasive, toxin producers

- *Bacillus anthracis*
- *Bordetella pertussis*
- *Clostridium botulinum*
- *Clostridium tetani*
- *Corynebacterium diphtheriae*
- [*Clostridium difficile*](#)

Invasive, protective responses to polysaccharides

- *Haemophilus influenzae*
- *Neisseria meningitidis*
- *Streptococcus pneumoniae*

Intracellular

- [*Francisella tularensis*](#)
- [*Mycobacterium tuberculosis*](#)
- [*Mycobacterium bovis*](#)

Enteric

- [*Campylobacter jejuni*](#)
- [*Salmonella Typhi*](#)
- [*Salmonella Typhimurium*](#)
- [*Shigella dysenteriae*](#)

Parasite

- [*Plasmodium spp*](#)

Other/emerging

- [*Staphylococcus aureus*](#)
- Allergenic products
- [Live biotherapeutic products \(probiotics\)](#)
- [Phage](#)
- [Microbiome-related products](#)

LMPCI presenters

- Scott Stibitz, PhD, Supervisory Microbiologist (PI)
- Paul Carlson, PhD, Senior Staff Fellow (PI)
- Qing Chen, PhD, Microbiologist
- Siobhán Cowley, PhD, Research Biologist (PI)
- Roberto dePascalis, MD, Research Microbiologist
- Steven Derrick, PhD, Microbiologist
- Madushini Dharmasena, PhD, Staff Fellow
- Karen Elkins, PhD, Supervisory Research Biologist (PI)
- Miranda Oakley, PhD, Biologist



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