

# **Overview of the Division of Blood Components and Devices Research Programs**

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**Director, Division of Blood Components and Devices**

**Blood Products Advisory Committee Meeting**

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# Division of Blood Components and Devices (DBCD)



Director: Orijei Illoh, M.D.  
Deputy: Wendy Paul, M.D.

**Device Review Branch (DRB)**  
Chief: Teresita Mercado

**Clinical Review Staff CRS**  
Team Lead: Salim Haddad, M.D.

**Blood and Plasma Branch (BPB)**  
Chief: Richard McBride

**Laboratory of Biochemistry and Vascular Biology (LBVB)**  
Chief: Abdu I. Alayash, Ph.D.  
PIs  
Abdu I. Alayash, Ph.D.  
Felice D'Angillo, Ph.D.  
Paul Buehler, Ph.D.

**Laboratory of Cellular Hematology (LCH)**  
Chief: Jaroslav Vostal, M.D. Ph.D.  
PIs  
Jan Simak, Ph.D.  
C.D. Atreya, Ph.D.  
Jaroslav Vostal, M.D. Ph.D.

Total Principal Investigators- 6

# DBCD Mission

- Assure the safety, efficacy and availability of blood and blood components and related biological products
  - Blood transfusion involves multiple processes including donor screening, testing, collection, storage and compatibility testing
  - Biological products include hemoglobin based oxygen carriers and volume expanders



# DBCD Review Activities

- Review applications and perform inspections related to:
  - Manufacture of blood and blood components for transfusion and Plasma for further manufacture
  - Devices used in manufacture of blood and blood components
  - Immunohematology reagents for blood compatibility testing
  - Plasma volume expanders
  - Hemoglobin-based oxygen solutions/therapeutics and Fluorocarbon-based oxygen solutions
- Investigational New Drug (IND) and Investigational Device Exemption (IDE) reviews, and other pre-marketing activities

# DBCD Regulatory Review Process

- Regulatory decisions are based on scientific data showing safety, efficacy and purity
  - Internal review by reviewers/ research-review staff and supervisors
  - Facility inspections
  - Presentations to Advisory Committees e.g. novel blood product or device
  - Public workshops

## Additional DBCD Activities

- Develop regulations and guidance governing practices related to blood donor eligibility and product manufacturing
- Liaisons with industry, government agencies (e.g. NIH, CDC), regulatory agencies of foreign governments, international bodies
- **Conduct mission relevant research to facilitate the development, manufacture and evaluation of products DBCD regulates**

# DBCD Research Goals and Objectives

Assess and promote safety and effectiveness of transfusion products and related devices and technologies

Examples include:

- Evaluation of the safety and effectiveness of oxygen carrying solutions, platelet-derived products and related biologics
- Evaluation of pathogen reduction technologies applicable to whole blood and blood components
- Development of animal models to evaluate RBC quality

# Summary

- DBCD research complements the regulatory mission
  - Enhances DBCD's ability to promote the review and development of safe blood products and related devices
  - Contributes to the development of regulatory policies for product development and review
- DBCD research staff have made significant contributions to the field and are recognized internationally for their work