Welcome to the FDA Workshop for the Reproductive Tissue Industry

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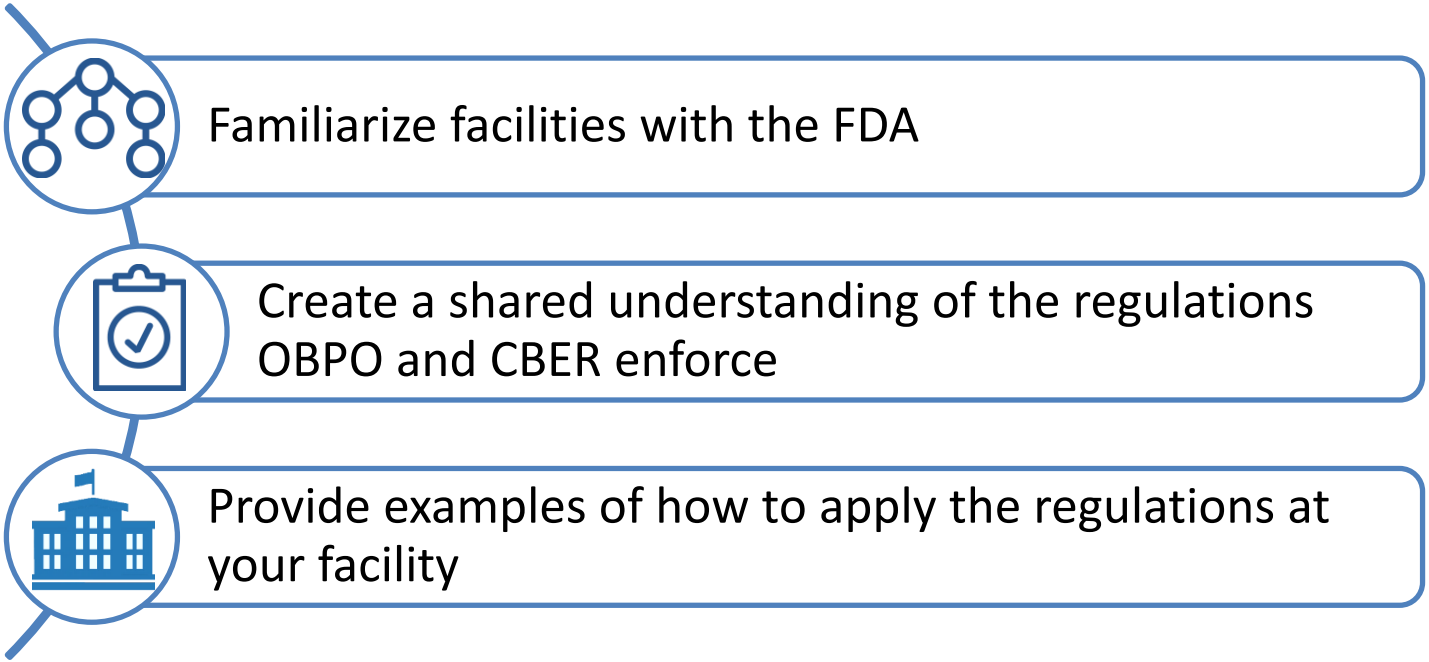
WELCOME

FDA Workshop
Co-hosted by the Office of Biological Products Operations (OBPO) and
Center for Biologics Evaluation and Research (CBER)

Purpose of Reproductive Facilities Workshop: *Sharing Information*



Why is This Workshop Needed?

OBPO noticed a trend across the country that firms are having difficulty:

- Remaining current with regulations; and
- Knowing where to find regulatory documents and updates on the FDA website.

The impact of this is:

- Lack of knowledge may lead to non-compliance; and
- Non-compliance increases risks to recipients.

Focus of Workshop

The workshop will cover a range of topics of practical interest, including:

Guidance Documents

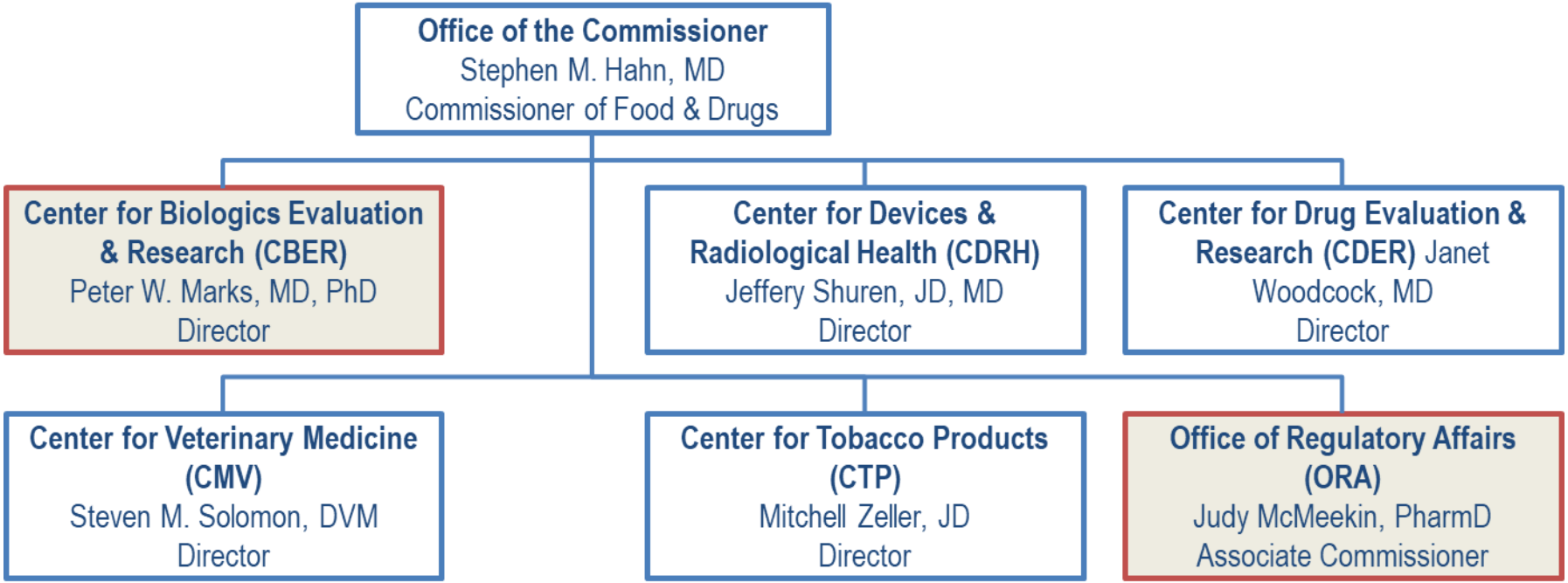
What to Expect on an Inspection

Donor Screening and Testing

…Among others.

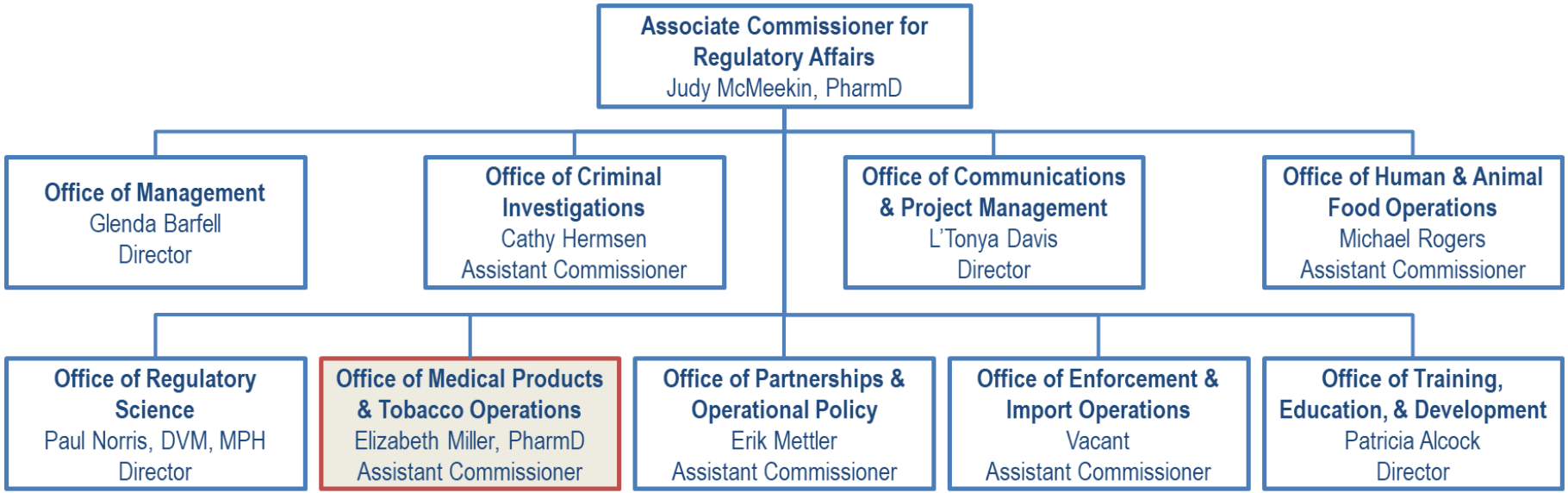
OVERVIEW OF FDA

FDA Organization

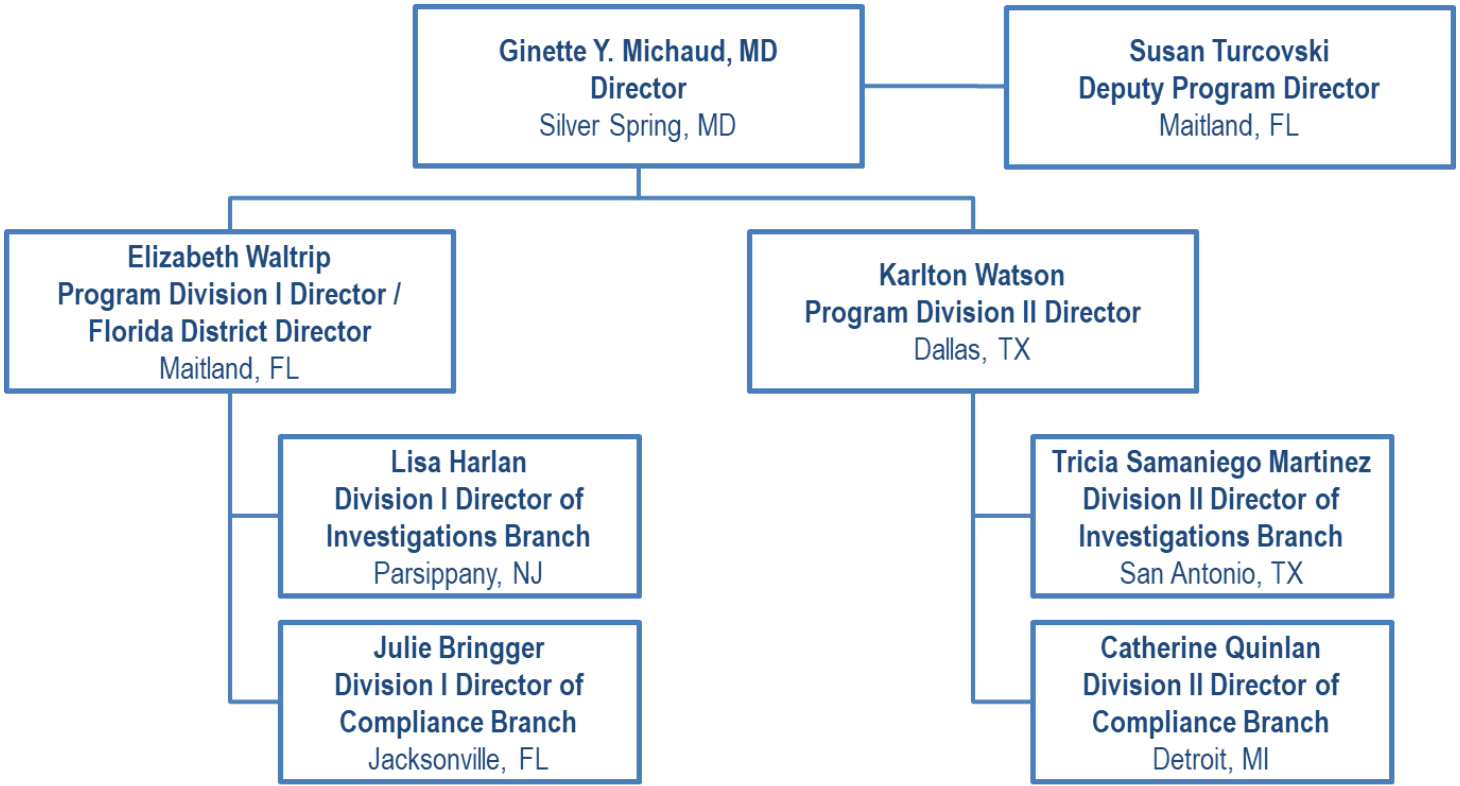


OVERVIEW OF
OFFICE OF BIOLOGICAL PRODUCTS OPERATIONS (OBPO)
&
OFFICE OF REGULATORY AFFAIRS (ORA)

ORA Organization



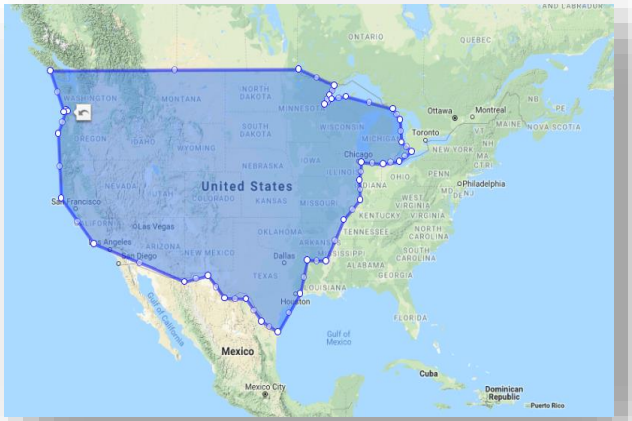
OBPO Organization



OBPO Divisions

OBPO has two divisions with the same functional duties; boundary maps shown below.

Division 1: Alabama, Connecticut, Delaware, Florida, Georgia, Kentucky, Louisiana, Maryland, Massachusetts, Maine, Mississippi, New Hampshire, New Jersey, New York, North Carolina, Ohio, Pennsylvania, Puerto Rico, Rhode Island, South Carolina, Tennessee, Vermont, Virgin Island, Virginia, West Virginia



Division 2: Alaska, America Samoa, Arizona, Arkansas, California, Colorado, Guam, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Mariana Islands, Michigan, Minnesota, Missouri, Montana, Nebraska, Nevada, New Mexico, North Dakota, Oklahoma, Oregon, South Dakota, Texas, Utah, Washington, Wisconsin, Wyoming

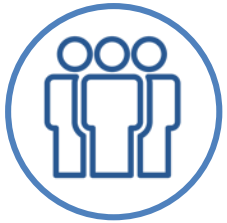
What Does OBPO Do?

OBPO consists of a specialized workforce that conducts inspections, investigations, and compliance activities for reproductive tissue as well as other biological products.

- Manage field operations, domestically and internationally, for biological products regulated by CBER. Operations include inspections and investigations, as well as recommending legal actions and enforcing approved actions.
- Develops and maintains cooperative relationships with State, local, and other federal agencies and services as the subject matter expert on field operations relative to cross-Agency biologics programs.
- Provide advice and counsel to the Assistant Commissioner for Medical Products and Tobacco Operations (ACMPTO) and other agency leaders on emerging trends, program needs, and local or state issues.

OBPO Investigations

OBPO conducts close to **280 inspections** of reproductive tissue establishments annually



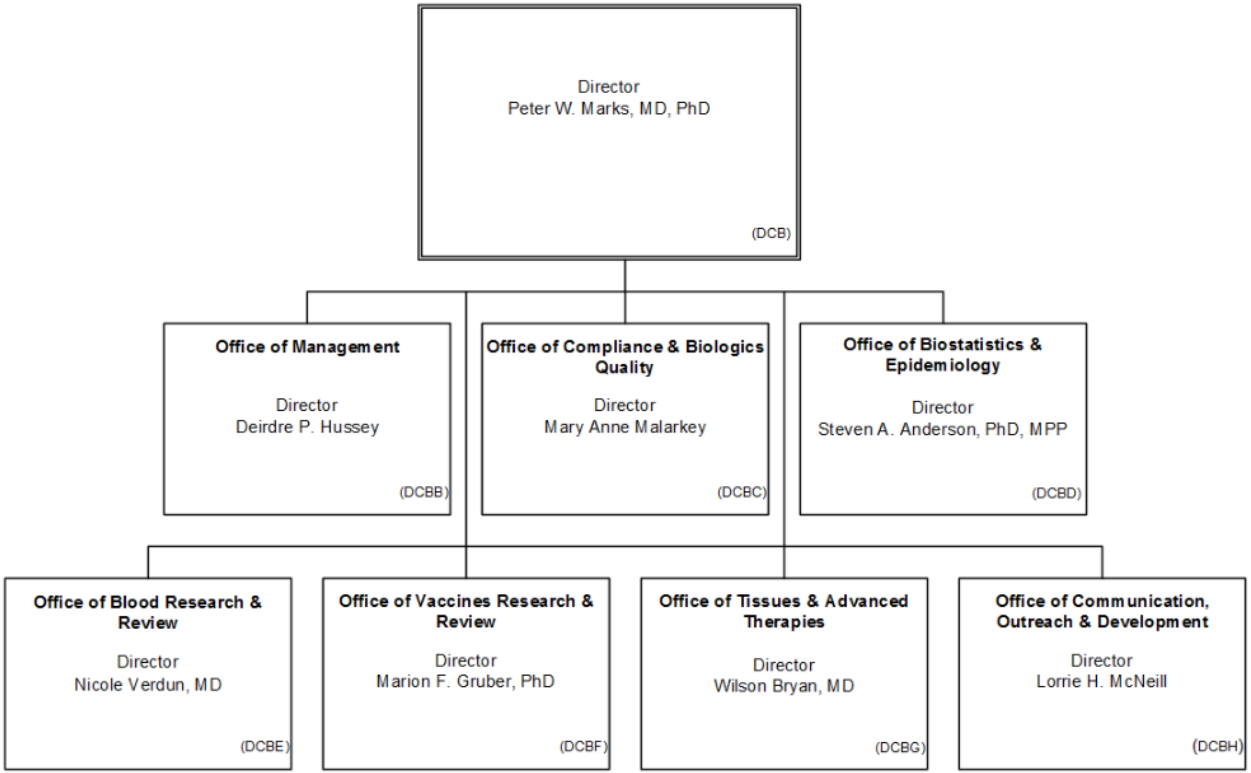
Our workforce includes **89 investigators**, completing inspections for all types of HCT/Ps, many of whom participated in planning this workshop

Workshop Speakers and Organizers

- Tania Hall, OBPO
- Marla Cassidy, OBPO
- Kimberly Miles, CBER
- Jennifer Sheehan, OBPO
- Simone Porter, CBER
- Ping He, CBER
- Ranilo Catalasan, CBER
- Wendy Hively, CBER
- Irina Gaberman, OBPO
- Julie Bringger, OBPO
- Stephany Kersten, CBER
- Dan (Kelly) Wang, CBER
- Samantha Pinizzotto, OBPO
- Cherlita Honeycutt, OBPO
- Lisa Harlan, OBPO
- Colleen Aspinwall, OBPO
- Jennifer Custodio, OBPO
- Courtney Gilbert, OBPO
- Valerie Grecek Trinh, OBPO
- John Fraser, OBPO
- Douglas Fiorentino, OBPO

OVERVIEW OF CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)

CBER Organization



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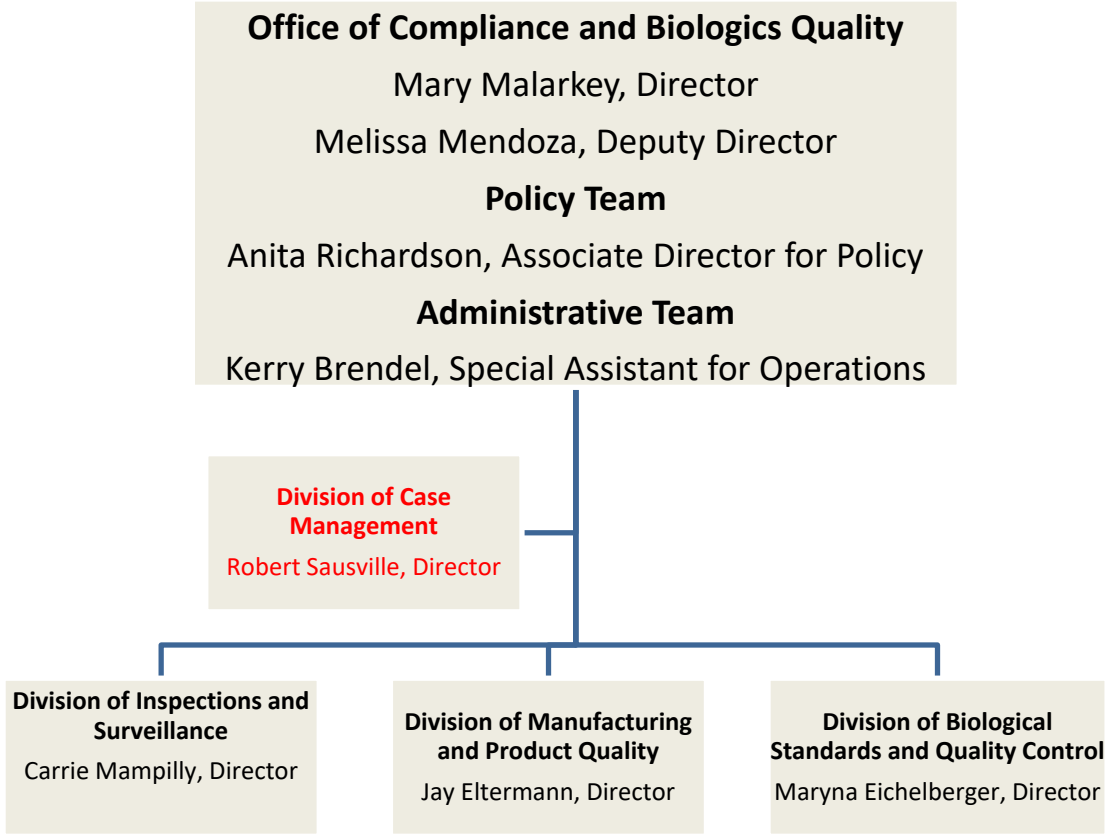
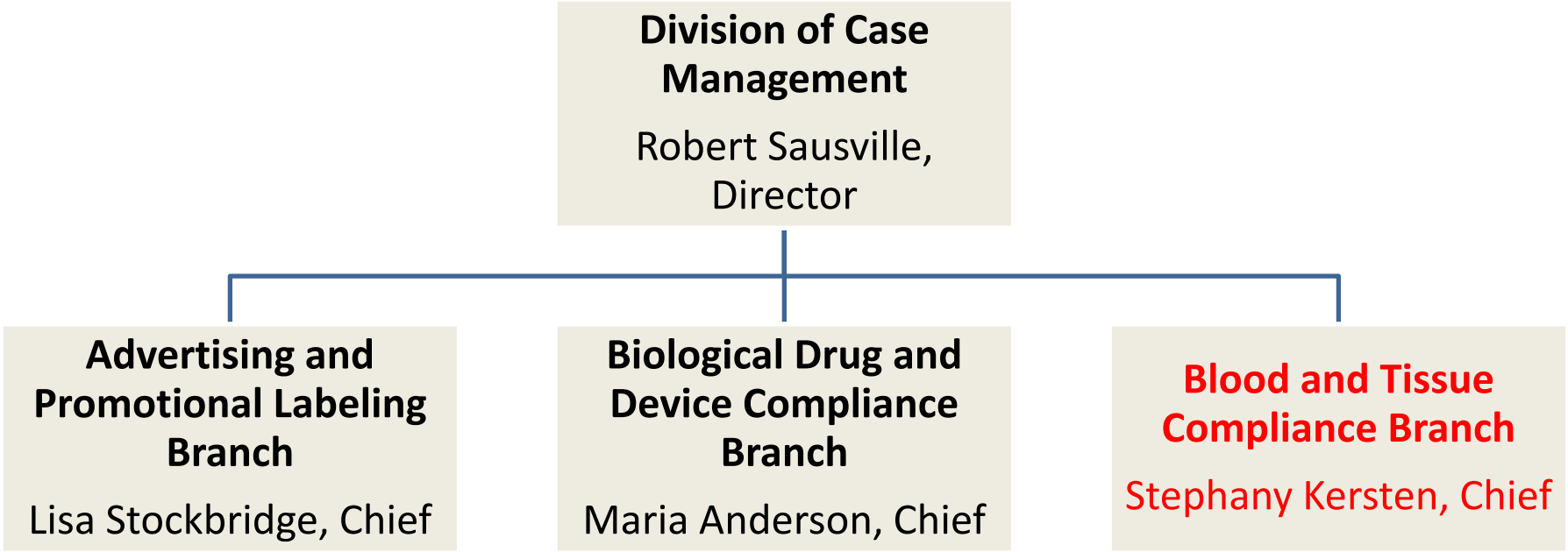
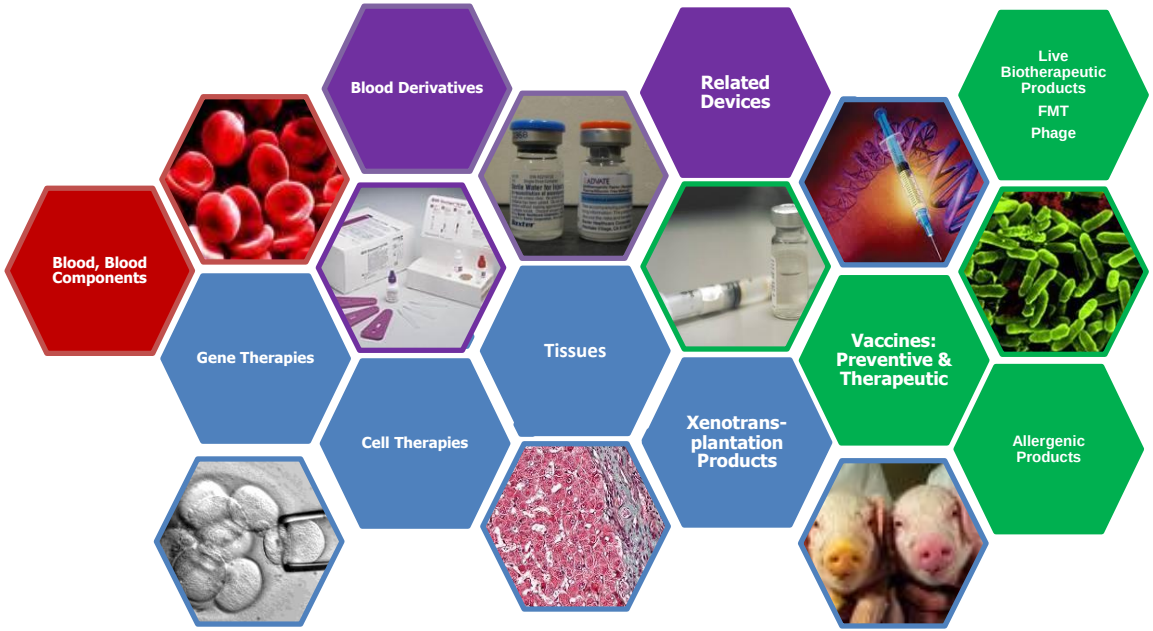


CBER Organization (Continued)



CBER Regulated Products

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