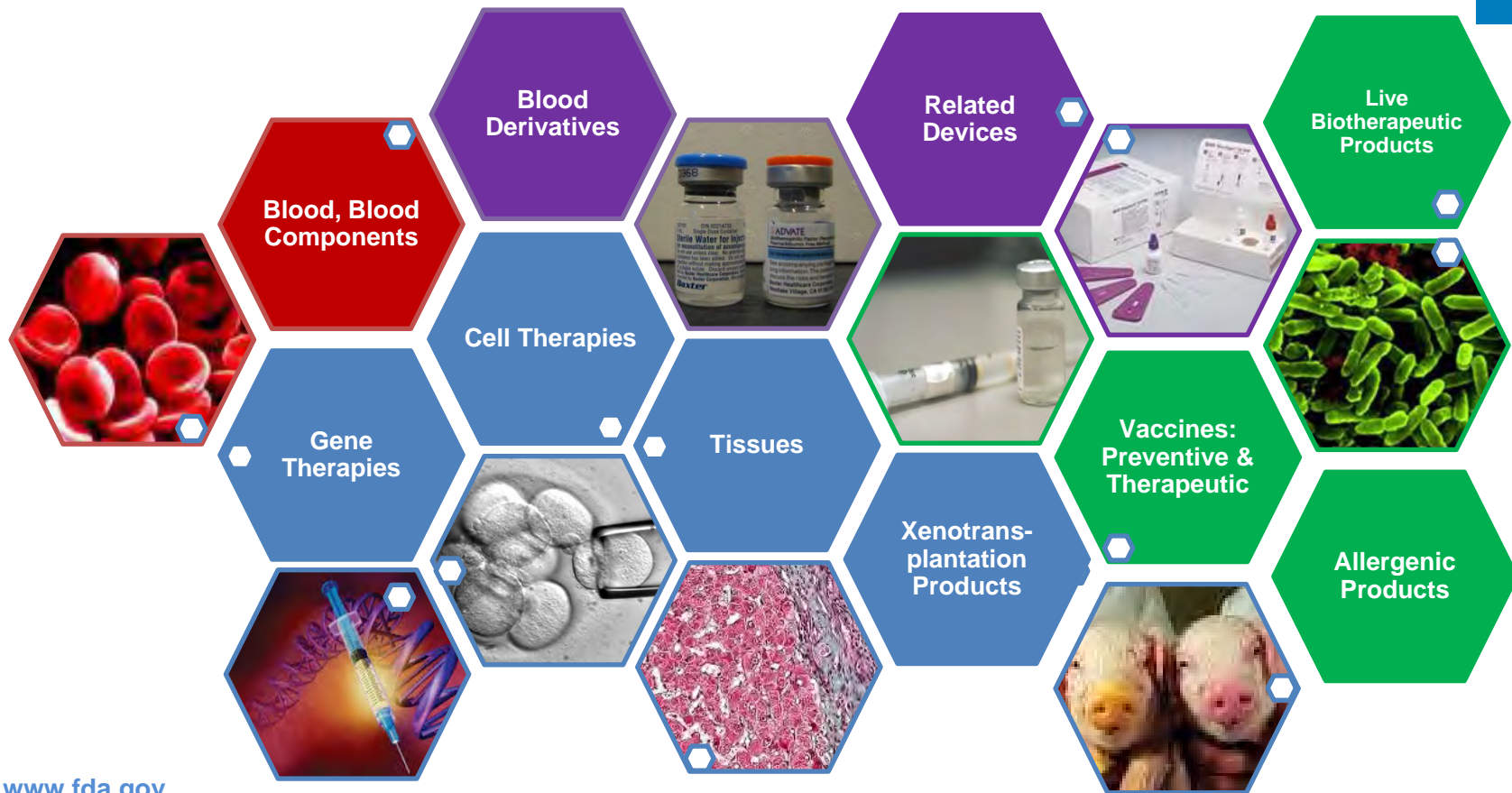




Center for Biologics Evaluation and Research (CBER) Presentation

Emily Braunstein, PhD
CBER Research Program Manager

CDER Regulates Complex Biological Products



CBER Research Goals

Advancing the scientific basis for regulation of biologics, human tissues and blood by:

**Priority
1**

Develop and evaluate technology and tools to support non-clinical evaluation of medical products.

**Priority
2**

Enhance the validity and efficiency of clinical evaluation through use of innovative statistical, analytical, and modeling approaches.

**Priority
3**

Proactively address public health challenges and emerging infectious diseases.

**Priority
4**

Advance scientific capabilities to assess novel technologies and innovative medical products to inform regulatory oversight.

CBER BAA Priorities

- I. Harness regulatory science to modernize development and evaluation of FDA-regulated products
 - **Advanced Manufacturing Approaches**
 - **Analytical and Computational Methods**
- II. Harness regulatory science to strengthen post-market surveillance and labeling of regulated products
 - **RWD to serve as RWE**
 - **Utilizing and Validating Artificial Intelligence**
 - **Adverse Event Reporting and Surveillance**



CBER Advanced Technologies Program

Promoting the Development and Adoption of
Advanced Manufacturing Technologies

[CBER Advanced Technologies Program | FDA](#)

Advancing Innovative Manufacturing Technologies through Extramural Funding



Awarded 23 grants and contracts



Addresses knowledge and experience gaps

Examples of Supported Projects

<https://www.fda.gov/vaccines-blood-biologics/industry-biologics/cber-advanced-technologies-program-extramural-research-funding>

- Novel manufacturing approaches for cell therapy products
(CQA discovery, purification, continuous production)
- 3D Bioprinting for tissue engineering
- End-to-end manufacturing of gene therapy products
(Continuous manufacturing of AAV vectors)
- 3D-printed single-use miniature bioreactors
- Process modeling/simulation
- Non-destructive analytics (NMR) for evaluating product quality
- Integrated and continuous manufacturing of vaccines

FY23 CBER BAA Advanced Manufacturing Priority Areas

Section I.B - Advanced Manufacturing Approaches

Biologics: Explore novel applications of advanced manufacturing processes for complex biological products

Section I.C – Analytical and Computational Methods

Cross-cutting: Develop and evaluate the use of model-based digitally integrated systems, artificial intelligence, machine learning and simulation in production or quality system activities

Summary

- CBER is committed to supporting the **development** and **adoption** of advanced manufacturing technologies and is doing so by supporting advanced R&D research to develop innovative technologies



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