

Medical Devices in CBER

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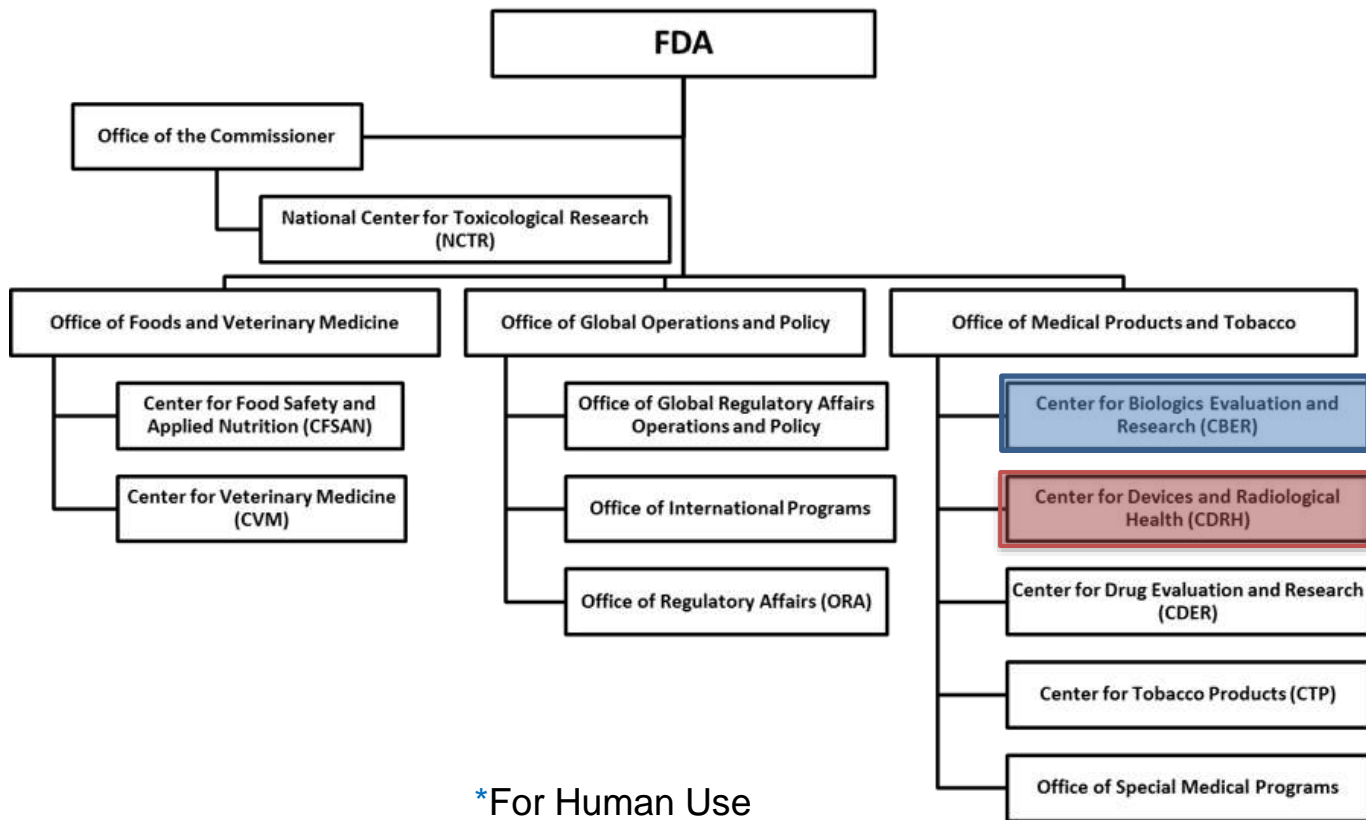
Learning Objectives

- Identify the product offices that review medical devices in the Center for Biologics Evaluation and Research (CBER)
- Describe the types of medical devices reviewed in CBER
- Describe delivery device considerations for biological products



Medical Devices Reviewed in CBER

Medical Devices* in FDA



*For Human Use

Submission Types: CBER & CDRH

- Third Party Pre-market Notification (510(k))
- CLIA Categorizations

CDRH

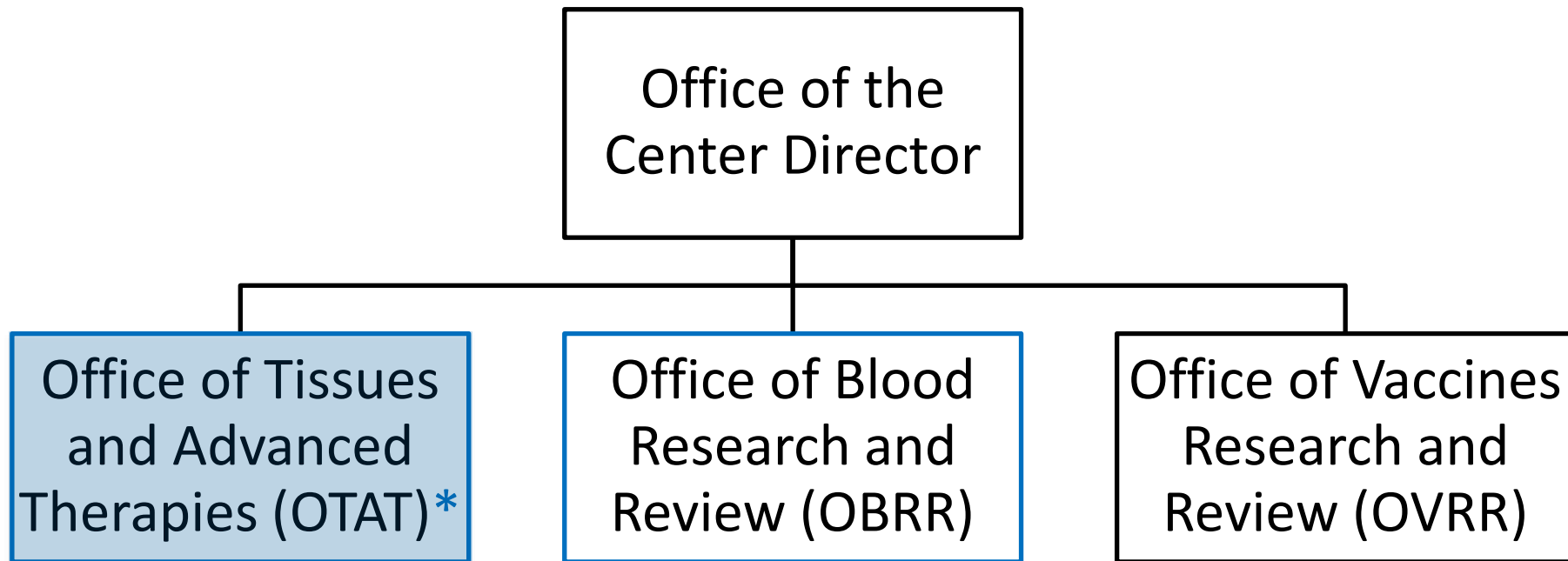
- Q-Submissions
- Investigational Device Exemption (IDE)
- Pre-market Notification (510(k))
- De-Novo Classification Request
- Premarket Approval (PMA)
- Humanitarian Device Exemption (HDE)
- 513(g) Request for Information

CBER

- Pre-submissions (pre-IND, INTERACT)
- Investigational New Drug (IND)
- Biologics License Application (BLA)
- Device BLA ★
- New Drug application (NDA)
- Abbreviated New Drug Application (ANDA)

- ★ e.g., Donor screening assays
- ★ 21 CFR 809.3 In vitro Diagnostics (IVDs) are devices and **may also be biological products subject to section 351 of the Public Health Service Act**
- ★ 21 CFR 600s and some 800s apply, MDUFA fees and timelines

Medical Devices in CBER Product Offices



*Formerly the Office of Cellular, Tissue, and Gene Therapies (OCTGT)

Devices in CBER/OTAT

Devices that **collect, process, and/or store** HCT/Ps (Human cells, tissues and cellular and tissue-based products) for a therapeutic use

AXP II AutoXpress Platform for Cord Blood
(BK190198)



Cryogenic Storage Container
for Hematopoietic Progenitor
Cells (BK100049)



<https://chartermedical.com/>

Devices in CBER/OTAT

Devices intended to process
HCT/Ps ex vivo to generate a
therapeutic device output at
the **point-of-care**

Avita Medical
RECELL® Autologous
Cell Harvesting Device (BP170122)



<https://recellsystem.com/>

Miltenyi CliniMACS® CD34 Reagent
System (BH110018)



<https://www.miltenyibiotec.com/>

Devices in CBER/OTAT

Devices that process **peripheral blood** to generate platelet-rich plasma (**PRP**) or platelet-rich fibrin (**PRF**) for therapeutic use

Arthrex Angel® cPRP System & Kit
(BK180180)



Zimmer Biomet GPS® III Platelet
Concentration System (BK070026)
<https://www.zimmerbiomet.com/>

RedDress RD2 System (BK200464)



Reaplix 3c
Patch® Kit
(BK200471)
<https://3cpatch.com/>

Devices in CBER/OTAT

In Vitro Diagnostics (IVDs) for enumerating cell populations in HCT/Ps

NanoEnTek ADAMI™ CD34 System
(BK180283)



<http://www.nanoentek.com/>

BD™ Stem Cell Enumeration Kit
(BK110037)

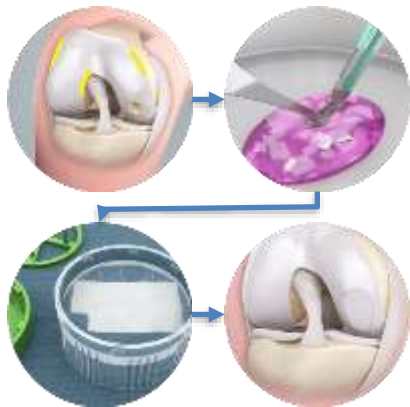


<https://www.bdbiosciences.com/>

Devices in CBER/OTAT

Device Constituents of certain biologic-led combination products (21 CFR 3.2(e)), for example:

Scaffold combined with cells to make tissue engineered constructs for regenerative medicine



Vericel MACI® (autologous cultured chondrocytes on porcine collagen membrane, BLA 125603)

<https://www.maci.com/>

Certain devices used to administer biological products (delivery devices)



Pre-filled Delivery Devices
(Single Entity)

(Baxter TISSEEL Fibrin Sealant, BLA 103980)

<https://advancedsurgery.baxter.com/products/tisseel>

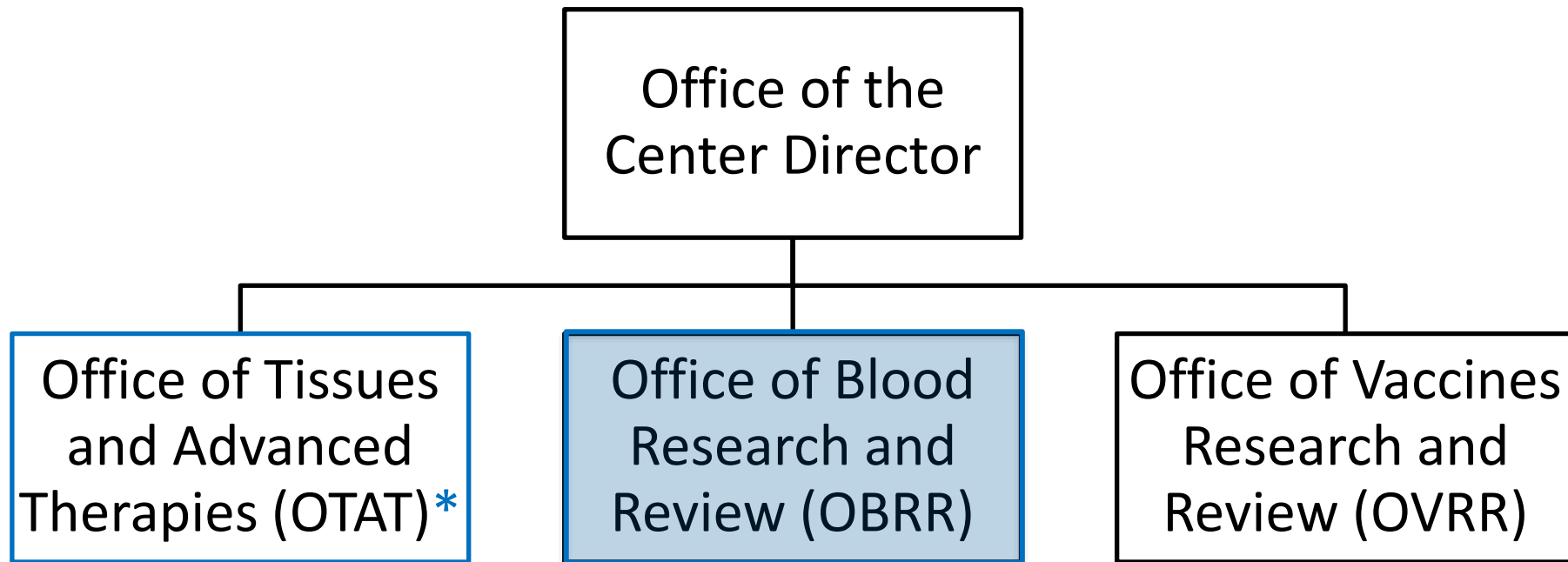


Cross-Labeled or Co-packaged
Delivery Devices

(Ethicon VISTASEAL™ Applicators, BK180287, BK190324)

<https://www.ethicon.com/>

Medical Devices in CBER Product Offices

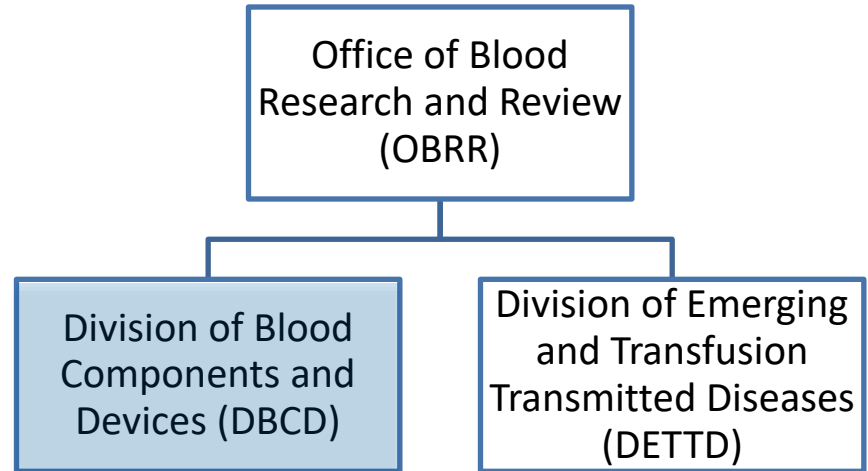


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Devices Reviewed in CBER/OBRR



- Devices used in establishments that manufacture Blood and Blood Products (21 CFR 864 Subpart J)



Devices Reviewed in CBER/OBRR/DBCD



- Blood and blood component collection devices
- Medical devices used to **test, collect, process** or **store** donated blood and blood components

Fresenius Kabi Amicus Separator System
(BK160112)



<https://www.fresenius-kabi.com/>

Devices Reviewed in CBER/OBRR/DBCD



- IVD immunohematology products, such as:
 - Human Leukocyte Antigen (HLA) Kits
 - Blood Grouping Reagents
 - Reagent Red Blood Cells
 - Anti-Human Globulins

Bio-Rad Biotestcell and Erytypecell
(Device BLA 125207)



Bio-Rad TANGO optimo Automated Blood Grouping
and Antibody Test System (BK080013)



<https://www.bio-rad.com/>

Devices Reviewed in CBER/OBRR/DBCD



- Medical devices (other than reagents) intended for use in the **preparation of, in conjunction with, or for the quality assurance of** a blood bank related licensed biological product or practice, such as:
 - Blood Establishment Computer Software (BECS)
 - Dosimeters and thermal indicators for blood irradiators
 - Microwave ovens used for thawing blood products

Fremont Scientific ZipThaw® 202 Plasma warming device
(BK190401)

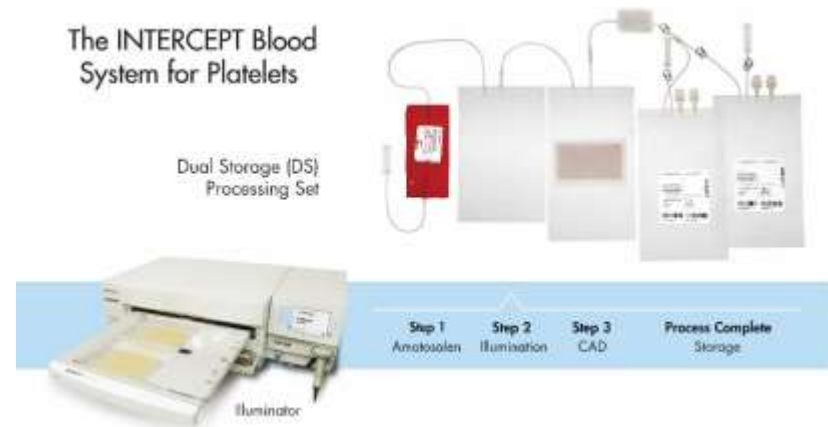


<https://fremonscientific.com/>

Devices Reviewed in CBER/OBRR/DBCD

- Medical devices and combination products used to **prepare**, **preserve**, and **store** blood products, including:
 - Bacterial detection
 - Pathogen-Reduction Technologies

Cerus Corporation INTERCEPT® Blood System for Platelets (BP140143)

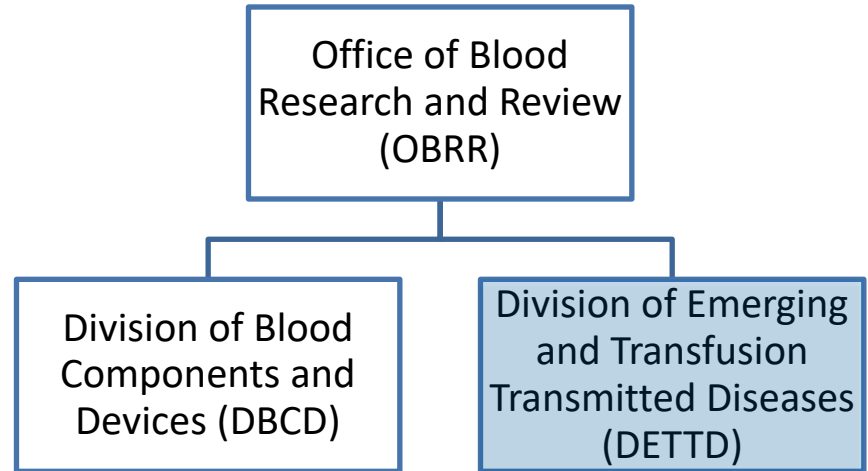


<https://www.interceptbloodsystem.com/>

Devices Reviewed in CBER/OBRR



- Devices used in establishments that manufacture Blood and Blood Products (21 CFR 864 Subpart J)



Devices Reviewed in CBER/OBRR/DETTD



- Donor Screening Assays and Multiplex for Infectious Agents (Device BLAs)
 - Human T-Lymphotropic Virus Types I & II (Anti-HTLV-I/II Assay)
 - *Trypanosoma cruzi* (T. Cruzi) (Anti-T. Cruzi Assay)
 - West Nile Virus (WNV)
 - Hepatitis B (HBV)
 - Hepatitis C (HCV)
 - Zika virus
 - Babesia
 - HIV-1/2
- Retroviral Diagnostic Tests (HIV) (PMA)

Alinity s HTLV I/II Antigen
and Synthetic Peptides
used with Alinity s System
(Device BLA 125675)



<https://www.transfusion.abbott/>

OraSure Technologies
OraQuick In-Home HIV
Test
(BP120001)

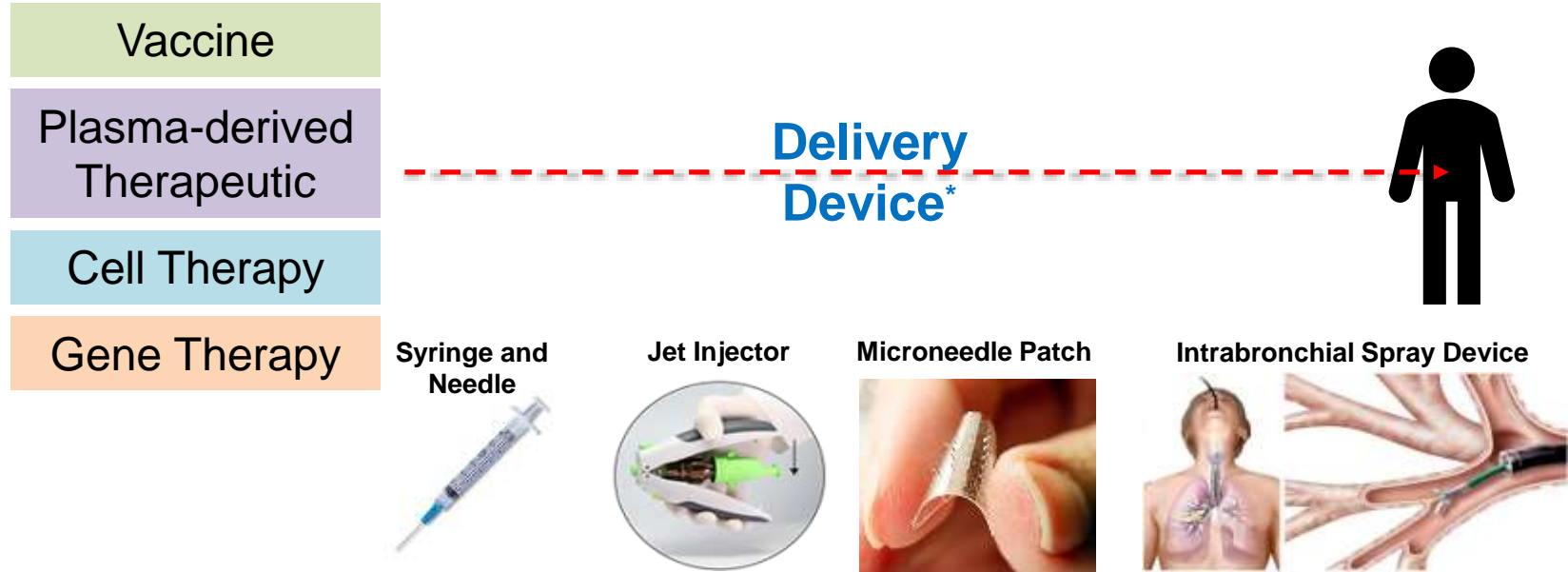


<http://www.oraquick.com/>



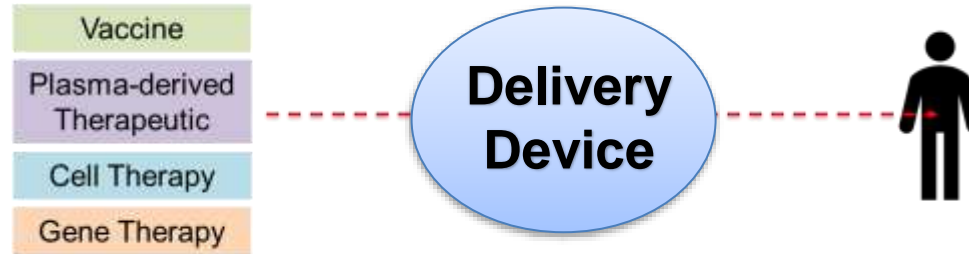
Delivery Devices for Biological Products

What is a delivery device?



***Not including** scaffolds, wound coverings, or encapsulation materials which are typically considered to provide more than a delivery function

Delivery Device Considerations



- Safety and effectiveness of the delivery device is **critical** for safety and efficacy of the biological product
- Performance requirements for the delivery device determined by the Sponsor
- Submissions should include information on the device(s) used to administer the biological product

Combination Products

Combination of biologic, drug, and/or device constituents as defined in 21 CFR 3.2(e)

(1) Physically, chemically, or otherwise combined or mixed and produced as a **single entity**



(2) Two or more separate products packaged together in a single package or as a unit (**co-packaged**)



(3) Packaged separately and **cross-labeled** for use only with an *approved product* (approved product labeling must be changed)



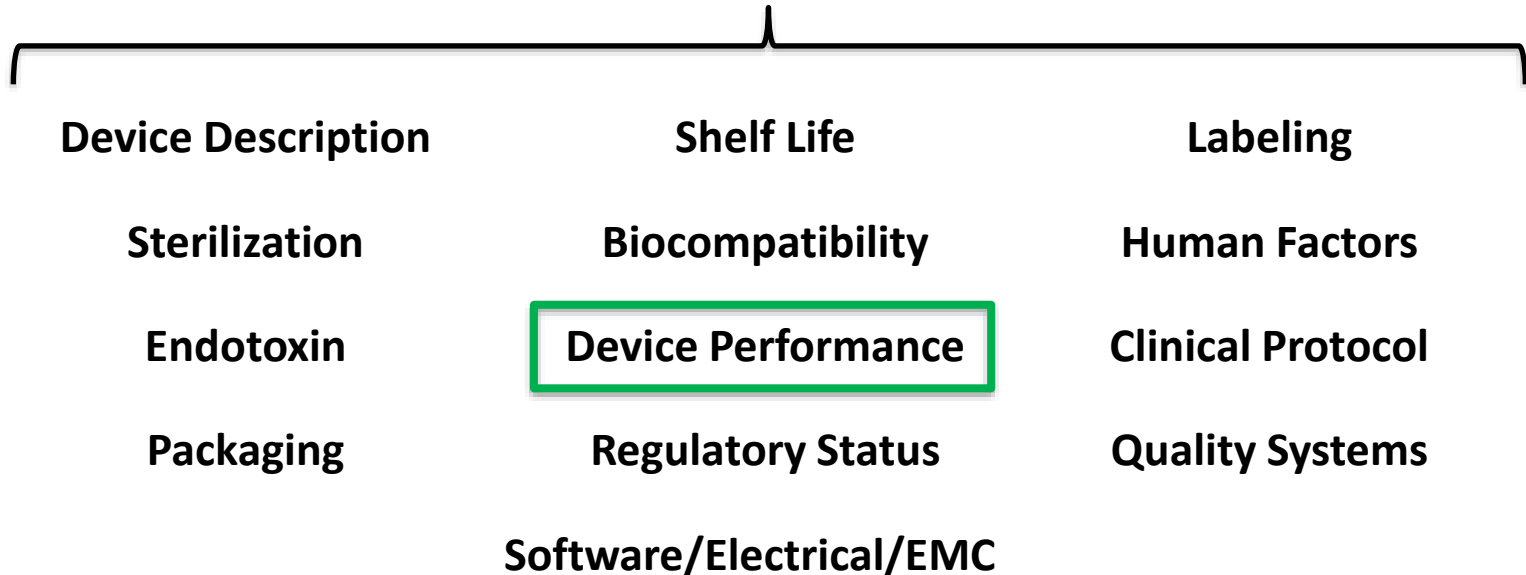
(4) Packaged separately and **cross-labeled** with another *investigational product*



Delivery Device Information



Information to assess the safety & effectiveness of the delivery device



Delivery Device Performance



- Testing to ensure the delivery device meets specified performance/function requirements (design verification) and achieves its user needs and intended use (design validation)
 - Bench testing
 - Pre-clinical animal testing using the same or representative delivery device and procedure
 - Clinical studies in intended population, use environment, etc. (validation)
- Relevant performance metrics should also be included in drug product stability program

Delivery Device Performance



- Important to identify and control the design outputs necessary to deliver the intended drug dose to the intended delivery site, including product preparation and dose delivery initiation, progression, and completion
- Biological product/device compatibility testing
 - Ensure drug product quality and device performance maintained when used together
 - Should utilize worst case clinical parameters

Summary



- CBER regulates medical devices, primarily reviewed in OTAT and OBRR
 - Related to collection, processing/point of care manufacturing, storage, and diagnostic analysis of HCT/Ps, blood, and blood products
 - Used in establishments that manufacture blood and blood products
 - Certain device constituents of some biologic-led combination products
- Device design verification and design validation is critical for delivery devices used to administer biological products to patients
 - Delivery devices should be compatible with the final biological product

Challenge Question #1



A manufacturer intends to market a device that collects and stores cord blood in the USA. What group in FDA will review their submission?

- A. CDRH
- B. CBER/OBRR
- C. CBER/OTAT
- D. CBER/OVRR

Challenge Question #2



Which of the following statements is NOT true?

- A. Some devices that deliver/administer biological products are reviewed by CBER.
- B. In vitro diagnostic devices intended to diagnose HIV are reviewed by CBER/OBRR.
- C. Blood establishment computer software is considered a medical device and reviewed by CBER/OTAT.
- D. Devices that prepare PRP at the point of care for therapeutic use would be reviewed by CBER/OTAT.

Challenge Question #3

_____ is testing to ensure the delivery device meets specified performance/function requirements.

- A. Design Verification
- B. Combination Product
- C. Design Validation
- D. Shelf Life

Resources

- [CBER Product Jurisdiction](#)
- [CBER Regulated Products](#)
- [Devices Used to Process Human Cells, Tissues, and Cellular and Tissue-Based Products \(HCT/Ps\)](#)
- [FDA and Industry Procedures for Section 513\(g\) Requests for Information under the Federal Food, Drug, and Cosmetic Act](#)
- [Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program](#)

Contact information



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FDA Headquarters

- **OTAT Learn Webinar Series:**
<http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/ucm232821.htm>

- **CBER website:** www.fda.gov/BiologicsBloodVaccines/default.htm

Phone: 1-800-835-4709 or 240-402-8010

- **Consumer Affairs Branch:** ocod@fda.hhs.gov
- **Manufacturers Assistance and Technical Training Branch:** industry.biologics@fda.gov
- **Follow us on Twitter:** <https://www.twitter.com/fdacber>



