

Guidance Agenda: Guidance Documents CBER is Planning to Publish During Calendar Year 2025

(January 2025)

This is the list of guidance topics CBER is considering for development during Calendar Year 2025. The list includes topics that currently have no guidance associated with them, topics where updated guidance may be helpful, and topics for which CBER has already issued Level 1 draft guidances that may be finalized following review of public comments. We currently intend to develop guidance documents on these topics; however, the Center is neither bound by this list of topics, nor required to issue every guidance document on this list. We are not precluded from developing guidance documents on topics not on this list.

For further information regarding specific topics or guidances, please contact the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002, 1-800-835-4709 or 240-402-8010, ocod@fda.hhs.gov.

Guidance Documents CBER is Planning to Issue in 2025:

CATEGORY – Blood and Blood Components:

- Considerations for the Development of Blood Collection, Processing, and Storage Systems for the Manufacture of Blood Components Using the Buffy Coat Method; Guidance for Industry
- Collection of Platelets by Automated Methods; Draft Guidance for Industry
- Recommendations for Testing Blood Donations for Hepatitis B Surface Antigen; Draft Guidance for Industry
- Revised Recommendations to Reduce the Risk of Transfusion-Transmitted Malaria; Draft Guidance for Industry
- Recommendations for the Evaluation of Blood Collection, Processing, and Storage Devices Using Non-Di(2-ethylhexyl) Phthalate (non-DEHP) Materials: Draft Guidance for Industry

CATEGORY – Therapeutic Products:

- Frequently Asked Questions — Cell and Gene Therapy Products; Guidance for Industry
- Considerations for the Use of Human- and Animal- Derived Materials and Components in the Manufacture of Cell and Gene Therapy and Tissue-Engineered Medical Products; Guidance for Industry

- Safety Testing of Human Allogeneic Cells Expanded for Use in Cell-Based Medical Products; Guidance for Industry
- Potency Assurance for Cellular and Gene Therapy Products; Guidance for Industry
- Accelerated Approval of Human Gene Therapy Products for Rare Diseases; Draft Guidance for Industry
- Use of Platform Technologies in Human Gene Therapy Products Incorporating Human Genome Editing; Draft Guidance for Industry
- Potency Assessment of Therapeutic Vaccines; Draft Guidance for Industry
- Post Approval Methods to Capture Safety and Efficacy Data for Cell and Gene Therapy Products; Draft Guidance for Industry
- Recommendations to Reduce the Risk of Transmission of *Mycobacterium tuberculosis* by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); Guidance for Industry
- Recommendations to Reduce the Risk of Transmission of Disease Agents Associated with Sepsis for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); Guidance for Industry
- Recommendations to Reduce the Risk of Transmission of Human Immunodeficiency Virus (HIV) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); Draft Guidance for Industry
- Recommendations to Reduce the Risk of Transmission of Hepatitis C Virus (HCV) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); Draft Guidance for Industry
- Recommendations to Reduce the Risk of Transmission of Hepatitis B Virus (HBV) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); Draft Guidance for Industry
- Recommendations for Determining Eligibility of Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); Draft Guidance for Industry

CATEGORY – Other:

- Standardized Format for Electronic Submission for Marketing Applications Content for the Planning of Bioresearch Monitoring (BIMO) Inspections for Center for Biologics Evaluation and Research Submissions; Guidance for Industry

- Recommendations for Validation and Implementation of Alternative Microbial Methods for Testing of Biologics, Draft Guidance for Industry