Association for the Advancement of Blood & Biotherapies

Mitigating Risks to Blood Safety and Availability During Cybersecurity Events: Current Considerations for Shared Manufacturing

April 2025

This Toolkit is intended to:

(1) Assist centers seeking to improve the resiliency of the blood supply and mitigate risk for patients requiring transfusion during cybersecurity events.

(2) Identify the regulatory resources currently available under FDA's regulatory framework for blood centers considering flexible licensing strategies for a shared manufacturing arrangement.

(3) Support blood safety and availability during cybersecurity events, and compliance with FDA's requirements-

Questions on the shared manufacturing arrangement should be directed to the CBER OBRR BPB Inquiry line at CBEROBRRBPBInquiries@fda.hhs.gov to ensure full compliance based on your facility's operations.

Mitigating Risks to Blood Safety and Availability During Cybersecurity Events:
Current Considerations for Shared Manufacturing
April 2025

BACKGROUND

The Blood Centers of American (BCA) identified shared manufacturing as a viable strategy to improve blood resiliency by mitigating the impact of cyberattacks and the resulting risk for patients requiring lifesaving blood transfusions. The impacts of recent cybersecurity events underscore the importance of the shared manufacturing option as one of the strategies necessary to support blood safety and availability during these events.

AABB joined BCA in its efforts to identify the current regulatory framework for a shared manufacturing strategy. The goal of this toolkit is to:

- Provide detailed regulatory resources for shared manufacturing arrangements that are fully compliant with existing FDA requirements.
- Support blood centers seeking flexible licensing strategies for shared manufacturing to improve continuity in operations, strengthen blood safety and availability, and mitigate risk for patients requiring transfusion during challenging cybersecurity events.

FDA'S CURRENT REGULATORY FRAMEWORK FOR SHARED MANUFACTURING

Following our inquiry with FDA, we confirmed that:

(1) The agency has received similar questions about "shared manufacturing during cybersecurity events, when blood is collected under one license and sent to a manufacturing site that is under a different license and distributed from there."

(2) This manufacturing strategy, also referred to as a "divided manufacturing arrangement," exists within the current regulatory framework, as described in FDA's Nov 2008 Guidance, Cooperative Manufacturing Arrangements for Licensed Biologics.

- Under SCOPE on page 1, the guidance states the Food and Drug Administration is "*issuing this guidance on cooperative manufacturing arrangements applicable to biological products subject to licensure under section 351 of the Public Health Service Act (PHS Act) (42 U.S.C. 262). This document is issued jointly between the Center for Biologics Evaluation and Research (CBER) and the Center for Drug Evaluation and Research (CDER). This guidance describes our current thinking on licensing strategies for meeting the increased need for flexible manufacturing arrangements."*
- FDA specifically states, "*FDA registered manufacturers of biological products and transfusion services may also choose to follow this guidance*."

NEXT STEPS:

Centers interested in implementing shared manufacturing should:

a. Submit a CBE labeling supplement.
b. Refer to ICCBBA ISBT CS 4.0 (p. 158, Table 12) describing that the label should show both manufacturers (that collected the product and modified the product).
c. Refer to additional information on page 5, section IV, Divided Manufacturing Arrangements, FDA's Nov 2008 Guidance for Industry, Cooperative Manufacturing Arrangements for Licensed Biologics, which states:
"*Divided manufacturing is an arrangement in which two or more manufacturers, each registered with FDA in accordance with 21 CFR Parts 207, 607, or 807 as applicable, and licensed to manufacture a specific biological product in its entirety, participate jointly in the manufacture of that product*."

We encourage centers to review all details of FDA's current thinking (referenced above, including the Nov 2008 guidance) to determine if a shared manufacturing arrangement could meet the facility's unique operational needs and help address blood safety and availability challenges during cybersecurity events.

Questions on the shared manufacturing arrangement should be directed to the CBER OBRR BPB Inquiry line at CBEROBRRBPBInquiries@fda.hhs.gov to ensure full compliance based on your facility's operations.