



Regulation and Licensure of Whole Blood and Blood Components

American Association of Blood Banks (AABB)

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This book captures the content of the September 2009 FDA workshop, intended to educate industry on the licensure requirements and license application procedures for whole blood and blood components, including Source Plasma. This volume builds on and updates the much-used resource published by AABB in 1995 after a similar FDA workshop. Generally applicable material is supplemented by focused content on both blood and plasma.

Topics include:

- Requirements for licensure.
- Applicable regulations and guidance documents.
- The managed review process.
- Review criteria for various submissions.
- Establishment registration and product listing requirements.
- Inspections of establishments pending licensure and approval.
- Exceptions and/or use of alternative procedures.

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