

Free Guide

BLA: Biologics License Application



Skills management software
for frontline workers

www.ag5.com | info@ag5.com | [+31 20 463 0942](tel:+31204630942)

What is a Biologic License Application (BLA)?

If any organization wants to sell a biologic product in the United States, it must submit a BLA to the Food and Drug Administration (FDA). Specifically, a successful BLA grants permission for an organization to distribute a biologic product across state lines.

A biologic product includes:

- Vaccines
- Blood and blood components
- Allergens
- Somatic cells
- Gene therapy
- Tissues
- Recombinant therapeutic proteins

Who needs to submit a BLA?

Any company or entity that wants to market a biological product in the U.S. must submit a BLA to the FDA. It is mandatory for regulatory approval under the Public Health Service (PHS) Act before commercial distribution.

How to submit a BLA

Organizations interested in obtaining a biologics license must fill and submit [Form FDA 356h](#) to the Center for Biologics Evaluation and Research (CBER).

The submission process also encompasses:

- **Data compilation.** Gathering preclinical, clinical, manufacturing, and labeling information
- **The FDA review process.** The FDA evaluates safety, efficacy, and manufacturing compliance.
- **Facility inspection.** The FDA may inspect manufacturing sites for compliance with [Good Manufacturing Practices \(GMP\)](#) compliance
- **Approval.** The FDA either approves, requests more information, or rejects the application

Renewal requirements for BLA submissions

While a biologics license does not require renewal, organizations must comply with regulatory requirements to maintain its validity. These include:

- **Annual reports.** Biologics license holders must submit yearly reports detailing manufacturing, safety, and quality updates
- **Adverse event reporting.** Companies must track and report adverse events, following pharmacovigilance regulations
- **Manufacturing and FDA inspections.** Facilities must comply with GMP regulations
- **Labeling and lot release.** Updates to safety labeling must be submitted for FDA review. Some biologics require pre-distribution lot release, ensuring each batch meets quality, potency, and stability requirements before public distribution

The benefits of BLA approval

A biologics license several benefits to organizations. Some key advantages include the following.



Market exclusivity

A BLA approval grants market exclusivity, preventing generic competition for a defined period. This allows companies to maximize revenue, strengthen brand recognition, and establish a leadership position in the biologics industry.



Regulatory credibility

FDA approval of a BLA signifies compliance with high safety and efficacy standards, boosting credibility. In turn, this facilitates easier regulatory approvals in international markets.



Manufacturing and quality control

An approved BLA ensures adherence to GMP standards, proving that an organization maintains consistent quality and supply chain integrity.

Challenges in submitting a BLA

Earning a biologics license may pose several challenges to employees and organizations. They include the following.



Regulatory complexity

BLA submissions require extensive preclinical, clinical, and manufacturing data. Navigating evolving FDA guidelines and addressing regulatory queries can lead to prolonged review times and delays.



High development and compliance costs

Biologic products require costly R&D, large-scale clinical trials, and adherence to GMP regulations. Ensuring compliance with stringent FDA standards increases financial burdens, making BLA submission a resource-intensive process.



Manufacturing and scalability

Biologic production involves complex cell culture systems and stringent quality controls. Any process deviation or facility change requires FDA approval, making scalability and consistent manufacturing a significant operational challenge.

Tips and strategies for submitting a Biologics License Application

Here are a few tips for preparing a BLA:

- Read and study the [resources on the FDA's website](#)
- Read the [instruction sheet](#) for Form FDA 356h
- Conduct well-designed clinical trials that demonstrate safety, efficacy, and consistency
- Ensure compliance with GMP standards, detailing production processes, quality controls, and stability studies for regulatory approval
- Schedule pre-BLA meetings and regulatory consultations to address potential concerns

Resources for BLA submission

For more information and guidance on BLA submission, you can refer to the following resources:

FDA. The Food and Drug Administration offers a [wealth of resources regarding BLA submission](#). Its website should be the first stop for any organization seeking to enter the biologics market.

Skills management for Biologics License Applications

AG5 stores all certifications in the cloud, providing all authorized personnel with access to the right version of approved certifications. This helps you easily keep track of all data and documentation related to biologics licenses across your organization.

Using AG5's skills management software, you can monitor the status of any type of certification that is relevant to your workforce, leveraging intuitive dashboards that provide you with a clear understanding of exactly what is needed to keep your employees skilled and safe.

Frequently asked questions about BLA

What is the scope of a BLA?

A Biologics License Application (BLA) covers the manufacturing, safety, efficacy, quality, and distribution of biological products, including vaccines.

Is a biologics license certification mandatory?

Yes, a biologics license is mandatory and must be approved by the FDA.

How long does it take to obtain a biologics license?

Obtaining a biologics license (BLA) can take 10-12 months.

What are the cost considerations for BLA submission?

Costs vary widely but include preclinical, clinical trials, regulatory fees, and manufacturing expenses, often totaling millions.

What is the validity period of a biologics license?

Biologics licenses do not expire, but organizations must maintain compliance with a variety of regulatory laws to keep its validity.

Can a biologics license be integrated with any management systems?

Yes, a biologics license can integrate with Quality Management Systems (QMS) or [skills management software like AG5](#) to ensure compliance, track deviations, and manage document controls during BLA processes.

How can you learn more about the BLA submission process?

Visit the [FDA's website](#).

Sources

- [FDA](#)

Author



[Rick van Echtelt](#)

Rick van Echtelt is the Co-Founder and CEO of AG5, where he leverages over two decades of experience in entrepreneurship and developing skills management software.

[Read author profile](#)

Revisions

Original version | March 18, 2025

Written by: [Rick van Echtelt](#)

Copy edited by: [Adam Kohut](#)

[Please read our editorial process for more information](#)