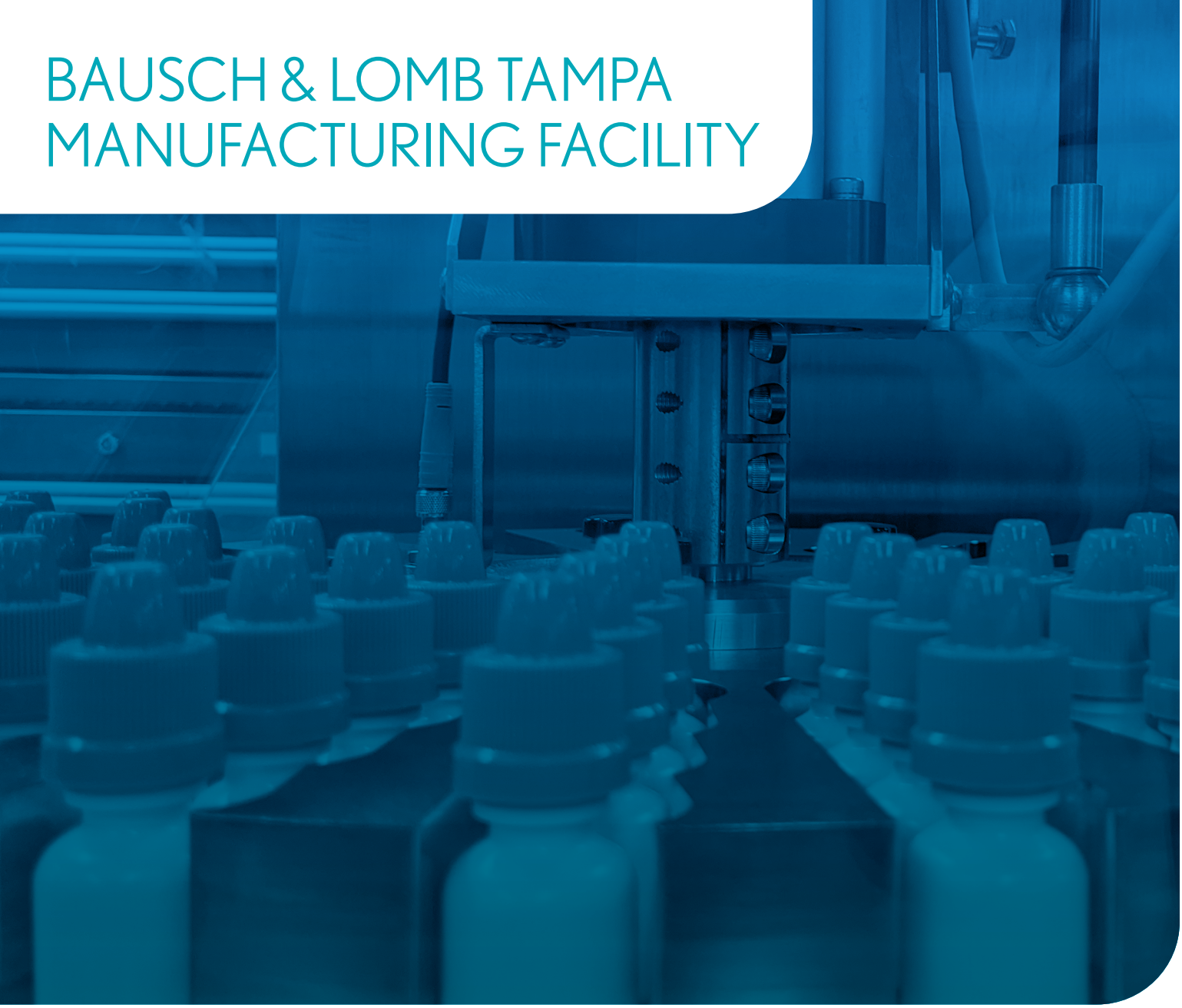
BAUSCH & LOMB TAMPA MANUFACTURING FACILITY



At the heart of patient safety, where exceptional quality in eye care begins

A LEGACY OF CONSISTENCY IN EXCELLENCE

Ours is a commitment to consistency that physicians and patients can rely on. As one of the U.S.'s oldest continually operating companies, we are dedicated to setting the gold standard for eye care products, today and into tomorrow.

STANDARDS YOU AND YOUR PATIENTS CAN RELY ON

Bausch & Lomb Incorporated (Bausch & Lomb) maintains current Good Manufacturing Practices (cGMP) as enforced by the Food and Drug Administration (FDA) and Ministries of Health around the globe.

OUR MISSION IS TO HELP YOU PRESCRIBE WITH CONFIDENCE

BAUSCH + LOMB

Sterility, testing, and repetition are key to consistency

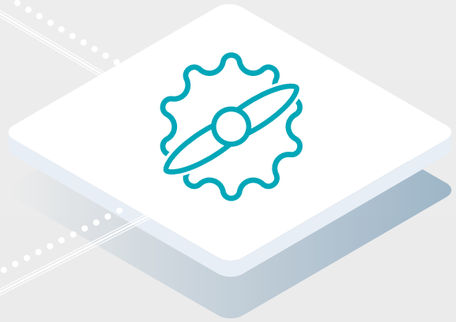
Our process relies on sterility, rigorous testing, strict protocols, recurring employee certification, and an uncompromising respect for the test of time. It is all part of a continuing cycle of cGMP that enables facility employees to perform their jobs with precision, integrity, and the utmost respect for the ultimate goal: unmatched patient care.

1 INTAKE OF INGREDIENTS

Every active ingredient must come from an FDA-approved supplier with a **drug master file (DMF)**. Upon arrival, ingredients enter a 4-week temperature-controlled quarantine in which they are sampled and tested prior to use.

Did you know?

Having a DMF means a factory has voluntarily provided the FDA with confidential, detailed information about its facilities, processes, and/or articles used in the manufacturing, processing, packaging, and storing of drug products.[1] Since the FDA does not require facilities to have a DMF, those that do illustrate a dedication to integrity, consistency, and cleanliness.

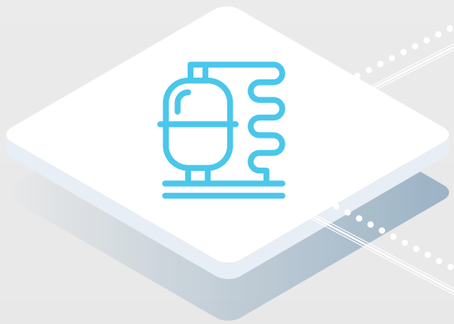


2 STERILIZATION OF INGREDIENTS

Active pharmaceutical ingredients are then sent to the pharmacy, where they are kitted while maintaining temperature control. From there, they are sent for sterilization, which provides advantages over competitive procedures, including high penetration, isothermal character, minimal-to-no residue, and a stronger assurance of product sterility than aseptic processing.[2]

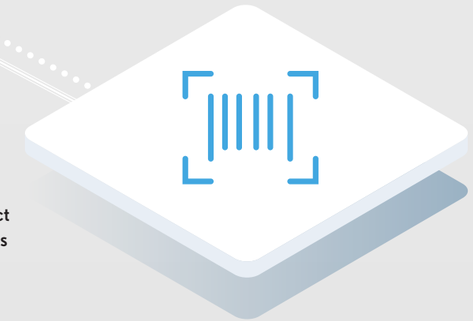
Did you know?

Sterilization can kill microorganisms by breaking their chemical bonds, which produces free radicals that attack their nucleic acid and prevent cellular division. This process is valued for its ability to attain 1 in 1 million probability of microbial survival without excessive heating of the product or exposing it to toxic chemicals.[2]



3 SAMPLING AND MANUFACTURING

Sterilized ingredients are returned to the Tampa facility under the correct temperature-controlled conditions. They are then scrutinized for sterility and potency under the facility's cGMP sampling plan before being manufactured. By the time this milestone is reached, it has been 90 days since the ingredients were first received at the Tampa facility.



4 SERIALIZATION AND PACKAGING

Serialization is another way Bausch & Lomb ensures pharmacovigilance. All materials and products are given their own one-of-a-kind identifiers as part of a multiphase process, which will eventually allow every drug product to be scanned at the pharmacy level and tied back to the Tampa facility. This also helps prevent counterfeiting while aiding in recalls, if needed.[3]

cGMP integrity demands relentless regulation

The Bausch & Lomb Tampa facility adheres to the latest and most stringent standards of excellence in site cleanliness, employee expertise, and cutting-edge technology.

Cleanroom protocol

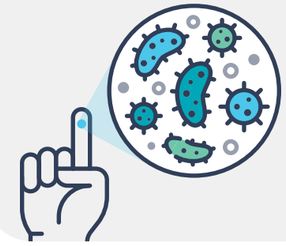
According to the FDA, a cleanroom is designed, maintained, and controlled to prevent particle and microbiological contamination of drug products.[4] The Tampa facility has 5 grades of cleanrooms, each governed by a strict protocol for air quality, surface cleanliness, employee garb, and employee clearance certification.

Cleanrooms undergo continual monitoring for contamination by measuring the number of microorganisms and nonviable particles per cubic meter of air. **In Grade A, the threshold for allowable microorganisms is 0.** This means that if even one organism is detected, a detailed investigation must be conducted to assess the potential product impact.

DID YOU KNOW?

One square centimeter of human skin contains up to 10 million nonpathological bacteria.[5]

Compare that to the zero-tolerance for particles in grade A and B cleanrooms.[5]



Employee certification

Select employees are granted cleanroom access only after completing 6 months of rigorous and detailed certification training. Once certified, these employees must continue to earn access by successfully completing a recertification test each year.

Preventive maintenance

In accordance with cGMP regulations, the Tampa facility closes for 2 to 3 weeks every 6 months for comprehensive and preventive maintenance.[6] This involves dismantling, cleaning/replacing, and rebuilding all systems, such as heating, ventilation, and air conditioning (HVAC). Additionally, all Grade A and B cleanrooms are sterilized with vaporized hydrogen peroxide, which is the industry gold standard.

State-of-the-art technology

Thanks to a significant recent investment, the Tampa facility now has a state-of-the-art restricted access barrier system (RABS), which elevates the facility's aseptic processing with barriers between workers and critical product exposure areas.

Above and beyond quality standards

The Tampa facility holds ISO 14001 and ISO 45001 certifications while meeting the standards of the FDA and the regulatory commissions of 30 countries, including the UK, Germany, Brazil, and South Korea.[6] What's more, the Tampa facility maintains a 24/7 open-door policy for FDA inspection.

THE BAUSCH & LOMB DIFFERENCE

THE TAMPA FACILITY ENSURES THAT ALL PRODUCTS ARE TESTED FOR CHEMICAL AND MICROBIOLOGICAL ATTRIBUTES PRIOR TO DISTRIBUTION.

Welcome to the Bausch & Lomb Tampa Manufacturing Facility

WHERE THE ART OF CONSISTENCY IS A 24/7 PURSUIT

FACTS AND FIGURES AT A GLANCE[6]

175,677ft²
FACILITY

ISO 14001
ISO 45001
CERTIFICATIONS

>600
EMPLOYEES

PRODUCT DISTRIBUTED TO
>30
COUNTRIES

87%
SOLUTIONS, SUSPENSION, AND GELS

13%
OINTMENTS AND OTHER PRODUCT CONFIGURATIONS

70
BULK FORMULATIONS

235
FILLED CONFIGURATIONS

2020
1,050
BATCHES IN 2020

1,200
BATCHES PLANNED FOR 2021
2021

HERITAGE OF TRUST

Bausch & Lomb was founded in Rochester, New York, in 1853. Since then, it has become one of the country's most enduring brands and a home to more than 10,000 global employees.[6]

CONSISTENCY IS KEY

From rigorous standards of sterilization and temperature control to recurring employee certification and cleanroom protocols, our process is one dedicated to detail and uniformity.

PRESCRIBE WITH CONFIDENCE

DO YOU KNOW HOW THE PRODUCTS YOU PRESCRIBE ARE MANUFACTURED?

References: 1. Food and Drug Administration. Drug Master Files (DMFs). https://www.fda.gov/drugs/forms-submission-requirements/drug-master-files-dmfs. US Dept of Health and Human Services. Accessed August 11, 2020. **2.** Hasanain F, Guenther K, Mullett WM, Craven E. Gamma sterilization of pharmaceuticals—a review of the irradiation of excipients, active pharmaceutical ingredients, and final drug product formulations. *PDA J Pharm Sci Technol*. 2014;68(2):113-137. **3.** Food and Drug Administration. Guidance for Industry: Standards for Securing the Drug Supply Chain—Standardized Numerical Identification for Prescription Drug Packages. US Dept of Health and Human Services; 2010. **4.** Food and Drug Administration. Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice. US Dept of Health and Human Services; 2004. **5.** Edmonds-Wilson SL, Nurinova NI, Zapka CA, Fierer N, Wilson M. Review of human hand microbiome research. *J Dermatol Sci*. 2015;80:3-12. **6.** Data on file. Bausch & Lomb Incorporated.

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