

FDA PreCheck Pilot Program

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Strengthening the domestic pharmaceutical supply chain

Program Overview

FDA PreCheck Program represents a strategic initiative to strengthen America's pharmaceutical supply chain by reducing regulatory barriers for domestic manufacturing facilities. Currently, more than half of pharmaceuticals distributed in the U.S. are manufactured overseas, with only 11% of Active Pharmaceutical Ingredient (API) manufacturers being U.S.-based, creating significant national security vulnerabilities. In response to Executive Order 14293, "Regulatory Relief to Promote Domestic Production of Critical Medicines," FDA hopes to facilitate the development of new U.S. drug manufacturing facilities by streamlining the review and inspection process for new construction manufacturing facilities that will supply finished dosage form (FDF) or API.

Phase I of the FDA PreCheck Pilot Program will select participants who are developing new pharmaceutical manufacturing facilities based on alignment to program priorities and will begin conducting FDA PreCheck activities in 2026. Companies selected for the program will benefit from FDA communication and feedback throughout the facility development process. The FDA PreCheck Pilot Program reflects FDA's commitment to create more efficient regulatory review processes and ensure access to life-saving medicines for American patients.

We have outlined below the eligibility criteria, selection criteria, submission details, and what companies can expect through program participation.



Strengthening Domestic Pharmaceutical Manufacturing

- Supports early facility readiness and engagement
- Helps streamline inspection and approval processes
- Advances domestic supply chain resilience

Learn more: <https://www.fda.gov/industry/fda-precheck-pilot-program>

CDER Small Business and Industry Assistance (SBIA)

Regulatory Education for Industry (REdI) 2026

 May 19 & 20



Session Highlight

FDA PreCheck (CDER Perspective)

May 20 |  9:55 AM ET

Event site: <https://www.fda.gov/news-events/regulatory-education-industry-redi-annual-conference-2026-innovative-regulatory-strategies-advance>