Notice on Ensuring the Proper Implementation of Work Related to the Segmented Manufacturing of Biological Products

China – General Affairs Department of the National Medical Products Administration

Main information

Scope of Application:

Implement the provisions on segmented production found in the newly revised Regulations for the Implementation of the Drug Administration Law

Effective Date:

April 1st, 2026

Related Provisions:

- Drug Administration Law
- Implementing Regulations of the Drug Administration Law
- Regulations and the Pilot Work Plan for the Segmented Manufacturing of Biological Products
- Announcement on Strengthening the Supervision and Administration of Entrusted Drug Manufacturing

Key Topics

Framework

- The notice applies to the segmented production of biological products and transitions policies from the prior pilot program to a **standardized national framework**.
- The notice standardizes the process across several key areas: production licensing, quality system requirements, CDE technical review, and cross-border production.

What's new

- Specific Experience **Exemptions**: It provides a flexible pathway for companies that may not have three years of commercial experience. Experience requirements can be extended to include R&D or manufacturing experience if the applicant meets specific criteria from the *Announcement on Strengthening the Supervision and Administration of Pharmaceutical Contract Manufacturing* (No. 134 of 2025), such as operating under a unified quality system within a corporate group or being a key participant in drug R&D for the product in question.
- **Simplified Cross-Border Documentation**: The notice introduces a significant change for cross-border segmented production. When applying to expand production capacity, manufacturers can now use foreign or domestic regulatory documentation (e.g., from the FDA or EMA) in place of materials that are not applicable to a cross-border context.

Sensitive Factors

- **Mandatory Unified Quality System**: A core requirement is that applicants and contract manufacturers must establish a single, unified quality assurance system that covers all production sites.
- Strict "**Three-Year Experience**" Baseline: The default rule is that at least one party (the applicant or the manufacturer) must have three or more years of commercial manufacturing experience with the same dosage form of biological products. While exemptions exist, this is a stringent requirement that could limit participation by newer companies.

Drivers

- Implementing a **Unified Quality System** for Successful Application: The strict requirement for a unified quality system across all sites is a key driver for implementation. Companies must establish this system as a central part of their application strategy.
- Leveraging **Flexible Experience Requirements**: Companies, particularly those with strong R&D but limited commercial history, can benefit from the exemptions to the three-year commercial experience rule. Proactively demonstrating that they meet the conditions (e.g., same corporate group with unified quality system) can provide a path to approval that was previously unavailable.