Announcement on Strengthening the Supervision and Administration of Entrusted Drug Manufacturing

China – NMPA, National Medical Products Administration

Main information

Scope of Application:

New rules on obligations and responsibilities of all parties; urge marketing authorization holders and entrusted manufacturers to jointly fulfil their primary responsibility for ensuring drug quality and safety

Effective Date:

December 31st, 2025

Related Provisions:

- Guidelines for Quality Risk Management of Co-line Drug Production
- Good Manufacturing Practice for Pharmaceutical Products
- Measures for Supervision and Administration of Drug Manufacturing

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Key Topics

Framework

- This Announcement complements the 2023 Announcement No. 132 (which focused on MAH responsibilities) by specifically addressing the obligations of contract manufacturing organizations (CMOs), thereby creating a two-sided regulatory framework for contract manufacturing

What's new

- **Mandatory Pre-Contract Assessment by CMOs:** The Announcement requires CMOs to conduct a comprehensive assessment of the MAH and the proposed product before signing any manufacturing agreement. The assessment must evaluate the MAH's qualifications, quality management capabilities, product risk factors, technology transfer feasibility, and co-line production risks.
- **Two-Tiered Stability Testing Requirements:** For most products, both the MAH and CMO must conduct retention sampling and stability testing. The requirement may be satisfied by only one party under specific conditions.
- "First B, Then C" Licensing Process: The Announcement establishes a standardized, sequential process for cross-provincial contract manufacturing.

Sensitive Factors

- **High-Risk Product Experience Requirements**: For sterile drug contract manufacturing, at least one party (MAH or CMO) must have **three or more years of commercial manufacturing experience** with the same dosage form
- **Prohibition on Unauthorized Changes**: CMOs must establish a change control system, but any changes affecting the manufactured product require MAH approval.

Drivers

- **One-Year Compliance Deadline:** MAHs and CMOs must conduct comprehensive self-audits against the new requirements. Those not in compliance must develop remediation plans, with completion generally required **within one year of the Announcement's issuance (January 2026).**
- **Incentives for Digital Systems:** The Announcement provides regulatory flexibility for CMOs that implement information systems to record all production/testing data and enable electronic data exchange with MAHs. Such CMOs may qualify for reduced on-site audit frequency (substituting non-site reviews) and may conduct stability testing on behalf of the MAH.