December 30, 2025

To: Global Pharmaceutical Industry Stakeholders
Subject: Rx-360 Position on Compliance with NMPA's Article 310 Appendices One and Two

Dear Colleagues,

Rx-360 would like to reaffirm its commitment to supporting the global pharmaceutical industry in meeting regulatory requirements across all jurisdictions. In light of China's National Medical Products Administration (NMPA) release of appendices one and two of Article 310 of the Good Manufacturing Practice for Pharmaceutical Products (2010 Revision), Rx-360 offers the following position on Provision 10, which states:

"Article 10: If an enterprise uses external personnel to conduct independent quality audits, it shall establish relevant management procedures and clearly define the qualification requirements, selection principles, and approval procedures in the procedures."

Rx-360's Joint Audit Program fully aligns with this requirement. Our audits are conducted by highly qualified professionals under robust governance and documented procedures that meet the standards outlined in Provision 10. Specifically, Rx-360's approach includes:

- Clearly defined auditor qualification and competency requirements
- Transparent and objective auditor selection process that supports expertise and independence
- Formalized approval, oversight, and documentation mechanisms embedded within our audit management framework

We are confident that Rx-360 audits satisfy the NMPA's expectations for independent quality audits. Furthermore, Rx-360 is prepared to provide detailed support and documentation to our Joint Audit Program customers to demonstrate compliance with these provisions whenever needed.

Thank you for your continued trust in Rx-360. Should you require assistance or clarification, please contact us at info@rx-360.org.

Sincerely,

Ben Mills
Senior Director, Quality and Audit Operations, Rx-360

Ryan Kelly
Interim CEO/Senior Director of Supply Chain Security and Brand Protection, Rx-360