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EAGLE Celebrates Accreditation to Audit ISO 15378

First CB in North America to be Accredited by ANAB for ISO 15378

Dayton, OH, February 9th, 2021 – EAGLE Certification Group is excited to announce accreditation to ISO 15378 - Primary packaging materials for medicinal products! The official news of the accreditation makes EAGLE the first US-based certification body (CB) to become accredited by ANAB for ISO 15378.

First published in 2006, ISO 15378 is an internationally recognized standard that integrates Good Manufacturing Practices (GMP) and ISO 9001 quality requirements to create a robust program aimed at attaining proper medicinal product packaging. Through this comprehensive approach, adherence to the standard enables companies to comply with legal requirements for pharmaceutical and medical device primary packaging materials.

From the [ISO.org website](https://www.iso.org), “ISO 15378 specifies requirements for a quality management system when an organization:

- a) needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and
- b) aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.”

EAGLE began researching the feasibility of adding ISO 15378 to its product line after receiving multiple requests from current clients. As they continued to study the need in the market, and knowing that the standard is newly accredited through ANAB, the company felt strongly that this standard would be a great addition to their current services.

Brad Shillito, EAGLE’s President, shared that, “EAGLE recognizes that the competition in the industry for packaging of medicinal products has expanded and that adherence to the standard could help prevent recalls due to defects or medicinal packaging failure. EAGLE wants to support the efforts of those companies producing medical packaging materials by offering auditing services that adhere to the stringent requirements of ISO 15378.”

Berry Global Inc. headquartered in Evansville, IN is an EAGLE client leading the industry in 15378 certification. Lee Moseby, Continuous Improvement Manager at Berry's Headquarters states "ISO 15378 certification helps demonstrate to our pharmaceutical clients that we are complying with their specifications and regulatory requirements. Berry believes in the value of an accredited audit because it ensures correct competencies and consistent interpretation of the standard. The 15378 certification program aligns with our proven ISO 9001 Management System and by teaming up with EAGLE as our certification body, we have found this to be a value-added program."

For more information about ISO 15378, visit the [ISO website](#).

About EAGLE Certification Group

Founded in 1994, EAGLE is an accredited third-party certification body that provides certification services for international food safety and quality management standards. We help clients maximize their management system to improve business results through conformance analysis and constructive feedback with a focus on continuous improvement, sustainability and customer satisfaction. EAGLE holds thousands of active certificates, employs over 100 competent auditors and serves over 20 countries.

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If you would like more information about this topic, please call Jessica Osborne at 937.293.2000, or email jessica.osborne@eaglecertificationgroup.com.