

Ashland diagnostic films medical device facilities achieve ISO certification

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WILMINGTON, Del., April 19, 2023 – Two Ashland diagnostic films facilities, Fiskeville, RI, and Bridgewater, NJ, have achieved ISO 13485:2016 certification. The ISO13485:2016 standard, based on renowned ISO 9001, includes additional requirements specific to the medical device industry. These requirements call for the sites to demonstrate the ability to provide medical devices and related services that consistently meet customer and regulatory requirements.

"Gafchromic [™]films and Rad-Sure [™]blood irradiation indicators are essential devices for healthcare professionals in radiation therapy and hematology spaces," said Maurice Biagini, business director diagnostic films, Life Sciences, Ashland. "What differentiates Ashland is our long-standing attention to regulatory compliance and consistent quality as we provide products that help improve patient outcomes. Improving outcomes for patients, especially those with special treatment needs, underscores how Ashland is responsibly solving for a healthier world."

Gafchromic[™] films support patient care in oncology. The films are designed to provide fast and highly accurate measurements for radiology and radiotherapy applications. Gafchromic films are used for machine and patient quality assurance applications, helping ensure that patients receive suitable radiology and radiotherapy treatment. Instant high-resolution images provide the data integrity needed to increase confidence and peace of mind for both the physician and the patient.

<u>Rad-Sure</u>[™]<u>blood irradiation indicators</u>, including Rad-Sure chromicVue [™]indicators, support patient care in hematology. Blood products are irradiated to prevent transfusion-associated graft-versus-host disease (TA-GvHD), a complication where donor white cells attack the recipient's immune system in immunocompromised patients. Rad-Sure [™]blood irradiation indicators provide easy visual verification that blood products received the minimum specified irradiation dose.

"Safety and quality are paramount in the medical device industry and Ashland is dedicated to achieving the highest standards possible. Regulatory requirements are increasingly stringent throughout every step of a product's life cycle," said Jennifer Leone, quality director, Ashland. "We have focused on earning certification at our medical device facilities for nearly two years."

Other products produced at Ashland's medical device sites are filmQA pro [™]software, dose-map [™]dosimetry system, gafchromic [™]quick phantom [™] device, and sterin [™]insect irradiation indicators.

ISO (International Organization for Standardization) is an independent, non-governmental international organization with a membership of 168 national standards bodies.

About Ashland

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