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Merck’s BioReliance services help to ensure purity, safety and efficacy

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• Provides critical information, analytics to help manufacturers make data-driven decisions to inform process development, mitigate risk and streamline regulatory development

Merck has launched its BioReliance® Product Characterization Portfolio of tests for quality assessment of biologic drugs. This new, comprehensive suite of tests, provides critical information that biologic manufacturers need as they design their production process.

The purity, safety and efficacy of a drug must be identified and continuously monitored in order to support development and meet regulatory requirements necessary for commercialization. Manufacturers can better understand their molecule’s function, through comparison of structure and activity, helping them to make critical decisions.

This portfolio of assays enables the characterization of mAbs, including physicochemical and immunochemical properties, biological activity, stability, and purity as outlined in the ICH Q6B guidelines, as well as EMEA and FDA regulatory requirements. In addition, specialized capabilities, such as hydrogen-deuterium exchange technology and highly sensitive surface plasmon resonance instrumentation, are available. Merck’s experienced team is prepared for all testing needs, along with the ability for GMP validation as needed.

Merck provides the industry's most comprehensive portfolio of high quality products, services, and testing for biopharmaceutical manufacturing. BioReliance® services offer risk-mitigating approaches, critical testing services and customized solutions to help bring life-changing therapies to market.