



Nelson Labs® Receives ASCA (Accreditation Scheme for Conformity Assessment) Accreditation from the U.S. FDA

Salt Lake City, UT, April 12, 2023 – Nelson Labs, a global leader in microbiological and analytical chemistry testing and advisory services for the medical device and pharmaceutical industries, announced this week that it is now an ASCA-accredited testing laboratory by the U.S. Food and Drug Administration (FDA) within the category of biocompatibility.

ASCA is an accreditation structure of the FDA, wherein accreditation bodies recognized by ASCA can grant ASCA accreditation to qualified testing laboratories based on their conformity to international standards (ISO/IEC 17025:2017) and FDA-identified specifications within the ASCA program.

This accreditation gives Nelson Labs an added measure of credibility with the FDA, as the applicable protocols, training requirements, and final report formats have met acceptable standards recognized by the FDA. The accreditation should save FDA reviewers time and effort, streamlining a part of the review process often bogged down by questions.

“An ASCA accreditation is recognition of Nelson Labs’ quality of FDA submissions containing biocompatibility-testing results,” states Thor Rollins, Vice President, and Global Market Segment Leader of Medical Devices at Nelson Labs. Rollins adds, “Consistency and reliability with test procedures and reports will help increase speed of acceptance and reduce any questions or concerns about biocompatibility testing.”

For medical device manufacturers who rely on Nelson Labs for biocompatibility testing, the ASCA accreditation should help to accelerate the speed to market for safe, quality medical devices.

About Nelson Labs: Nelson Labs is a global leader in outsourced microbiological and analytical chemistry testing and advisory services for the medical device and pharmaceutical industries. Nelson Labs serves over 3,000 customers across 15 facilities in the United States, Mexico, Asia, and Europe. We have a comprehensive array of over 900 laboratory tests supporting our customers from initial product development and sterilization validation, through regulatory approval and ongoing product testing for sterility, safety, and quality assurance. Nelson Labs is regarded as a best-in-class partner with a strong track record of collaborating with customers to solve complex issues.

Safeguarding Global Health® – with every test we complete.

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