Novugen Achieves ZERO Form 483 Citations
in USFDA Surveillance Inspection Audit

Novugen Pharma Malaysia has successfully completed a five-day surveillance inspection audit conducted by the U.S. Food and Drug Administration (USFDA) from 21st to 25th of October 2024. We are pleased to announce that the inspection concluded with ZERO Form 483 citations and no deficiencies, placing Novugen Pharma at the highest level of compliance with the USFDA.

According to the surveillance inspection, Novugen demonstrated a state of good control from a Good Manufacturing Practice (GMP) compliance perspective. Achieving the status of NAI (No Action Indicated) is a significant milestone that places us among a select few global companies meeting these standards, reflecting our team's dedication to quality and our commitment to continuous improvement.

This audit not only fulfills regulatory requirements for our operations in the USA but also highlights the strategic investments we've made in Malaysia to thrive in highly regulated markets. At Novugen, QUALITY is in our DNA, showcasing our strength, resilience, and commitment to excellence.