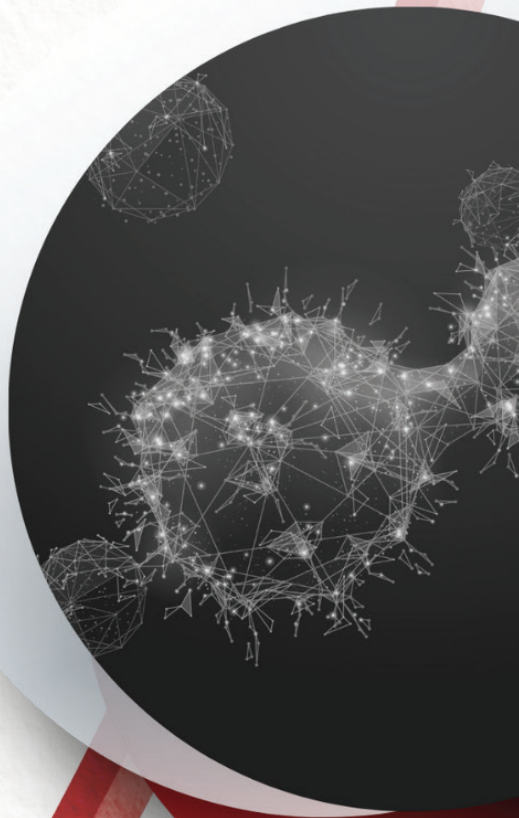
inSeption GROUP



Challenge

A new, emerging biotech company was preparing to submit their NDA. Anticipating an FDA inspection, they wanted to take a proactive approach to mitigate risks and identify potential concerns.

Solution

inSeption Group crafted a risk-based strategy, blending elements of mock inspections, clinical site preparation visits/audits, and review of critical documents (e.g., TMF), processes, and training—designed to thoroughly examine all elements of the company's clinical studies and Quality Management System.

Benefit

With this customized risk-based mock inspection, the sponsor was able to identify and address any potential gaps that could warrant more scrutiny within their application. Working with inSeption Group allowed the sponsor to be ready for every possible scenario, eliminating the stress and anxiety that often results from preparing for an FDA inspection.

"We are very, very grateful for your work and collaboration. This was an amazing achievement, and we have all of you to thank!

What's your secret? How do you do this time and time again?

You are gladiators!"

www.inseptiongroup.com