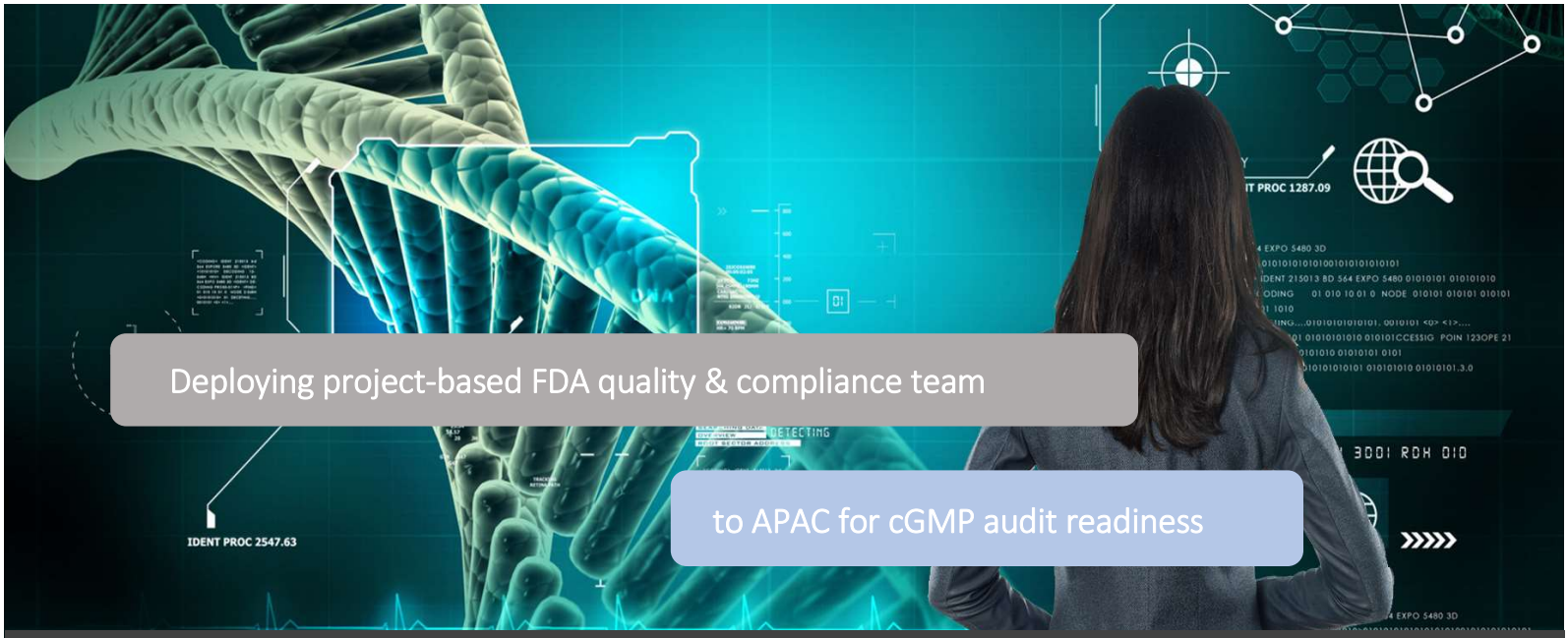

The Spanos Group and its network of senior SMEs have been providing critical project teams to the leading FDA-regulated biopharmas and medical device companies for over fifteen years. Our team of deployable experts are well-versed in remediating 483's, Warning Letters, and Consent Decree challenges using the latest up-to-date guidance, with maximum emphasis on cost efficiency for our customers.

the customer

a global pharma/med device (Combo Product - Part 4) based in southeast asia had just completed construction on a new manufacturing facility and required the entire site to be prepared for a cGMP FDA site inspection

the challenge

the customer was pressed for time with a pending inspection and no qualified resources in country and no current suppliers with talent deployable to asia on short notice

spanos solution

spanos proposed assembling a 5 person team of senior level (20+ years of exp) quality engineers, led by a sr. pm, to conduct all quality-related activities (CAPAs, CCRs, TMVs, complaints, reviews and approvals) and actively managed the engagement under a SOW

the outcome

by freeing the customer stakeholders to focus on acquiring in-country full-time talent while spanos deployed a small tactical team of sr SMEs the new facility was compliant within nine months while pivoting spanos to architecting a QMS initiative

Faced with a strict timeline and reduced budget in a foreign country, the customer felt they had few readily-available options to execute upon a mandated quality & compliance initiative to complete the CQV process. U.S. executives had already pre-planned for the import of new product from this new Asian facility and any delays in site certification would significantly impact the company's quarterly & annual financial statements.

By partnering with Spanos, we were able to immediately begin to remediate known deficiencies within cGMP, GLP, data integrity and training workstreams and then quickly develop a Quality Control team for all pending FDA inspection readiness functions. On time [13 months]. Under budget [$2.3mil US dollars].

To learn more about how we can meet your business objectives, visit www.thespanosgroup.com or reach out to one of our solutions experts at solutions@thespanosgroup.com

SPANOS GROUP LLC