



EXPERIENCE TO BRING YOUR PRODUCT TO MARKET

- Accustomed to worldwide requirements for Commercial production of products regulated by US FDA, EU, ANVISA & Health Canada
- Supporting Client Partners that are World Class Organizations
- Successful Track Record of Regulatory Inspection
- Positive PAIs in 2005, 2012, 2014 & 2015
- 2015 FDA inspection resulting in zero 483 observations
- Over 14 years of inspection history with no significant impact to the business

Quality philosophy

We are collectively responsible for the quality of the products we produce. We deliver on our commitments to provide uncompromised compliance, deliver high-quality products to patients, and achieve the key time-sensitive milestones that drive our clients' successes.

Quality is our passion and the paramount measure of our success. And it's our passion for quality that contributes to your success and, ultimately, to the health of your patients.

Quality

- We maintain a focused vigilance on ensuring robust, integrated quality systems and compliance with worldwide regulatory agencies.
- We execute with tenacity for improvement and effectiveness.
- We rigorously track our systems' performance to provide consistent, timely reporting that enables continuous compliance.
- We are committed to optimal risk management and quality without compromise.

Strength

- Robust quality systems that are compliant with U.S. FDA, EU and ROW regulations
- Excellence in regulatory inspections:
 - Over 15 years of inspection history with no significant impact to the business
 - Successful pre-approval inspections (PAIs) in 2005, 2012 & 2014 and 2015
 - 2013 and 2015 FDA inspections resulting in zero 483 observations
 - Current registrations and cGMP certificates
- Success in Client Audits:
 - Multiple audits each year with no critical observations

Our focus on quality goes hand in hand with our excellent inspection and compliance history, providing you with peace of mind in your choice of a CDMO partner.