Medical Product Development

Applying subject matter expertise and analytic rigor to safeguard human health.

Our Involvement

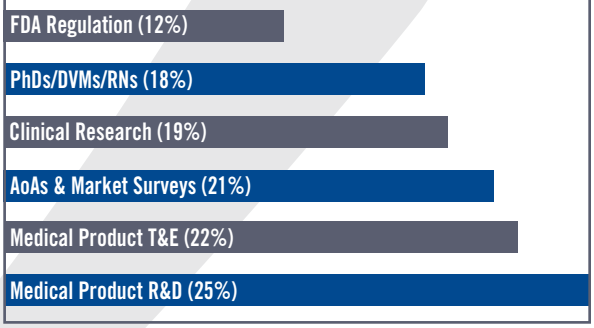
Full lifecycle support: R&D, acquisition, T&E, manufacture, sustainment, and regulatory affairs.

- We work at the intersection of DoD acquisition, DoD medical countermeasure development, and FDA regulatory affairs, including animal model development, assay development, and FDA's Animal Rule and Emergency Use Authorization.
- We design overall strategies for achieving FDA regulatory approval, ensuring our clients adapt their processes to reflect the current regulatory state of affairs.
- We provide guidance on cGLP-compliant and cGMP-compliant processes and protocols for testing drug candidates; animal rule requirements, application, and implementation; IND application submission, approval, and licensure; FDA Type A, B, and C meeting conduct and preparation; and FDA qualification of drug development tools.
- We provide DoD and DHS programs the full spectrum of non-clinical support, including facility/site selection, planning and execution of non-clinical studies, handling of protocol development and review, experimental design and statistical data analysis, and complete evaluation and reporting of results.
- We support the development of multiple drug candidates through DoD medical acquisition and private sector programs, assisting with planning, protocol development, and monitoring across all clinical trial phases.
- We coordinate clinical medical product logistics within DoD and DHS, and in coordination with FDA and CDC.
- We analyze and advise on pharmaceutical and medical countermeasure manufacturing programs. We have unique expertise with the flexible, platform-based, single-use systems equipment that is the cornerstone of the DoD-funded NANO-ADM large molecule manufacturing facility.
- We work with small and large molecule products, and we support pilot-scale development and troubleshooting through metric ton or 2500-liter batch size expression systems.
- We help our clients navigate the practical aspects of technology transfer packages, working in accordance with the requirements of contract manufacturing organizations, the FDA, and ISO.
- In readiness assessments for technology, manufacturing capability, and animal model development, we apply established criteria to evaluate promising technologies for incorporation into the DoD acquisition process.
- We provide engineering expertise regarding medical product test design, set-up, and execution, using MIL-STD-810 series and non-standard tests, as required.
- We provide sustainment planning for diagnostics and detection systems, considering current and planned capabilities, field and laboratory operations, test and evaluation, and logistics activities, for a DHS Office of Health Affairs program.

Our Expertise

Over 35% of The Tauri Group employees have medical product expertise.

We also have a significant number of employees with qualifications or experience in the following specialty areas:



Highlight: Approach to AoAs

- ***Recognize that each AoA is unique.*** – We always customize our study plan to the needs of the AoA.
- ***Identify critical technology elements for materiel solutions.*** – We analyze such factors as technology maturity, integration risks, manufacturing feasibility, and demonstration needs. For medical product AoAs, we also identify how FDA regulations contribute to technical and programmatic risks.
- ***Identify doctrine, organization, training, leadership and education, personnel, and facility (DOTLPF) implications.*** – We understand the essential role of these non-materiel factors in procurement decisions.
- ***Identify cost and schedule implications.*** – With deep insight of DoD acquisitions and applicable regulations (e.g., FDA), we craft realistic schedules and then apply models and toolsets to estimate costs.
- ***Engage in ongoing collaboration with the lead component and stakeholder community.*** – From the outset of the study to the final report, we rely on the expertise and experience of the client and intended users to ensure we identify and address their needs.

Contact Us

We want to talk about ways we can help you achieve your goals.
Call or email one of our corporate leads for more information about opportunities to work together.

CEO:
Cos DiMaggio
703-647-8076
cos.dimaggio@taurigroup.com

Business Development & Teaming:
Michael Brennan
571-303-2089
mike.brennan@taurigroup.com

Medical Product Development Lead:
John David
571-303-2050
john.david@taurigroup.com