TAMM Net®
Integrated Biomed Solutions

Quality Systems and Regulatory Affairs

From pathway assessment and strategy to final clearance or approval, TAMM Net has the knowledge and relationships to expedite the regulatory process. Our professionals can guide you to develop your quality system or custom design and write it. Then, we will train your team on implementation and compliance.

We strategically consult and negotiate with the appropriate regulatory application with the FDA to obtain a successful outcome. We perform facility audits for both Good Laboratory Practices (GLP) and Good Manufacturing Practices (GMP), and conduct system and process validations. Whether you need to outsource your VP Regulatory Affairs, or just need a facility audit, TAMM Net has the expertise.

Regulatory tasks we routinely perform for our clients:

- Develop regulatory strategy
- Coordinate with research activities
- File regulatory documents
- Develop a publications strategy
- Perform compliance auditing: GMP, GLP
- Assist in preparing and submitting: IND, IDE, 505(b)(2), 510(k), PMA, ANDA, 513, BLA, and NDA
- Perform due diligence for competitive issues

(855) 826-6638 • info@tammnet.com • **www.tammnet.com**