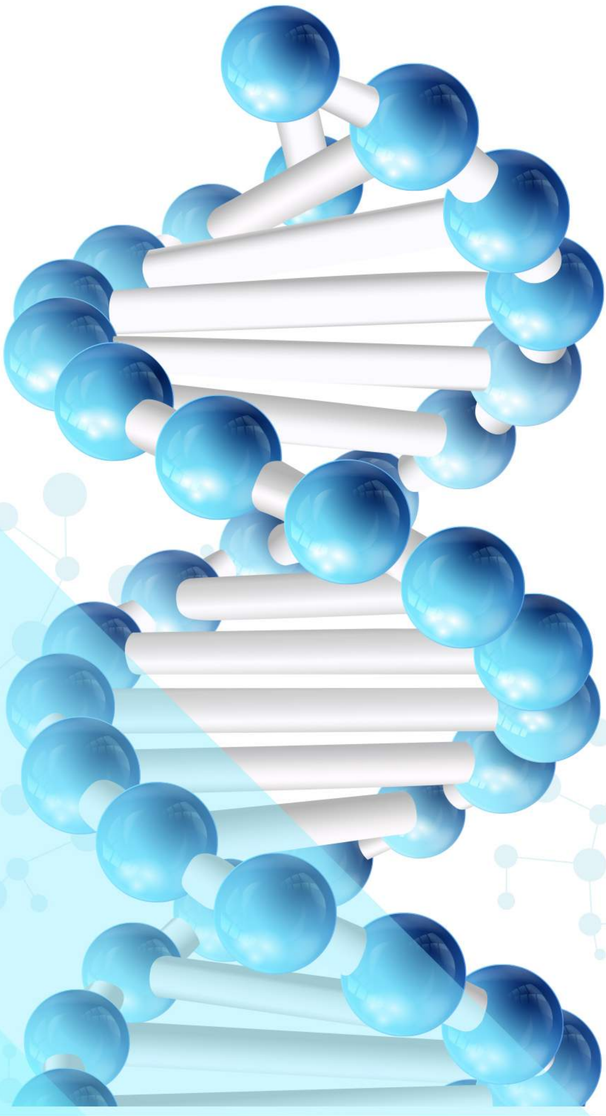
ZENBIOMED



Your partner for best in-class services & solutions in Regulatory Affairs, Quality Assurance, Compliance, Audit, and Talent Acquisition.

We provide training, strategic consulting, staffing & project-based solutions for our customers.

www.zenbiomed.com

About ZenBiomed

ZenBiomed, Inc. is a consulting firm that provides high-value services and staffing solutions to corporate clients in Life Sciences, primarily in Medical Device, Diagnostics, Clinical Laboratory, and Digital Health Industry. Our areas of expertise include Regulatory Affairs, Quality Assurance, Quality Audits, Medical Writing and Clinical Evaluation.

Life science Industry that We Serve:

- Medical Devices
- Diagnostics
- Digital Health
- Clinical Laboratories

Leadership Team

Alex Chang (Co-Founder and Partner)

20+ years of combined full-time and consulting experience in QA and Regulatory Affairs with early stage as well as mature companies in the IVD, Medical Device, and Digital Health space; Principal Consultant and Regulatory Advisor for a number of startups.

Anupam Talapatra (Co-Founder and Partner)

20+ years of hands-on & senior management experience in large corporates, early-stage start-ups, and global consulting companies; served in roles of increasing responsibilities in R&D, Product Development, QA and Regulatory Affairs, spanning the entire lifecycle of IVD Medical Devices.

John Vuong (Co-Founder and Partner)

25+ years of experience in a regulated environment, leading groups in Manufacturing, Product Transfer, Technical Operations, Process Development, Validation, QA and QC; expertise in setting up GMP Manufacturing infrastructure and Quality Systems at Biologics & Medical Devices companies as well as in CLIA labs.

Why Us

- 60+ years of combined RA/QA experience of leadership team
- 20+ highly qualified consultants with specialized expertise
- 20+ projects successfully completed
- Ecosystem of digital solution partners
- Expertise in US and international regulations
- Broad coverage of services & solutions across product life cycle
- In-depth understanding of gaps and requirements

Our
Services

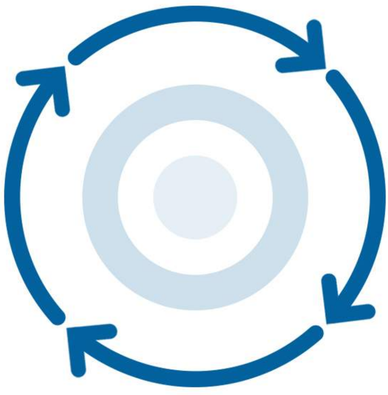
Your partner in QMS assessment, implementation and Product Quality Compliance

KEY AREAS OF EXPERTISE

Your partner in Regulatory assessment, strategy, submissions, Medical Writing, and Regulatory body engagement throughout the entire IVD/medical device lifecycle.

CONCEPT & PLANNING phase

POST-MARKET phase



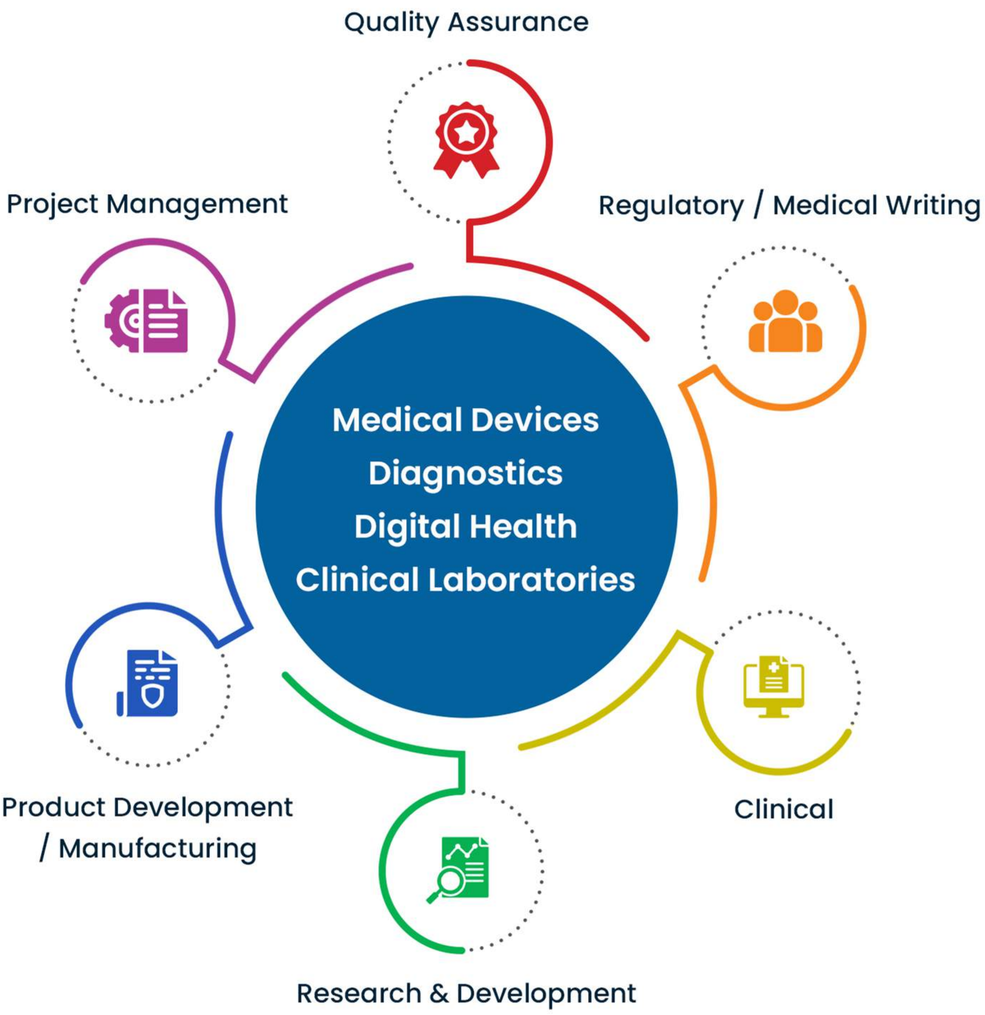
PERFORMANCE EVALUATION phase

SUBMISSION phase

KEY AREAS OF EXPERTISE

- Regulatory Strategy, Planning & Roadmap
- Regulatory Submissions
- Medical Writing / Technical Writing
- Other Regulatory Activities

Functional Areas for Talent Acquisition



Mode of Engagement

Contingency Workforce

Strategic Consulting

Project Based Services

ZENBIOMED

Contact Us

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Book Appointment

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