Zi-Medical Inc.
Company Introduction

Boston – San Jose – Beijing – Taipei

www.zi-medical.com

Confidential Info – do not distribute without permission

Zi-Medical, Inc.
Global Healthcare and Regulatory Innovations

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About Us

Delivering a medical product to market can be long, complicated, and seem insurmountable…

Our solution-One stop shop for registration and submission with 100% focus on medical devices and IVDs

Regulatory Consultations

Marketing Approval Submissions

Training and Education

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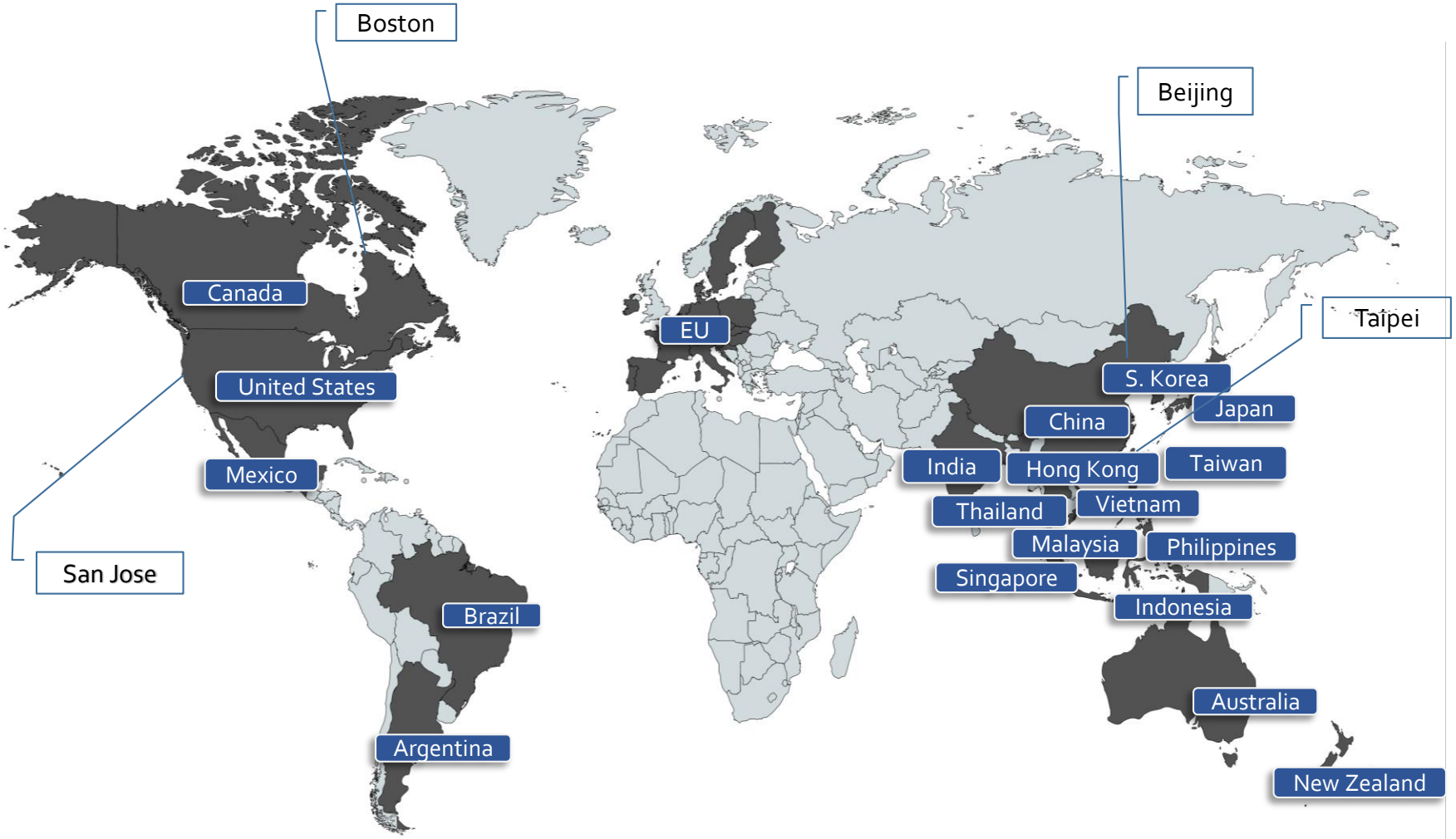
Global Footprint



XX Office Locations

XX Regions that we are providing regulatory consultation and registration services

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Strength

Decades of experience in over 20 countries …

- Global operations team for one stop shop in Asia, USA & EU
- Utilizing 100% med device SOPs in regulatory, and quality management
- Successfully registered products & completed GMP/QSR globally
- Services provided in English, Spanish and Chinese

Clients & Companies We've Worked With

BIOMET 3i · HAEMONETICS · CODDE COMPLIANCE · CLARAPATH · nanoString

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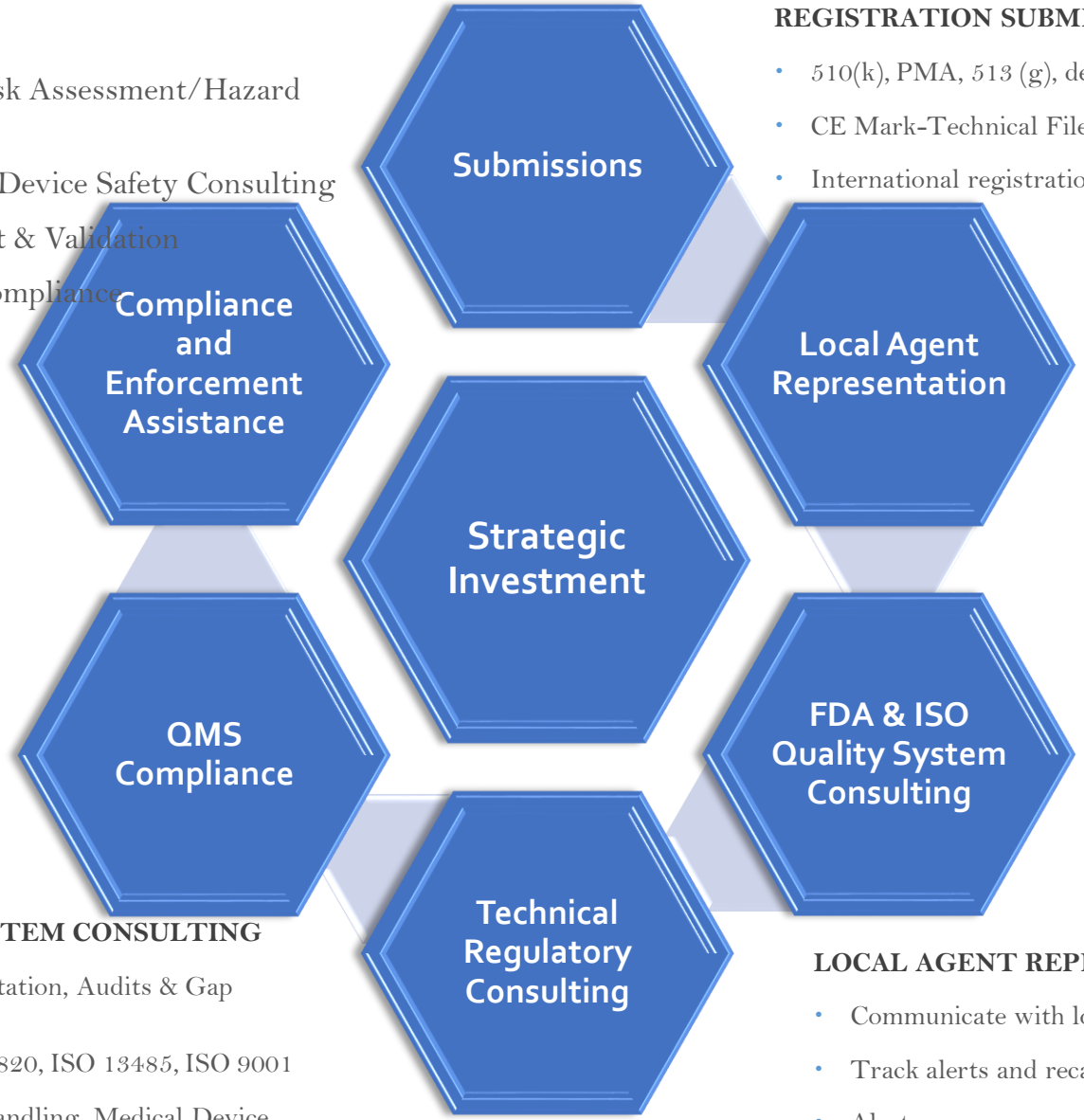
Services

TECHNICAL REGULATORY CONSULTING

- Design Control
- Risk Management/Risk Assessment/Hazard Analysis
- IEC 60601-1 Medical Device Safety Consulting
- Software Development & Validation
- HIPAA and GDPR Compliance



REGISTRATION SUBMISSIONS

- 510(k), PMA, 513 (g), de novo, IDE, etc.
- CE Mark-Technical File/Technical Dossier
- International registration submission

FDA & ISO QUALITY SYSTEM CONSULTING

- Quality System Implementation, Audits & Gap Assessments
- QSR/GMP-21 CFR Part 820, ISO 13485, ISO 9001
- Compliance; Complaint Handling, Medical Device Reporting (MDRs), Recalls, etc.
- In-house Training

LOCAL AGENT REPRESENTATION

- Communicate with local agency
- Track alerts and recalls
- Alert your company of new regulations
- Ensure appropriate conformity

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Team

Leadership Team

- Annie: Quality expert GMP, QSR compliance, enforcement action response, 10+ years experience in quality compliance;
- Mingzi: 10+ years experience in regulatory and quality, successfully completed hundreds of submissions worldwide;
- Tony: 20+ years project management in healthcare industry, specializing in technical regulatory consultation and process improvement;
- Bob: 20+ years device design & development, specializing in IVD and Software as a Medical Device working directly with FDA submission;
- Anna: EU MDR / IVDR expertise specializing medical writing, EU submission and CERs.

Contact Us

Zi-Medical, Inc.

Boston, MA

US: +1 (206) 981-0675

China: +86 15055111298

Marketing: Tony@zi-medical.com

Regulatory: Mingzi@zi-medical.com

Quality: Annie@zi-medical.com

Visit us on the Web at www.zi-medical.com

To learn more, please contact us now

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