



Quality Assurance and Compliance Services

Boston Biomedical Associates is committed to ensuring that total quality assurance is built into every project. We provide comprehensive services in the following areas:

Quality systems development and implementation

We have extensive experience in national and international quality system requirements, implementation, and compliance issues in accordance with QSR, ISO 9001, EN 13485 and 46001. We help clients review, evaluate, and modify their current systems or design, develop, and implement new ones.

Audit and training programs

We can perform audits and develop and conduct training for all areas of quality including:

- GCP
- GLP
- QSR
- MDR systems
- Design control
- Product/process validation

Corrective action planning and implementation

We can formulate practical and strategic solutions for responding to 483s, warning letters, and application integrity programs. We can provide crisis management support to implement steps needed to correct violations and bring companies and/or products into compliance.

Developing recall strategies

We develop strategies to assist in identifying, conducting, and reporting product recalls. We seek to maximize recall effectiveness and minimize the market exposure and liability implications.

Product development assistance

We can assist with protocol development (mechanical and animal) to meet pre-clinical testing requirements for regulatory approval.



BOSTON BIOMEDICAL ASSOCIATES

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