

Your Validation Partner

Regulatory Compliance:

Assess, develop & implement compliance at the level you need

Biomatic Technologies' validation programs and expertise help your company assess, develop and implement regulatory compliance at the level you need, including the FDA's Rule 21 CFR Part 11 and the EPA's CROMERRR.

□ As your partner, Biomatic can determine the level of compliance and validation appropriate for your company while customizing our services to compliment your in-house compliance and validation programs, allowing you to optimize resources. Our compliance/validation consultants and engineers are experienced in Quality System:

- Assessment and Evaluation
- Development and Planning
- Master Plan Implementation and Review

□ Biomatic's unique three-phase program allows you to pick the compliance level suitable to your needs.

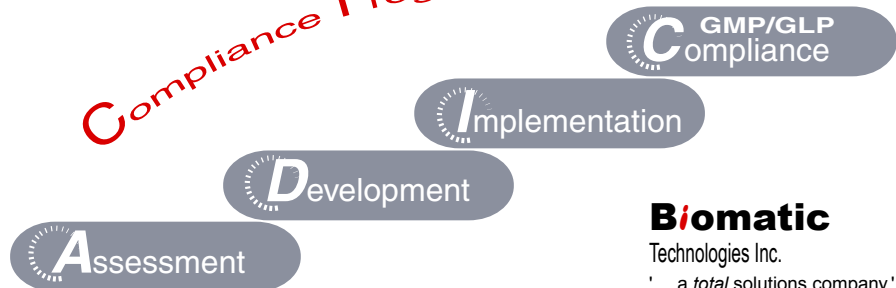
Phase I Regulatory Compliance Assessment: We examine and inspect laboratory guidelines; perform system and equipment reviews, and assist you through QA audits (pre-FDA inspections). We also provide compliance reviews and services for QC, manufacturing, and operations.

Phase II Regulatory Compliance Development: Biomatic assists you in creating, modifying or enhancing the effectiveness of your Quality Programs.

Phase III Regulatory Compliance Implementation: We assist you in executing the specifics of your compliance programs.

And as your regulatory compliance partner, Biomatic designs a solid strategy for future regulatory compliance objectives.

Compliance Programs



Biomatic □
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Biomatic
Technologies Inc.

'... a total solutions company.'

- Certified Refurbished Lab Equipment
- IQ, OQ, PQ of Instruments & Clean Rooms
- Asset Management & Inventory Control
- Service, Maintenance & Calibration of Lab Equipment
- Contract Research & Lab Consulting

As your regulatory compliance partner, Biomatic assists you in determining the scope of your regulatory needs, steers you through the appropriate levels of compliance, and designs a solid strategy for future regulatory compliance objectives.

Phase I: Regulatory Compliance Assessment

Biomatic examines and inspects laboratory guidelines; performs system and equipment reviews, and assists you through QA audits (pre-FDA inspections). We also provide compliance reviews and services for QC, manufacturing, and operations. Specifics include:

- Quality Programs (QA/QC)
- Documentation management
- Procedures and policies (SOPs)
- Compliance training for personnel
- Quality Control Testing
- Failure investigation
- Change control
- Method validation
- Equipment validation/qualification

Phase II: Regulatory Compliance Development

Biomatic assists you in creating, modifying or enhancing the effectiveness of your Quality Programs. Through consultation we address:

- Quality assurance/control development
- Conformity/compliance planning
- Regulatory compliance documentation
- Remedial/corrective action plans (failures, 483 responses)
- Project planning
- IQ OQ PQ instrument validation
- FDA's CFR 21 Part 11; EPA's CROMERRR
- Clean room validation and qualification

Phase III: Regulatory Compliance Implementation

Biomatic assists you in executing the specifics of your compliance programs, including:

- Achieving GMP/GLP status and accreditation
- QA/QC audit reviews
- Laboratory and manufacturing processes
- Remedial/corrective action plans (system failures and 483 responses)
- GMP/GLP training
- Execution of validation protocols, change control, and SOPs

Validation services provided by Biomatic are competitively priced and held to the highest standards. Our instrument validations are more detailed and specific than the manufacturers' and the cost is typically 50% less. Biomatic offers Validation Master Plans for:

- HPLC Systems
- GC Systems
- CE Systems
- Mass Spec Systems
- Atomic Absorption Spectrophotometers
- Ultra-Violet Spectrophotometers
- Clean Rooms (Class 100, 10K, 100K)
- Autoclaves
- Incubators (CO₂)
- Environmental Chambers
- Freezers (Cryo)
- Refrigerators
- Bio-Safety Benches (Laminar Flow)
- Hoods
- Vacuum Chambers
- Centrifuges
- Humidity/Drying Ovens
- Roller Bottle Apparatus