BLINE SOLUTION PRIVATE LIMITED
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QUALITY POLICY

MISSION AND COMMITMENT

We at BLine Solution Private Limited are committed to delivering reliable, validated, and compliant software, hardware and automation solutions that empower regulated-industry customers to protect patient safety and product quality.

Our work is carried out in strict accordance with applicable global regulations, guidelines, and standards. We ensure that our architecture bridges the IT-OT gap flawlessly, in alignment with ISA-95 principles, while ensuring data is born digital and remains audit-ready in real time.

REGULATORY & COMPLIANCE FRAMEWORK

To satisfy the stringent requirements of exports to regulated global markets, our platforms (BLine Suite and BLine Automation Suite) are designed, developed, validated, and maintained in compliance with the following regulatory frameworks, good practice guidelines, industry standards, and international inspection bodies.

- USFDA 21 CFR Part 11
- EU GMP Annex 11
- ALCOA+ principles
- Computer System Validation (CSV)
- GAMP 5 life-cycle approach
- GMP – Good Manufacturing Practice
- GCP – Good Clinical Practice
- GLP – Good Laboratory Practice
- GDP – Good Distribution Practice
- GSP – Good Storage Practice
- GAP – Good Agricultural Practice
- GDPR – General Data Protection Regulation
- HIPAA – Health Insurance Portability and Accountability Act

International Health Authorities & Harmonisation Bodies

- (USFDA) United States Food and Drug Administration
- (EMA) European Medicines Agency
- (MHRA) Medicines and Healthcare products Regulatory Agency (UK)

- (TGA) Therapeutic Goods Administration (Australia)
- (WHO) World Health Organization (WHO-GMP)
- (Schedule M) CDSCO (India)
- (PIC/S) Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme
- (ICH) International Council for Harmonisation
- (SFDA) Saudi Food and Drug Authority
- (MoHAP) Ministry of Health and Prevention (UAE)
- (EDA/NDA/MoH) Egyptian Drug Authority, National Drug Authorities, and Ministries of Health of other regulated markets
- (ISA-95) International standard for integrating enterprise (IT) and (OT) systems, defining the functional hierarchy, models, and information exchange between ERP, MES, and plant-floor automation

We follow strict security guidelines throughout the design, development, validation, and operation of our systems, with the clear objective that no loophole exists anywhere in the system.

No back-door, shared, or undocumented administrative access to the data layer.

We are committed to sustaining a culture of quality, supported by sound systems, web-native enterprise architectures, and robust processes that encourage quality-focused behavior. Every internal decision, from initial design, algorithm training, and software development to formal validation, commercial release, and technical support, is made on the basis of what is best for quality, data integrity, and the customer.

We continually improve our Quality Management System (QMS) and all its functional elements. Through ongoing training, technical development, and empowerment of our people, we build and maintain a resilient quality culture. We firmly believe that delivering safe, compliant, high-quality, and paperless manufacturing solutions is everyone’s responsibility.



Santosh Agrawal (M D & Group CEO)

BLINE SOLUTION PRIVATE LIMITED

Effective Date: [01-04-2026] | Rev: 01