

Regulatory Considerations

FDA Regulation

- SaMD Classification
- Clinical Trial Requirements
- Approval Pathway
- Post-market Surveillance

Liability

- Clarification of Liability
- Medical Malpractice Insurance
- Scope of Indemnity
- Legal Review

Audit & Validation

- Detailed Logging
- Complete Traceability
- Regular Validation
- Performance Monitoring

Data Privacy

- HIPAA Compliance
- GDPR Compliance
- Personal Data Protection
- Data Encryption