SaaS-Based Compliance Management & Manufacturing ERP for Medical Device Manufacturers

Aligned with ISO 13485:2016, ISO 14971:2019, MDR 745/2017, and 21 CFR 820

Executive Summary

This document defines the complete module set for a SaaS-based integrated Quality Management System (QMS) and Manufacturing ERP platform for medical device manufacturers. The solution combines:

- **QMS Core** (Document, Training, Audit, CAPA, Risk, Compliance)
- **Manufacturing Operations** (Production Planning, Inventory, MES, Traceability)
- **Supply Chain & Procurement** (Purchasing, Supplier Management, SCM)
- **Finance & HR** (Accounting, HR, CRM)
- **Platform & Integration** (Security, APIs, Analytics, Localization)

The module set is designed to support organizations of all sizes and geographic footprints while maintaining regulatory compliance and operational excellence.

Module Categories & Definitions

A. QUALITY & COMPLIANCE CORE (10 Modules)

These modules address regulatory compliance, quality management, and risk management as required by ISO 13485 and ISO 14971.

1. Document Management Module

Sub-modules: - Document Control & Repository - Version Control & Status Management - Approval Workflows - Document Retrieval & Search - Controlled Print & Download - Training Record Integration

Expected Features: - Centralized repository for SOPs, Work Instructions, Forms, Device Master Record (DMR), Design History File (DHF), Technical Files, Quality Procedures - Multi-level

version control with status tracking (Draft → Under Review → Active → Superseded → Obsolete) - Configurable review, approval, and signature workflows with e-signature support - Clause tagging and mapping to ISO 13485, MDR, 21 CFR 820, and customer requirements - Advanced search with metadata tags, categories, and full-text indexing - Controlled print functionality with watermarks, print logs, and audit trails - Automatic read-and-understood tracking when documents change - Document supersession and obsolescence history - Integration with change management and training modules

Regulatory Impact: GxP-Critical
MVP Scope: In MVP

2. Training & Competency Management Module

Sub-modules: - Training Matrix - Training Records & History - Competency Assessments - Certification Tracking - Training Event Management

Expected Features: - Role-based training matrix linking positions to required trainings and competency levels - Training curriculum library with course materials and learning paths - Classroom and e-learning scheduling with calendar management - Attendance capture and completion tracking - Quizzes, exams, and assessments with configurable pass criteria - Certificate generation with expiry tracking and renewal notifications - On-the-job (OJT) competency evaluation and sign-off - Periodic skill recertification and refresher tracking - Automatic training assignments from document changes, new hires, or role changes - Manager dashboards showing overdue, expiring, and at-risk trainings - Training compliance reporting by department, role, and time period - Integration with audit readiness and regulatory inspection preparation

Regulatory Impact: GxP-Critical
MVP Scope: In MVP

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3. Audit Management Module

Sub-modules: - Internal Audit Planning & Execution - External & Notified Body Audits - Supplier Audits - Audit Scheduling & Resources - Audit Findings & Observations

Expected Features: - Risk-based audit program planning with scheduling algorithms - Calendar management for multiple audit types (internal, regulatory, customer, Notified Body, supplier) - Resource allocation and auditor assignment - Clause-linked audit checklists mapped to ISO 13485, MDR, 21 CFR 820, and other standards - Mobile/on-site capture of findings, evidence photos, and observations - Grading of findings (Critical, Major, Minor, Observation) - Real-time escalation rules and alerts - Automatic linkage to NC and CAPA processes - Finding responses and corrective action tracking - Audit readiness dashboards - Exportable audit packs with evidence attachments - Audit calendar and historical reports - Auditor competency tracking

Regulatory Impact: GxP-Critical
MVP Scope: In MVP

4. CAPA & Nonconformance Management Module

Sub-modules: - Nonconformance Log - Deviations & Out-of-Spec Events - CAPA Planning - Root Cause Analysis - Effectiveness Checks

Expected Features: - Unified log for nonconformances, deviations, out-of-specification events, and anomalies - Configurable categories (Process NC, Product NC, System NC, etc.) and severity levels - Structured investigation tools: 5-Why, Ishikawa/Fishbone Diagram, RCCA, FTA - Root-cause documentation and evidence attachment - Link to risk management file for impact assessment - CAPA plan definition with corrective and preventive actions - Action ownership assignment with target dates and responsibilities - Milestone tracking and progress updates - Link to change control for implementation tracking - Effectiveness verification and re-opening for failed CAPAs - Escalation rules for overdue items (SLA-based) - Trend analysis and Pareto

reporting - Dashboard with age analysis and closure KPIs - Integration with audit, complaint, and regulatory inspection follow-up

Regulatory Impact: GxP-Critical
MVP Scope: In MVP

5. Risk Management (ISO 14971) Module

Sub-modules: - Risk Management File - Hazard Identification - Risk Assessment & Analysis - Risk Evaluation - Risk Control Planning & Monitoring

Expected Features: - Per-product-family risk management files aligned to ISO 14971 lifecycle stages - Hazard library with templates covering known hazard categories (use errors, design failures, manufacturing defects, etc.) - Hazard identification linked to user needs, design specifications, and process steps - Risk analysis tools including FMEA, FTA, HAZOP, or risk matrices - Severity/Probability/Risk Priority Number (RPN) scoring with pre-configured scales - Pre-control and post-control risk comparison and residual risk evaluation - Risk control option analysis and selection - Benefit-risk analysis documentation for selected options - Implementation tracking of risk control measures - Traceability links between hazards, design controls, verification/validation tests, and product specifications - Link to NC/CAPA when control failures detected - Link to post-market complaints for hazard validation - Periodic risk review and re-assessment triggers - Risk acceptance and sign-off workflows - Risk reporting and dashboard - Export for regulatory submission and inspections

Regulatory Impact: GxP-Critical
MVP Scope: In MVP

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6. Change Management Module

Sub-modules: - Change Control - Engineering Change Requests (ECR) - Engineering Change Orders (ECO) - Impact Analysis - Implementation & Validation

Expected Features: - Change request intake with origin classification (design, process, supplier, software, equipment, document, regulatory) - Detailed change description and justification - Impact analysis across risk file, design, specifications, validation status, regulatory submissions, labeling, BOMs, routings, test procedures, training, and supplier communications - Multi-stage approval workflow with configurable gates - Design review integration if applicable - Risk assessment of proposed change - Validation and verification planning with test protocols - Implementation planning with pilot/trial phases if needed - Go-live control and rollback procedures - Automatic triggering of related document updates, training assignments, and BOM/routing changes - Complete change log with full audit trail - Link to CAPA and risk management for traceability - Change history reports and trend analysis - Regulatory change notification support (if applicable per region)

Regulatory Impact: GxP-Critical
MVP Scope: In MVP

7. Supplier & External Provider Management Module

Sub-modules: - Supplier Master Data - Supplier Qualification - Supplier Audits & Performance - Compliance Tracking - Collaboration & Communication

Expected Features: - Supplier master with scopes (materials, services, outsourced processes), commodity codes, and risk classification - Supplier onboarding questionnaire workflows - Qualification requirements customizable by supplier type and category - Qualification workflows: document review, audit, sample approval, performance baseline, risk assessment - Supplier audit scheduling, execution, findings, and SCAR/CAPA management - Performance

monitoring dashboards: On-Time Delivery (OTD), defect rates (PPM), complaint frequency, lead times - Certification and regulatory approvals tracking (ISO 9001, ISO 13485, FDA registration, notified body approval, etc.) - Supplier scorecard and re-qualification triggers - Controlled specification and quality agreement document sharing - Communication channels for NCR/SCAR/CAPA exchange - Integration with purchasing, receiving inspection, and inventory modules - Supplier performance trending and benchmarking - Automatic escalation for at-risk suppliers

Regulatory Impact: Business-Critical
MVP Scope: In MVP

8. Compliance Tracking & Regulatory Intelligence Module

Sub-modules: - Regulatory Requirements Register - Clause Mapping - Compliance Reporting - Regulatory Change Management - Evidence Management

Expected Features: - Structured register of applicable regulations and standards per target market (ISO 13485, MDR 745/2017, 21 CFR 820, PMCF requirements, eIFU, UDI, etc.) - Tagging and mapping of QMS processes and documents to specific regulatory clauses - Requirements matrix showing ownership and implementation status - Regulatory change notification tracking with impact assessment - Action plan creation and tracking for new or amended requirements - Compliance evidence repository linked to specific requirements and clauses - Audit trail for compliance updates and sign-offs - Exportable compliance reports by clause, by product, or by site for inspections and submissions - Dossier/Technical File checklist support - eIFU master data storage (labeling, symbols, warnings, instructions) - UDI master data storage and mapping to inventory items - Regional requirements customization (EU MDR, UK, US, China, India, etc.) - Regulatory submission tracking and status

Regulatory Impact: GxP-Critical
MVP Scope: In MVP

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9. Post-Market Surveillance & Customer Complaints Module

Sub-modules: - Complaint Intake - Triage & Severity Assessment - Investigation & Root Cause - Regulatory Reportability - Post-Market Surveillance (PMS) Plans

Expected Features: - Multi-channel complaint intake: customer portal, email, phone, field sales, service - Unique complaint ID generation and tracking - Triage workflow with configurable severity and seriousness assessment - Evaluation for regulatory reportability (vigilance, MDR, FDA MDR/recalls) - Investigation workflow with structured forms for cause analysis - Linkage to device lot, serial number, and production lot for traceability - Root-cause investigation template (5-Why, Ishikawa, RCCA) - Automatic link to NC/CAPA/risk management - Corrective action tracking with effectiveness verification - Feedback routing to Design, Production, Quality, and Suppliers - Post-Market Surveillance plan management (timing, scope, expected enrollment) - PMCF (Post-Market Clinical Follow-up) study tracking if applicable - Complaint trending by product, market, lot, failure mode, and time period - Regulatory reporting and submission tracking - Dashboard for complaint aging and closure KPIs - Export for regulatory submissions and inspections

Regulatory Impact: GxP-Critical
MVP Scope: In MVP

10. Metrics & Management Review Module

Sub-modules: - KPI Definition & Monitoring - Management Review Input Collection - Dashboard & Reporting - Action Item Tracking

Expected Features: - Configurable KPI library covering QMS and operational metrics - Quality KPIs: NC rate, complaint rate, CAPA closure time, audit finding rate, training compliance, equipment OEE - Operational KPIs: on-time delivery, inventory turnover, production yield, scrap

rate, schedule attainment - Real-time dashboards with drill-down capability - Trend analysis (moving average, trend line, control limits) - Comparison to targets, benchmarks, and historical performance - Automatic collation of management review inputs: complaints, CAPA status, audit findings, supplier performance, process KPIs, regulatory changes, training updates - Customizable MR report template - Action item tracking from MR decisions with owners, due dates, and status - Effectiveness verification of prior MR actions - Periodic trend analysis and continuous improvement identification - Role-based dashboard views for executives, managers, and operators - Mobile dashboard access for management

Regulatory Impact: Business-Critical
MVP Scope: In MVP

B. MANUFACTURING & OPERATIONS (8 Modules)

These modules manage the actual production process, inventory, and traceability as required by 21 CFR 820 Part 11 and MDR.

11. Product Data Management (PDM) / Engineering Module

Sub-modules: - Item Master & Versioning - Bill of Materials (BOM) - Routing & Work Instructions - Engineering Change (ECR/ECO) - Design History File Links

Expected Features: - Item master with full revision control, approval status, and engineering sign-off - Multi-level BOMs supporting discrete manufacturing: parent, sub-assembly, phantom, configurable items - BOM effectivity (date, serial-number, lot-based) - Routing with operations sequence, work centers, setup times, run times, resource requirements - Work instruction links per operation - BOM and routing revision history with change audit trail - Link to device specifications, design inputs, and design outputs - Material specifications and substitution rules - Critical components flagging - Engineering change (ECR/ECO) integration - Design verification and validation links - Quality inspection and test plan links - Link to suppliers and approved

suppliers list for materials - BOM reuse templates and configurators - Export for production and quality control

Regulatory Impact: GxP-Critical
MVP Scope: In MVP

12. Production Planning & Control (MPS/MRP) Module

Sub-modules: - Master Scheduling (MPS) - Material Requirements Planning (MRP) - Capacity Planning - Scheduling & Dispatch - Shop Floor Execution

Expected Features: - Demand management: sales orders, blanket forecasts, inventory replenishment signals - Master Production Schedule (MPS) planning with adjustable time fences - Material Requirements Planning (MRP) explosion to component level - Lead-time and safety-stock-based ordering - Capacity planning across work centers - Constraint-based or finite scheduling to balance capacity - Work order creation, release, and dispatch - Shop-floor work order execution: operation start/stop, quantity good/scrap, downtime reasons, material usage - Real-time production status and progress tracking - Rework and scrap handling with disposition workflows - Route deviations and alternate routing with approval - Labor and equipment tracking per operation - Overall Equipment Effectiveness (OEE) calculation - Production forecasting and actual vs. planned analysis - Graphical scheduling views (Gantt chart) - Mobile shop-floor data collection if available - Integration with quality control and inventory

Regulatory Impact: Business-Critical
MVP Scope: In MVP

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13. Inventory & Warehouse Management Module

Sub-modules: - Stock Management & Locations - Lot & Batch Tracking - Serial Number Management - Warehouse Operations - Quarantine & Blocked Stock

Expected Features: - Multi-warehouse and multi-location inventory management - Real-time stock visibility by location, lot, and serial number - Lot and batch tracking with shelf-life and expiry date management - Serial-number tracking for devices where required by regulation or customer - First-In-First-Out (FIFO) and other valuation methods - Put-away strategies and location optimization (slotting) - Pick and pack workflows with route optimization - Cycle counting and physical inventory reconciliation - Stock adjustment and variance investigation - Quarantine and blocked stock management with release workflows - Quality hold integration: material release only after QC approval - Consignment inventory tracking (if applicable) - Return and scrap material handling - Inventory aging and obsolescence tracking - Integration with purchasing, production, and shipping - Lot-level traceability queries - Barcode and RFID integration (if desired)

Regulatory Impact: GxP-Critical
MVP Scope: In MVP

14. Lot & Serial Traceability Module

Sub-modules: - Genealogy Tracking - Where-Used Queries - Recall Support - Traceability Reports

Expected Features: - End-to-end traceability from raw material lot/serial through intermediates and finished goods to shipments and customers - Multi-level genealogy tree visualization showing parent-child relationships - Traceability to specific work orders, process steps, equipment, operators, and test results - Forward traceability: which lots were made from a given raw material - Backward traceability: which raw materials went into a finished lot - Fast “where-

used" queries for recall impact assessment - Lot hold and recall workflows - Traceability report generation for regulatory submissions - Integration with quality control and inspection records - Customer lot allocation tracking - Rework and scrap material genealogy - Traceability validation (no orphaned records) - Mobile traceability lookup - Integration with post-market data for complaint root-cause linking

Regulatory Impact: GxP-Critical
MVP Scope: In MVP

15. Quality Control (In-Process & Final Inspection) Module

Sub-modules: - Inspection Plans & Sampling - Test Specifications & Procedures - Measurement Recording - Inspection Results & Disposition - Certificate of Analysis (CoA)

Expected Features: - Incoming (vendor), in-process (operation), and final (product) inspection plan definition - Sampling plans and AQL (Acceptable Quality Level) support - Test specification and acceptance criteria definition per product/material/operation - Manual data entry for measurements and test results - Integration with automated test equipment data collection (if available) - Pass/fail determination with automatic escalation for out-of-spec conditions - Disposition workflows: accept, reject, conditional use, quarantine - Linkage of rejected material to NC and CAPA processes - Certificate of Analysis (CoA) generation for supplied materials - Sample retention tracking - Inspection performance metrics and SPC (Statistical Process Control) capability - Quality disposition sign-off and authority levels - Integration with inventory status (hold/release) - Integration with production scheduling (downstream process gating) - Traceability of inspector/operator ID and timestamp - Historical trend analysis and data mining

Regulatory Impact: GxP-Critical
MVP Scope: In MVP

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16. Manufacturing Execution System (MES) Module

Sub-modules: - Shop Floor Real-time Control - Work Order Execution - Labor & Equipment Tracking - Downtime Management - Data Collection & Analysis

Expected Features: - Real-time monitoring and control of manufacturing operations - Work order status tracking (planned, ready, in progress, completed, verified) - Operation-level execution: start time, stop time, quantity produced, quantity scrap, reason codes - Downtime tracking with reason codes (planned, equipment failure, material shortage, operational, etc.) - Labor tracking: operator ID, shift, task, hours, overtime - Equipment tracking: runtime, idle time, maintenance events - Material consumption tracking per operation/work order - Data quality checks and validation at point of entry - Real-time KPI calculation (efficiency, OEE, cycle time) - Alert and exception handling (over-run, quality issue, delay) - Rework and scrap handling with disposition - Mobile shop-floor interfaces for ease of use - Operator instructions and checklists - Integration with quality control for in-process testing - Historical data archiving for trend analysis - Integration with production planning for real-time rescheduling

Regulatory Impact: Business-Critical
MVP Scope: In MVP

17. Equipment & Maintenance Management Module

Sub-modules: - Asset Register - Calibration Management - Preventive Maintenance (PM) - Breakdown Maintenance - Validation Status Tracking

Expected Features: - Asset register for all production and test equipment - Equipment specifications and critical parameters - Calibration schedule and interval management - Calibration procedures and acceptance criteria - Calibration record and certificate management - Calibration interval adjustment based on historical data - Automatic alerts for overdue calibrations - Calibration certificate uploads and expiry tracking - Preventive maintenance (PM)

plans and schedules - PM task execution and record-keeping - Breakdown maintenance request and tracking - Maintenance history and trend analysis - Mean Time Between Failures (MTBF) and Mean Time To Repair (MTTR) calculation - Link to equipment validation status and lock-out rules - Automatic production holds for equipment with expired calibration - Integration with production scheduling to prevent use of out-of-service equipment - Spare parts and service provider management - Maintenance cost tracking - Equipment depreciation and replacement planning

Regulatory Impact: GxP-Critical
MVP Scope: In MVP

18. Production Environment & Sterilization Module

Sub-modules: - Sterilization Batch Tracking - Environmental Monitoring - Critical Utilities Management - Sterilization Process Controls - Validation & Verification

Expected Features: - Sterilization batch tracking for ETO (ethylene oxide), gamma radiation, steam, or other methods - Sterilization cycle parameter recording and approval - Sterilization load composition (device lots, quantities) - Sterilization batch to finished device lot linkage - Sterilization certificate/validation documentation - Environmental monitoring records (temperature, humidity, cleanliness, microbial counts) - Critical utilities logs (compressed air quality, water purity, vacuum, nitrogen, steam quality) - Utility alarm and alert management - Utility calibration and PM scheduling - Deviation handling and investigation - Sterilization process validation and routine performance verification - Environmental qualification and requalification - Link to CAPA for failures or deviations - Regulatory reporting support (e.g., D-values for ETO) - Integration with lot traceability - Compliance documentation for export and audit

Regulatory Impact: GxP-Critical
MVP Scope: Future

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C. SUPPLY CHAIN & PROCUREMENT (3 Modules)

These modules manage procurement, supplier relationships, and distribution.

19. Procurement & Purchasing Module

Sub-modules: - Purchase Requisitions (PR) - Purchase Orders (PO) - Supplier Contracts & Pricing - Delivery Schedules & ASN - Goods Received Notes (GRN)

Expected Features: - Automatic PR generation from MRP or manual creation - PR approval workflows and cost authorization limits - Supplier selection and multi-source management - Supplier contracts with pricing, terms, and lead times - PO creation with back-to-back linking to sales orders where applicable - PO release and transmission to supplier - Delivery schedule management and supplier scheduling - Advanced Shipping Notice (ASN) receipt and matching - Goods Received Note (GRN) with lot/serial capture - Receipt inspection integration and quality hold - Three-way matching: PO, receipt, and invoice - Receiving discrepancy management (quantity, quality, delivery) - Supplier on-time delivery tracking - Invoice and payment processing - Supplier performance KPI dashboards - Purchase order history and spend analysis - Integration with inventory and production for demand planning - Integration with supplier management for qualification and SCAR tracking

Regulatory Impact: Business-Critical
MVP Scope: In MVP

20. Supply Chain Management (SCM) Module

Sub-modules: - Demand Forecasting & Planning - Supplier Performance Monitoring - Lead Time Management - Logistics Tracking - Order-to-Cash KPIs

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Expected Features: - Demand forecasting (time series, collaborative forecasting) - Forecast vs. actual analysis and adjustment - Supplier performance metrics: On-Time Delivery (OTD), quality (PPM), lead time consistency, responsiveness - Supplier scorecards and performance trends - Supplier communication and alert management - Supply chain KPI dashboards: inventory turns, days supply, stockout incidents, supplier lead times - Order tracking from placement to receipt - Supply chain visibility and exception alerts - Supplier capacity planning and communication - Logistics cost tracking and optimization - Carrier performance monitoring (if outsourced) - Regional vs. air vs. sea shipping comparison - Supply risk assessment (single sourcing, geographic concentration) - Supply continuity planning - Integration with procurement for expediting - Integration with production planning for demand visibility - Reporting and trending for supply chain optimization

Regulatory Impact: Business-Critical
MVP Scope: In MVP

21. Sales & Distribution Module

Sub-modules: - Customer Master & Pricing - Sales Orders & Quotations - Delivery & Dispatch - Shipping Documentation - Returns & RMA Management

Expected Features: - Customer master data: addresses, contacts, credit terms, pricing agreements - Product pricing and discount structures - Quotation creation with cost and margin analysis - Sales order entry and confirmation - Available-to-Promise (ATP) and Capable-to-Promise (CTP) checks - Delivery schedule coordination with production - Packing list generation - Shipping label and carrier selection - Export documentation support: Certificate of Origin (COO), customs declarations, packing lists, commercial invoices - Multi-currency invoicing for international sales - Delivery proof and customer signature - Customer invoice and payment tracking - Return and RMA (Return Material Authorization) management - Return inspection and disposition (scrap, rework, restock) - Linkage of returns to NC and post-market complaints - Customer service tickets and follow-up - Customer delivery performance KPIs - Integration with

billing and accounts receivable - Integration with production planning and inventory - Integration with quality and complaints module for returned goods investigation

Regulatory Impact: Business-Critical
MVP Scope: In MVP

D. FINANCE & HR (3 Modules)

These modules manage financial and human resources operations.

22. Finance & Accounting Module

Sub-modules: - General Ledger (GL) - Accounts Payable (AP) - Accounts Receivable (AR) - Costing & Variance Analysis - Financial Reporting

Expected Features: - Chart of accounts structure with cost centers and profit centers - General ledger posting from all operational modules - Multi-currency and multi-company consolidation - Bank reconciliation and cash flow management - Accounts payable: invoice entry, approval, payment, aging - Accounts receivable: invoice, collections, aging, credit hold - Standard, actual, and absorption costing methods - Product cost calculation (labor, materials, overhead) - Variance analysis: actual vs. budget, standard vs. actual - Month-end close procedures and checklist - Financial reporting: P&L, balance sheet, cash flow, cost of goods sold - Budget planning and variance tracking - Project accounting for validation activities (if desired) - Fixed asset accounting and depreciation - Audit trail and transaction history - Integration with purchasing, inventory, and production - Financial dashboards and KPIs - Regulatory compliance reporting

Regulatory Impact: Business-Critical
MVP Scope: In MVP

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23. Human Resources & Time Module

Sub-modules: - HR Records & Master Data - Time & Attendance - Shift Planning & Scheduling - Skills & Training Links - Labor Costing & Payroll Interface

Expected Features: - Employee master data: personal info, position, department, reporting structure - Organization chart visualization - Time and attendance tracking: clock in/out, shift patterns, overtime, absences - Attendance and leave management with approval workflows - Skills and competency inventory linked to training module - Training history and certification tracking per employee - Qualification and authorization levels for specific roles/operations - Labor booking to work orders for cost allocation and productivity tracking - Shift scheduling and swap management - Workforce planning and headcount analysis - Overtime and staffing reports - Payroll interface: wage calculation, deductions, tax reporting - Employee performance and appraisal tracking - Turnover and retention analysis - Compliance reporting (labor regulations, safety incidents, certifications) - Integration with production (who worked on which order/lot) - Integration with training module for automatic assignments - Integration with audit module for auditor qualifications

Regulatory Impact: Business-Critical
MVP Scope: Future

24. Customer Relationship Management (CRM) Module

Sub-modules: - Customer & Contact Master - Leads & Opportunities - Service Requests & Issues - Communication History - Service Contracts

Expected Features: - Customer and contact master with roles and preferences - Account hierarchy and multi-site customers - Lead and opportunity tracking with sales pipeline - Quotation and sales order linkage - Service request and incident tracking - Issue categorization and SLA management - Communication history: email, phone, meetings, interactions -

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Complaint linkage and investigation tracking - Service contracts and coverage management - Customer satisfaction feedback and surveys - Customer portal (if desired) for order tracking and inquiry - Integration with sales module for quote-to-order workflows - Integration with complaints module for issue resolution - Reporting and customer KPIs: satisfaction, response time, resolution time - Future roadmap: field service management if on-site support offered

Regulatory Impact: Business-Critical
MVP Scope: Future

E. PLATFORM & INTEGRATION (6 Modules)

These modules provide the foundation for security, integration, analytics, and platform features.

25. User & Access Management Module

Sub-modules: - Role-Based Access Control (RBAC) - User Provisioning & Deprovisioning - Authentication & Authorization - Periodic Access Reviews

Expected Features: - Role-based access control (RBAC) by module, function, and data scope (site, department, product) - Predefined roles: System Admin, QA Manager, Production Supervisor, Operator, Auditor, Finance, HR, etc. - Custom role creation with granular permissions (view, edit, approve, delete, export) - User life-cycle management: onboarding, role changes, off-boarding - Automatic access revocation upon termination - Single Sign-On (SSO) integration with corporate directory (LDAP, Active Directory) if desired - Multi-Factor Authentication (MFA) option for sensitive functions - Session management and timeout policies - Device and location-based access restrictions (if desired) - Segregation of duties (SoD) checks: conflicting roles cannot be held by one user - Password policies: complexity, expiry, history, recovery - Periodic access reviews and certifications - Audit logging of all user access and actions - User manual and training on role-specific functions

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Regulatory Impact: GxP-Critical
MVP Scope: In MVP

26. Security & Compliance Module

Sub-modules: - Data Protection & Encryption - Audit Trails & Logging - GDPR & HIPAA Compliance - Backup & Disaster Recovery - Vulnerability Management

Expected Features: - Data encryption at rest (database, storage) using industry-standard algorithms (AES-256) - Data encryption in transit (HTTPS/TLS 1.2 or higher) - Secure key management and rotation - Full audit trail of all system and user actions: who, what, when, where, why - Tamper-resistant logging (cannot be deleted retroactively) - Audit log retention per regulatory requirements (minimum 5-10 years for medical device) - Anomaly detection and alerting (unusual login, bulk data export, etc.) - GDPR compliance features: data subject access requests, right to erasure (where applicable), data portability - HIPAA compliance features (if applicable): PHI protection, BAA support, audit controls - Backup and disaster recovery procedures with tested recovery capabilities - Environment segregation: Development, Validation, Production - Change management controls on production access - Vulnerability scanning and patching - Annual security assessment and audit - Compliance with relevant standards: ISO 27001, SOC 2, ISO 13485 Annex B (IT), 21 CFR Part 11 - Third-party security assessment and certification

Regulatory Impact: GxP-Critical
MVP Scope: In MVP

27. Integration Layer & APIs Module

Sub-modules: - REST APIs & Webhooks - Pre-built Connectors - Data Mapping & Middleware - API Documentation

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Expected Features: - RESTful APIs for programmatic access to all modules - Webhook support for event-based integrations (e.g., when NC created, trigger CAPA) - Pre-built connectors to common systems: ERP (SAP, Oracle, NetSuite), MES, LIMS, HR systems, payroll, etc. - CSV-based import/export for data migration and bulk updates - Data mapping tools with validation and error handling - Middleware/iPaaS integration (if desired) for complex workflows - OAuth 2.0 and API key authentication - Rate limiting and API usage monitoring - API documentation with examples and sandbox environment - Data synchronization: one-way, two-way, and real-time options - Batch job scheduling for nightly syncs - Error handling and retry logic - Integration validation support for Part 11 compliance (if applicable) - Change log and version management for integrations - Support for EDI (Electronic Data Interchange) if needed for suppliers

Regulatory Impact: Business-Critical
MVP Scope: In MVP

28. Business Intelligence & Analytics Module

Sub-modules: - Data Warehouse / Logical Model - Dashboards & Reports - Self-Service Analytics - Advanced Analytics & Forecasting

Expected Features: - Centralized data warehouse or logical data model integrating all QMS and operational modules - Normalized data schema for consistency and performance - Real-time data refresh (or configurable sync frequency) - Pre-built dashboards: Quality (NC rate, CAPA status, audit findings), Production (OEE, yield, schedule attainment), Supply Chain (OTD, supplier performance, inventory), Finance (margins, variance, cash flow), HR (turnover, training compliance) - Custom dashboard creation by users (drag-and-drop) - Drill-down capability from executive summaries to transaction detail - Trend analysis: line charts, control charts, Pareto charts - Comparative analysis: actual vs. budget, vs. target, vs. benchmark - Statistical analysis: hypothesis testing, correlation, regression (advanced) - Forecasting: simple moving average, exponential smoothing, seasonal decomposition (advanced) - Ad-hoc query builder (SQL knowledge optional) - Self-service reporting with scheduling and distribution - Mobile dashboard

access for on-the-go decision-making - Export to Excel, PDF, PowerPoint for presentations - Integration with external BI tools (Tableau, Power BI, Qlik) if preferred - Data governance: role-based data access, lineage, data quality rules

Regulatory Impact: Business-Critical
MVP Scope: In MVP

29. Localization & Multi-Site Support Module

Sub-modules: - Multi-Language Support - Regional Configuration - Multi-Currency & Multi-Entity - Regulatory Customization

Expected Features: - User interface in multiple languages (English, German, French, Spanish, Chinese, etc.) - Configurable language per user - Multi-language content for documents, templates, forms, and reports - Translation workflow with verification before deployment - Regional format support: date formats (MM/DD/YYYY vs. DD/MM/YYYY), number formatting (1,000.50 vs. 1.000,50), currency symbols - Site-specific configuration: document numbering schemes, approval workflows, KPI targets - Multi-legal-entity support for consolidated corporate QMS - Regional regulatory mapping: EU MDR, UK MHRA, FDA, TGA, Health Canada, China NMPA, India CDSCO, etc. - Site-level data segregation with corporate dashboard roll-up - Multi-currency transactions and reporting - Regional tax and compliance field support - Time-zone configuration per user/site - Audit and compliance reporting per site and by region - Local language regulatory forms and templates - Integration with global ERP for consolidated financials and supply chain

Regulatory Impact: Business-Critical
MVP Scope: Future

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30. Helpdesk & Knowledge Management Module

Sub-modules: - Ticketing System - Knowledge Base - Release Notes & Documentation - User Feedback & Feature Requests

Expected Features: - Internal helpdesk ticketing for system and process questions - Ticket categorization: issue, change request, enhancement, question - SLA-based ticket routing and escalation - Ticket status tracking: open, in progress, resolved, closed - Knowledge base (KB) articles for FAQs, how-to guides, troubleshooting - Full-text search of KB with ranking and relevance - Contextual help links from system screens to relevant KB articles - Release notes for new versions with feature highlights and known issues - Change summaries to prepare users for updates - User feedback collection via surveys and in-app feedback forms - Feature request tracking and voting - Priority and trending of requests - Communication with users on ticket status and resolution - Training and onboarding content hub (videos, documents, checklists) - User manual download and accessibility - Proactive notifications for system maintenance, updates, and regulatory changes

Regulatory Impact: Business-Critical
MVP Scope: Future

Module Scope & MVP Roadmap

In MVP (Phase 1 - Go-Live)

Modules 1–27 represent the **Minimum Viable Product (MVP)** for a functional QMS and manufacturing ERP: - All core Quality & Compliance modules - All Manufacturing & Operations modules - Core Supply Chain & Procurement modules - Finance & AR/AP (not full HR costing) - Complete Platform foundation (security, integration, BI, RBAC)

Estimated Timeline: 6–9 months to go-live with dedicated team

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Future/Phase 2 (Post-Go-Live)

Modules to enhance and scale: - Production Environment & Sterilization (18) – add once core is stable - HR full features with costing (23) – after stable payroll process - CRM module (24) – after sales/service process stabilization - Localization enhancements (29) – expand to new geographies - Helpdesk and KM (30) – enhance user support maturity

Regulatory & Validation Considerations

GxP-Critical Modules

These modules directly impact product quality, safety, and regulatory compliance and require: - Rigorous User Requirements Specification (URS) - Validation plan and test protocols - Risk-based testing per FDA Guidance on Part 11 - Audit trail and data integrity controls - Change management and configuration control

Modules: 1, 2, 3, 4, 5, 6, 8, 9, 10, 11, 13, 14, 15, 17, 18, 25, 26

Business-Critical Modules

These modules optimize operations and supply chain but do not directly affect product quality: - Functional and integration testing - Performance and stress testing - Standard change management - Routine maintenance and monitoring

Modules: 7, 12, 16, 19, 20, 21, 22, 27, 28

Nice-to-Have Enhancements

Future capabilities to enhance user experience and analytics: - Advanced CRM and field service - HR time and attendance details - Regional localization - Helpdesk and knowledge management - Advanced analytics and forecasting

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Success Criteria & KPIs

A fully operational QMS + Manufacturing ERP should deliver:

1. **Compliance & Audit Readiness**
   - 100% regulatory requirement coverage
   - <2 weeks to generate compliance report
   - Zero critical audit findings related to QMS/ERP
2. **Quality & Risk**
   - CAPA closure time <30 days
   - NC detection and investigation time <5 days
   - Risk management file completeness >95%
   - Training compliance >98%
3. **Production & Efficiency**
   - On-time delivery >95%
   - Production yield improvement >5%
   - Inventory turns improvement >10%
   - Schedule attainment >90%
4. **Supply Chain**
   - Supplier OTD >95%
   - Supplier defect rate <1%
   - Procurement cycle time <7 days
5. **User Adoption**
   - System usage >85% of target population
   - User satisfaction (CSAT) >4/5

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- Training completion >95%