

CRITICAL ERP FEATURES FOR MEDICAL DEVICE MANUFACTURERS



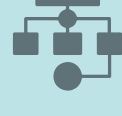
Adherence to ISO 9001, ISO 3845, & FDA Compliance Standards



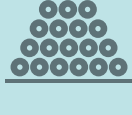
Track non-conformance data throughout the production process recorded on a centralized database.



Maintain user-defined list of part specifications, their target values & tolerances.



Visibility of quality parameters at every manufacturing stage owing to Manufacturing, CRM, CAPA, Finance & Accounting integration.



Advanced material traceability from cradle to grave with quality specifications, serial genealogy & controls.



Assign tasks, generate automatic emails/reminders, & document corrective & preventive action using 8D methodology.



Analyze quality metrics for suppliers, parts, manufacturing, & operations using quality management dashboards.



Material Traceability & Product Serialization

Track products from procurement till dispatch, serial genealogy, & controls for FDA, 21 CFR Part 11, ISO 9001 & ISO 3845.



Track heat numbers, material composition data and attach mill certificates to lot numbers.



Maintain lot items using Barcode Scanner & Auto Inventory Transfer (Bar Code).



Track real-time inflow + outflow of inventory, parts origin & get great visibility of the entire supply chain.



Integrate with shipping modules for online shipment initiation and tracking.



Employee Training & Certification

Document employee details such as educational qualification, certifications & work-experience for specific tasks.



Maintain in-house training records of employees & track certification progress for each of them.



Track training expiration, generate auto-alerts for new training requirements.



Track eligibility requirements for individual processes & link qualified employees.



Auto-generate production schedules based on employee eligibility.

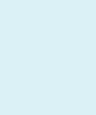


Audit Trail & Data Security

Comprehensive change logs with time & date stamps per employee/department.



Audit trail, log management and documentation for FDA audits.



Track changes to actual field data over a period of time.



Analyze transaction level detail for all orders, equipment specifications, financial numbers etc.



Data encryption to prevent data leakage and misuse.



Electronic signature & password security for secured transactions by authorized personnel.



Distribution

Manage your distributor & end-user data, day to day communication with them in CRM.



Provide self-service capability and items reorder using partner portals.



Manage and maintain multiple warehouses and track inventory movements between them.



Maintain shipment information and track each shipment from inception till delivery.

