Compliance with 21 CFR Part 11

Electronic Record Electronic Signature enabled supply chain execution for Medical Device and Drug companies
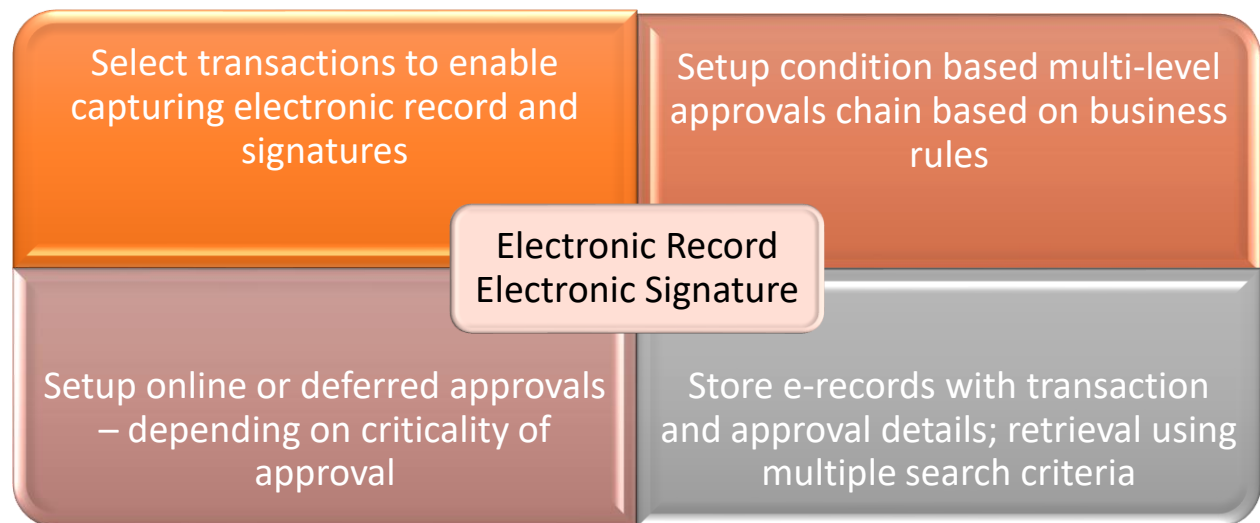

TRINAMIX WHITE PAPER,

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Anyone working in manufacturing and distribution of medical devices and drugs is well versed with the '21 CFR Part 11' requirements. In 1997, US Food and Drug Administration (FDA) issued regulation popularly known as "21 CFR Part 11". The regulation aims to assure that computerized records are safe, accurate and secure. As per the regulations, **the software application's role is to ensure that the data pertaining to manufactured goods is electronically captured, manipulated, extracted and coded during the manufacturing of the product**.
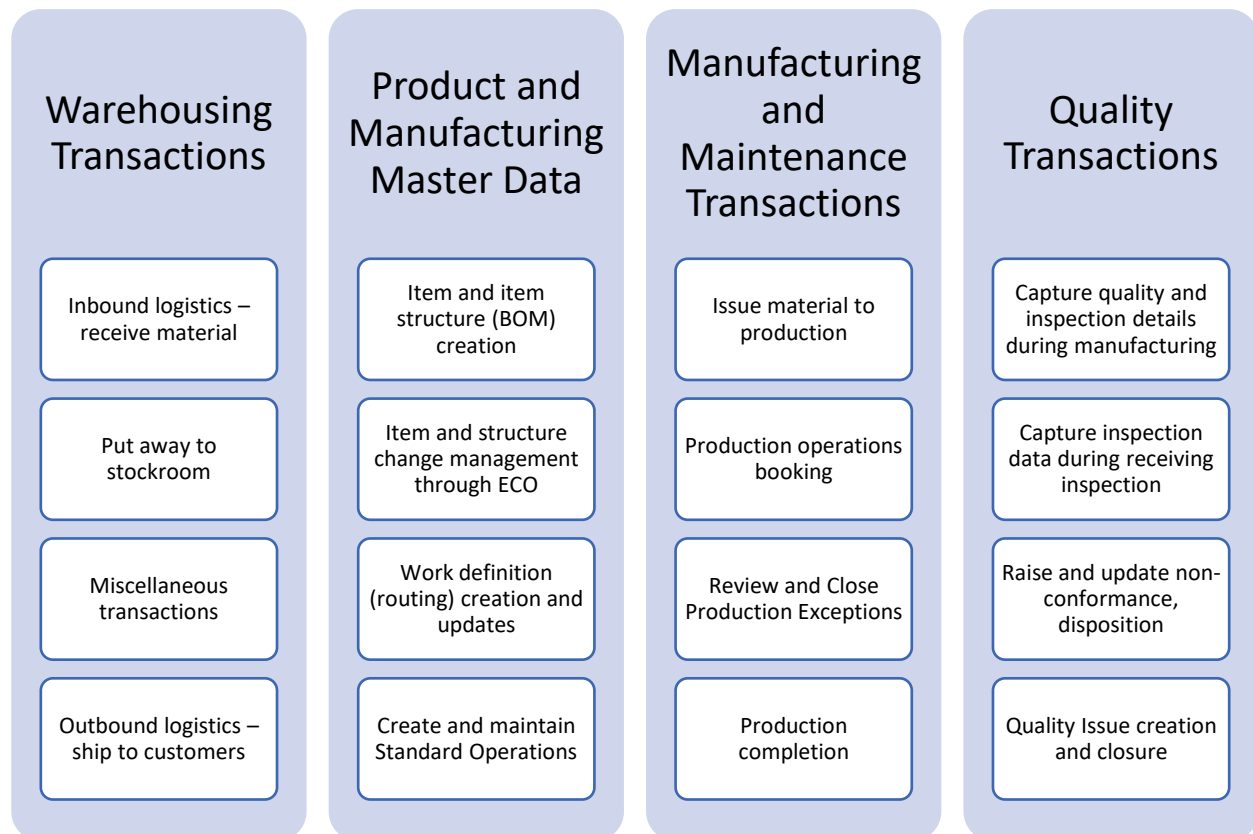
Oracle Supply Chain Execution Cloud has built-in features to ensure manufacturing and quality transactions are in compliance with 21 CFR Part 11. The regulation does not specify transactions that must be secured using electronic signature. Oracle Supply Chain Execution modules can be configured to capture electronic signatures for the transactions that are applicable to your manufacturing process and business requirements. In addition, the application enables routing of approvals based on configurable rules and ability to capture online or deferred approval.

Trinamix has implemented Oracle Cloud ERP Electronic Record Electronic Signature (ERES) enabled operations for leading medical devices and drugs manufacturing organizations across the globe. Trinamix not only helps implement standard Oracle features but also brings pre-configured solution set and best-in-class practices to accelerate the design and deployment of Oracle Cloud applications.

Select transactions to enable capturing electronic record and signatures	Setup condition based multi-level approvals chain based on business rules
Setup online or deferred approvals – depending on criticality of approval	Store e-records with transaction and approval details; retrieval using multiple search criteria

Electronic Record Electronic Signature

Enabling transactions for E-signatures:

You can pick and choose transactions from the list below for Electronic Record and Signature capture. If a transaction is enabled for ERES, user must sign electronically and submit the transaction for approval. The record is stored as an electronic document along with the user e-signature. Application provides flexibility to enable transactions at manufacturing plant or warehouse level. This flexibility is needed when medical device manufacturers produce and stock different products at dedicated plants that have specific electronic record capture and signature verification requirements.

Warehousing Transactions	Product and Manufacturing Master Data	Manufacturing and Maintenance Transactions	Quality Transactions
Inbound logistics – receive material	Item and item structure (BOM) creation	Issue material to production	Capture quality and inspection details during manufacturing
Put away to stockroom	Item and structure change management through ECO	Production operations booking	Capture inspection data during receiving inspection
Miscellaneous transactions	Work definition (routing) creation and updates	Review and Close Production Exceptions	Raise and update non-conformance, disposition
Outbound logistics – ship to customers	Create and maintain Standard Operations	Production completion	Quality Issue creation and closure

Fully configurable rules engine using Oracle Business Process Manager (BPM):

ERES enabled transactions are associated with an approval rule and approval route. Oracle Business Process Manager (BPM) is used to setup the approval rules and routes. Oracle BPM provides transaction specific conditions to allow a flexible approval routing mechanism. Any number of approval groups can be setup in Oracle BPM to suit an organization's business requirements. Approval groups allow a single or multi-level approval mechanism where approvals are routed through a position-based hierarchy or through a configured chain of approvers. Approvals can be sought in series or in parallel.

A typical manufacturing facility has central warehousing team responsible for receiving material, issuing to production lines, storing, and shipping finished goods. Whereas production supervisor and managers are dedicated to production cells or production lines. Oracle BPM allows setting up approval routes such that production exception closure notification can be routed to the managers of the respective

Transaction based approval routing

- Rules can be configured at plant or warehouse levels enablign maximum flexibility
- Different criteria are availabel for different types: for example manufacturing transactions allow conditions based on work center, production line, operation type; whereas quality data capture can be set using conditions as type of collection, type of non-conformance

Single /Multi-level approvals

- Transaction specific approval groups and levels can be set
- Approval groups can follow supervisor-manager hierarchy or a hierarchy with specific people can be set

## Configurable and flexible approval mechanism

- Approvals can be sought in series or in parallel
- One or more than one approver can be set at any level
- Rules can be such that approval from all is necessary or approval of any one is sufficnent

production cell/lines. Approvals for material issue to work order can be routed to the warehouse manager irrespective of the production cell/line to which it is issued to.

Inline vs Deferred approvals:

There exists a significant variation in the nature of transactions performed and criticality of approval in the medical device and drug manufacturing industry. A one size fits all solution cannot work in such a landscape. Precisely for this reason, Oracle applications can be setup either to request approval in-line without which transaction is not recorded or save transaction in a pending state and commit on receiving approval through the predefined approval route.

An organization can choose to set in-line approval where it is necessary to approve transaction immediately such as production operation booking and set other transactions such as closure of quality issue in a deferred mode. In either of the case, the transactions are not approved until it is approved by the competent authority.
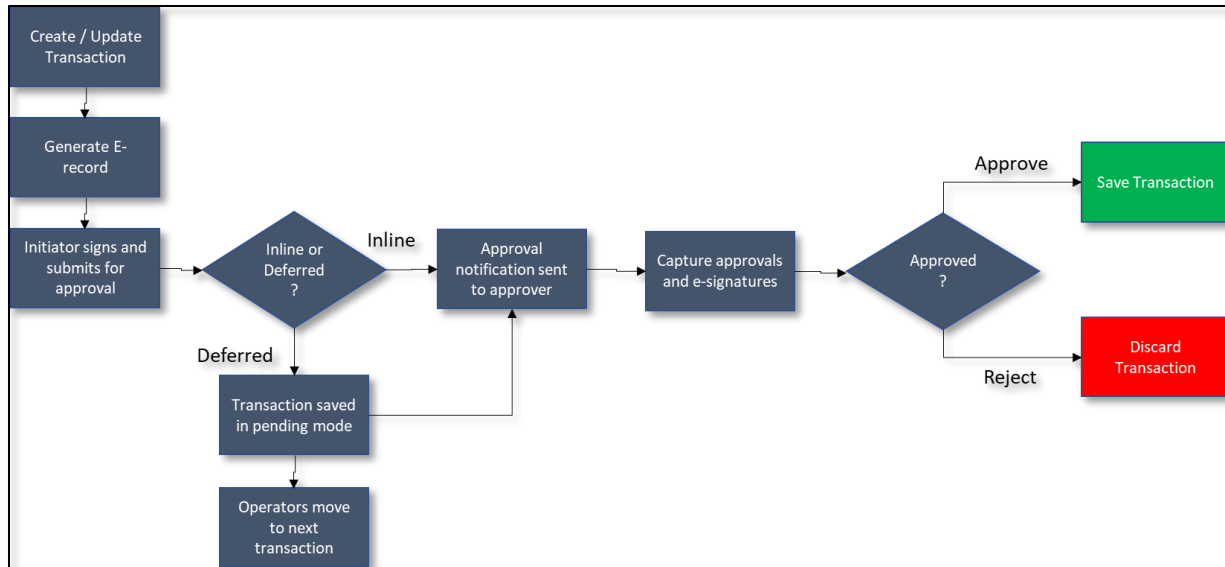
Storage, search and retrieval through Electronic Records Work Area:

Electronic records are generated for every ERES enabled transaction. The record stores all the details associated with transaction. For example, a quality issue will record issue number, source of issue, comments logged, issue lifecycle whereas material issue to work orders electronic record stores work order number, work center, item lot/serial numbers and locators from where each item was picked and issued. Electronic record also stores the e-signature and comments of the initiator and approvers.

The electronic records are indexed and then stored in Electronic Records Work Area. Users can easily search any record by transaction identifier. A work order operation booking electronic record can be retrieved by entering work order number or transaction dates or work center where it was performed or a combination of these.

Conclusion:

Compliance with 21 CFR Part 11 is must for any medical device and drug manufacturing company. Oracle Supply Chain Execution Cloud comprises of inventory (warehousing), manufacturing, maintenance and quality functional areas. Material, production and quality related transactions performed can be made compliant with 21 CFR Part 11 regulations with easy to set flexible configurations.

Trinamix brings extensive experience in implementing Oracle Electronic Record Electronic Signature for medical device and drug companies. Trinamix accelerates implementations by providing predefined solution sets, preconfigured instance for show-and-tell sessions and best-in-class process libraries.

About the Author:

Shantanu is experienced ERP professional. He has experience working with diverse domains from Industrial to Medical Device Manufacturing across the globe. His area of expertise is supply chain execution, supply chain planning and costing. Shantanu is a PMP certified professional. His educational background is Engineering and MBA in operations management.

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