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ROLE OF ERP SYSTEMS IN OBTAINING CE & ISO: 13485 CERTIFICATION FOR MEDICAL DEVICES

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Abstract: To launch any biomedical device or medical device in European market, it is indispensable to obtain CE & ISO: 13485 certifications, this means the quality standards of the product should comply with CE standards as per registered notified bodies. There are numerous companies across the world which deals with manufacturing of medical devices however there are unable to penetrate in international markets due to issues with comply with international quality standard which means not able to get CE & ISO: 13485 certifications. Here the objective of the paper is to emphasis the role of ERP system which would not only enable companies to obtain CE & ISO: 13485 certifications but also helpful in managing the other important aspects of organisation like customers , suppliers , production planning , quality control , document control and the most important traceability.

Keywords: CE certification, ISO: 13485, Trackability, Quality control, Document control

Introduction: ERP system is the business process management software which allows organisation to integrate and automate business operations. The ERP software can have modules like CRM, SRM, Production, Quality control, Document control, Inventory management, Finance management (Accounts) and Reports. These modules are fully customizable as per company requirements. The quality control module and associated reports is the most important feature of ERP system which helps companies to comply with CE & ISO: 13485 standards and penetrate there products in European market.

Quality control: The quality control process starts with the specification document. The specification documents contain all the information related to product composition, manufacturing process and quality control methods. A separate specification document maintained of each product.

The specification document is managed with document management system which is very critical and any change in the specification document leads to new version of the specification document and old goes to obsolete document library.

At the time of production planning of any product the specification documents are followed by the production manager and therefore it became extremely important that the latest version of specification document should be available and followed which is controlled by ERP system.

The specification document is created by the researchers and product development team which is separate department all together. Once specification document is approved by the competent authorities, it became live with current version and production department follows that.

Now, the emphasis is on the quality control part of specification document. In the section the complete procedure mentioned for doing QC of that particular product. When the production is completed, a notification goes to QC head ERP portal that particular product is ready for QC.

The QC team takes the samples as per specification document from that lot no which is generated by ERP system and start the quality control process. The quality control process begins as per specification documents. All the

information and procedures which need to follow for QC starts appearing in QC team ERP system.

For example analysis of the composition of material i.e. constitutes present, the tensile strength, mechanical properties, measurements of that product from different angles and the equipment's required to do the inspection mentioned in the ERP system and the end user just has to take measurements of the samples collected and by the end of complete QC process the report will generated automatically which says whether the product passed or failed. All the acceptable range of measurements is mentioned in specification document and same replicated in user entry form mode.

Notified Bodies: There are notified registered bodies like InterTek, TUV Rheiuland who are authorized to provide CE certifications. The representatives of the body do all the audits work every year as per regulatory body guidelines than they share findings with the company who applied for CE certification, the findings can be minor or major. If there are not many major findings the auditor generally gives time to the applicant to correct the shortcomings in specified period of time. If the auditor conveniences with the correction of the shortcomings done by the company, the auditor recommend the body to give approval for CE certification. The certificate is valid for 3 years however the audits will be performed ever year to make sure the manufacturing company are complying with the procedures.

Traceability: It plays a vital role in executing audit. In the part of procedure of auditor, the auditors of the notified body goes to the stock room and randomly pick any products and request the company to share the complete details of the product as per lot no and Part No mentioned in the product label.

In the ERP system, the traceability section is in report form. When the lot no or part No is entered it gives all information i.e Raw material used, manufacturing process followed, suppliers qualification, dates of manufacturing, any failure during manufacturing process, the team who was involved in manufacturing and most important quality control mechanism followed and reports associated with the quality control generally called CCR reports, customers who supplied this lot products, any complaints from the customer are mentioned in the traceability report so this traceability mechanism is extremely important to give in depth information to auditor.

Backup & Restore Mechanism: To obtain CE certification, it is must to comply with the procedures of backup and recovery mechanism of data. At the time of any unusual activity which caused system failure or any cyber-attack or any catastrophic failures , it become important to recover the data from the failure. The ERP system provides automatic mechanism to backup data in the cloud environment and can easily recover.

Security of data: The ERP system is fully secured and covered from any outside threats however the ERP system recommends to follow certain security protocols like antivirus and firewalls so to protect data completely.

Document Control: The document control in the ERP system is the most important part as most of the companies are struggling in managing there documents. i.e When any specification updated for anything , it is must to have the latest version become available immediately so to avoid any misrepresentation and to carry other processes which are dependent on that documents. In the ERP system, the document control version system makes documents to manage very easily. Whenever a document updated, the old version of that document went to obsolete document library and the new updated version become live with new version.

Dirty Data: Day to day operations planning and decision-making functions in ERP is highly dependent on transaction

data**.** This data can be entered electronically and manually. After that organized, managed and extracted for decision-making . Entered data can be used to facilitate building, shipping, and invoicing goods and extracted data can be used to evaluate factory and sales force performance in the short term . Long term data using to operate and make decisions regarding business such as relative efficiency of operations or protecting is data integrity .

Data which has used for many years by the organizational users are called as dirty data dissimilar data structures for the same customer data (spelling discrepancies, multiple account numbers, address variations), incomplete or missing data, lack of legacy data standards, actual data values being different from meta-labels, use of free-form fields etc . Those problems can be solved by cleaning up those disparate data stores in the companies.

These data can be caused to incorrect order taking, products not built to specification, or errors in packaging, documentation, or billing . The result is dissatisfied customers, loss of shareholder confidence, labour and unnecessary material costs, real and opportunity costs of time spent correcting errors resulting from dirty data. If we are not aware to check in the System that Avoid human error, we will have dirty data .“Bad data can put a company at a competitive disadvantage” some computer-literate criminals who are staging crashes and taking advantage of dirty data in corporate databases . The study found out that in one case several insurance firms lost fifty six million dollars to one fraud ring because of dirty data. The use of ERP system can protect from Dirty Data.

Conclusion:

As it is clearly understood that the impact of ERP system in obtaining the CE and ISO: 13485 certifications. The most importance aspect is quality control which is very much managed by ERP system with the features like Traceability, Inventory management and Document control and inter dependency of all the modules on each other. The specification document is the most important document which is the base of quality control and it is well managed by versioning and obsolete feature therefore ERP system is very helpful not only to obtain CE and ISO : 13485 but also to smoothly running of business operations.

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