CASE STUDY

Convert paper-based manufacturing to electronic batch records

FOR MANUFACTURERS OF FDA REGULATED PRODUCTS

InstantGMP™ PRO is an all-in-one manufacturing and quality system that streamlines the manufacturing process, meets all quality and regulatory requirements, and makes converting to electronic production and inventory

Instant GMP recently worked with a biopharmaceutical company to convert their paper-based manufacturing operation to an electronic process. The implementation went well, and the company is currently operating with their new electronic batch records. The customer is pleased and excited about how InstantGMP put all their documents and production records in one easy to use accessible format.

Prior to the start, an audit was requested to confirm the validation of the InstantGMP software. An audit plan was written requesting the needed information. The audit was a virtual audit and the required documents made accessible to the client. The quality management module of InstantGMP provided for tracking and approval of the audit. This function was used to show the needed steps for the audit and to track completion and approval. The approved audit is now available in the software for verification purposes.

The initial process for setting up the customer instance involved several steps. The initial training was provided to the quality manager. The quality manager's plan was to delegate parts of the set-up process and train his quality personnel on system use. This process worked well. The initial task of adding material was assigned to inventory personnel. He also assigned the setting up of equipment and facility logs. The materials were added to the system using the import function in the software. The materials and required information were populated on the import spreadsheet supplied by the InstantGMP system. All the information was then transferred to InstantGMP to generate the material list and import current inventory quantities. To complete the set-up, specifications for each material were required. The client had specifications for all the materials in another software and chose to attach these files to complete the specification. This allowed the process to move forward quickly and easily.

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Convert paper-based manufacturing processes to electronic

Another part of the implementation process involved the creation of managed documents in the Document Management System (DMS) of the software. The Standard Operating Procedures that were supplied with the system were updated and then approved by the client. Also, all the client specific documents were input into the system. The client used a dedicated group of personnel to complete this task. It turned out that this was the largest and most time-consuming part of the process. The quality manager took the lead to assign tasks and to ensure associates understood how to use the InstantGMP document management system.

In order to move from paper records to fully compliant electronic records the client chose to prioritize the set-up of the inventory, document management and quality modules prior to creating master records. When all the set-up steps were completed with a total time of approximately 30 days, approval of master production records and batch production records started. Once the complete focus turned to creating master records it took another 30 days for the client to be ready to begin production with electronic batch records.

This has been a detailed review of a specific customer implementation. At InstantGMP, we know every implementation will be unique. That is why we design our software to be highly configurable. We also field a team of experts to train new users and assist in the setup process. If you are in a regulated industry, or need solid GMP documentation for your product and process, look to us.