

Paperless Manufacturing

Richard Soltero, Ph.D.
PharmaDirections, Inc.

A paperless GMP manufacturing operation sounds counter-intuitive. Almost all operations use paper forms especially pharmaceutical manufacturing. When you think about the simplest processes such as ordering and receiving materials there has to be paper in use. Or maybe not. PharmaDirections has spent the past 7 years developing paperless manufacturing procedures and incorporating these in their latest release of InstantGMP. The foundation of their paperless approach is built into their web based software application for virtual manufacturing.

Almost all manufacturing systems have a list of vendors and a way to assign part numbers to the materials and components that will be ordered from those vendors. Since InstantGMP is a data-base application it easily stores all the vendor and material information and makes it accessible on-line. It also automatically assigns part numbers as new materials are entered.

An important criterion for each material is its specification. The spec should be established and approved before a material is ordered to assure the product produced with that material remains consistent from batch to batch. In traditional operations specifications are paper based forms that are manually signed. In the InstantGMP application the specs are maintained in the data base and are approved digitally.

Once vendors and specs are in place a material can be ordered. Following the virtual mode provided by InstantGMP a purchase request is automatically generated and is e-mailed to the purchasing department. The request contains the vendor part number, the ordering information, any special handling requirements and whether a COA or an MSDS is needed. The purchase request is always available on-line for review or for reordering.

Receiving materials at the warehouse is also a paperless operation in InstantGMP. The warehouse operator can access the Inventory Receipt screen and enter the information on the shipping ticket. Once the Operator verifies the information on-line the material is automatically moved into the active inventory screens.

All inventory functions such as changing status, removing samples for QC or depleting for use in production are done in the data base. There is no need for paper in any inventory functions. An added advantage is that all inventory changes or uses can easily be viewed by anyone with an internet connection and appropriate security clearance.

While virtual manufacturing systems can handle routine functions within the data base it is inevitable that paper documents will show up. These can be easily handled by scanning these documents, making them into PDF files and then storing them in electronic files. If these require some form of approval the PDF can be signed digitally using a readily available system such as Veri-Sign. This process handles the extraneous paper that appears. InstantGMP does the rest to maintain a paperless manufacturing environment.