

## Electronic Batch Records: Best Practices for Implementation and Validation

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Electronic batch record systems (EBR) are increasingly commonplace in pharmaceutical and biotechnology manufacturing environments. EBR systems are used for the automation of the execution of a batch record; they can be interfaced with many different types of systems, equipment, and instruments. Control of the batch record use when manufacturing pharmaceutical and biotechnology products is a regulated process of critical importance to assure product quality and patient safety. Therefore, the implementation strategy, validation, and on-going control of EBR is of utmost significance and interest to regulatory authorities when they perform inspections of manufacturing facilities. This paper discusses current topics, considerations, and controls necessary for the implementation and validation of EBR.

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