prepare and produce sterile products. Scheduling involves proper coordination of facilities, lines, equipment maintenance and repairs, raw materials, and human resources. Scheduling must be flexible to work quickly and efficiently around unplanned events such as testing failures, facility problems, change in forecasts, and production delays.

BATCH RECORD AND OTHER DOCUMENTATION

The batch record is the most important document in sterile product manufacturing, although many other documents and records are part of the batch record. The batch record is the complete record of the manufacture and control, distribution of a single batch of a product.

It is critical and essential that the documentation of a batch record is accurate, complete, readily followed, and reviewed. Table 12-2 lists the essential information that must be contained in a batch record.

Other key pieces of documentation include process and material records, deviation reports, validation records, complaint records, and all standard operation procedures (SOPs) associated with the batch production.

Good documentation practices (GDP) are activities that require that all raw data, written entries, and records to be accurate, legible, traceable (defensible), reproducible, complete, and verified. All entries must be signed and dated by the individual who made the entry on the date that the entry was made. All records must contain proper identification on each page. When mistakes are made, there are proper practices to follow, such as never erasing a mistake, single-line cross-outs, adding the correct entry with one's initials, date, and reason for the correction. All original records must be archived. There is the classic FDA position that if something is not written down or written correctly, it was not done. Documentation failures are perhaps the most frequently cited observations during GMP regulatory inspections by FDA and other government inspections. Both good training practices and good employee attitudes are key to following GDP.

Electronic batch records have replaced paper records at many pharmaceutical companies. GMP regulations require that electronic batch records must substantiate that every significant step (e.g., batch dates, identity of equipment/facilities used, components, in-process and laboratory control results, all labeling records, sampling, personnel and supervision, verification of all steps, etc.) in the production, packaging, and hold of each batch of drug product was accomplished according to GMP. The FDA began to accept electronic batch records after the 1997 publication of 21CFR Part 11—Electronic Records and Electronic Signatures—that define criteria under which electronic records and electronic signatures are considered to be trustworthy and equivalent to paper documentation. Updates and/or revisions of the original 1997

Table 12-2 Example of Batch Record Information

- Product identification
- Document identification
- Company name
- Dates of manufacturing
- Step-by-step list of unit operations and tests
- Specifications/limits of each step
- Data for blanks to be filled in during the process
- Formulation information—names, quantities, ID numbers
- Control numbers for each component with quality approval
- Start and completion times for each operation
- Chemical weight checks; QA counter checks
- Identity of all processing equipment
- Process details
- Deviation investigations/reports
- Labeling requirements
- In process sampling procedures, test requirements
- Final test results
- Material accountability
- Signatures