

Table 12-1 Major Sterile Manufacturing Topics

-
- GMP basics
 - Overview of processing flow
 - Facilities
 - Environmental monitoring
 - Equipment
 - Packaging/siliconization
 - Cleaning and sanitization
 - Sterilization
 - Depyrogenation
 - Raw materials
 - Water for Injection
 - Documentation
 - Personnel
 - Gowning
 - Compounding/mixing
 - Filtration
 - Filling/stoppering
 - Barrier isolator technology
 - Lyophilization
 - Process validation
 - Closing/sealing
 - Finishing/inspection
 - QC tests and release
 - New/advancing technologies
-

- Validating critical processes to be sure that the equipment used and the processes followed will ensure that the finished product will have the qualities expected (CFR 211.63, 211.65, 211.67, 211.68, 211.182).
- Maintaining a production environment suitable for performing the critical processes required, addressing such matters as orderliness, cleanliness, asepsis, and avoidance of cross contamination (CFR 211.42, 211.46, 211.56, 211.113).
- Confirming through adequate quality-control procedures that the finished products have the required potency, purity, and quality (CFR 211.160, 211.165, 211.167).
- Establishing through appropriate stability evaluation that the drug products will retain their intended potency, purity, and quality until the established expiration date (CFR 211.137, 211.166).
- Ensuring that processes always are carried out in accordance with established written procedures (CFR 211.100; many segments of CFR 211 make the statement, "There shall be written procedures. . .").
- Providing adequate conditions and procedures for the prevention of mix-ups or cross-contamination (CFR 211.80, 211.105, 211.113, 211.176).
- Establishing adequate procedures, with supporting documentation, for investigating, correcting, and preventing failures or problems in production or quality control (CFR 211.100, 211.192, 211.194).
- Providing adequate separation of quality control responsibilities from those of production to ensure independent decision making (CFR 211.22).
- Establishment of time limits for each phase of production (CFR 211.111).
- Requirements for the ability to reprocess unit operations (CFR 211.115).
- Requirements for label control (CFR 211.122, 211.125, 211.130).
- Documentation requirements for master production records and batch records (CFR 211.186).

The pursuit of cGMP is an ongoing effort that must blend with new technological developments and new understanding of existing principles. Because of the extreme importance of quality in health care of the public, the United States Congress has given the responsibility of regulatory scrutiny over the manufacture and distribution of drug products to the Food and Drug Administration (FDA). Other nations have done similar actions with their own FDA-like