TABLE 1. Examples of Quality Systems Relevant to Sterile Product Manufacturing and Quality.

QUALITY SYSTEM	SPECIFIC EXAMPLES
Document Control	All Information Management Systems Electronic Data Management Systems Logbooks Records and Record Retention Document Reviews
Batch Records	Batch Record Release Exception (Deviation) Reporting Rejected Product Returned Product QA Hold
Change Control	Standard Operating Procedures Work Orders Validation Change Control Process Validation Change Control Regulatory Commitment Documents Vendor Documents Facility Shutdown Procedures Bill of Material Changes Master Batch Record Revisions
Validation	Sterility Assurance Validation Finishing Validation Business and Facility Systems (IT) Validation Manufacturing Equipment IQ/OQ/PQ
Production Systems	Scheduling Equipment Coordination Preparation Formulation Filling Capping Lyophilization Sampling Inspection Packaging Label Control
Laboratory Control	Quality Control Chemistry—Raw Material, In-Process Finished Product, Stability, Equipment Release, LIMS Quality Control Metrology Method Validation Method Transfer Quality Control Microbiology Environmental and Personnel Monitoring Sterility Bioburden LIMS Identifications Classified Area Performance Qualifications Water for Injection Nitrogen and Other Compressed Gases Clean Steam
Material Management, Warehousing, Identification and Traceability	Receiving Raw Material Sampling/Testing/Release Damaged Material Returned Product Shipping Storage and Labeling Material Transfer Inventory Control
Purchasing Controls and Supplier Management	Purchase Orders Bill of Material Global Supplier Quality Supplier Corrective Action Reports Inventory Control
Training	Curricula Course Review Compliance Metrics Record Keeping Departmental Training Programs Training Effectiveness Performance Qualifications
New Project Implementation	Potential Project Evaluation New Product Introduction Process Validation Cleaning Validation Technology Transfer
Periodic Product Quality Evaluation	Release Data All Batches That Failed Specifications Production Deviations and Investigations Adequacy of All Corrective Actions Complaint Data Stability Data In-Process Control Data Internal Limits Changes in Processes and/or Methods Regulatory Specification Control Product Recalls Returned and Salvaged Products Review of Previous Evaluations
Regulatory Affairs	Change Notifications Regulatory Hold Pre- and Post-Approval Submissions Drug Master Files Site Master Files Product Recalls
Quality Management Systems	Responsibilities of the Quality Unit Management Review Meetings Regulatory Inspection Commitments Internal Audits Corrective and Preventive Actions

TABLE 2. Some Examples of Good Documentation Practices (GDPs) "Do's and Don'ts."

DO'S	DON'TS
Take your time to record original data clearly and legibly in ink (if written) or per electronic requirements	Cover data with whiteout Scratch over data Write over data Erase data Destroy data
Record original data as soon as you observe it	Record data from memory Write in a result of a check that was not made in the first place Record results before a check is made
Record only your own results	Record anyone else's check
Record data accurately	Round data outside specification Change data to meet tolerance levels
Ask supervisor about any questions	Guess at the data
Report immediately any GDP violations to supervision	Turn a blind eye if another employee is violating GDP

TABLE 3. Common Sources and Types of Particulate Matter.

SOURCE	TYPE OR EXAMPLE
Chemical	Undissolved substances—starch, zinc oxide, crystalline substances Trace contaminants
Solvent Impurities	Insoluble forms
Packaging Components	Glass Plastic Rubber—zinc oxide, carbon black, talc IV administration sets
Environmental Contaminations	Air Surfaces Insect parts Microorganisms
Processing Equipment	Glass Stainless steel Rubber Plastic components Rust
Filters	Fibers—cellulose
People	Skin Hair Gowning

TABLE 4. Basic Procedure for Manually Inspecting Clear Solutions for Visible Evidence of Particulate Matter and Other Defects.

1. Container of parenteral solution must be free of attached labels and thoroughly cleaned. Use a dampened nonlinting cloth or sponge to remove external particles.
2. Hold container by its top and carefully swirl contents by rotating the wrist to start contents of the container moving in a circular motion. Vigorous swirling will create air bubbles, which should be avoided. Air bubbles will rise to the surface of the liquid; this helps to differentiate them from particulate matter.
3. Hold the container horizontally about 4 inches below the light source against a white and black background. Light should be directed away from the eyes of the inspector and hands should be kept from under the light source to prevent glare.
4. If no particles are seen, invert the container slowly and observe for heavy particles that may not have been suspended by swirling.
5. Observation should last for about 5 seconds each for the black and white background.
6. Reject any container having visible particles at any time during the inspection process.

FIGURE 1. LAL Reaction Mechanism (Simplified).