Table 1-1 Glossary of Terms Related to Parenteral Drug Technology (*Continued*)

Isolator—A decontaminated unit, supplied with Class 100 (ISO 5) or higher air quality that provides uncompromised, continuous isolation of its interior from the external environment. Isolators can be closed or open.
Closed—exclude external contamination from the isolator's interior by accomplishing material transfer via aseptic connection to auxiliary equipment, rather than by use of openings to the surrounding environment.
Open—allow for continuous or semicontinuous ingress and/or egress of materials during operations through one or more openings. Openings are engineered, using continuous overpressure, to exclude the entry of external contamination into the isolator.
Laminar Flow—An airflow moving in a single direction and in parallel layers at constant velocity from the beginning to the end of a straight line vector.
Lyophilization—The removal of water or other solvent from a frozen solution through a process of sublimation (solid conversion to a vapor) caused by combination of temperature and pressure differentials. Also called freeze-drying.
Media Fill—Microbiological evaluation of an aseptic process by the use of growth media processed in a manner similar to the processing of the product and with the same container/closure system being used.
Micron (μ)—One millionth of a meter. Also referred to as micrometer (μm).
Needle Gauge—Either the internal (ID) or external (OD) diameter of a needle. The larger the gauge the smaller the diameters. For example, a 21-G needle has an ID of 510 μ and an OD of 800 μ. A 24-G needle has an ID of 300 μ and an OD of 550 μ. An 18-G needle has an ID of 840 μ and OD of 1,250 μ.
Nominal Rating—The size of particles, which are retained at certain percentages. A 0.2 μ nominal membrane filter indicates that a certain percentage of particles 0.2 μ and higher are retained on the filter.
Overkill Sterilization Process—A process that is sufficient to provide at least a 12-log reduction of a microbial population having a minimum D-value of 1 minute.
Parenteral—Literally, to avoid the gastrointestinal tract. Practically, the administration of a drug product that is not given by mouth, skin, nose, or rectal/vaginal. Parenteral conveys the requirement for freedom from microbiological contamination (sterile), freedom from pyrogens, and freedom from foreign particulate matter.
Pyrogen—Fever producing substances originating from microbial growth and death.
Reverse Osmosis—A process used to produce water for injection whereby pressure is used to force water through a semipermeable membrane where the solute content (ions, microbes, foreign matter) of the solution is retained on the filter while the solvent (pure water) passes through.
Sterile—The complete lack of living (viable) microbial life.
Sterility—An acceptably high level of probability that a product processed in an aseptic system does not contain viable microorganisms.
Sterility Assurance Level—The probability of microbial contamination. A SAL of 10^{-6} means that there is a probability of one in one million that an article is contaminated. Also called probability of nonsterility or sterility confidence level.
Surface Active Agents—Solutes that locate at the surface of water and air, water and oil, and/or water and solid to reduce the interfacial tension at the surface and enable substances to come together in a stable way. Examples include polysorbate 80 and sodium lauryl sulfate.
Terminal Sterilization—A process used to produce sterility in a final product contained in its final packaging system.
Tonicity Agents—Solutes used to render a solution isotonic, meaning similar in osmotic pressure to the osmotic pressure of biological cells. Sodium chloride and mannitol are examples of tonicity agents.
ULPA—Ultra-Low Penetration Air filter with minimum 0.3 μm particle retaining efficiency of 99.999%.
Validation—The scientific study of a process to prove that the process is doing what it is supposed to do and that the process is under control. Establishing documented evidence that provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes.
Worst Case—A set of conditions encompassing upper and lower processing limits and circumstances, including those within standard operating procedures that pose the greatest chance of process or product failure.

add the author's own research into this area. Table 1-2 summarizes the highlights of the history of the development and application of inventions and advances in sterile drug manufacturing and therapy.

In 1656, the first experimental injection was performed on dogs by Christopher Wren, the architect of St. Paul's cathedral in London. The first primary packaging system was an animal (goose) bladder, and the first type of needle used was the quill of a feather. In 1662, the first recorded injection into man was performed by J. D. Major and Johannes Elsholtz, as depicted