Appendix B: Glossary

510(k) clearance—Section 510(k) of the Federal Food, Drug, and Cosmetic Act requires device manufacturers to notify the U.S. Food and Drug Administration of their intent to market a medical device at least 90 days in advance. High-risk devices are designated as Class III and require 510(k) clearance prior to marketing.

Adult patient—patient at least 17 years old and weighing at least 45 kg.

Alert fatigue—tendency to ignore or minimize the potential negative impact of a technology alert when presented with multiple alerts with varying degrees of importance.

Ambulatory pump—portable infusion pump.

Barcode—optical machine-readable representation of data presented in one- and two-dimensional formats relating to the object to which it is attached.

Beyond-use date (BUD)—date for compounded preparations, generally in days or months, indicating the date that the product should be discarded.

Biomedical services—department within a health system concerned with storing and maintaining biomedical equipment and technology.

Bolus dose—medication dose meant to be delivered over a very short period of time.

Clinical advisory—alert entered for a drug that will be displayed on the pump before setup to notify the pump user of specific information about that drug.

Clinical care area—area of the hospital or health system representing a certain group of patients who are located in one patient care unit, specialty area, or have similar patient care needs. For purposes of the infusion pump, a clinical care area is part of the pump programming that allows medications needed in the particular area to be separated into one particular list for one particular area. One example of a clinical care area is an intensive care unit.

Clinician compliance—extent to which caregivers use the pump as intended; programming the pump using the safety software.

Compounded sterile products (CSPs)—sterile products made either in the pharmacy or acquired from a registered outsourcing facility (e.g., 503B outsourcing facilities).

Compounding—act of combining, mixing, or alteration of a drug or medication under the supervision of a licensed pharmacist.

Continuous epidural infusion (CEI)—mode of drug delivery that provides the patient with a continuous drug dose. Within an epidural drug library, this is programmed as milliliters per hour (mL/hr).

Critical criteria—criteria chosen by a selection team. These criteria, when present, are thought to bring a higher value to the object being evaluated.

Delivery limit method—total number of doses that can be administered within a defined period of time. Within an epidural drug library, this can be set as either a delivery limit per time (i.e., total milliliters per time) or as the maximum number of doses per hour.

Demand dose or patient-controlled epidural analgesia (PCEA)—mode of drug delivery that allows for administration of a patient-requested dose. The patient controls this dose via a button attached to the epidural pump. Within an epidural drug library, this is programmed in milliliters.

Demand dose lockout—period of time the patient must wait between administrations of patient-controlled epidural analgesia doses. Within an epidural drug library, this is programmed in minutes.

Dose error reduction software (DERS) or safety software—term used to describe software built into intelligent infusion devices (smart pumps) that is designed to catch dosing or administration errors. In this case, it represents the programming of minimum and maximum dose limits in an infusion pump and the alerts presented to the clinician when programmed doses are exceeded.

Dose limit—total amount of an analgesic medication that can be given in any one- or four-hour period.

Dose parameters—measurable factors for medication dose that include drug selection, initial loading dose, PCA dose, lockout interval, infusion rate, and dose limits.

Drug library—comprehensive list of medications and fluids that are to be delivered using the infusion pump. This library includes any dose, volume, or rate limitations that are programmed into the software.

Drug library push—act of updating pumps using wireless technology. The new drug library is "pushed" from the software housing the library out to the individual pumps.

Drug library subset—subset of the larger drug library that includes all drugs needed for a specific patient population or area. Other names that pump vendors use for these subsets are personalities, profiles, and clinical care areas.

Elastomeric pump—nonelectronic pump that infuses via pressure.

Electronic medical record (EMR)—systematized collection of patient and population electronically-stored health information.

Entity—single factor within the health system (individual hospital, clinic, or infusion center).

Failure Mode and Effects Analysis (FMEA)—systematic method of proactive risk assessment used to improve the safety of complex processes by identifying ways in which failure can occur.

Cause—reason for the failure.

Detection—ranking number associated with recognition of a problem with a product or process.

Effect—consequence of the failure on the system or end user.

Failure mode—manner in which an item or process will potentially not meet or deliver the intended function.

Function—purpose of an item or process.

Item—specific steps in a process or product development assessed in the FMEA.

Probability—ranking number associated with the likelihood that the failure mode and its associated cause will occur.

Risk priority number (RPN)—numerical ranking of each potential failure mode that is the product of the severity of effect, likelihood of occurrence, and detection scores.

Severity—ranking number associated with the most serious effect for a given failure mode.

Go-live—day chosen to switch from a current pump to a newer smart pump. On go-live day, old pumps must be exchanged for new pumps or swapped out. Nursing, pharmacy, and information technology (IT) must collaborate to provide new tubing, new medication infusions, and to accurately re-program the new pumps.

Healthcare FMEA (HFMEA)—adaptation of a FMEA tool for healthcare.

Home infusion—intravenous (IV) infusion given in a patient's home.

Human factors—human interactions with devices, processes, and systems.

Infusion pump—device that uses pressure to deliver specific volumes of fluid; used for fluid, blood, and medication administration.

Interprofessional team—team made up of individuals from diverse disciplines, such as pharmacy, nursing, information technology, biomedical engineering, and infection control.

Large-volume pump—an infusion device used to deliver medications for which a very small volume or rate of infusion is not necessary.

Line labels—practice of labeling infusion tubing to identify which medication is infusing in the tubing. Smart pumps display the drug name on the pump itself.

Loading dose—clinician (nurse or physician)–activated dose administered through the PCA pump for initial titration to the minimum effective analgesic concentration.

Lower "hard" dose limit—a low dose limit programmed into a pump; the pump cannot be programmed lower than a low "hard" limit. The user must use a dose higher than this limit.

Lower "soft" dose limit—a low dose limit programmed into a pump; the pump will alert the user that the dose is unusually low; however, the user can still proceed.

Manufacturer and User Facility Device Experience (MAUDE)—online database maintained by the FDA of voluntary reports of adverse events involving medical devices.

Minimum effective analgesic concentration (MEAC)—lowest steady-state serum concentration of an analgesic medication at which pain is relieved.

Mode of administration (delivery mode)—administration method, which includes PCA dose only, continuous infusion only, or PCA dose plus continuous infusion.

National Drug Code (NDC)—unique 10-digit, three-segment number that identifies the labeler, product, and trade package size.

Neonatal patient—a patient less than one month old.

Nesting—grouping various drug concentrations under a single drug name. This avoids having both concentrations show up on the main screen and is a safety feature.

Outsourcing facility—facility engaged in the compounding of sterile drugs, registered with the FDA, and in compliance with all requirements of section 503B of the Drug Quality and Security Act.

Overrides—action of continuing to program or activate a pump at the bedside with entered doses, concentrations, or rates despite receiving high- or low-dose alerts.

Password protection—feature of some pumps that requires input of a password code to gain access to a medication library, if the library is thought to include particularly high-risk medications, concentrations, or dose limits.

Pediatric patient—a patient older than one month but younger than 17 years and weighing less than 45 kg.

Periodic automatic replenishment (PAR)—the average or normal amount of a supply that should be kept in stock so that it does not run out prior to restocking.

Programmed intermittent epidural bolus (PIEB) or automated mandatory bolus (AMB)—mode of drug delivery that provides an automated bolus dose at a programmable interval. This bolus is programmed in advance, during the initiation or titration of the epidural infusion.

Pump edits—action of modifying pump programming at the bedside in response to a high- or low-dose alert.

Rate units—units used to express the rate of infusion of a drug.

Request for proposal (RFP)—invitation for suppliers, often through a bidding process, to submit a proposal for a specific commodity or service.

Return on investment (ROI)—performance measure used to evaluate the efficiency of an investment.

Scrolling—reading through drug names on the pump to find the desired drug name. If a drug list is long, scrolling can be inefficient.

Secondary Infusion—medication dose meant to be delivered over a relatively short period of time; this medication is infused through pump tubing that is connected to the primary infusion tubing.

Smart infusion pumps—new infusion pumps that incorporate dose limiting software into the pump hardware designed to prevent infusion-related programming errors. The Joint Commission, in the 2006 National Patient Safety Goals, defined a smart pump as a "parenteral infusion pump equipped with IV medication error–prevention software that alerts operators or interrupts the infusion process when a pump setting is programmed outside of pre-configured limits." Smart pumps are designed to recognize prescription errors, dose misinterpretations, and keypad programming errors.

Sterile services—department within a health system concerned with cleaning and sterilizing supplies.

Super-users—individuals involved in the selection and implementation of smart pumps who feel familiar enough with the processes to educate others. Superusers may mentor other users not as familiar with the technology and conduct formal training sessions.

Supply chain—department within a health system concerned with obtaining products and supplies from vendors.

Syringe pump—small infusion pump used to deliver small amounts of fluid using a syringe. The pump compresses the syringe plunger at a controlled rate.

System—all entities within the health system.

System FMEA model—analysis tool that focuses on the functions and relationships of the system as a whole including safety, integration, interfaces, and interactions of subsystems.

Tall man lettering—means of depicting drug names so that similar looking names can be differentiated. The part of the name that differentiates the two drugs is labeled with capital letters (for example, DOPamine, DOBUTamine).

Upper "hard" dose limit—upper dose limit programmed into a pump; the pump cannot be programmed higher than an upper "hard" limit. The user must use a dose lower than this limit.

Upper "soft" dose limit—upper dose limit programmed into a pump; the pump will alert the user that the dose is unusually high; however, the user can still proceed.

Usability testing—users test of a system or device within a realistic scenario to yield information on how well the device or system is likely to perform in the environment for which it was intended.

Value analysis—systematic, objective means to measure the value of an object (usability divided by cost) in comparison to other like objects.

Weighted decision matrix—process of assigning numerical values to object attributes; the higher the number, the more important the attribute. If an object performs exceptionally well in an attribute with a high matrix value, it is thought to provide more value overall.