SOTERA HEALTH COMPANY
GLOSSARY OF INDUSTRY TERMS AND DEFINITIONS

Analytical chemistry lab testing: A critical part of the pharmaceutical drug and medical device development and manufacturing process, this testing provides first-hand information as to the content, quality and safety of raw materials, intermediates and finished products.

Biocompatibility: The property of being biologically compatible by not producing a toxic, injurious, or immunologic response in living tissue.

Bioburden reduction testing: Also known as microbial limits testing, bioburden is typically defined as the number of microorganisms living on a non-sterilized surface or device. It can also relate to the bioburden, or natural flora, present in such things as active pharmaceutical ingredients (APIs).

Cobalt-60 ("Co-60"): Co-60 is a radioactive isotope that emits gamma radiation that sterilizes items by killing contaminating micro-organisms. Cobalt-60 is the key component in the gamma irradiation process. Gamma irradiation is needed by medical device manufacturers and sterilizers including Sterigenics. Co-60 decays and must be replaced over time to produce the desired level of irradiation.

Gamma irradiation: A process in which products are exposed to gamma rays emitted by Co-60. Gamma rays can penetrate even dense materials to kill microbes. Gamma is particularly effective at sterilizing high-density medical products such as sutures, surgical tools and stents.

Electron beam ("E-beam") irradiation: A process in which products are exposed to machine-generated radiation in the form of a stream of electrons. E-beam is particularly effective for low density homogenous products such as glass labware. Several medical devices products also rely on E-beam as an effective form of sterilization, including certain types of syringes. In addition to medical device sterilization, E-beam can also be used as an effective technology for materials modification, such as the crosslinking of certain polymers or for enriching the color of gemstones.

Ethylene oxide ("EO"): A gas sterilization process in which pallets of packaged goods are loaded into a secure chamber that is then injected with EO gas to penetrate the packaging. EO is the most widely used gaseous sterilization agent in the world and has been in use for nearly 90 years. The broad application to a range of medical devices is attributed to the fact

that EO is compatible with many materials that cannot tolerate or are degraded by radiation or moist heat sterilization. For this reason, it is commonly the only method available to safely and effectively sterilize procedure kits, PPE and many devices used in cardiac procedures.

Extractables: In May 1999, the FDA mandated that pharmaceutical manufacturers demonstrate the safety of materials used in production systems, container closure systems and/or drug delivery devices. As part of these studies, the risk of material degradation is studied usually using some form of solvent. Extractables are those compounds found to be present as a result of this testing, and extractables studies are typically performed to create a worst case scenario, which is helpful to the manufacture and FDA in assessing risk.

Leachables: Chemical species that make their way into the product under normal product, application or storage conditions; some leachables may also be classified as a subset of extractables.

Microbiological testing: Help to identify and measure the potential risks of microbes to a product and ensure that the quality of the products is maintained.

Nelson Labs medical device lab testing services include: microbiology, biocompatibility and toxicology assessments, material characterization, sterilization validation, sterility assurance, packaging validation and distribution simulation, reprocessing validations, facility and process validation and performance validation and verification of PPE barriers and material.

Nelson Labs pharmaceutical lab testing services include: microbiology, biocompatibility and toxicology assessments, extractables and leachables evaluations of pharmaceutical containers, sterilization validation, sterility assurance, packaging validation and distribution simulation and facility and process validation.

Stereotactic radiosurgery devices: stereotactic radiosurgery is the process of aiming radiation at growths or lesion in the body, including cancer, to reduce their size and/or destroy them. Most often doctors use stereotactic radiosurgery to treat problems around the brain, breast or spinal cord.

Terminal sterilization and irradiation: Terminal sterilization is the process of sterilizing a product in its final packaging. It is an essential, and often government-mandated, step in the manufacturing process of healthcare products before they are shipped to end-users.

NRC: Nuclear Regulatory Commission.

EPA: Environmental Protection Agency.

FDA: U.S. Food and Drug Administration.

IAEA: International Atomic Energy Agency.

ICRP: International Commission on Radiological Protection.

Source: Sotera Health (11/12/20)