MODALITIES OVERVIEW

There are several factors to consider when choosing the right technology for your product. Understanding the variables of each technology and its effect on different materials should be considered as early as possible.

RADIATION

ELECTRON BEAM

E-beam irradiation exposes products to high-energy electrons

TECHNOLOGY VARIABLES	PRODUCT CONSIDERATIONS	POSSIBLE EFFECTS	EXPOSURE TIME TO RADIATION FIELD
ORIENTATION TO BEAM **BEAM ENERGY** **BEAM POWER** **PRODUCT CONVEYANCE** **PROCESSING TIME**	**MATERIAL COMPATIBILITY** Qualified at maximal dose received during routine process **DENSITY** Moderate to low penetration on dense products	Reduced (potential) material impact effects than gamma and X-ray	**SECONDS TO MINUTES** Time varies based on dose requirements

ISO 11137
ISO 13485

GAMMA IRRADIATION

Gamma irradiation exposes products to a Cobalt 60 radiation field

TECHNOLOGY VARIABLES	PRODUCT CONSIDERATIONS	POSSIBLE EFFECTS	EXPOSURE TIME TO RADIATION FIELD
PROCESSING TIME **ISOTOPE ACTIVITY** **PRODUCT CONVEYANCE**	**MATERIAL COMPATIBILITY** Qualified at maximal dose received during routine process **DENSITY** Good penetration on dense products	On certain materials, embrittlement, discoloration, change in viscosity due to irradiation	**HOURS** Time varies based on dose requirements

ISO 11137
ISO 13485

X-RAY

X-ray irradiation uses ionizing energy from high-powered electron beam accelerators

TECHNOLOGY VARIABLES	PRODUCT CONSIDERATIONS	POSSIBLE EFFECTS	EXPOSURE TIME TO RADIATION FIELD
PRODUCT CONVEYANCE **PROCESSING TIME**	**MATERIAL COMPATIBILITY** Qualified at maximal dose received during routine process **DENSITY** Excellent penetration on dense products	Similar to gamma, but less pronounced due to improved dose uniformity and processing time	**MINUTES** Time varies based on dose requirements

ISO 11137
ISO 13485

GAS

ETHYLENE OXIDE

Ethylene oxide sterilization uses a 3-stage gas process that includes pre-conditioning, sterilization, and post-conditioning (aeration)

TECHNOLOGY VARIABLES	PRODUCT CONSIDERATIONS	POSSIBLE EFFECTS	EXPOSURE TIME
PROCESSING TIME **TEMPERATURE** **HUMIDITY** **EO CONCENTRATION** **100% EO OR POSITIVE PRESSURE PROCESS** **CHAMBER SIZE** **SINGLE CHAMBER OR MULTI-CHAMBER**	**MATERIAL COMPATIBILITY** Very few compatibility concerns Liquids generally not recommended Packaging must be breathable Sources of ignition (e.g. batteries, moving parts) require additional assessment **DENSITY** May impact distribution of some technology variables and therefore exposure time **GAS PATHWAY** Relies on vaccum to remove non-condensable gas and must reach surface requiring sterilization	Due to accumulation of EO residuals products may require prolonged aeration	**HOURS TO DAYS** Time varies based on validation approach and time required for degassing

ISO 11135
ISO 13485

VAPORIZED HYDROGEN PEROXIDE

VHP is a deep vacuum, low temperate 3-phase vapor process that includes conditioning, sterilization, and post-conditioning

TECHNOLOGY VARIABLES	PRODUCT CONSIDERATIONS	POSSIBLE EFFECTS	EXPOSURE TIME
PROCESSING TIME **TEMPERATURE** **HUMIDITY** **PRESSURE (VACUUM)** **VHP CONCENTRATION**	**MATERIAL COMPATIBILITY** Compatible with most materials Cellulose-based materials and highly absorbent materials are not compatible Packaging must be breathable **VAPOR PATHWAY** Relies on vacuum to remove non-condensible vapor and must resach surface requiring sterilization **DENSITY** Surface sterilization process (limited penetration capabilities)	VHP breaks down safely into water and oxygen Low residual levels No known oxidation or discoloration effects	**HOURS** Time varies based on cycle requirements

ISO 22441
ISO 13485

MOIST HEAT (STEAM)

Steam autoclaving is a 3-stage high-temperature gas process that includes pre-conditioning, sterilization, and post-conditioning

TECHNOLOGY VARIABLES	PRODUCT CONSIDERATIONS	POSSIBLE EFFECTS	EXPOSURE TIME
PROCESSING TIME **TEMPERATURE** **SUBATMOSPHERIC PRESSURE** Pre-condition and post-condition **SUPERATMOSPHERIC PRESSURE** Exposure phase	**LIQUID PRODUCTS** Can effectively sterilize contained liquids and gels (syringes, vials, bottles, etc.) **MATERIAL COMPATIBILITY** Chemically compatible with most materials Ductility and melting of solids need to be considered due to high temperatures **GAS PATHWAY** Relies on vacuum to remove non-condensable gas (air) to achieve sterilant (steam) contact with internal surfaces	Damage to heat-sensitive, pressure-sensitive, or moisture-sensitive equipment Melting, distortion, and potential corrosion Water is the only residual / by-product	**MINUTES TO HOURS** Time varies based on product temperature limitations and validation approach

ISO 17665
ISO 13485