



February 2022

Purity One Quality Management System and Manufacturing Requirements:

Quality Management System

- Quality Management System meets the requirements of, and is certified to, ISO 13485:2016
- Quality Management System complies with applicable sections of 21 CFR Part 820

Cleanroom Certification

- Products are produced in a certified cleanroom meeting ISO 14644-1: 2015 Class 7 requirements

Product Materials

- All product contact materials are USP Class VI and are made from and processed with materials that are free from animal-derived ingredients/products (ADI/APD) or meet the requirements of the CHMP Note for Guidance EMA/410/01/Rev 3

Manufacturing Requirements

- Dose audits are performed quarterly on simulated product to ensure continued gamma irradiation compliance
- Endotoxin and particulate testing are performed quarterly on simulated product to ensure production processes are in control. Endotoxins are tested per USP <85> and meet the requirements of USP <161>. Particulates are tested in alignment with USP <788> and USP <790>