

Sterilization Validation Programs



To help clients validate products for sterilization, AppTec provides validation studies for a variety of commercially available sterilization methods, including:

- **Radiation**
- **Ethylene Oxide (EO)**
- **CO₂ / H₂O₂ / VHP, etc.**
- **Liquid Chemical (Steris System 1[®], glutaraldehyde, etc.)**
- **Steam – Pre-Vacuum and/or Gravity (121-123°C and 132-135°C)**

AppTec is a unique single source for comprehensive GLP/GMP-compliant testing, contract research and development, and specialized cGMP manufacturing services for biopharmaceuticals, medical devices, cellular therapeutics, and tissue-based products. We provide our clients the highest level of state-of-the-art science, regulatory expertise and individualized customer service.

RADIATION STERILIZATION VALIDATION

AppTec specializes in radiation sterilization validation and our unmatched expertise includes all the standard methodologies:

Method 1

Sets a sterilization dose based on the product's bioburden level. Requires approximately 150 samples and takes about 5-6 weeks to complete.

Method 2

Sets a sterilization dose based on the product's bioburden resistance. Requires from 580-650 samples and takes about 6-8 weeks to complete.

VDmax Method

Substantiates one of nine (9) selected doses – from 15 kGy to 35 kGy – based on the product's bioburden level. Requires approx. 50 samples and takes about 5-6 weeks to complete.

Service Level Options

For radiation sterilization validation and dose audit programs, clients can choose from different levels of service options to meet their particular needs.

Testing Services

We perform all the tests required for a particular validation or dose audit.

Testing Services + Irradiation Services

We perform all the required tests for a particular validation or dose audit, plus we provide complete irradiation services (including dose calculations and all interaction with the sterilizer), confirmation/verification of irradiation services, and – for dose audits – a dose audit summary.

Total Management of Your Validation

We perform all the required testing, provide complete irradiation services, and produce a manual or summary report that includes all the supporting documentation you need.

Dose Audit Reminder Program

Under AppTec's dose audit reminder program, a notice is sent to you whenever dose audits are due for each product or family of products. Plus, we will automatically review your dose audit requirements to inform you of your options. This is especially important because the requirements for Method 1 and Method 2 may allow for reduction in the number of samples as well as the frequency of audits, based on certain criteria.



For more information about our wide range of services, contact an AppTec Account Manager at 888.794.0077.

www.apptec-usa.com