



Single Source Solution

SteriPro® Consulting

From concept development through FDA approval, the early stages in the life of a medical device or pharmaceutical product can be extremely challenging.

To assist customers in bringing products to market in the fastest, most efficient fashion, as well as to help assure the development of cost-effective, long-term sterilization solutions, Sterigenics offers its pioneering SteriPro Consulting program.

With a single call to SteriPro, customers large and small have access to an entire network of consultants—both internal and external.

All are proven healthcare professionals with years of experience in materials selection, project team development, protocol set-up, manufacturer selection, testing and validation, plus proven expertise in navigating the ins and outs of the FDA regulatory process.

The result is not only faster, more efficient regulatory approval, but more cost-effective sterilization solutions for long-term use.

For the large, multi-national corporation or the entrepreneurial start-up with a great idea, SteriPro Consulting is today's single-source solution for accomplishing more, while spending less.

The Nature of SteriPro Consulting

A unique blend of consultative analysis, technical assistance and laboratory services, the SteriPro program focuses on the pre-sterilization area of the supply chain, enabling medical device and pharmaceutical product manufacturers to develop and maintain the most cost-effective sterilization processes for their products.

While SteriPro Consulting is proud to count many of the nation's healthcare leaders among its customers, the program is equally relevant for smaller companies who do not enjoy the luxury of an internal staff skilled in the technical and regulatory challenges associated with the sterilization process.

Experienced Sterigenics consultants work directly with customers, overseeing the management of all aspects of the preapproval process. Many of the tests and processes are outsourced to third parties, all of whom are considered "approved vendors" based on a record of successful partnership with Sterigenics.

Removing Time from the Supply Chain Is Our #1 Goal

Specifically, SteriPro Consulting was created to help clients navigate Stages 1–4 in the life of a medical device or pharmaceutical product, including:

- Material characterization
- Biocompatibility
- Manufacturing and environmental process control
- Release and audit testing

Stage One: Material Characterization

Prior to selecting material for a product, its components and packaging, it is essential to establish the effect sterilization will have on those materials. To that end, the material characterization process utilizes a series of tests to delineate the properties of a proposed material before and after sterilization. Test procedures include:

- Assessment of the overall biological safety of a device
- Leachate analysis of extractable components for health-based risk assessment
- Equivalence to clinically established materials
- Equivalence of finished product or device to prototype
- Screening of potential new materials for use in medical devices or pharmaceutical products

Stage Two: Biocompatibility

The second phase of testing appraises biocompatibility based on the intended use of the component material or finished product. Evaluation programs follow FDA guidance and ISO 10993 standards and include:

- Tests for genotoxicity, carcinogenicity and reproductive toxicity
- Tests for interaction with blood
- Tests for cytotoxicity (in vitro)
- Tests for local effects after implantation
- Ethylene oxide (EO) sterilization residuals
- Reference materials—biological
- Degradation of materials related to biological testing
- Test for sensitization and irritation
- Systemic toxicity assessment
- Identification and qualification of degradation products from polymers, ceramics, metals and alloys
- Toxicokinetic study design for leachables

Stage Three: Manufacturing, Environmental Process Control

In Stage Three, testing verifies that manufacturing process controls are sufficient for pre-production quality assurance requirements and product specifications. Follow-up studies ascertain the effectiveness of these controls and assess the biological impact of processing aids added during the manufacturing process. Tests fall into four categories:

- Environmental control
 - Environmental monitoring program
 - Microorganism identification
 - Viable and nonviable particulate analysis
- Manufacturing process control
 - Raw material characterization (infrared analysis, cytotoxicity and physiochemical tests establish effects of the sterilization characteristics determined in phase one above)
 - Bioburden: the amount of living organisms on a device prior to sterilization
 - Process waste system validation
 - Bacterial endotoxins (LAL)
 - Qualification of device cleaning processes
 - Package qualifications
- Sterility
 - Biological indicator studies (spore count, d-value)
 - Sterilization cycle development and validation
 - Dose determination and validation
 - Sterility tests (ISO/AAMI/USP)
- Package validation
 - Finished product qualification
 - Physical testing for functional and performance stability
 - EO dissipation curve studies and assessment of user exposure levels
 - Other chemical residues
 - Bacterial endotoxins: in vitro (LAL) or in vivo (rabbit Pyrogen)
 - Biocompatibility assessment
 - Nonviable particulate analysis
 - Label claims, instructions for reusable devices
 - Shelf-life qualifications

Stage Four: Audit and Release Testing

Stage Four includes a final range of testing to satisfy regulatory requirements (ISO and QSR) for finished product for distribution, and batch release on periodic basis to assure product consistency and compliance with label claims and quality systems regulations. Tests include:

- Bacterial endotoxins (LAL)
- Rabbit Pyrogen
- Safety
- EO residuals
- Sterility test
- Bioburden
- Microbial limits
- Cytotoxicity
- Materials characterization

A Network of Experts to Ease the Regulatory Process

For many customers, regulatory consulting is a key value of the SteriPro Consulting program. From preparation of the initial product application, through defense and approval, experienced professionals are available whenever and wherever help is needed. When testing is required, SteriPro Consulting can recommend approved vendors and internal resources. Additionally, customers may choose a SteriPro retainer to serve as an insurance policy covering on-going assistance with regulatory issues; sterility questions and FDA audit requirements.

Four Distinct Service Programs to Meet Every Need

SteriPro Consulting offers four distinct service programs, Platinum, Gold, Silver and Bronze, each developed to satisfy the diverse and individual requirements of today's device manufacturer.