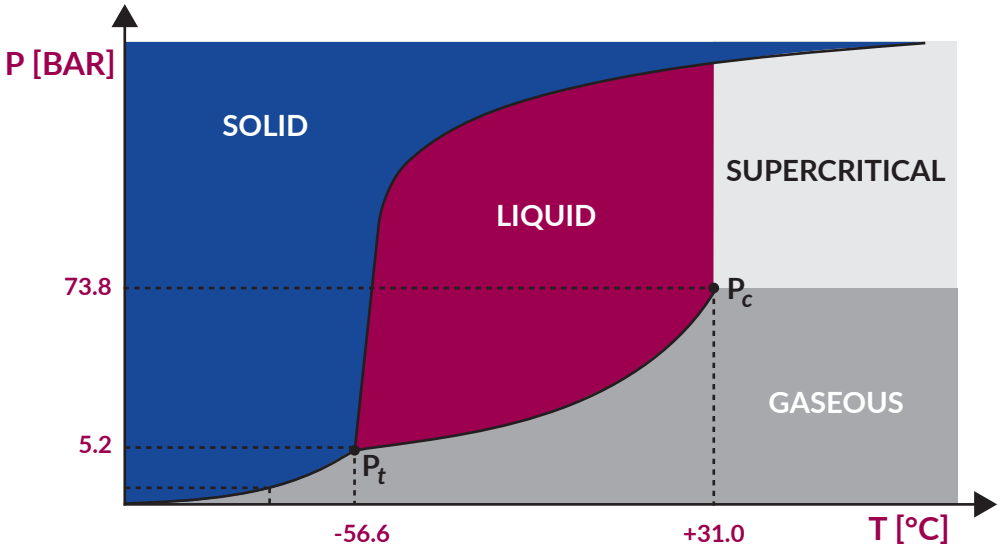
CHARACTERIZATION AND VALIDATION OF SUPERCRITICAL CO_2 STERILIZATION METHODS

To provide safe and sterile products, healthcare manufacturers must determine and describe appropriate sterilization cycle parameters through a sterilization validation process. In support of these efforts, iFyber offers customized characterization and validation services for clients using the NovaSterilis supercritical carbon dioxide ($scCO_2$) sterilization system. During the validation process, our multidisciplinary team will help guide you in process optimization, material compatibility studies, measurement of sterilant residuals, and development of microbiological recovery methods for qualifying $scCO_2$ terminal sterilization of your medical device or biological product.

Supercritical CO_2 sterilization

The NovaSterilis technology is a novel sterilization modality that uses CO_2, sterilant additives, and instrumentation to achieve terminal sterilization to sterility assurance level (SAL) 10^{-6}. When exposed to pressures and temperatures above 73.8 bar and 31°C, respectively, CO_2 transitions to a supercritical state, which lends itself to deep penetration of substrates and inactivation of a wide variety of microbiological contaminants.

Through a multi-year collaboration, iFyber has gained a deep understanding of the $scCO_2$ sterilization technology and has established a strong relationship with the NovaSterilis team. We are therefore in the unique position to work directly with both NovaSterilis and our clients to ensure that the $scCO_2$ sterilization process will consistently achieve the required sterility assurance level for regulatory clearance or approval without detrimental effects on the product and packaging.



WHAT SERVICES CAN IFYBER OFFER?

All products have unique designs, materials, and packaging configurations. Therefore, the sterilization conditions that may be adequate for one product are likely not sufficient for another. Because of this, all sterilization processes must be validated based on the unique characteristics of the specific product. iFyber specializes in designing and executing customized test strategies suited to your needs. Our quality, regulatory, and technical teams can help you navigate these requirements through each of the four phases listed below, including characterization of the $scCO_2$ sterilization agent and development and validation of the $scCO_2$ sterilization process per ISO 14937, selection of a process challenge device (PCD), and validation of appropriate biological indicators per ISO 11138.

PHASE 1 DEVELOPMENT

- Material compatibility and characterization of sterilized products
- Verification and validation testing strategies
- Regulatory support: Q-submissions and representation at FDA Pre-Sub meetings
- Process challenge device (PCD) identification
- Biological indicator (BI) characterization and validation
- Development of microbiological recovery methods for resistance studies
- Draft work instructions and standard operating procedures (SOPs)

PHASE 2 VERIFICATION

- Develop sterilization process inputs and outputs
- Performance verification
  - Quantifying sterilant residuals and chamber mapping
  - Survivor curve analysis
  - D-value determination

PHASE 3 VALIDATION

- Validation plan
- Installation Qualification/Operational Qualification (IQ/OQ)
- Performance Qualification (PQ)
- Transfer to manufacturing: re-validation or bridging studies

PHASE 4 REGULATORY SUBMISSIONS

- Drafting sterilization sections for FDA submissions
- Responses to additional information (AI) requests
- Representation at FDA meetings

iFyber is a preclinical research organization offering customized services to companies that operate at the interface of chemistry, microbiology, and materials science. iFyber is unique. We pride ourselves on providing access to top scientists and creatively solving problems with quick turnaround times.

THINK OF IFYBER AS:

- Consultants with a laboratory to back up ideas with data
- An academic lab, solving R&D problems on corporate or start-up timelines
- A testing lab that develops new methods tailored to clients' products and services
- An extension of your quality, regulatory, and R&D teams

For more information on iFyber's services: www.ifyber.com | info@ifyber.com | 607.374.8868