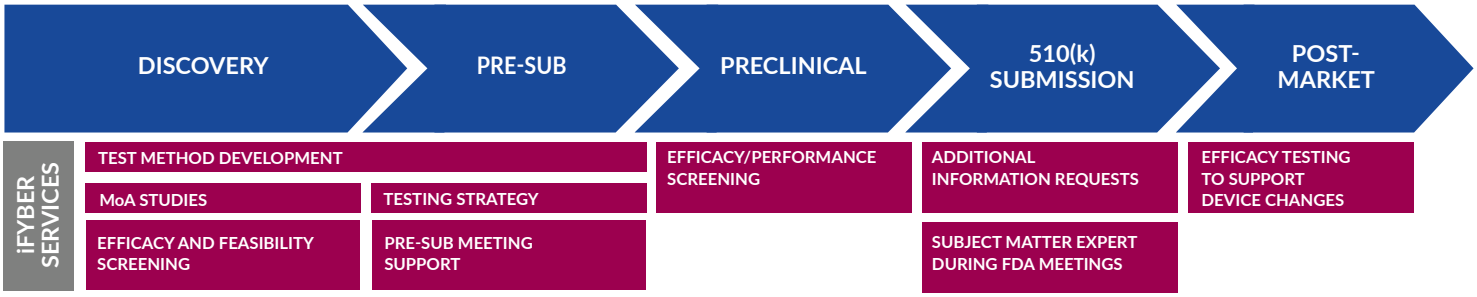
# EFFICACY DATA PACKAGES IN SUPPORT OF 510(K) SUBMISSIONS FOR WOUND CARE PRODUCTS

iFyber offers both standard and custom non-GLP and GLP preclinical efficacy testing and data packages, which can be submitted to FDA in support of substantial equivalence decisions for traditional medical devices and combination products, such as wound dressings combined with drugs. During the process we will help guide you in performance test method development, selection, and execution; identification of worst-case scenario test articles; Q-submissions; Pre-submission meetings; 510(k) submission support; and FDA additional information requests.




## NON-GLP, GLP, GMP, AND GCP

### WHAT IS THE DIFFERENCE?

- Studies that are performed to determine product performance and not product safety can be **non-GLP** (e.g., custom antimicrobial testing, chemical characterization).
- Product safety testing (e.g., cytotoxicity, sensitization, and implantation) that utilizes an animal, plant, or microorganism test system intended for FDA submission must be performed using Good Laboratory Practice (**GLP**).
- To determine whether the product meets manufacturing specifications, Good Manufacturing Practice (**GMP**)-compliant testing and controls are used. This testing can include bioburden, sterility, stability/shelf-life, and process validations.
- If clinical trials are performed, they must follow Good Clinical Practice (**GCP**) to protect the rights, safety, and welfare of human participants are protected and assure the quality, reliability, and integrity of data collected.

## EXAMPLE: WOUND DRESSINGS COMBINED WITH DRUGS

### WHAT TESTING DO YOU NEED IN YOUR 510(k)*?

Most performance claims are based on *in vitro* testing; however, the FDA does not recognize any *in vitro* antimicrobial effectiveness testing standards that can be directly applied to antimicrobial wound dressings without modification. **Companies must define what is appropriate for their specific device and provide adequate justification.** All testing must be completed on the final product configuration at the end of the shelf-life and conditioned to emulate factors of clinical use. iFyber can help in identifying these worst-case and clinically relevant test articles and developing and executing customized testing to fit the intended use of your product.

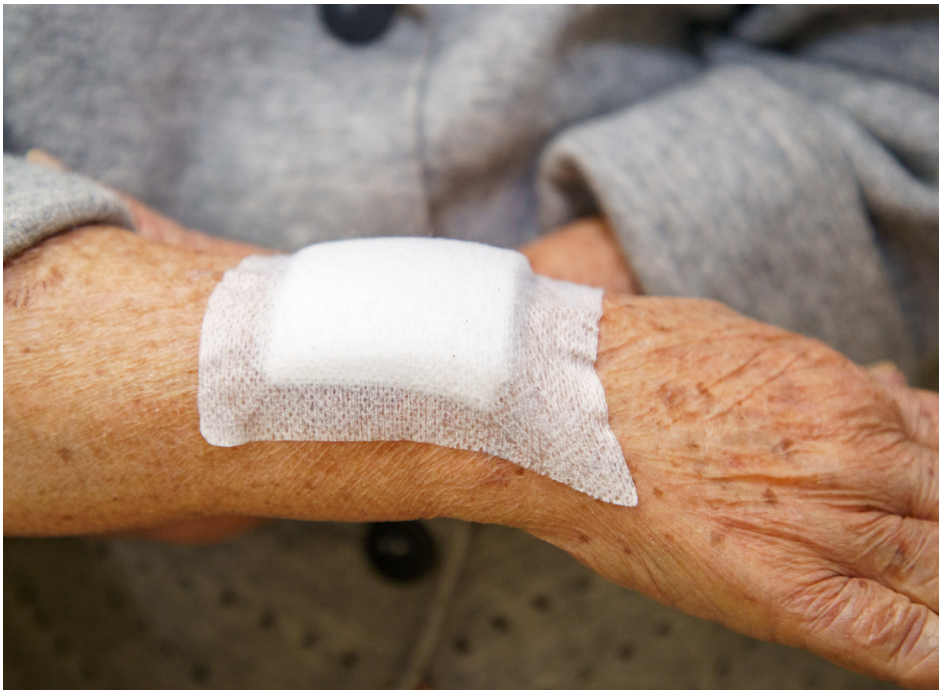
| | | |
|---|---|---|
| Material Performance Testing (e.g., Absorption) | Non-GLP | Product-specific testing; no testing compliance requirements |
| Antimicrobial/Preservative Effectiveness | Non-GLP | |
| Biocompatibility/ Toxicological Risk Analysis | GLP | 21 CFR Part 58 |
| Animal Testing** | GLP | |
| Shelf-life Testing | GMP | 21 CFR Part 820 |
| Sterility and Bioburden | GMP | |
| Clinical Testing** | GCP | 21 CFR 50, 54, 56, and 812 |

**When appropriate

*Based on recommendations by the General and Plastic Surgery Device Panel of the Medical Device Advisory Committee (Classification of Wound Dressings Combined with Drugs; Sept 2016)

**iFyber focuses on product- and application-specific efficacy testing.**

We specialize in designing and executing customized test methods suited to your needs. Our scientists will develop an appropriate testing strategy to support your performance claims and the resulting high-quality data package can be submitted to FDA as part of your 510(k) premarket notification.



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