Our Manufacturing

We understand the importance of manufacturing under stringent standards to create consistent, safe and scalable high-quality FMT products. We prioritize quality and safety in every aspect of our operations, and our commitment to producing high-quality FMT products is reflected in our use of Good Laboratory Practices (GLP) and our current goal of obtaining our Health Canada Drug Establishment Licence (DEL) and GMP certification.

OUR STANDARDS

Novel Biome has spent several years perfecting the FMT manufacturing process and investing significantly to ensure safe, effective and convenient FMT products. Our sole focus is on FMT manufacturing and producing the best FMT products possible. We want to make our products available to a broader market to best support the growing need for this life-saving treatment.

Novel Biome provides four product formats: enema, colonoscopy, capsules and oral powder created in our specialized microbiota laboratory, which includes finished product testing. All our FMT products are created utilizing our highly screened and vetted donor network, exceeding industry standards.

SPECIALIZED FMT MANUFACTURING

At Novel Biome, we adhere to GLP standards to ensure our FMT product's quality, safety and consistency. GLP stresses the importance of having highly trained personnel, quality facility and lab equipment, optimization of test systems and processes, and adverse event reporting.

To ensure the Quality, Safety and Consistency of our FMT products, we place the highest stands on:

- **Hiring the Very Best Lab Personnel**
- **Purchasing the Best Facility and Laboratory Equipment**
- **Ensuring our Test Systems and Processes are Optimal**
- **Exceptional Manufacturing Processes, Quality Assurance and Standard Operating Procedures**
- **Stringent Donor Screening, Blood, and Stool Testing**
- **Adverse Event Reporting**

N**ovel Biome is currently in the process of obtaining our GMP certification.** Following GMP guidelines, all finished product testing is completed in-house on every batch of FMT products, and a CoA can be shared upon request.

GMP is a set of guidelines established by regulatory agencies that ensure the quality, safety and efficacy of pharmaceutical and medical products, such as FMT. These guidelines cover all aspects of the manufacturing process, from raw materials screening, standard operating procedures (SOPs) and quality assurance processes to packaging and labelling of finished products.

OUR CUSTOM-BUILT MICROBIOME LABORATORY MANUFACTURING SPACE




Novel Biome

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