Small-volume Manufacture of Active Pharmaceutical Ingredients

Dual suites with flexibility to support scale-up, clinical and small-volume commercial requirements at our R&D center of excellence in Athens, GA

Noramco™

From development to commercial scale

Noramco offers a flexible high-containment suite with controls in place to produce compounds of OEL<500 ng/m3 and systems in place to create NSP-grade APIs for parenteral applications. Special adaptions in suite design, equipment design, operations and process safety afford developers a one-stop location to produce on an R&D scale, then advance to clinical scales and finally to commercial production of small-volume APIs.

Table 1. Flexible Suite Design

- **Scale from 2L to 50L**
- **Multiple isolation and drying capabilities**
- **Fitzmill and jetmill sizing capability**

Table 2. Commercial Suite Design

- **Two 50L GLS Reactors, 100L phase split vessel**
- **Hastelloy filter dryer**
- **Closed charging/discharging**
- **BPCS control and trending**

Suite design is state of the art with separate entry and egress airlocks for improved containment, and further prevention of material tracking. Noramco supports best-in-class cross-contamination prevention between products – an essential requirement of ultra-high potency API manufacture and cGMP.

A suite for special projects

Pharmaceutical companies working on product line extensions, or special grades of APIs, and pharmaceutical manufacturers in need of clinical batches or small-volume APIs may also consider Noramco's small-scale facility for short and long term services. The overall suite design and service offering afford companies the option to acquire small-scale quantities of GMP materials within tight timeframes. Working with Noramco, you have access to an R&D team through all stages of your projects.

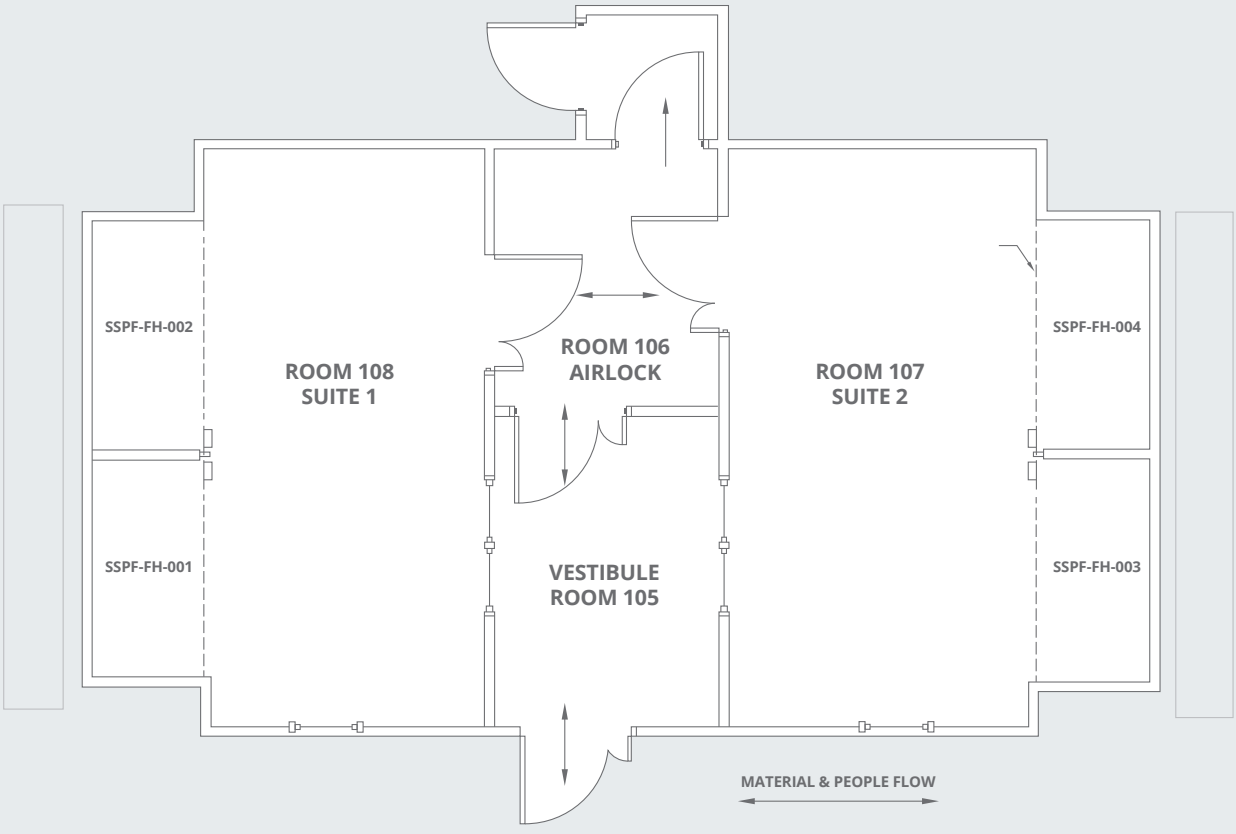

Table 3. State-of-the-art facilities include:

- **Class 100,000 clean room environment**
- **Additional design features and procedures to operate as class 10,000 for NSP grades**
- **Dual processing with differential pressure control and interlocked access doors**
- **Stability chambers**
- **Specified gowning and material flow procedures**
- **Cleaning of surfaces and materials**
- **External mechanical area**

A solutions provider

A major producer of controlled substance APIs, Noramco offers the skills, knowledge and production assets essential to the manufacture of synthetic or natural molecules. An in-house team of chemists and engineers help to optimize small-scale manufacturing, while our regulatory affairs team provides full documentation, from IND support to commercial filings. Ask how Noramco serves as a "turnkey" solutions provider for companies that require small-volume cGMP APIs produced within the United States.

Table 4. Benefits of working with Noramco for small-scale volumes of APIs

Manufacturing and compliance

- **Expertise in highly efficient routes to API manufacture**
- **Outstanding cGMP track record at facilities in Delaware and Georgia (USA)**
- **Extensive knowledge of controlled substance and DEA requirements**

Technology

- **Comprehensive analytical, regulatory, physical properties, and stability support**
- **Integration of quality by design to API development and manufacture**

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