

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

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 manufacture non-sterile parenteral grade APIs. Special adaptations 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.

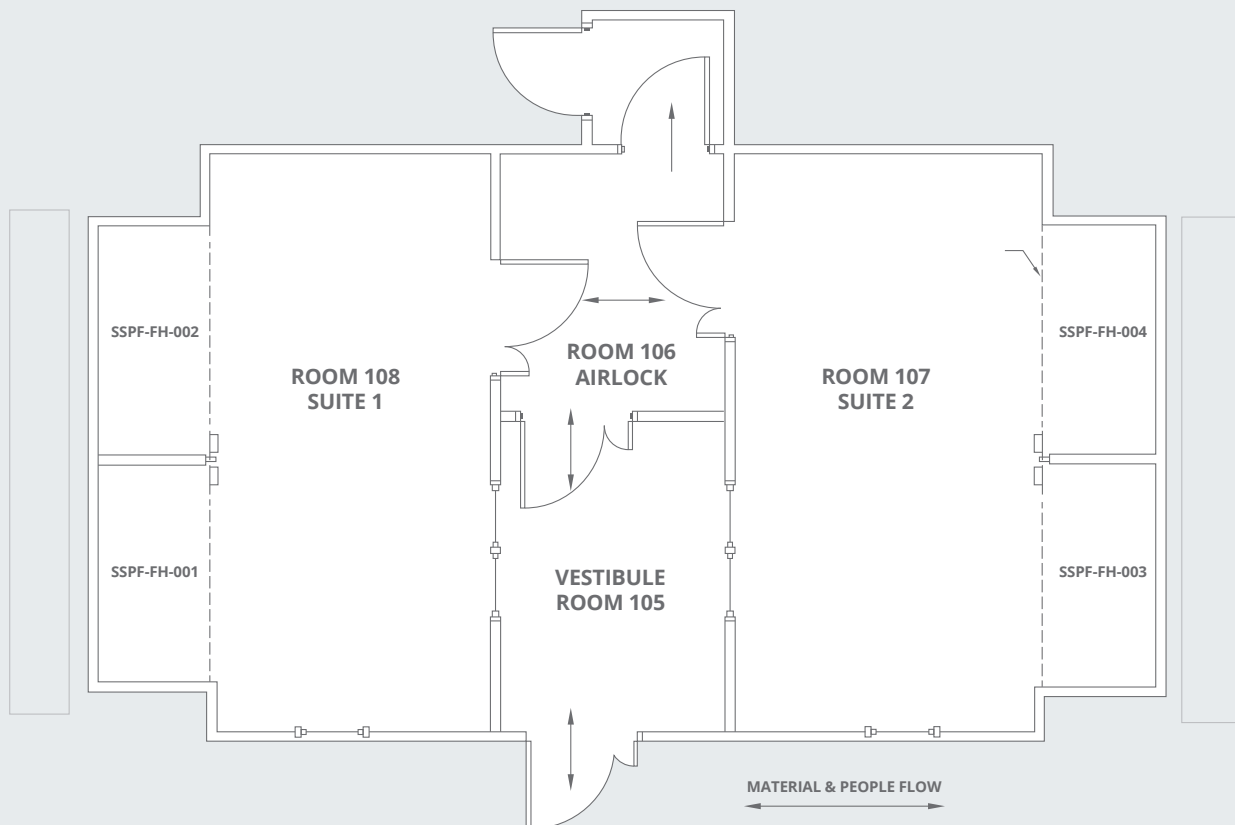




Table 3. State-of-the-art facilities include:

- **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

Small-Scale Manufacturing Services

E-mail: info@noramco.com
Phone: +1-706-286-8234

Georgia Location

1550 Olympic Drive
Athens, GA 30601

Delaware Location

500 Swedes Landing Road
Wilmington, DE 19801

www.noramco.com



This information is based on our present knowledge and is intended to provide notes on our products and their uses. It should not be construed as guaranteeing specific properties of the products described or their suitability for a particular application. Any existing industrial property rights must be observed. The quality of our products is warranted under our General Conditions of Sale.