



APPE Student Guidebook

ADVANCED PHARMACY PRACTICE EXPERIENCE PROGRAM

Welcome to SanKav!

We're so excited for you to join our team!

This guide offers a comprehensive look at SanKav Pharmaceuticals and prepares you to make meaningful contributions from day one.



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About Us

Who We Are

As an FDA-registered 503B outsourcing facility offering contract manufacturing and laboratory testing services, SanKav Pharmaceuticals develops and supplies high quality small-molecule pharmaceuticals for our clients.

Mission Statement

We are committed to expanding access to essential medicines for diverse populations in rural and urban communities. We envision a world where people of all ages have access to proper nutrition, essential medical care, and effective treatments regardless of their background, financial situation, or geographic location.

SanKav Headquarters



20 Newburgh Road,
Washington Township, NJ
07840



Overview of 503B Facility

- 1 Compliant with cGMP (current Good Manufacturing Practices) as required by the FDA
- 2 Licensed to manufacture and supply ready-to-use drugs in advance of patient-specific prescriptions, ensuring timely access during shortages or when commercially available products are unsuitable
- 3 Capabilities include both sterile preparations (intravenous, intramuscular, subcutaneous, ophthalmic, etc.) and non-sterile preparations (ointments, creams, liquids, capsules)



Overview of SanKav's Departments

Department	Primary Role	Key Responsibilities
Microbiology	Sterile safety of products	<ul style="list-style-type: none">• Environmental monitoring (air, surfaces)• Bioburden & sterility testing• Endotoxin/Pyrogen testing
Quality Control	Testing and verification of raw materials, in-process, and finished goods	<ul style="list-style-type: none">• Analytical testing (e.g. HPLC, GC, etc...)• Methodology development & validation• Stability testing
Manufacturing	Produces drug products according to cGMP guidelines	<ul style="list-style-type: none">• Manufacture compounded sterile preparations (CSPs)• Compliance with FDA cCMP and USP <797> / <800> standards
Quality Assurance & Regulatory Affairs	Governance of quality systems and compliance to FDA regulations and USP standards	<ul style="list-style-type: none">• Oversee SOPs, documentation control• Audit management (internal & external)• Training and qualifications of personnel• Regulatory submissions & state licenses



Past APPE Student Testimonials

“Being part of a startup for my APPE rotation has been an eye-opening experience. I’ve gained a deeper appreciation for the effort and precision that goes into both the lab work and the manufacturing side. Watching a company grow from the ground up and contributing to that process has been incredibly rewarding.”

Nihala Razack

Fairleigh Dickinson University - School of Pharmacy

“As an APPE student, I’ve really enjoyed experiencing the dynamic environment of a startup company. I love seeing how innovative ideas take shape and being part of the behind-the-scenes processes in the lab and manufacturing. It’s been inspiring to witness the early stages of product development and the teamwork that drives it forward”

Marissa DiFulco

Fairleigh Dickinson University - School of Pharmacy



APPE Program Overview

Objectives of SanKav Pharmaceuticals APPE Program

- Understand how drugs are developed and manufactured
- Summarize FDA regulations applicable to manufacturing processes, including GMP, GLP, etc...
- Describe the various components involved in drug manufacturing, including facility design, raw materials sampling, testing laboratories, QA/QC management, SOP development, and others
- Explain the development process of a new drug from laboratory to commercial distribution of the product
- Overview of Code of Federal Regulations (CFR) and FDA Guidances
- Define all phases of clinical trials in drug development process
- Discuss inspections and audits of drug manufacturing facilities
- Identify the marketing pathways of drug products (e.g., NDA, ANDA, BLA, OTC Monograph)
- Recognize the United States Pharmacopeia (USP) standards that apply to drug manufacturing



What to Expect?



**Develop
standard
operating
procedures
(SOPs)**

**Create training
documents**

**Conduct data
review on
batch records
and analytical
results**

**Perform
regulatory
affairs
activities**

**Hands-on
experience**

**You'll learn
something
new
everyday!**

Weekly APPE/Intern Meetings

Weekly collaborative meeting **every Friday**

- **Purpose:** Broaden collective knowledge and keep the team aligned
- **Project updates:** Share progress across active initiatives
- **Peer education:** Built-in learning component each week through student presentations
- **Rotating presentations:** Students take turns presenting on various topics
- **Topics covered:** Industry regulations, best practices, and relevant developments, etc...



Helpful Tips

Stay Organized

Be Proactive

Network

**Practice
Aseptic
Cleanroom
Technique**

**Review State
and Federal
Regulations**

**Ask
Questions**



Local Bites & Coffee Shops



STARBUCKS



Panera
BREAD®



DUNKIN'



SanKav Pharmaceuticals

FAQs

1. What time should I arrive on the first day?

Please arrive by 9:00 AM. Orientation begins promptly with a meeting in the conference room.

2. Where do remote students join the orientation?

Remote students will join via Zoom. The link will be sent out in advance.

3. What is the dress code?

Business casual. No jeans. Sneakers are acceptable for comfort while working in labs.

4. Do I need to bring a white coat?

No. SanKav will provide lab coats, if required.

5. Should I bring lunch?

Yes, please bring your own lunch. A kitchen with a fridge and microwave is available.

FAQs (cont.)

6. What are the working hours?

Monday–Friday (except major holidays), 8 hours per day with a 1-hour lunch break.

7. Can I eat lunch with other interns?

Absolutely. There are many interns onsite and you're encouraged to take lunch together.

8. Do I need to bring my own laptop?

Yes. Bring your own laptop in case there are issues with your assigned desktop.

9. Is parking available?

Yes, ample free parking is available on-site. Carpooling is encouraged but not required.

10. Anything I should do before my first day?

Yes, please visit the SanKav website to familiarize yourself with the company.



Thank you

PLEASE CONTACT PRECEPTOR, KIMBERLY DEFRONZO, FOR ANY QUESTIONS

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