

# Your Roadmap to Opening a Successful Compounding Pharmacy

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STEP  
1

## Research and Understand Regulations

- Familiarize yourself with state and federal regulations governing compounding pharmacies, such as USP 795, USP 797 and USP 800 standards and FDA guidelines.
- Ensure compliance with the Drug Quality and Security Act (DQSA) and state board requirements for compounding practices.

### Why?

Regulatory compliance is critical to avoid penalties, legal issues and reputational damage.

STEP  
2

## Create a Business Plan

- Define your services (sterile, nonsterile, veterinary, etc.).
- Conduct market research and develop a pricing strategy.
- Outline costs for rent, equipment, staffing and APIs.

### Why?

A clear plan helps attract investors and secure financing.

STEP  
3

## Secure Financing

- Estimate startup costs (typically ranging from \$300,000 to \$1,000,000\*) and explore funding options such as SBA loans and local bank loans.
- Identify potential grants for healthcare businesses.

### Why?

Proper funding ensures smooth operations and sustainable growth.

*\*Actual costs vary based on location, business specifics and other factors.*

STEP  
4

## Choose the Right Location

- Look for high-visibility areas near healthcare providers.
- Ensure compliance with pharmacy zoning regulations.
- Plan space for cleanrooms and specialized equipment.

### Why?

A strategic location improves accessibility and regulatory adherence.

STEP  
5

## Consult with Experts

- Work with attorneys, financial advisors and pharmacy startup consultants.
- Partner with professionals who understand compounding pharmacy design and pharmacy law.

### Why?

Expert guidance helps prevent costly mistakes.

## STEP 6

### Obtain Licensing and Certifications

- Secure state pharmacy licenses and compounding permits.
- Register with the DEA if handling controlled substances.
- Seek accreditation to build credibility.

#### Why?

Proper licensing establishes legal compliance and builds trust with patients and prescribers.

## STEP 7

### Build Your Compounding Lab & Acquire Equipment

- Design and construct your compounding space ensuring you meet USP 797 and USP 800 standards.
- Invest in essential equipment like powder containment hoods, autoclaves and balances.

#### Why?

A compliant workspace is crucial for high-quality compounding.

## STEP 8

### Source High-Quality APIs

- Partner with trusted suppliers committed to quality and regulatory compliance.

#### Why?

Ingredient integrity impacts the safety and efficacy of compounded medications.

## STEP 9

### Hire and Train Staff

- Recruit experienced compounding pharmacists and technicians.
- Provide comprehensive training in compliance with USP standards.

#### Why?

Well-trained staff ensure safe, accurate and efficient operations.

## STEP 10

### Develop Your Marketing and Referral Strategy

- Build strong relationships with local prescribers.
- Educate the community on the benefits of compounding.
- Utilize digital marketing and social media to grow your customer base.

#### Why?

A strong network and brand presence drive referrals and business growth.

### PCCA: Your Complete Compounding Pharmacy Resource

PCCA provides the highest quality APIs, industry-leading education and expert guidance to help you launch and grow your compounding pharmacy.

**LET US BE YOUR PARTNER ON THIS JOURNEY!**