Patient Focused Certification

PFC Training helps you achieve quality standards. Staff Certification is now available online
www.PFCtraining.org
jahan@safeaccessnow.org
Outline

● What is ASA?
● What is PFC?
● Operations/business certification
● Training and Education
● Research and PFC companies
● Staff Certification is now available online
  www.PFCtraining.org
Americans for Safe Access

What is ASA?
● 501(C)3 organization
● ASA’s mission is to ensure safe and legal access to cannabis (marijuana) for therapeutic use and research
● Grassroots organization with over 100,000 members nation-wide
● In all 50 states, Guam, Puerto Rico, and the District of Columbia

Our goals:
● Resolve federal and state conflict on medical cannabis laws
● Ensure safe and legal access to medical cannabis throughout the nation
● End stigma and discrimination associated with medical cannabis use and research
● Regulate cannabis like an herbal medicine
● Make cannabis a frontline medicine
What is PFC?

- Nonprofit Third Party Certification
- Peer Reviewed
- Seed to Consumption Quality Standards
- Staff Training
- Educational Materials
- Documentation & Facility Audits
- Compliance Oversight
- Government Relations
Standards

AHPA
AMERICAN HERBAL PRODUCTS ASSOCIATION

AHP
American Herbal Pharmacopoeia

ACS
Chemistry for Life

University of Maryland
School of Pharmacy
Center for Innovative Pharmacy Solutions

ASA
PATIENT FOCUSED CERTIFICATION

ICCI
International Cannabis and Cannabinoids Institute

The American Association for Laboratory Accreditation
“World Class Accreditation”
PFC Seal of Approval

- Compliance with state and local regulatory guidelines
- Compliance with AHPA and AHP standards
- Trained staff
- Commitment to purity and identity of products
- Implemented standardized methods for
  - Cultivation,
  - Manufacturing,
  - Laboratory Testing, or
  - Distribution
PFC Certifications

Available in US and internationally
PFC Reduces Company Liability

- Employee and management training
- Patient and caregiver educational materials
- Implementation of product safety protocols
- Adverse-event reporting
- Complete product recall programs
- “Standard and Function” development
  - Case Studies
  - Non-FDA Claims
  - Botanical and Nutraceutical appropriate descriptions for cannabis & cannabis product actions
PFC Certification Process

1. **CHOOSE:** Which certification program works for your business. Depending on the focus of your business or the state in which it is located, different certifications may be required.

2. **APPLY:** Apply for a free quote. The PFC process begins with filling out an online application that will be followed by a price quote and contract.

3. **AUDIT:** PFC staff will then walk your business through the audit process, which includes a Documentation Audit, **Staff Training**, and On-site Facility Audit.

4. **REVIEW:** Await the PFC staff review of audit findings.

5. **CERTIFY:** Receive the certification decision, which you can either accept or appeal. An affirmative decision will mean your business is now PFC certified.
Documentation

All PFC Companies:

- Documentation
  - Implementable product recall protocols
  - Batch-number-based
  - Adverse-event reporting
- Federal, state, and local compliance with environmental laws

Lab Testing Facilities:

- American Herbal Pharmacopoeia Cannabis Plant Monograph
- Equipment calibration
- Protocol evaluation
- Methodology standardization
PFC Peer Review Board

Peer Review Board Oversight:

● Regular review and update of audit methodologies and program standards including training

● Process and review all certification appeals and revocation actions

● Uphold the integrity of the PFC program
PFC Peer Review Board

Over 300 Years of Combined Expertise

- Complementary and Alternative Medical (CAM) therapies
- USDA food and product safety protocols
- Federal regulatory development
- Medical cannabis research
- Medical cannabis industry
- Pharmacology
- Biochemistry
- Education
Special offers for PFC Clients and Associations

- Discounts on staff trainings
- Regulation Tracking and Updates
- Discounts on consulting fees
- Discounts for certification program (5-10%) with Industry Association Endorsement
# PFC Staff Training Requirements

<table>
<thead>
<tr>
<th>Training Event</th>
<th>Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PFC Training: Total Hours</strong></td>
<td>6</td>
</tr>
<tr>
<td><em>PFC Core Cannabis Training: Cannabis as Medicine</em></td>
<td>1</td>
</tr>
<tr>
<td><em>PFC Core Cannabis Training: Cannabis Business Operations</em></td>
<td>1</td>
</tr>
<tr>
<td><em>PFC Core Cannabis Training: Understanding Cannabis Law</em></td>
<td>1</td>
</tr>
<tr>
<td><em>PFC Core Cannabis Training: State and Local Legal Compliance</em></td>
<td>1</td>
</tr>
<tr>
<td><em>PFC National Cannabis Standards Training: Distribution Operations</em></td>
<td>2</td>
</tr>
<tr>
<td><em>PFC National Cannabis Standards Training: Manufacturing, Packaging, Labeling and Holding Operations</em></td>
<td>4</td>
</tr>
<tr>
<td><em>PFC National Cannabis Standards Training: Cultivation and Processing Operations</em></td>
<td>2</td>
</tr>
</tbody>
</table>
# Current Training Offerings PFC

<table>
<thead>
<tr>
<th></th>
<th>Live Training</th>
<th>PFC Company</th>
<th>Add Printed Materials</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CULTIVATION</strong></td>
<td>$750.00</td>
<td>$500.00</td>
<td>$100.00</td>
</tr>
<tr>
<td><strong>DISTRIBUTION</strong></td>
<td>$750.00</td>
<td>$500.00</td>
<td>$100.00</td>
</tr>
<tr>
<td><strong>MANUFACTURING (processing)</strong></td>
<td>$750.00</td>
<td>$500.00</td>
<td>$100.00</td>
</tr>
</tbody>
</table>
## Training Offerings PFC with CIPS

<table>
<thead>
<tr>
<th></th>
<th>Online Training</th>
<th>PFC Company</th>
<th>Non-PFC Company</th>
<th>Add Printed Materials</th>
</tr>
</thead>
<tbody>
<tr>
<td>CULTIVATION</td>
<td>$500.00</td>
<td>$250.00</td>
<td>$400.00</td>
<td>$100.00</td>
</tr>
<tr>
<td>DISTRIBUTION</td>
<td>$500.00</td>
<td>$250.00</td>
<td>$400.00</td>
<td>$100.00</td>
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<tr>
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<td>$100.00</td>
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</tbody>
</table>
PFC Training prepares your staff to be partners as your organization reaches for higher quality standards.
What is new?

Medical Cannabis staff training is now available online in the areas of cultivation, processing, dispensing and laboratory standards.

Over 26 instructional hours!

Americans for Safe Access (ASA) Patient-Focused Certification (PFC) curriculum Partnership between ASA and University of Maryland School of Pharmacy’s Center for Innovative Pharmacy Solutions.
www.PFCtraining.org

PFC Staff Certification: Cultivation and Processing Standards
PFC Staff Certification: Manufacturing, Packaging, Labeling, and Holding Operations
PFC Staff Certification: Laboratory Standards
PFC Staff Certification: Distribution Operations

Combined certificates are also available online

Sign up online and select your state of operation. New states will be coming online and webinars will be offered for state-specific training.

Questions? Contact cips@rx.umaryland.edu
PFC Staff Training Learning Objectives

Cannabis Business Operations

• Learn customer service strategies, how to identify and handle medical emergencies, patient education, and information about the Patient’s Bill of Rights.
• Understand how to handle interactions with Federal Law Enforcement, what to do if arrested and how to answer questions, and when Miranda warnings apply.
• Explore what to do if a raid or robbery occurs, various security and safety protocols designed to help prevent robbery and reduce the risk of Federal Conflict, and learn how to set up effective action plans.
• Determine how to ensure the safety of your product, including how to spot contaminants and maintain safe and sanitary conditions, as well as considerations such as patient screening, diversion prevention and security.
Cannabis as Medicine

• Learn about what current research is revealing about the therapeutic use of cannabis.
• Explore a brief history of opioids and cannabinoids, and learn how the endocannabinoid system was discovered and how it works in our body.
• Learn the varieties of cannabis and cannabinoids and the effects of cannabis.
• Learn about the various cannabis pharmaceuticals currently available throughout the world and how cannabis extracts and concentrates are used.
PFC Staff Training Learning Objectives

Understanding the Law

• Learn about the conflicting Federal law issues including the Controlled Substances Act, the Drug Enforcement Agency, and its role as Federal law enforcement, Sentencing Laws and Guidelines, and other applicable laws.
• Explore the history of medical cannabis reform efforts, opposing efforts, and Federal legislative efforts.
• Learn about States and patient’s rights, Federal landmark cases, and the current status of medical cannabis law.
PFC Staff Training Learning Objectives

State and Local Legal Compliance

- Learners will understand the state law and regulations
- Learners will understand key aspects of the state program such as reciprocity, residency requirements, and other fundamental points
- Understand the requirements for Patients and caregivers, age limits, doctors, and staff
- Understand how to detect, identify, and prevent diversion
- Understand possession, growing and consumption limits
- And any other applicable statutes
PFC Staff Training Learning Objectives

NCST Cultivation

- Subject operations & general definitions
- Good cultivation, processing and distribution practices
- Protocols and operating procedures (with overview of pesticide guidance)
- General product safety guidance
- Personnel training & workplace safety
- Physical facilities: fire prevention, sanitation practices, electrical & ventilation systems, disposal & waste practices, and security provisions
- Water resource management: including agricultural irrigation and discharge waters, as well as potable water for employee use
- Good record keeping practice & disclosure responsibilities
- Adverse event recording & product recall programs
PFC Staff Training Learning Objectives

NCST Distribution

- Understand the basics of dispensing operations
- Be familiar with best practices and standards for dispensing operations
- Understand the standards for facilities maintenance and security
- Be able to describe different types of cannabis products
- Be familiar with the core requirements for adverse event reporting and recall plans
PFC Staff Training Learning Objectives

NCST Manufacturing

- Subject operations & general definitions
- General awareness of other statutory rules and regulations that may apply
- Good manufacturing practices for the acquisition & distribution of plant material & derived products
- Component control protocols, batch records, process monitoring & control, representative sampling & reserve samples, and specification documentation
- Personnel training, responsibilities & safety, and supervisor requirements
- Physical facilities - appropriate design & construction considerations, sanitations requirements & security protocols
- Proper protocols, sanitation, and handling practices for equipment & utensils
- Packaging & Labeling process controls including packaging & labeling protocols, batch records, label content for both plant material & derived products
- Holding controls including protocols for proper identification as well storage & handling
- Good record keeping practices including materials inventory, distributed materials, reconciliation of records, and record retention
- Adverse event recording & product recall programs including protocols for complaint files, returned products and recall procedures
PFC Staff Training Learning Objectives

NCST Laboratory

• Laboratory operations, what they do and the training all personnel should have for these operations
• Physical facility maintenance requirements
• Record keeping and documentation practices
• Understand Procedures for sample handling, result reporting, reference standards,
• maintenance, calibration and cleaning of all lab equipment and instruments.
• Understand requirements for method validation and analysis proficiency
PFC Staff Training Learning Objectives

PFC Enrichment Courses:

- Quality Control/Quality Assurance and Batch Sampling
- Pesticide Guidance and Integrated Pest Management
- Internal and External Auditing for Cannabis Operations
- Advanced Endocannabinoid System
- Sustainable Cultivation

Patient Focused Certification

1-888-929-4367
patientfocusedcertification.org
Basics of Staff Training

• Federal and State medical cannabis laws, regulations and other laws & regulations pertinent to the agent’s responsibilities;
• Standard operating procedures;
• Detection and prevention of diversion of medical cannabis;
• Security procedures; and
• Safety procedures, including responding to: a medical emergency; fire; a chemical spill; and
• Threatening event such as: armed robbery; an invasion; a burglary; etc.

Retain training materials and attendance records and make the training materials available for inspection.
### PFC Staff Training and MD Regs

<table>
<thead>
<tr>
<th>MD Regulatory Training Requirement</th>
<th>Training Module</th>
<th>Certificates</th>
</tr>
</thead>
</table>
| Federal and State medical cannabis laws, regulations and other laws & regulations pertinent to the agent’s responsibilities | CCT*: Understanding the Law  
CCT: Intro to Cannabis as a Medicine  
SSCT- Maryland State Specific and Legal Training | Staff Certification  
Manufacturing and Cultivation                                                 |
| Standard operating procedures                                                                                             | NCST**: Cannabis Operations                                                  | Staff Certification  
Manufacturing and Cultivation                                                 |
| Detection and prevention of diversion of medical cannabis                                                               | CCT: Understanding the Law  
NCST: Cannabis Operations                                                      | Staff Certification  
Manufacturing and Cultivation                                                 |
| Security procedures                                                                                                       | CCT: Business Operations                                                      | Staff Certification  
Manufacturing and Cultivation                                                 |
| Safety procedures, including responding to: a medical emergency; fire; a chemical spill                                   | CCT: Business Operations  
NCST: Cannabis Operations                                                      | Staff Certification  
Manufacturing and Cultivation                                                 |
| Threatening event such as: armed robbery; an invasion; a burglary; etc.                                                   | CCT: Business Operations  
SSCT: State Specific and Legal Training                                       | Staff Certification  
Manufacturing and Cultivation                                                 |
Facility Auditors
All PFC Auditors have a minimum of 5 years applicable experience

Cultivation Auditors
- In the field of medical cannabis cultivation; or
- Inspecting food crops for the Department of Food and Agriculture
- Inspecting food crops for other appropriate certification body

Manufacturing, Packaging, Labeling, and Holding Auditors
- In the field of medical cannabis manufacturing; or
- Inspecting operations that produce products intended for human consumption, including topical applications

Distribution
- In the field of medical cannabis distribution management; or
- Inspecting traditional and/or Complementary Alternative Medical facilities

Laboratory Analysis
- Engaging in laboratory analysis of medical cannabis
- Degree in Bio-chemistry

[Logos and contact information]
Cannabinoid Dose and Label Accuracy in Edible Medical Cannabis Products

Discussion | Edible cannabis products from 3 major metropolitan areas, though unregulated, failed to meet basic label accuracy standards for pharmaceuticals. Greater than 50% of products evaluated had significantly less cannabinoid content than labeled, with some products containing negligible amounts of THC. Such products may not produce the desired medical benefit.

Medical Professional and Patient Education

Medical Professionals

Patient & Caregivers

Companies & Organizations
Auditing /Assessment Scenarios
Auditing /Assessment Scenarios
Health and Safety Auditing Deficiencies?
Health and Safety Auditing Deficiencies?
Summary

ASA created PFC to address issues of quality control and product safety in the Cannabis industry and to ensure that patients, healthcare providers and governments can rely on high-quality Cannabis products and services.

PFC addresses quality control and product safety through:
• Developing and Implementing Industry Standards
• Industry Training
• Certification Program
PATIENT FOCUSED CERTIFICATION

STANDARDS. EDUCATION. VERIFICATION.

What is PFC?

PFC offers third-party certification and support services to companies cultivating, manufacturing, analyzing or distributing medical cannabis products and is the nation’s only certification program based upon the AHPA and AHP standards.

Our Standards

Our standards were developed in two parts: 1. AHPA Recommendations to Regulators & 2. The AHP Monograph & Therapeutic Compendium for Cannabis. PFC companies are compliant with state & local regulations, AHPA & AHP standards.

Industry Certification

Available to cannabis companies in states with medical cannabis and/or legal adult use laws in place. PFC is designed to show the commitment of cannabis companies to providing quality care and standards to patients and/or consumers.

Visit Us Online to Learn More! PatientFocusedCertification.org