



## PCMAP - UNDERSTANDING AND IMPLEMENTING COURSE

2 Day Course | \$1,145 per person | 1.4 CEUs

### COURSE OBJECTIVES

This 2-day interactive training course will help you understand the essential components of the Personal Care Manufacturing Assessment Program (PCMAP). Course attendees will gain the skills and knowledge required to implement a quality and safety management system that ensures the proper production, control, storage and shipment of cosmetic and personal care products. PCMAP incorporates selected elements of ISO 9001, Good Manufacturing Practices (GMPs), and ISO 22716, ensuring an effective management system infrastructure exists.

ISO 22716 marked a major step in the realization of a globally recognized standard for cosmetic and personal care products safety, which has enabled manufacturers and suppliers to exceed customer needs and expectations. PCMAP draws heavily upon this standard, course attendees will learn how this standard is applied through the program ensuring successful assessments.

A key attribute of PCMAP is the ability to account for the perceived level of risk for different manufacturing categories, facilitating compliance with GMPs and applicable regulatory requirements. All of these attributes of PCMAP and more are covered during this activity packed course.

For course dates and locations please visit:  
[www.saiglobal.com/pcmap](http://www.saiglobal.com/pcmap)

### In-House Training

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To request a quote please email us at:  
[training.americas@saiglobal.com](mailto:training.americas@saiglobal.com)



### ✓ KEY SESSION TOPICS

- In-depth review of PCMAP requirements
- Introduction to regulatory (domestic and international) requirements, such as 21 CFR 210/211
- Supply chain tier categories as defined by PCMAP and applicable requirements for each category
- Benefits of GMP processes
- Planning for a successful implementation
- Impact on QMS success and field performance
- Key lessons learned that impact certification

An optional written exam is conducted at the end of the course to ensure attendees achieve the necessary competencies to implement a system that conforms to PCMAP.

### ✓ WHO SHOULD ATTEND

- Functional managers
- Regulatory Personnel
- Engineers (Quality, Manufacturing/Process, Design)
- Process owners
- Internal and External Auditors of Quality Management Systems
- Steering Committee Team Members

### ✓ PREREQUISITE

Prior knowledge of ISO 9001, and/or FDA 21 CFR 210/211 is highly recommended.



## PCMAP - AUDITING COURSE

2 Day Course | \$1,195 per person | 1.4 CEUs



### COURSE OBJECTIVES

This 2-day auditor course provides attendees with practical and challenging tasks on how not only to audit the PCMAP requirements but also ensure compliance with GMPs. Course attendees will learn how to assess an organizations compliance with PCMAP requirements, and more importantly to ensure an effective quality management system infrastructure exists to meet and exceed customer expectations.

Attendees will learn through instructor-led presentations, interactive class discussions, workshops, examples and a case study, to assess the requirements both internally and externally (i.e., supplier audits or certification audits). The methodology is based on the ISO 19011 standard and follows good audit practices to ensure proper planning, implementation, reporting and follow-up audit activities.

Guidelines provided by the Council and the assessment criteria are key inputs to this training. This includes viewing the ISO 22716 guidelines as 'shall' statements rather than 'should' statements.

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### ✓ KEY SESSION TOPICS

- Overview of auditing principles
- Review of the Key Phases of auditing
  - Planning
  - Executing
  - Reporting
- Interpretation of the GMPs through case study
- Understanding the difference between Process auditing and Elemental auditing
- Effective use of checklists
- Writing effective audit findings
  - Nonconformance
  - Observations (Strengths and Opportunities for Improvement)
  - Preparation of an Executive Summary Report
- Corrective Action follow-up, verification and close out
- Key lessons learned that impact certification

A written exam at the end of the course is utilized to ensure attendees demonstrate key competencies required for conducting effective assessments of PCMAP.

### ✓ WHO SHOULD ATTEND

- Internal and External Auditors
- Regulatory Personnel
- Process Owners
- Top Management

### ✓ PREREQUISITE

Completion of the PCMAP - Understanding and Implementing course.