



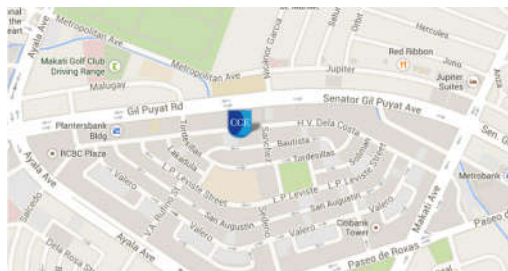
ATENEO DE MANILA UNIVERSITY
GRADUATE SCHOOL OF BUSINESS

CCE CENTER FOR CONTINUING EDUCATION

PCPM - Ateneo CCE Diploma in Pharmaceutical Medicine & Management

VENUE

Ateneo de Manila University - Salcedo Campus 3/F Ateneo Professional Schools Bldg., 130 H.V. Dela Costa St., Salcedo Village, Makati City, Philippines



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November 29, 2018



PCPM - Ateneo CCE Diploma in Pharmaceutical Medicine & Management

batch 4



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PCPM - Ateneo CCE Diploma in Pharmaceutical Medicine & Management

Pharmaceutical Medicine is the medical scientific discipline concerned with the discovery, development, evaluation, registration, monitoring and medical aspects of the marketing of medicines for the benefit of patients and the health of the community.

In terms of governance, pharmaceutical physicians/ medical & regulatory personnel are accountable for the nature, quality and standards, including ethical standards, of their work to their employers, to their professional bodies, and under the law as administered by the National Drug Regulatory Authority.

The *Ateneo-PCPM Diploma in Pharmaceutical Medicine and Management* consists of seven modules that aim to provide the technical knowledge and skills that will equip the pharmaceutical physicians/ medical and regulatory personnel with a core set of competencies aligned with international standards for the appreciation and/or practice of pharmaceutical medicine, at same time in line with Ateneo's thrust on nation-building.

WHO SHOULD ATTEND

Medical doctors, allied health professionals, and management executives who want to gain competencies in the disciplines involving discovery, development, evaluation, monitoring and medical aspects in marketing of medicines for the benefit of patients and public health.

Successful participants may earn 3 units as MBA and MBA-H electives.

ABOUT CCE

The Ateneo Center for Continuing Education (CCE) supplements and complements the Ateneo Graduate School of Business' (AGSB) program offerings by addressing issue-specific industry concerns that require immediate, purposeful, and focused response. CCE is an industry resource and partner, doing advocacy on emerging critical issues and convening interested entities so that together, they can tackle a common concern.

OBJECTIVES

After the course, you will develop the competencies of the International Federation of Associations of Pharmaceutical Physicians (IFAPP):

1. Understand and apply medical science principles and statistics in the evaluation, development, and discovery of new medicines within the context of regulatory environments;
2. Design, execute clinical trials and prepare manuscripts or reports for publication and regulatory submissions;
3. Interpret effectively the regulatory requirements for the clinical development of a new drug, product life cycle, to ensure its appropriate therapeutic use and proper risk management;
4. Evaluate the choice, application, and analysis of post-authorization surveillance methods to meet national/international agency requirements for proper information and risk minimization to patients and clinical trial subjects;
5. Combine the principles of clinical research and business ethics for the conduct of clinical trials and commercial operations;
6. Appraise the pharmaceutical business activities in the healthcare environment to ensure they remain appropriate, ethical, and legal to keep the welfare of patients and subjects in the promotion of medicines and design of clinical trials; and
7. Able to apply the principles and practice of people management and leadership, effective communication, and interpersonal skills to influence key stakeholders and achieve scientific and business objectives.

PROGRAM CONTENT

I. Discovery of Medicines and Early Development

- A. Therapeutics in pharmacology
- B. Discovery of new medicines
- C. Planning and organization
- D. Regulation and ethics
- E. Pre-clinical drug development
- F. Exploratory clinical development
- G. Clinical Pharmacokinetics

II. Clinical Development and Clinical Trials

- A. Clinical trial planning and management
- B. Clinical trial designs, conduct, and documentation
- C. Trial design, hypothesis testing, power
- D. Measurement and types of data
- E. Data collection and management
- F. Types of analysis
- G. Interpretation of study design, analysis and results

III. Medicine Regulation

- A. Legal and medicines regulation
- B. Good practices, harmonization, CTD, labels, AR reports, drug abuse-dependence
- C. Clinical trials, ethics, drug classification

IV. Drug Safety Surveillance

- A. Drug safety regulation
- B. Drug safety in preclinical phase
- C. Drug safety in clinical trials
- D. Pharmacovigilance
- E. Pharmacoepidemiology

V. Ethics and Subject Protection

VI. Healthcare Marketplace

VII. Communication and Management

- A. Role of medical department

ABOUT PCPM

The Philippine College of Pharmaceutical Medicine (PCPM) continues to actively take part in the affairs of the Philippine Medical Association (PMA), the new Philippine Food and Drug Administration (PFDA), the newly reconstituted National Formulary Executive Council and other local bodies on issues relevant to the practice of pharmaceutical medicine.

PCPM recognizes the need to take an active part in healthcare issue of national interest of the patients in particular.