

NATIONAL SEMINAR
On
**Regulatory and Industrial Perspective on GMP and GLP in
India vis a vis Developed Countries**

11th February 2010

Sponsored by



Council of Scientific and Industrial Research

Organized by



SHRI SARVAJANIK PHARMACY COLLEGE

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PREAMBLE

Good Manufacturing Practices (GMP) & Good Laboratory Practices (GLP) are essential parts of quality management system popularly known as Quality Assurance (QA) in a pharmaceutical company.

GMP is that part of QA which ensures that products are consistently produced and controlled to appropriate quality standards and involves all facets of manufacturing, warehouse, production, testing and engineering. GMP is practiced by law worldwide following different guidelines like 21 CFR- part 210 and 211 in USA, EUGMP in Europe and WHO-GMP in over 100 member countries. At home, GMP was enacted as Schedule M to Drug and Cosmetics Rules in 1988 and upgraded in 2003 as revised Schedule M. Implementation of GMP ensures quality manufacturing that is essential for domestic and international market.

GLP is a quality system concerned with safety of human beings and environment and applicable to chemical, pharmaceutical, cosmetics, pesticide and food industries. GLP is practiced internationally following different guidelines OECD in most countries, 21 CFR part 58 in USA and GLP regulation in UK. At home, we have national GLP compliance authority working under department of science and technology. Besides, recently promulgated Schedule L to Drug and Cosmetics Rules which prescribes GLP for pharmaceutical industry will become effective from October 2010. Implementation of GLP is a global requirement for all preclinical research work and ensures very good business for CRO by contract research.

Industry is improving its stance on GMP and is learning to adopt GLP. Academia must learn these subjects for improving teaching and promoting industry academia interaction. It is essential that postgraduate and undergraduate students of pharmacy colleges learn about recent trends and methodology in GMP and GLP.

PROGRAMME SCHEDULE

Thursday, 11 February 2010

9:00- 9:30	Registration and Break fast
9:30-10:30	Inaugural Function and Address by Chief Guest Mr. H.G. Koshia, Commissioner, Food and Drug Control, Gujarat State
10:30-11:00	Session I: Schedule M and Beyonds Dr. J. B. Dave, Prof. and PG Director, SSPC, Mehsana
11:00-12:00	Session II: Evolution and Implementation of WHO GMP guidelines and Schedule M Dr. Ram Kishan, Additional Drugs Controller , CDSCO , Ahmedabad
12:00-13:00	Session III: Scope and Implementation of GMP Guidelines for Europe, USA and Regulated markets Mr. S.G. Belapure, Sr. President (Operation), Zydus Cadila Health Care Ltd., Ahmedabad
13:00-14:00	Lunch Lunch
14:00-15:00	Session IV: Overview of OECD and other GLP guidelines Dr. Ashwini Shrivastava, GM (Quality), Cadila Pharmaceutical Ltd, Ahmedabad
15:00-16:00	Session V: GLP in India: Present and Future Prospective Mr. Hiten Shah, Senior Scientist, Bioanalytical Laboratory, TRC, Ahmedabad
16:00-16:30	Session VI: Open session for interaction and distribution of certificates
16:30	High tea

REGISTRATION FORM

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Name (in Capitals):

Designation:

Organization:

Address:

Contact No: E-mail:

Registration Details:

Cash:

Cheque / DD No:

DD:

Drawn on:

Date: Place:

Signature of Participant:

Signature of the forwarding authority with seal*:

(*For students)

Notes: Photocopy of registration form can be used. Confirmation of registration will be informed by email.

ABOUT THE INSTITUTE

Shri Sarvajanik Kelavani Mandal

Shri Sarvajanik Kelavani Mandal, Mehsana, has pioneered in providing educational facilities to the people of Mehsana and neighboring areas for more than 50 golden years, since its inception in the year 1955. The trust has been managing twenty-one educational institutions, which include kindergarten to secondary schools in Hindi, Gujarati and English medium, four colleges (A. S. Chaudhary Mahila Arts College, B. Ed. & M.Ed. College, PTC College & Pharmacy College) and a computer center.

Shri Sarvajanik Pharmacy College

The trust-instituted Shri Sarvajanik Pharmacy College was established in the year 1998 and is celebrating the decennial year in 2008-2009. The college is situated in the heart of Mehsana city in the vicinity of bus and railway station. The college offers B. Pharm, M. Pharm (Quality Assurance, Clinical Pharmacy, Pharmaceutical Chemistry and Pharmaceutics) and Ph.D courses. The college is well developed in terms of infrastructure including general amenities and faculty cabins, well equipped laboratories, library with installation of SOUL software, computational facilities with internet. The research laboratories are equipped with modern sophisticated instruments including UV/Visible double beam spectrophotometer, FTIR spectrophotometer, spectrofluorimeter, HPTLC, HPLC, auto analyzer etc. The college is affiliated to Hemchandracharya North Gujarat University, Patan, Gujarat Technology University and is approved by All India Council for Technical Education (AICTE) and Pharmacy Council of India (PCI). The college has qualified teaching faculty with rich academic, industrial and research experience. The college is poised to get accreditation from NBA-AICTE for B.Pharm course in near future.

REGISTRATION DETAILS

Registration & Fees

PG Students/UG Students:	Rs. 150/-
Academicians/ Industry delegate:	Rs. 250/-
Spot Registration:	Rs. 350/-

Participants are required to send their completed registration forms along with the registration fee by cash or DD drawn in favor of " Principal, Shri Sarvajanik Pharmacy College" payable at Mehsana, to the following address **on or before 6th February 2009**.

ORGANIZING COMMITTEE

PATRONS

Mr. D. J. Chaudhary
Secretary
SSKM, Mehsana

Dr. C. N. Patel
Principal & Professor
SSPC, Mehsana

ORGANIZING SECRETARY

Dr. J. B. Dave
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