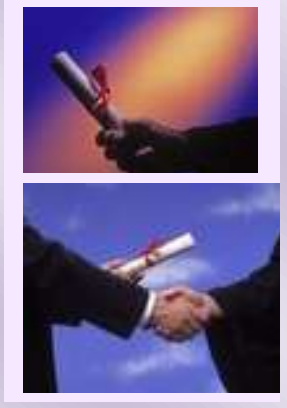
INSIGHT'S PROFESSIONAL MANAGEMENT ACADEMY

IPMA SINCE 18 YEARS!

DIPLOMA IN GMP

ADMISSIONS OPEN FOR THE CURRENT BATCH NOW !

This is a unique correspondence course (DISTANT LEARNING) which shall add value to your professional endeavors and shall prove to be a right choice for growth and progress in your career. This exhaustive course provides detailed inputs on current aspects of Good Manufacturing Practice



LIMITED INTAKE, ADMISSIONS ON FIRST COME, FIRST SERVE BASIS !

For Information and Action

Course Commences:
Batch 1 – August 1,
Batch 2 – January 1,
of each academic year.

Admission Closes – A day before of the course commencement date per batch. (i.e. July 31st for batch one and December 31st for batch 2)

Write to us for for obtaining prospectus - please send a DD/at par Cheque / NEFT of Rs. 350/- in favour of 'Insight's Professional Management Academy' on following address along with **your complete address, phone nos. and e mail id.** (for direct payment to bank option write a mail to dgmpipma2000@gmail.com)

(This amount spent on obtaining the prospectus shall be waived off from course fee for all the students seeking admission for this course diploma in GMP.)

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CONTACT :

INSIGHT'S PROFESSIONAL MANAGEMENT ACADEMY
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Tel : +91 20 25368620/25361165 (telefax)
Mobile : 09822208197.
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SYLLABUS SYNOPSIS

- Introduction to Pharmaceuticals (API / FDF) and various timelines from molecule to market place.
- Quality : definition, evolution, attributes, concepts, current trends and specific aspects to include modern Pharmaceutical Quality Systems (PQS)
- GMP and its relationship with quality; from basics to specific requirements
- History of GMP and its evolution & progress and trends till date across the globe,
- Progress of GMP with current status regulatory status and trends of various regulatory agencies with important milestones and requisite updates
- Interpretations and applications of GMP in line with National and International GMP regulations and standards as essential for Pharmaceuticals
- Requirements, scope, objective and principles and practices of GMP with emphasis on GMP requirements of:

  - WHO;
  - TGA;
  - MHRA;
  - MCC;
  - HPFBI;

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- PICS;
- EU;
- ICH;
- HSA
- USFDA and
- The revised Schedule M *and*
- *Specific references to other regulatory requirements different from those mentioned above.*

- Obtaining International GMP Certification and maintaining the GMP standards through design and implementation of effective pharmaceutical quality systems (PQS – Q10) with drivers as technology transfer, deviation & change management, Corrective And Preventive Actions) CAPA and Quality Risk Management (QRM).
- GMP requirements for pharmaceutical manufacturing from procurement to distribution and post marketing aspects.
- Principles of Quality Assurance and Quality Management Systems for monitoring of GMP
- Principles and Practices of Good Quality Control Laboratory Practices (GQCLP),
- Extensive Validation Studies & Techniques (including qualification studies for:

  - Equipment & instrument, design, installation, operation, performance (4Q approach from DQ-PQ),
  - Good Engineering Practices (GEP), GAMP V & ASTM model,
  - cleaning,
  - analytical methods validation, computer systems validation & revalidation)
  - with particular emphasis on HVAC & water systems validation with a Risk based approach to manufacturing of pharmaceuticals.

- Good Documentation Practices, data integrity requirements
- GQCLP and Stability studies, Good Distribution Practices
- Advances in GMP requirements, Training and Auditing in GMP, Handling international GMP inspections effectively and successfully, references to relevant pharmcoepial requirements as they interface with GMP
- Implementing GMPs in your organization through quality risk management, and getting the most out of quality by maintaining the GMP continuum.

A detailed syllabus is provided in the prospectus

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Students Feedback .... Encouraging Words.... *straight from the heart*

We are very thankful for the comfortable atmosphere created for the written examination and viva and the hospitality extended.

As far as course is concerned it fetches ourselves beyond expectation. Course material provided is more than required, with more focus on current guidelines, which in turn helps to know the current regulatory requirement. This course is really required for people who work in QC, QA, production and RA.

After doing this course you really get a feeling of some achievement, complete satisfaction on the concept of GMP and its implementation. In due course it is deeply nerved in the brain. Hence this course is not only upgrading yourself, it also brings self confidence to put your head up and to look ahead for GMP and other regulatory Audits.

Only request is, we have two response sheets to be completed in due course. , which can be initiated with one topic – one month response sheets which will enable us to thoroughly understand the concept.., as initial phases of the course you have to make yourself busy for completing the response sheets with diverting your mind with too many topics. Thereafter you feel time left is insufficient.

We should also have some interacting session like quiz for the chosen topic of the month. This will definitely make us to get involved in the subject and develop our skill.

Above all what attracted me more is during the viva session, there were discussions on Midterm career change, by Mr.A.Shirgaonkar. It was really wonderful. Having completed 13 yrs. with the profession, I never thought of changing the career midterm. This session made me to explore myself to these thoughts and touched my heart to make my creativity alive and explore my potential by way of developing my own identity outside the organization.

Finally I thank once again Mr. & Mrs. Shirgaonkar for making this course very interesting and giving an opportunity to interact with other big professionals experts of the Pharma industry. It was indeed a happy moment to share few thoughts with professional expert like Mr. Paranjpe and others during viva.

Regards

Parvati B Kumar

We continue to receive encouraging feedback from students every year echoing similar sentiments as mentioned above. We express our deep gratitude and best wishes to all our students.

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ADMINISTRATIVE DETAILS :

Duration :

Ten (10) months

Methodology : Exhaustive Course Material , Internal Submissions, Online assessments.

Eligibility :

B.Pharm, M Pharm, BSc., MSc., B Chem., M Chem., Doctorates in science disciplines, BE, DE and Professionals working in the pharma industry as chemical engineers, commerce graduates working in stores, purchase and other personnel with relevant experience from various disciplines and departments.

Procedure to obtain prospectus

Please send DD payable at Pune or Cheque payable at par of Rs. 350/- drawn in favour of "INSIGHT'S PROFESSIONAL MANAGEMENT ACADEMY" on the address mentioned on page 1 of this brochure, **along with your complete address, phone nos, e mail ids.** (for direct payment to bank option write a mail to dgmpipma2000@gmail.com) After obtaining the prospectus, please fill in the complete admission form and examination form along with prescribed attachments to reach us on or before **the deadlines mentioned above.**

Advantages of enrolling for this course Diploma in GMP :

Awareness in GMPs of International norms, Personal growth tool, Practical Knowledge and Skills, Enhances your placement chances, Future Career planning and Advancement, benefits you and your organization equally !

Our Clients, Educational Institutes, Teachers & Students realize our strength as :

- Committed in building learning organisations and result oriented professionals,
- Knowledgeable Faculty with practical know-how & Excellent Proven Track Record,
- Rich Experience in various facets of the industry & Wealth of useful knowledge,
- Involvement and Commitment of the institute towards training and development.
- Sustainable improvement initiatives
- Striving to maintain the quality continuum