ISSUE No. 4

# Pharma Web

## Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

Tamilnadu Pharmaceutical
Sciences Welfare Trust



**TAMILNADU PHARMACEUTICAL SCIENCES WELFARE TRUST**
AB Block, Baid Metha Complex,
New No. 16, Little Mount, Anna Salai,
Saidapet, Chennai - 600 015.
Ph: 044 - 22300992 ,22200854 Fax : 044 - 22355864
e-mail : pictrust@hotmail.com
Website : www.pictrust.com

# Pharma Web

## Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

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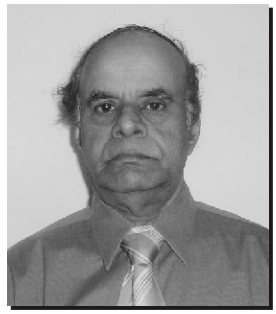
# EDITORIAL



**Dear Readers,**

I am happy to inform all the readers that our Trust has successfully released three issues of Pharma Web newsletter so far in a time bound manner.

This is the fourth issue for the quarterly period of July - September 09. This issue contains three articles namely "Clinical Research - Opportunities & Challenges In India" by Dr. M. D. Nair, "Good Laboratory Practices (GLP)" by Dr. N. Murugesan and "Guideline for the fresh Pharmacy graduates appearing for various job opportunities" in industry, regulatory and academic etc. by Mr. Sanjay Dasmohapatra. In order to benefit the pharmaceutical manufacturers as well as research fellows, we have listed the names of clinical research laboratories recognized by Drugs Controller General of India for conducting bioavailability and bioequivalence studies on new molecules. Likewise, a list of Government approved drug testing laboratories is also brought out in this issue in order to send drug samples to ascertain its quality through third party testing. This issue also contains various important news items related to Pharmacy profession. The important news items like opportunity in outsourcing pharma facility, innovation of new vaccine for swine flu, E-Clinical trial approval through E-governance etc.

The Central Drugs Standard Control Organization (CDSCO) is taking over further responsibility like issue of COPP for all the Pharmaceutical industries who intend to export their drugs and pharmaceuticals to other countries. It is pertinent to point out that this certificate was so far issued by the respective State Drugs Controllers in our country. It is very much essential to augment their drug inspectorate staff in order to issue the certificate in a time bound manner and also expeditiously.

Our Trust has procured important books like Pharmacology book written by different authors like Tripathi and Lippincott, Pharmaceutical Dosage Forms and Comprehensive Pharmacy Review. These books will be more useful for the entire pharmacy students as well as academicians. The Trust has also taken initiative to award scholarships to the M. Pharm students for their best projects for the year 2009 - 10.

I hope the readers may utilize this issue for the guidance and also give their valuable suggestions for future issues.

Best regards,
**R. Narayanaswamy**

# ARTICLES

## CLINICAL RESEARCH OPPORTUNITIES & CHALLENGES IN INDIA

**By Dr. M.D. Nair**
Pharma Consultant, Chennai

### Drug Discovery Process

The well-established model of new drugs discovery involves the identification of a candidate drug for development through extensive in-vitro and and animal studies, toxicological and histo-pathological investigations in rodent and mammalian species for extended periods of time, with the drug administered both by the oral and parenteral routes, studies on absorption, distribution, metabolism and excretion in animals and trials in healthy volunteers and human beings in various phases. In spite of rapid advances in rational design of drugs including application of functional genomics and proteomics, molecular targets, combinatorial libraries and high throughput screening, neither in developmental costs nor time requirements, has drug discovery become less arduous. Costs of discovery of a single new drug has been placed at over $ 800 million and a time period of 10 to 15 years, which, of course includes the costs of failures in terms of time spent and money expended.

### Role of Clinical Research

However impressive the data on animal experiments are with respect to safety and/or efficacy of an experimental drug, the role of validation through human experiments cannot be minimised. This is because, most of the disease models developed in animals do not simulate the human diseases, in aetiology, progression or prognosis. The metabolic enzymes involved may be different in animals and consequently the metabolites formed in-vivo also could be significantly different. This is significant, since in the case of many drugs, the active drug could very well be the metabolite rather than the original molecule. Since the first priority in drug discovery is to ensure that the new moiety is safe to the patients, Phase 1 Clinical trials are meant for establishing safety in humans, by understanding the profile of the drug and its behaviour in healthy volunteers and patients. Phase 2 of the trial concentrates on dose-searching for efficacy in selected patients, while Phase 3 is devoted to multi - centric trials, if warranted, in comparison with a placebo(non-drug) and/or a competitive drug. Only when all these phases are successfully completed in a statistically significant number of cases can the drug be approved for marketing. The drug is further evaluated after it is marketed through Post-Marketing Surveillace studies to ensure that unacceptable adverse reactions do not present themselves in the field.

Such an accepted model of new drug development, while not 100 % fool-proof, is the best available one at present, and historically, it has served the patients and society by delivering practically all the modern drugs which are in use today. Responsible large Corporations and Organisations involved in New Drugs Research will never by-pass the above route, nor will they belittle the known and potential risks posed by new drugs, since their first obligation is to the patients and not to the share-holders, apart from the fact that liability litigations can indeed push Corporations into bankruptsy. For example, companies which developed Silicon Breast Implants and Shiley Heart Valves went bankrupt, due to liability suits from subjects, including from those who were never harmed by their use.

## Ethics In Human Experimentation

The Helsinki Declaration of 1964 provides the guiding principles for conducting biomedical research on humans. Article 11.3 of the Declaration mandates that all patients, whether in an active treatment group or control group should receive the best possible therapy , although it allows the use of a placebo, when no such treatment exists. Article 11.6 stipulates that research in patients is justified only if it is of potential value to the patient in the best judgement of the investigator and the Ethical Committee whose clearance is mandatory. The Declaration also requires investigators to obtain subjects' freely given and non-coerced informed consent, in writing. These well-laid out procedures prior to initiating human trials are to-day the best possible safeguards against drug-related harm to the patients.

## Tragedies Still Strike

In spite of all these safeguards, tragedies still strike, not only with experimental drugs , but also with marketed drugs. In fact due to the vigilance exercised by the investigators and regulatory agencies on use of experimental drugs in humans, mishaps in this category are less than in the case of marketed drugs. Right from the days of the Thalidomide disaster in 1962, which maimed over 10,000 children due to the drug's teratogenic effect, there have been several serious side effects including fatalities which were related to marketed products, such as Benoxaprofen, Clioquinol, Phenyl Butazone, Troglitazone, Amidopyrine, Cisapride and even human Insulin.

As a general rule, assessment of the risk involved and ensuring an acceptable risk-benefit ratio is based on the nature and stage of the disease, availabilty of alternates and the extent of the projected benefits from the drug. The recent episodes of the death of a healthy volunteer during the trial of an anti-asthma drug by Johns Hopkins University and the death of Jesse Gelsinger who participated in a Gene therapy trial for a rare genetic disorder are examples of cases , where even with maximum vigilance, mishaps did occur.

## GLOBAL SCENARIO

The National Institute of Health (NIH) in U.S.A. along with the U.S.FDA under U.S. Public Law 1210-85 has set up an INternational Clinical Trial Registry. The objective is to ensure a more clearly defined, transparent and consistent standard for the reporting of clinical trials data. The registry contains 75629 entries from U.S.A and 168 other countries and 40 million pages of documents with an average addition of 50,000 pages per day.. Of these 46% are from U.S.A, 32 % from W. Europe, 10% from E. Europe, 3.2 % from Asia (outside Japan) of which only 1.2% is from India and others together 9%. The largest number of trials at present are in the area of cancer (oncology) drugs.

## INDIAN SCENE

### Contract Research & Manufacturing Services (CRAMS)

The Indian Pharmaceutical Industry has in recent years moved into the CRAMS (Contract Research And Manufacturing Services) space in a major way. The Industry's turnover from these activities have reached almost 10% of it's total turn over. Of this, clinical research contributes 15%, Contract research 13% and Contract Manufacture 70%. The costs of conducting clinical trials are estimated to be 50-60% of U.S. costs, while for contract research it is as low as 30%. Depending on the narure of the contract research, these percentages vary a great deal.

In India, the medical profession, the drug manufacturers and the regulatory agencies have all accepted international mandatory regulations as well as ethical standards embodied in the Hippocrates Oath, Helsinki Declaration and the International Harmonisation efforts in Clinical research (ICH/GCP Guidelines). The general convention followed is that for drugs developed abroad, trials in a Phase earlier to what has been carried out abroad would be permitted in India. Exceptions, once again are made for concurrent trials and fast-track approvals depending upon the nature of the product and the medical needs. It is obvious that for drugs discovered in India, approvals are granted even for Phase I trials (first time entry into humans, volunteers or patients). Even though India does not allow use of unapproved drugs in patients, in exceptional cases, physicians are allowed to import life-saving drugs, which have not received marketing permission in India.

Clinical research by its very nature is an extremely complex and sensitive activity which involves high risks and large number of failures. Indian investigators are relatively new in areas of ethical issues and reviews, Informed consents and specialised areas of documentation, pooling and analysis of data. None of the medical curricula at the graduate or even post graduate level address these issues and provide education and training for medical professionals medical colleges and in other academic institutions .

In India, in recent times many new regulations have been brought in, which has enabled clinical trials in India accepted by the global drug regulatory agencies. They include adoption of ICH/GCP guidelines, new amended version of Schedule M to meet cGMP Standards of manufacture, setting up of Clinical Trials Registry of India (CTRI) by the ICMR in consultation with WHO, mandatory requirement for registration of clinical trials from the 15th of June 2009, ICMR guidelines for ethics committees' functions and a WHO CDSCO sponsored Pharmacovigilance system.

The frequent allegation that unapproved drugs are clinically tested in developing countries, thereby treating the patients as guniea pigs is not valid, since no responsible Corporate body or Physician will risk such an unacceptable option. It is possible that due to the nature of the disease and its endemicity, certain drugs have to be necessarily tested in certain populations around the globe. By and large, new drug research and medical practices have maintained high levels of ethics, since after all, everyone realises that ultimately only ethical business will sustain and will turn out to be good business.

## Conclusions

The overall conclusion is that considering the advantages of availability of a variety of patient populations affected by both diseases of the Western World as well as those of the Developing Countries, the inherent skills of the medical professionals specialised in Clinical research, advantages of the language (English) and communication facilities and substantial costs savings, India could possibly emerge as one of the leading countries and a major hub for the conduct of quality Clinical research and trials. From a meagre 1.2 % of global trials carried out in India at present to 10% could substantially augment revenues for the Indian industry and by 2012 a turn over of around $ 5 billion is a distinct possibility.

# GOOD LABORATORY PRACTICES (GLP)

**By Dr. N. Murugesan**
Director- Incharge, Central Drugs Testing Laboratory, Chennai

## Introduction:

Good Laboratory Practice (GLP) is a vast subject in its own, but it must be accepted that it complements GMP and without GLP it is difficult to achieve accurate results which may in turn lead to reprocessing or reworking of the final product. One important challenge for an analytical laboratory is staying in regulatory compliance while maintaining maximum output. Simultaneous productivity and compliance can only be achieved by laboratories that have competent chemists, high quality managers and a strong QA system.

Good Laboratory Practice (GLP) embodies a set of principles that provides a framework within which laboratory studies are planned, performed, monitored, recorded, reported and archived. These studies are undertaken to generate data by which the hazards and risks to users, consumers and third parties, including the environment, can be assessed for pharmaceuticals, agrochemicals, veterinary medicines, industrial chemicals, cosmetics, food and feed additives and biocides. GLP helps assure regulatory authorities that the data submitted are a true reflection of the results obtained during the study and can therefore be relied upon when making risk / safety assessments.

## 1. What is GLP?

GLP generally refers to a system of management controls for labs, manufacturing and research organisations to ensure consistency and rehabilitation results as per national regulations. GLP is a quality system concerned with the organizational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported. Laboratories adopting Good Laboratories Practices (GLP) should have a written quality policy, quality objectives and well defined organisational structure.

## 2. GLP for Non-Clinical Laboratory Studies:

It is clear by the term, "non-clinical laboratory study" that studies utilizing human subjects, clinical studies, or field trials in animals are not included. However, taking into consideration the definition of "test system" and "non-clinical laboratory study" together it makes clear that the scope of coverage is confined to studies performed on animals, plants, micro-organisms or subparts thereof. There is a wide range of products for which safety data is required by the agency. Examples of these include

- Implantable medical devices;
- Indirect food additives which may occur in food in small quantities;
- Direct food additives which may be consumed on daily basis in larger quantities;
- Animal drugs intended for use in pets and other companion animals of social importance;
- Drugs used in food producing animals;
- Radiation products used in the diagnosis and / or treatment of a disease or condition;
- Vaccines;
- Blood products & derivatives

GLP should be applied to the non-clinical safety testing of test items (natural or biological origin and living organisms) contained in :

- pharmaceutical products
- pesticide products
- cosmetic products
- veterinary drugs
- food and feed additives
- industrial chemicals

### 3. GLP Guidelines:

These GLP regulations provided the basis for developing the Organization for Economic Cooperation and Development (OECD) Principles of Good Laboratory Practice. These were developed by an Expert Group on GLP established in 1978 under the special programme on the control of chemicals. The group was chaired by Dr. Carl Morris of U.S. Environmental Protection Agency.

The OECD Good Laboratory Practice (GLP) guidelines embody a set of principles that provide a framework within which laboratory studies are conducted. GLP concerns all aspects of a laboratory study from initial planning of the work to archiving of the study data. The purpose of GLP is to help assure regulatory authorities that the data submitted are a true reflection of the results obtained during the study and therefore may be relied upon when identifying hazards and assessing risk.

The OECD principles of GLP were first published by the OECD in 1982 in the Testing of Chemicals and subsequently revised in 1997. These principles were adopted by the European Community (EC) and published in the appendix to Directive 2004/10/EC. As a result of this directive EC member states must incorporate into their national laws the requirement for all non-clinical safety studies, which are listed in sectored directives, to be conducted to GLP, and that the premises conducting such studies must be regularly inspected by a national authority.

### 4. Good Laboratory Practice Regulations/Amendment:

The Food and Drug Administration (FDA) issued a final rule on October 5, 1987 that amended the regulations that specify good laboratory practice (GLP) for nonclinical laboratory studies. The amendments clarify, delete or amend several provisions of the GLP regulations to reduce the regulatory burden on testing facilities. The changes also achieved a substantial reduction in the paperwork burden imposed upon the regulated industries by the current regulations. Significant changes were made in the provisions respecting quality assurance, protocol preparation, test and control article characterisation, and retention of specimens and samples based on FDA's experience in implementing the regulations. The agency determined that the changes would not compromise the objective of the GLP regulations, which was to assure the quality and integrity of the safety data submitted in support of the approval of regulated products.

### 5. GLP significance in India:

In India, increasing toxicological awareness and consumer protection awareness led to the need of GLP guidelines. GLP guidelines were formulated in 1983. Major progresses were not made for a decade because of lack of mobilization of adequate resources. However more recently Indian government agencies have taken action to ensure that laboratories are able to comply with GLP Standard.

Analytical laboratories are not immune from unexpected problems like power failures, instruments breakdown, accidental spills, etc. These however don't cause regulatory problems since the reasons for repetition can be justified. A Quality Assurance system that includes regularly scheduled equipment calibration, coupled with monitoring tools will be able to determine whether bad data are due to analytical system problems (equipment methods) or chemist error. Analytical system problems can be fixed or explained, but chemist errors may or may not be explained in spite of laboratory investigation.

All the deficiencies in a laboratory can be minimized by proper training through Standard Operating Procedures that describe both basic laboratory techniques and general laboratory procedures. The laboratories organisation should meet the necessary requirements in the areas listed below:

1. Organisation Structure
2. Personnel
3. Equipment
4. Maintenance, Calibration, Validation and Testing of the Equipment
5. Standard Operating Procedures
6. Reagents and Solutions
7. Raw Data and Records
8. Animal Care
9. Microbial Cultures
10. Test and Control Article Characterization
11. Protocol
    Records Storage and Archival

**Quality Control:**

The universal regulatory process applied to problems of product quality, is called as "quality control".

Under WHO GMP text, quality assurance has been defined as under:

*"Quality control is a part of concerned with sampling, specification and testing and with organization, documentation and release procedures which ensure that necessary and relevant tests are actually carried out and that materials are not released for use, nor products released for sale or supply, until their quality has been judged to be satisfactory. Quality control is not confined to laboratory operation but must be involved in all decisions concerning the quality of the product".*

The concept may be further simplified by starting that it is implementation of good clinical practices (GCP), good manufacturing practices (GMP), good laboratory practices (GLP), good pharmacy practices (GPP) and any other measures taken to achieve the intended objectives. In context with pharmaceutical industry, quality assurance can be represented as:

**Quality assurance = GCP + GMP + GLP + GPP + other measures**

WHO GMP text also states that the system of quality assurance appropriate to the manufacture of pharmaceutical products should ensure that

*"Pharmaceutical products are designed and developed in a way that takes account of the requirements of GMP and other associated codes such as those of good laboratory practice (GLP) and good clinical practice (GCP)".*

## 6. GLP Guidelines for Laboratories:

Reading of GLP guidelines is reserved for those nights when insomnia threatens you and you need a good defence toward it. But still a brief synopsis from those guidelines is absolutely necessary for us at any cost.

The GLP guidelines are divided into nine subparts dealing with general provision, organisation and personnel, facilities, equipment, testing facility operations, test and control sample, protocol for and conduct of laboratory testing, records and reports and disqualification of testing facilities. The following is the summary of GLP requirements:

**(a) Personnel:**

Personnel must possess appropriate education, training and experience to perform the assigned tasks. The lab must have the number of personnel required to perform each task as mentioned in the Standard Operating Procedure (SOP). Personal must take all necessary precautions to avoid contamination of any testing materials.

Information regarding the scientific disciplines, education, training, or expertise of the personnel participating in the analysis should be maintained. Efforts should be made to provide adequate job training and to qualify those individuals to perform the assigned duties. The management should provide sufficient persons for the timely and proper conduct of the analysis according to the protocols.

**(b) Responsibilities:**

- The management must treat a quality assurance unit (To assure the test materials are assayed as required).
- To make available personnel, resources, facilities, equipment, materials and methodologies as scheduled.
- Assure that the testing personnel clearly understand their duties and assure that any deviations from protocols and SOPs are communicated, corrected and documented.
- Unforeseen circumstances are noted and corrective active is taken and documented.
- QA SOPs and documented related to all typing works should be made available for regulatory inspections.

**(c) Facilities:**

Testing facility should be suitable in size. Separate areas are needed for receipt, storage and preparation of products. The GLP regulations require that the testing facility be suitable in size and construction. A separate laboratory operations area is needed. Storage space to archive specimens and data must be adequate. To avoid contamination and mix-ups between test and control articles, separate areas are needed for receipt, storage and preparation of materials and the storage of products.

**(d) Instrumentation:**

Instrumentation must be appropriate design and have adequate capacity to function per the protocol and SOP. A detailed written SOP is needed for each instrument. All instrumentation must be adequately operated, inspected, cleaned, maintained, tested, calibrated and standardized. Equipment performance, use and maintenance are documented.

**(e) Standard Operating Procedures (SOP):**

Standard Operating Procedures (SOP) are written procedure for the different activities being conducted in a laboratory. They define how to carry out protocols specified activities. They should be written in a chronological order testing different steps leading to analysis of drugs. The GLP SOP states exactly how the procedure is to be done each time, every time. The SOP must be current, clearly written, immediately available to staff, adhered to and authorized. A historical file of SOPs is maintained. The regulations list those procedures requiring SOPs. It is always advisable to allow acceptable approaches for any method, if a more specific, restrictive and defined activity is not necessary to assure quality parameters.

**(f) Reagents and Solutions:**

Reagents and solutions are labelled with their identity, titre or concentration, storage requirements and expiration date. Reagents and solutions must not be used if deteriorated or outdated.

**(g) Animal Care:**

The guidelines governing animal care are quite detailed. The reader should consult the regulations for further information.

**(h) Test and Control materials:**

The identity, strength, purity, composition and stability of test and control material must be determined and documented. They should be handled in such a way to ensure receipt documentation, proper identification, appropriate storage and adequate distribution process to avoid contamination, deteriorate or damage.

**(i) Data recording:**

Since consumer safety decisions are based on lab data, the lab must ensure quality and integrity of all the data it produces through proper documentation. All data entries should initial and identification of equipment used should be entered or authorized.

**(j) Final report:**

The final listing report of the lab must state the name and address of lab, start and end dates of test, objectives and procedure of the protocols, methods used and identification of test and control articles.

**(k) Archives:**

Archiving is an assigned responsibility because access to the archives is restricted to authorized personnel only. Archiving must be timely and all archived data is indexed to permit expedient retrieval.

## 7. Adherence to National and International GLP Guidelines:

Ideally, all data supporting the validity of a test method should be obtained and reported in accordance with GLP guidelines (i.e., OECD 1998; EPA 2003a, 2003b; FDA 2003). These guidelines provide an internationally standardized approach for the reporting requirements of studies designed for regulatory submissions, internal audits of laboratory records and data summaries, the archive of study data and records, and information about the test protocol and laboratory personnel, to provide assurances regarding the integrity, reliability, and accountability of the study.

**8. Data Quality Audits:**

Formal assessments of data quality, such as a QA audit, generally involve a systematic and critical comparison of the data provided in a study report with the laboratory records generated for the study.

**9. Availability of Laboratory Notebooks or Other Records:**

All records are stored and archived by the participating laboratories and are available for inspection.

**10. Need for Data Quality:**

Data quality is a critical component of the validation process. To ensure data quality, all data generated during the validation of a test method be available, along with the detailed protocol(s) under which the data were produced. Original data should be available for examination, as should supporting documentation such as laboratory notebooks. Ideally, the data should adhere to GLP guidelines.

**11. Reporting Deviations Guidance Document:**

The purpose of this guidance document is intended to provide information on the management and documentation of deviations from SOPs and study protocols under the direction of the University of Texas Medical Branch-Galveston (UTMB-Galveston) personnel participating in Good Laboratory Practices (GLP) facility operations and studies. Individual laboratories may establish internal business operations to handle such deviations, but the minimum requirements are stated within this document.

**12. Responsibilities:**

***Associate***

- Reports deviation from protocols and/or SOPs.
- Submits the Deviation Reporting Form to the Study Director.

***Study Director***

- Assures deviations from study protocol and/or SOPs are reported and documented.
- Assures corrective actions are taken and documented.
- Investigates unforeseen circumstances that may affect the quality and integrity of the GLP study.
- Acknowledges the deviation after the completion of the deviation reporting process.
- If the deviation involves another GLP regulated area, notifies the Study Director/Unit Management responsible for the area involved in the deviation.

***Unit Management***

- Assures Study Director is aware and acknowledges the deviation.

***QAU***

- Audits deviation reporting process for compliance with study protocol, SOPs, and GLP regulations.

## 13. Types of Deviations:

***1. SOP Deviation***

A SOP deviation can be a planned one-time change for a particular study or it can be an inadvertent change due to an oversight, equipment failure, etc.

SOP deviation may relate to a specific study or they might occur as a change to a facility type procedure such as the schedule for equipment maintenance or QAU facility inspections.

***2. Protocol Deviation***

A protocol deviation is an inadvertent change from a particular study protocol due to an oversight or error. A planned change from a protocol should be addressed as a protocol amendment.

## 14. When to document a deviation?

Any deviation from an established SOP or protocol should be documented as soon as possible by the individual planning or discovering the change.

Documentation needs to include a description of the change;

- ► The reason for the change;
- ► The date discovered; and
- ► The dated signature of the individual recording the change

## 15. SOP deviations:

***Study Specific***

For study specific SOP changes, the study director needs to assess the impact to the quality and integrity of the study and sign (authorize) SOP changes that are specific to the study. This documentation is retained with the appropriate study file.

Any permanent or reoccurring planned changes established to a GLP SOPS shall be authorized by the study director and shall be documented in the raw data.

***Equipment***

Changes to facility SOPs are approved/authorized by the supervisor of the area. For example, a deviation to a centrifuge maintenance SOP would be signed by the supervisor of that laboratory and the deviation report maintained in that centrifuge's equipment notebook.

***Protocol Deviation***

For protocol deviations the study director also needs to assess the impact to the quality and integrity of the study and sign and date the Deviation Documentation Form. The completed form shall be maintained in the study file.

***Deviation Investigation***

Upon receiving the Deviation information, it is suggested that the Study Director shall:

- ► Identify the root cause of the deviation.
- ► Identify the scope of the deviation.
- ► Assess the impact of the deviation on the GLP study.
- ► Evaluate the protocol or SOP involved in the deviation.
- ► Assess the adequacy of the study's support components such as SOPs, training, staffing, and equipment if necessary.
- ► Document the findings.

### 16. Correction Action and Preventive Action:

After the completion of deviation investigation, the Study Director shall:

- ► Implement action to mitigate the consequences of the deviation.
- ► Correct the cause of the deviation to prevent future occurrences.

### 17. Actions Resulting from GLP Non-compliance:

Where only minor non-compliance have been found, such that the integrity of studies will not be compromised, the GLP MA may grant or continue to grant GLP compliance, as appropriate, provide the Receiving Authority which requested a specific study audit with a detailed report of the findings. Where major non-compliances are found, the action taken by the GLP MA is dependent upon the particular circumstances of each case. Action may include:

a) Issuing a recommendations to a Receiving Authority that a study be rejected;
b) Issuing a statement to the facility and the Receiving Authority of the inadequacies or faults found which might affect the validity of studies conducted in the facility; or
c) Refusing to grant or continue to grant recognition of GLP compliance. Such an action may include the removal of the facility from the program, a corresponding notation in the GLP MA list of inspected facilities and notification to the applicable receiving authorities, and the OECD.

### 18. Facility GLP Compliance Status:

1. OECD GLP Assessors must report facility compliance to each other and do so as: Incompliance; Pending; or Not-in-compliance. However, being declared Not-in-compliance can have grave consequences to a facility as it could mean a world-wide receiving authority rejection of study submissions. The GLP Assessors will use the category Not-in-compliance only as a last resort.
2. If a facility inspection or study audit identifies GLP non-compliances which will not significantly compromise the integrity of studies, and the facility proposes to address them within an acceptable time frame, an In-compliance status may be granted to the facility.
3. If non-compliances are not or cannot be addressed within an agreed period, the facility's compliance is deemed to be Pending until further notice of satisfactory completion of said actions. Typically, if the facility cannot complete the required actions within three months, it shall be subject to a Not-in-Compliance status. For a recognized facility the In-compliance status will be changed to Pending (with qualification) and can lead to a Not-in-compliance (Withdrawn) status.
4. A facility that does not adhere to the requirements shall be subject to a Not-in-compliance (Withdrawn) status, and shall be withdrawn from the program.

### 19. Why GLP training is important?

In order to avoid all the above said deviations and GLP Non-compliances, GLP training is recommended for the personnel involved in the laboratory. Any organizations conducting a non-clinical study is required to follow good laboratory practices, which help assure regulatory authorities that the data submitted is a true reflection of the results obtained during the study and can therefore be relied upon when making risk/safety assessments. GLP training is important so your organisation can implement GLP and produce reliable data that complies with regulatory agencies, GLP guidelines, specifications and regulations.

## 20. Conclusion:

The GLP helps the scientists to recognise the opportunities to contribute to quality laboratory testing for public safety. The laboratory analysts who are well trained in quality managements will find those skills to be transferrable to other fields where quality of laboratory is important.

To stream line the good laboratory practices followed by different stake holders, Government of India has introduced a new schedule, namely Schedule L1, GLP-compliance which will be discussed in the future articles. GLP is not the matter for allopathic drugs alone. It is a thing to be followed by other system of medicines like Ayurvedic, Unani, Siddha, Homeopathy etc. to ensure the quality of drugs. As mentioned in the beginning of this article, Good Laboratory Practice is a vast ocean and I'm sure the efforts put down so far, may have thrown light on it.

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II. GLP Guidelines for Drug Testing Laboratories in India (CDSCO, Ministry of Health, Government of India).
III. UTMB GLP Guidance document www.UTMBGLPguidelines.com [UTMB-GUID-000-0001-Vol1]
IV. Guidelines for certification of compliance with Industrial Safety.
V. Good Laboratory Practice verus CLIA by Dr. Janine Dennis Cook.
VI. Guidelines on CGMP and Quality of Pharmaceutical products by S. Iyer.
VII. How to practice GLP by P.P. Sharma.


# GUIDELINES FOR FRESH PHARMACY GRADUATES LOOKING FOR AN OPENING


**By Sanjay Kumar Dasmohapatra**
Vice President - Technical
Medopharm, Chennai.


This article is aimed at providing knowledge about the manners and professional approach for job openings for Pharmacy professionals.

### STEPS TO FOLLOW FOR SURE SUCCESS IN INTERVIEWS:

**Be clear about you career goals based on your area of interest.**

Any profession is interesting but the results purely depend on the interest of the performer. So be sure and confident about your choice at the initial stage itself to avoid frequent changes at the later stage resulting in loosing of seniority. Even the hiring authority will ensure the same prior to appointment.

**Resume and Covering Letter: Plays a very important role for getting short listed.**

A resume cannot be of a general kind which you can take numerous photocopies and start applying blindly as if distributing handbills with a common covering letter having fill in the blanks to fill the addressee details manually and most of the time not filled and not signed. (A frequent experience of mine)

Read reviews about the companies in the net. Short list the companies you have gained interest related to your area of work. Visit their website to acquire sufficient knowledge about their mission, vision, infrastructure, best selling products, growth rate, opportunities, openings, future plans, etc. because it is not only for sake of salary you are seeking a job but job satisfaction and growth plays an important role for stability and future recognition

Once you have selected your profession and identified the companies, create your resume highlighting the strengths of yours related to that profession and use the keywords what the company is looking for that position and post it to the correct person as mentioned. When resumes are short listed through automated refining process based on the keywords, your resume will always get selected for the interview call or telephonic interview in the 1st Phase.

**Note:** Always cross check to ensure there is no spelling mistake and grammatical error or else resume will loose it's value giving a wrong impression about your image.
In this manner you have won the 1st round.

Your covering letter can create a big difference if framed in proper manner. It must be catchy highlighting your strengths related to the interest of company. It must be crisp, clear and not exceeding more than one page.

Do not restrict your choice only for the multinationals or top few companies what you have heard. There are many good companies of medium and large scale whom you might not have heard but their growth rates are potentially high. Those companies can really give good boost to your career although you may start with a very decent salary.

**Follow these 7 Golden Rules to achieve success in an interview:**

1. Never reach late. It is always better to reach 15 minutes early, cool down the heat and be comfortable. Recheck and confirm all the required papers are in place in the file to pull out when asked for. Few extra copies of resumes are available although submitted earlier, true copies of the certificates and other proofs are available for HR verification, passport size photographs are in stock. Even while waiting for interview, you might be getting watched through CCTV. So do not show your restlessness by cracking your fingers, shaking your leg, etc. Before appearing for the interview, the mobile phone must be switched off.
2. While attending an interview, always dress in formal attire with a confident and professional outlook; never apply strong perfume, the other person may be allergic; never smoke before attending an interview to beat the stress. It may prove fatal creating irritation in other person's mind. Be polite when meeting any official although he / she may not be the interviewer. Shake hands with confidence during self introduction. Maintain eye contact.
3. Your gesture will reflect confidence if you are well prepared related to little background information about the company, your subjects related to their requirement, etc.
4. Pay attention to the question being asked and understand before replying. Do not answer what you like to tell but reply what the interviewer is interested to know. If you are not clear, ask politely to repeat, ask for some hint for better understanding. If you are not aware about the subject, accept it and allow the person to ask next question rather than replying irrelevant. Never be overconfident and argue. Never blame past situation, people to cover your weakness. Be transparent, if you are not clear on any topic.

5. There are certain question which are very common, prepare yourself in advance by framing the replies. (Not listed due to space constrain, you can check with other colleagues who already faced multiple interviews). It will boost your confidence. Don't be too fast to prove you know the answer give pace while talking, judge by face reading to check if the interviewer is intending to ask some intermittent question. In this manner you will be in a position to hold his interest to continue with the dialogues.
6. If you are interviewed by multiple persons sitting on the other side, gaze at one person who is asking question and not all around as it will lower your confidence. Moreover you will create a situation, welcoming for overlapping questioning.
7. If any interview is fixed through some reference, do not be overconfident and attend without preparation hoping that you have a backup. Rather, you must be more serious and responsible to safe guard the position of the person who backed you by concluding the interview outcome in a better manner.

## WHAT EXACTLY INDUSTRY IS EXPECTING FROM THE PHARMACY GRADUATES?

**If joining in Production Department:**

Basic knowledge about the concept behind the formulation of different dosages , flow of manufacturing process, equipment/s used for manufacturing, knowledge about the excipients used in the formulations and their usage like binder, lubricant, coating agents, diluents, disintegrating agents, knowledge about the common APIs, basics of the environmental conditions required in core areas (sterile manufacturing and filling / non-sterile manufacturing and packing), classification of areas, understanding about contamination and cross contamination, importance of cleaning and validation, idea about the quality of water used in pharmaceutical preparation, type of dosages, some information on different types of packaging materials and their roles to safe guard the product quality, basic knowledge about cGMP requirements and its importance in pharmaceutical industry, the basic idea about SOP and importance of documentation,

**Note:** While undergoing industrial training (in between the course) all the above topics can be covered by the trainee for practical understanding.

If you are allergic or sensitive to dust / powder, certain drugs then it is always safe to select job option where you will not be getting directly exposed to such environment to safeguard your health. Tell it to the management before joining.

**If joining in Quality Assurance:**

The candidate must be having good hold on spoken English, dynamic, sincere, having logical mind with low acceptance towards compromises, having natural interest to investigate the root cause behind issues and can suggest solutions to resolve any problem, good subject knowledge, keen to learn and update self, having thorough knowledge about Drug and Cosmetic Act, WHO regulations and other international regulations for implementation of cGMP in line with their requirement who can take the responsibility for creating SOPs, impart training, carry out periodical quality checks, carry out internal audit, etc.

**Note:** If willing to join in Quality Assurance department make a habit to go through the different official websites of different MOH, understand their requirement by reading the guidelines, go through the warning letters issued as 483's. Go through GMP trends, Pharma Pulse magazine, IDMA bulletin, ICH guidelines, CDER guidelines, WHO guidelines, Revised Schedule M, Refer 21 CFR part 11, UK MHRA guideline, Health Canada guideline, MCC, SA guideline, ISPE and WHO guideline for HVAC, WHO guideline for water.

**If joining in Quality Control Department:**

You must have early experience and interest to handle sophisticated instruments like HPLC, HPTLC, GC, Spectrophotometer, etc. Have basic knowledge how these instruments are operated and calibrated. You must know how to carry out other chemical analysis, have basic knowledge about the chemicals, reagents, knowing how to do the dilutions, having knowledge about basic criteria of sampling, its importance, documentation, storage and analysis of sampling of Raw and Packaging materials, must be well versed with the stability guidelines and have gone through different Pharmacopeias like IP, BP, USP earlier during industrial training and knows which are the current versions been followed.

If willing to join in Microbiology department then you must focus on the requirements of environmental condition required in a Microbiology laboratory, good knowledge on pathogens and other micro-organisms. Must know how the sterile SCD agar plates are prepared, how the plates are exposed, how microbial assays are tested. How water is tested, what is LAL test, how Sterility test is carried out, what is MLT and why it is tested for oral formulations, operation, validation and calibration of Autoclave, Laminar air flow unit, etc.

**If joining in Marketing Department:**

You must be of dynamic nature with a good pleasing personality, your English must be good, get prepared for frequent traveling, lot of meetings with doctors, stockiest, chemists, managers. There are good and bad sides in this field, be ready to face challenges, competition, pressure but simultaneously handsome incentives, quick promotions, growth is always possible for the smart working, deserving candidates.

**If joining in Regulatory and Documentation:**

This is a good department and in future the demand will increase constantly for search of experienced candidate in this field. More and more countries are implementing stringent requirements and registrations of drugs in other countries are not simple now like earlier days.

The candidates must go through the guidelines of different MOH where they clearly specify their countries requirement to register a product. Have knowledge about the pharmacopeias, understand the production process, have basic idea about the QC testing. Without understanding these areas it will be difficult to compile the documents and attend the technical queries.

For any further guidance, feel free to email at the following email address:
sanjaydas@medopharm.com

# INFORMATION

## List of Government Recognised Bioavailability / Bioequivalence Testing Centres in South India

**1. M/s. Actimus Biosciences Pvt. Ltd.**
4th floor, Varun towers, Kasturba marg,
Siripuram, Vishakapattanam - 530 003

**2. M/s. Apotex Research Pvt. Ltd**
Plot No: 1, Bommasandra Industrial Area,
4th Phase, Bommasandra Industrial Estate
(Post office), Bangalore 560 009
Phone No: 91-080 22891000
Fax No: +91 080 22891099

**3. M/s. Clingene International Pvt. Ltd.**
a) 20th K. M, Hosur Road, Electronics City P. O
Bangalore - 560 041

b) Sargar Appollo Hospital,
Bangalore 560 041

c) Plot No: 31 P-11, Electronic City Phase II,
Bangalore

**4. M/s. Clintrac International Pvt. Ltd.**
Easr II, III floor of Vyedhi Hospital
82, EPIP Area Whitefield, Managalore 560 066

**5. M/s. College of Pharmaceutical Sciences**
A Unit of Dr. T. M. A Pai Foundation,
Manipal 5761191, Karnataka

**6. M/s. Gokula Education Foundation**
Ramaiah Educational Institutions
MSRIT Post, MSR Nagar, Bangalore 54

**7. M/s. GVK Biosciences Pvt. Ltd**
7th floor, Swarna Jayanthi Commercial complex
Ameerpet, Hyderabad 500 038

**8. M/s. Huclin Research Ltd.**
Ticel Biopark, Fourth Floor,
CSIR Road, Taramani Chennai 600 113

**9. M/s. Icon Clinical Research**
7-1-58, 2nd floor, Amrutha business complex,
Opp Lal Bungalow, Hyderabad 500 016

**10. M/s. JSS College of Pharmacy**
Ooty (T. N.), Roacklands, Ootacamund
Tamilnadu (0423) 43393, 438747, 43647

**11. M/s. Lotus Labs Lts.**
No: 582, KCA Enclave, 8th block,
Koramangala, Bangalore 560095
Fax No:91-80-5704176 Phone: 91-80-5704175

**12. M/s. Lotus Labs Lts.**
No: 5, 80 ft,road, S. T. Bed 4th block,
Koramangala, Bangalore 560 095

**13. M/s. Lotus Labs Lts.**
C/o Sharon Cancer centre
18, Tanmang road, Vinayagumpatti,
Salem - 636008

**14. M/s. Lotus Labs. Pvt. Ltd.**
"Lotus House" # &, Jasma Bhawan Road,
Opp. Gurunanak Bhawan Millers Tank Bed Area,
Vasanth Nagar, Bangalore 560052
Phone No: 91-80-22370912/13/14/15.

**15. M/s. Lotus Labs Pvt. Ltd.,**
St. John's National Academy of Health Services;
141/2, John's Nagar, Opp. Koramangala III block,
Bangalore- 560034

**16. M/s. Lotus Labs Pvt. Ltd.,**
# 56 (Old no: 116), Ragas building, 4th floor,
Dr. Radhakrishnan Salai
Mylapore, Chennai - 600 004

**17. M/s. Manipal Acunova Pvt. Ltd**
Manipal Towers, 14 Airport Road
Bangalore

**18. M/s. Manipal Acunova Pvt. Ltd**
Mebius Towers, SJR I-Park, EPIP,
Whitefilld, Bangalore - 560 066

**20. M/s. Manipal Acunova Pvt. Ltd**
5th Floor, dental block, KMC Hospita
Attavar, Mangalore

**21. M/s. Microtherapeutic Research Lab. Pvt. Ltd**
Hasthinapuram, Main road, Nehru Nagar
Near MIT Gate Campus
Chrompet, Chennai - 600 044

**22. M/s. Quest Life Sciencs (P) Ltd.**
SDF III, MEPZ, Tambaram,
Chennai 600 045

**23. M/s. Dr. Reddy's Labs Ltd.**
7-1-27 Ameerpet, Hyderabad 500 016

**24. M/s. Reliance Clinical Research services**
1st phase Relclin BE and BA study facility,
2nd Stage, BTM layout, Bangalore 560 076

**25. M/s. Semler Research Centre Pvt. Ltd**
No: 18, Tanmag Road, Vinayagampatti
Salem 636 008

**26. M/s. Sipra Labs**
Space 7 on 4th floor, Nilgiri, Aditya Enclave
Nilgiri, Amarpreet, Hyderabad

**27. M/s. Suven Pharma Ltd.**
5th floor, Serene Chambers, Road no: 7,
Banjara Hills, Hyderabad 500 034

**28. M/s. Trident life sciences**
Plot No: 33 to 35, Mirra hospital
Ist floor, Alluri Seetaramju Colony,
Opp. JPN Colony, Mayapur,
Hyderabad 50

**29. M/s. Trident life sciences**
Sy. NO. 66(Part) and 67(Part), Miyapur
Serilingampally Mandal,
Hyderabad 500 050

**30. M/s. Torrent Research centre, Pharmaceuticals**
Opp. Ashram house, Ahemedabad.

**31. M/s. Vimta Labs**
141/2 & 142 IDA. Phase II, Cherlapally,
Hyderabad 500 051,
Andhrapradesh.

**32. Vimta VSH Research Centre(A Unit of Vimta Labs ltd.)**
The Voluntary Health Services, T. T. T. I Post
Adyar, Chennai 600 113

**33. M/s. Well Quest clinical research**
IVth floor, Mirra Kamshetty Mall
Ramanthapur. R. R. District
Hyderabad

***Source :*** *CDSCO, South Zone*

## Editorial Policy and Disclaimer

The objective of this newsletter is to impart current news to the readers and the newsletter is circulated free of cost. Description or reference to any information or publication does not implement endorsement by us.

Every effort has been made to ensure the timeliness and accuracy of information presented in this newsletter. The authors, editors and publisher will not in any way be held responsible for the timeliness of information, errors, omissions and inaccuracies in this publication. Users are advised to recheck the information with original resource material before applying to patient care or other purpose.

This issue of Pharma Web is also available online at the Trust website www.pictrust.com

## List of Government Approved Drug Testing Laboratories in Tamilnadu

**1. M/s. Actavis Pharma**
**Development Centre Pvt. Ltd.**
Ticel BIO Park, III Floor, Taramani, Chennai- 113

**2. M/s. Apex Laboratories Ltd.**
B-23, SIDCO Pharmaceutical Complex
Alathur 603 110, Thiruporur
Kanchepuram District

**3. M/s. The Astoria Research & Analyticals**
No, 114/82, Mount Road
Guindy, Chennai 600 032

**4. M/s. Atoz Pharmaceuticals P. Ltd.**
B-23, SIDCO Pharmaceutical Complex
Alathur 603 110, Thiruporur
Kanchipuram District

**5. M/s Burgeon Pharmaceuticals (P) Ltd.**
No: 82, Senkundram Vilalga
Gokulapuram, Singamperumal Koil 603 204

**6. Dr. Ceeal Analytical Labs**
(Unit of C. L. Baid Mehta College of Pharmacy)
,No.1/8, Balaji Nagar, Ambattur
Chennai 600 053

**7. The Director Central Institute of Plastics Engineering Technology**
(Ministry of Chemical Fertilizer)
(Govt. of India) Guindy, Chennai 600 032

**8. M/s. Chennai Industrial**
**Co-operative Analytical Labs Ltd.**
Ind.686 (Mical), A-3, Sidco Industrial Estate,
Alathur 603 110
Kanchipuram District

**9. M/s. Hexa Analytical Research Laboratories**
3/340, Main Road, Madandapuran Porur
Chennai 600 116

**10. M/s. The Principal**
**J. S. S. College of Pharmacy**
Mahavidhya Peedam, Rocklands
Uthagamandalam

**11. M/s. The Madras Industrial**
**Co-operative Analytical Laboratory Ltd.**
626, Thiru- vi-Ka Industrial Estate
Tinu Sector, Guindy, Chennai 600 032

**12. M/s. Madras Medical College Testing Labs**
Madras Medical College
Dept of Pharmaceutical Chemistry
Chennai 600 003

**13. M/s. Madras Research and Analytical Lab**
No: 137 B, Old Mahabalipuram Road
Thorapakkam, Chennai

**14. M/s. Malladi Drugs and**
**Pharmaceuticals Ltd.**
(Unit III), Plot No: 7B & 7C, Sipcot
Industrial Complex, Ranipet 632 403

**15. M/s. Medopharm**
No:1 Thiruvika Road, Chennai 600096

**16. M/s. Micro Labs Ltd.**
No: 92, Sipcot Industrial Complex
Hosur 635 126

**17. M/s. Mount Mettur Pharmaceuticals Ltd.**
C-2, Sipcot Industrial complex
Gummidipoondi 6014 201

**18. M/s Pharma Research &**
**Analytical Laboratory**
No: 8, Old Trunk Road
Pallavaram, Chennai 600 043

**19. M/s. The Rajapalayam Laboratories**
566/15, 1st Floor, Rajapalayam Road
Chatrapati 626 102

**20. M/s. Sai Mirra Innopharm (P) Ltd.**
Plot No: 288, Sidco Estate, Ambattur
Chennai 600 098

**21. M/s. Sargam Laboratory Pvt. Ltd**
**Block No: A (I&II) Floor)**
2, Ramavaram Road, Manapakkam
Chennai 600 089

**22. M/s. S. G. S. India Ltd.**
Genesis Laboratory No: 21, New Street
Kottur, Chennai 600 032

**23. M/s. Spic Pharma Analytical Labs**
No: 3 & 4, NH 7 Maraimalai Nagar 603 209

**24. M/s. Sri Meena Surgical Cotton Laboratory**
'No. 24-A14, Chatrapatti Road
Samusigapuram, (Via) Rajapalayam

**25. M/s Tablets (India) Ltd.**
179, T.H. Road, Chennai - 600 081. Tamil Nadu

**26. M/s. Testing Laboratory for Oil and Soap**
Tamilnadu Khadi & Village industries Board
(Testing Cosmetics), Kuralagam
5th Floor, Chennai 600 108.

***Source:*** *Director of Drugs Control, Tamilnadu*

## The modalities for grant of WHO - GMP Certificate of Pharmaceutical Product by CDSCO, DGHS, Ministry of Health & Family Welfare , Govt. of India from 1st October, 2009

In continuation to the letter No. X.11053/1/2009-D dated 1/9/2009 issued/published (on CDSCO website) by this directorate wherein, it was decided to issue the WHO GMP (Certificate of Pharmaceutical Product) by Drugs Controller General (India) , the modalities of the scheme as decided are being clarified here as under for benefit of all concerned.

The application for grant of WHO GMP (Certificate of Pharmaceutical Product) shall be made to respective zonal/sub zonal officers as per the requirement prescribed below. The COPP will be issued by zonal/sub zonal officers on behalf of Drugs Controller General (India) after inspection and satisfactory clearance by CDSCO officers as per WHO GMP guidelines.

The Certificate of Pharmaceutical Product will be issued only in the format recommended by WHO (Model COPP annexed)

All COPPs including additional products etc. after 1st October 2009, will be granted by DCG (I) / identified CDSCO officer on behalf of DCG(I) after following the procedures.

Those who are already holding COPP shall continue to hold it till its expiry.
Initially, fees is not going to be charged for application till final decision is taken and published in this matter. For any further Clarifications the applicant may contact respective zonal/sub zonal offices.

**General requirements for submission of application for issue of COPP:**

1. A forwarding letter/application shall be addressed to DDC(I)/ADC(I) of respective CDSCO zonal/sub zonal offices with copy of covering letter & product summary sheet to DCG(I) (WHO-cell) by authorized person only.

2. The forwarding letter/application shall be accompanied with List of products applied for grant of COPP, along with the product permission copy (manufacturing license issued by the SLA) & notarized product summary sheet, site master file as per WHO-GMP requirement.

**Proforma for Product summary sheet:**

| S. No. | Name of the product | Number of batches produced in last two years (with scale R&D /Pilot/ Commercial) | Stability studies (maximum period completed) in months Accelerated / Real time | | Process Validation | Analytical Method Validation | Cleaning Validation/ verification | Annual Product Review | If permitt -ed by DCGI Y/N/NA |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | Completed/ Not completed | Completed/ Not completed | Completed/ Not completed | Completed/ Not completed | |
| | | | Acc | R. T. | | | | | |
| 1 | Example Tablet | 20 (Commercial) | 6 M | 36 M | Completed | Completed | Completed | Not Completed | Y |
| 2 | | | | | | | | | |
| 3 | | | | | | | | | |

3. List of major/master documents like master validation plan, quality manuals, specifications, master formula records maintained by firm and list of SOP's (to indicate the documentation system of firm)

4. Manufacturing layout (it is preferred if men and material flow, pressure flow drawing are also given)

5. HVAC schematics and details of areas (Where in clearly specify the filtration level & classification of core areas & rooms as required in section 3.3 of SMF) and Water system Schematic diagrams along with the components

6. List of personnel (with designation, qualification & experience), List of equipments, instruments, utilities along with make and model & capacity.

7. List of primary & secondary Impurity and Reference standards/cultures available with the firm (relevant to the applied products for grant of COPP).

**Note:** The names of the officers of CDSCO who have been delegated the power to sign and issue the COPP certificate as well as all the other annexure and documents may be seen in the website www.cdsco.nic.in

## SHRI BHASKARAN ELEVATED AS DIRECTOR OF DRUGS CONTROL, TAMILNADU

We are pleased to inform that Shri. Bhaskaran, Director of Drugs Control (in charge - DC) has been elevated as full-time DIRECTOR OF DRUGS CONTROL, TAMIL NADU on 29.09.2009.

He is a member of Advisory Board of our newsletter Pharma Web. We congratulate him and wish him success.

# NEWS

## Delhi HC Ruling a boost for firms making copies of patented drugs

In a major win for Indian companies, the Delhi High Court (HC) on Tuesday dismissed German drug major Bayer Healthcare's attempt to stop the drug regulator from giving marketing approval to Indian company Cipla for the generic version of Bayer's patented cancer drug, Nexavar.

This case was watched by the pharma industry and health activists because it had much wider ramifications. A favorable decision for Bayer would have given legal mandate to global pharma major's demand of not granting marketing approval to low-cost drug makers for patented drugs. This would have become an entry barrier for Indian companies. But the ruling now allows companies to launch generic versions of patented drugs with the risk of paying damages, if found guilty of patent infringement.

Last November, the Delhi HC had prevented Drug Controller General of India (DCGI) from giving marketing rights to Cipla for the generic versions of Nexavar after Bayer alleged that it would infringe upon its patent. It also said that Cipla's drug was spurious. The German firm got the patent for Nexavar, (chemical name Sorafenib tosyalte) in India in March 2008. Indian patent laws provide the patent holder exclusive marketing rights for 20 years with no competition from generic low-cost companies.

Pratibha Patil, Cipla's lawyer for this case, told ET the HC dismissed Bayer's pleas because unpatented drugs are not spurious drugs and Bayer's petition was an attempt to weak public policy. Besides, the HC asked the German firm to pay Rs. 6.75 lakh to the government and Cipla as legal cost. Cipla's joint MD Amar Lulla said, "It's a fair, logical and historic decision and patients will benefit from the ruling." Alok Pradhan, VP (Corporate Communications), Bayer group in India, said "Bayer Healthcare disagrees with the court's decision and will consider its legal options in this regard".

***Source:*** *The Economic Times, 19th August 2009*

## E-governance for clinical trials soon

The Health Ministry is planning to introduce e-governance for clinical trials in the next four years. The move will enable drug companies that want to carry out clinical trials in India to register online from any part of the world. Once the required approval for conducting the trials is obtained, the companies can also submit research data online to the country's drug regulator, Drug Controller General of India (DCGI), seeking marketing approval for their drug.

The idea is to fast-track the process of clinical trial approvals in the country. India would be the first country to implement such a concept, a Health Ministry official said. The drug regulator has proposed to install software which would facilitate e-governance of clinical trials and ease the process of giving approvals. "With e-governance in place, companies would be able to send online all required information for filing for clinical trial approval. The DCGI office would then examine the data provided online and generates queries," the official said on conditions of anonymity. To maintain confidentiality, once the data is fed into the system, the software will split the information into components and no one individual would have an access to the complete information provided by a company. "Confidentiality of the

data submitted by companies would be taken care of," the official added. The software will automatically send relevant data to various departments for clearances.

The drug regulator would deliver online approvals to companies after validating all the information submitted by companies. According to the official, it would take about four years to put the system in place and e-governance is expected to be implemented in the country by 2013.

***Source:*** *The Economic Times, 20th August 2009*

## Low rains hit drug sales too

Retail sales of medicines grew 8.9% in July over the year-ago period, down from 18.3% in the month of June, due to deficient monsoon. This is because sales of anti-infectives, cough & cold preparations, anti-diarrheals, anti-asthmatics and anti-inflammatory saw lower growth. They normally show a seasonal spurt in the month of July due to rainfall, consultancy firm ORG IMS said. The Rs. 36,000-crore drug industry has been growing at 14-15% over the last few years, but sales in June rose 18.3% as stockists bought more drugs in anticipation of higher demands during the rainy season. ORG IMS tracks the sales figures of stockists and not the actual sales of drugs sold by over five lakh chemists across the country.

***Source:*** *The Economic Times, 28th August 2009*

## Ease control on clinical Trials

Multinational Pharma firms asked the government on Thursday to lift restrictions on clinical trials during the initial stages to attract more investments and high quality research in the sector. Speaking at industry body CII's Life Science Conclave, Pfizer Managing Director Kewla Handa said clinical trials market is huge but phase-I is not open to multinationals. "Why not allow phase-I trials to MNC's?" Handa asked. For new molecules developed outside the country, the phase-I clinical trials rules governing the regulation have not yet been framed completely.

***Source:*** *The Economic Times, 28th August 2009*

## Mission China: Drug inspectors to visit manufacturing facilities

The Health Ministry is planning to send a team of drug inspectors to China to inspect drug manufacturing facilities that supply bulk drugs to India. Bulk drugs are raw material used for manufacturing medicines or formulations. India imports a huge quantity of bulk drugs from china due to the low pricing of Chinese raw material. The country's top drug regulator Drug Controller General of India (DCGI) has recently raised concerns about the quality of the drugs imported from china and used in medicines manufactured in India, a health ministry official said.

"The drug regulator has raised certain issues related to the quality of bulk drug imported from China. Since we import huge qualities of raw material from china and use them in medicines that are sold domestically as well as exported to other countries, we must check and inspect the facilities from where we are sourcing the raw material," the official said.

Indian drug manufacturing firms depend on the bulk drugs or raw materials which are imported from China. According to an industry official, China is the largest supplier of raw material for bulk drugs to India and controls over 70% of the Rs. 15, 000-crore annual market for imported bulk drugs.

"China has been dumping a large number of cheaper bulk drugs into the Indian market for the last ten years. Despite the government imposing anti-dumping duty on several bulk drugs and active ingredients and intermediates, the import of cheaper drugs has continued," the industry official said. The government is now of the view that quality of medicines should not get compromised in order to have a pricing advantage.

The proposed move, to inspect the Chinese drug manufacturing facilities by Indian drug inspectors, comes close on the heels of confiscation of 700,000 doses of fake antimalarial drug, manufactured in China and bearing 'Made in India' label, in Nigeria.

The Chinese government has also recently admitted that the shipments confiscated by the Nigerian government had originated from China and it will take action against the manufacturers involved in it. Nigeria's drug regulatory authority, his National Agency for Food and Drug Administration and Control (NAFDAC) has identified 50 companies involved in the crime.

***Source:*** *The Economic Times, 7th August 2009*

## Low-cost version integral part

Global majors have accepted that low-cost versions of off-patented drugs have now become an integral part of their business. Indian firms can no longer rely on their traditional business model by busting drug patents of innovator companies as there are just a few patents left to target. A couple of years back, they used to confront each other. For example, GSK and Pfizer used to sue several Indian companies for allegedly infringing the patents of their drugs.

A senior executive from one of the Indian Pharma firms acquired by a global major said: "One can expect one or two buyouts of Indian companies and a few similar drug supply deals before the consolidation ends. The opportunity is too limited for an Indian company to remain focused on generic drugs alone and the global generic industry would be dominated by a handful of big companies."

Indian companies led by Ranbaxy, Dr. Reddy's, Cipla, Sun Pharma, Glenmark and Zydus Cadilla became a force to reckon with after they became the first to revoke patents of innovator companies and launch their own low-cost generic drugs. But now, they have either become a subsidiary or are supplying their drugs to the innovator companies.

Private equity firm ChrysCapital MD Sanjiv Kaul says other Indian companies will eventually have to enter into long-term supply agreements. And, they will realign their strategy for each market. "The one-size-fits-all strategy (make low-cost drugs) will no longer work. Companies will adopt different business models even within a particular geography," he said.

At present, generic drugs accounts for 15% or $90 billion of the $650 billion global drug market but emerge into a larger pie as global majors look for alternate revenue through generics, resulting in further consolidation.

CLSA's Pharma analyst Hemant Bakhru says the trend is not limited to India alone as companies like GSK and Sanofi Aventis have

Either partnered or bought generic companies globally. But there are pure generic firms such as Teva, Watson, Sun, Cipla and others in Europe that continue to bank on their low-cost drug development capabilities.

In the mid and late 90s, a few Indian companies such as Divi Laboratories, Dishman, Jubilant Organosys, Nicholas Piramal decided to focus on contract manufacturing and research to partner with global majors. But now, that has changed. Piramal Healthcare Director Swati Piramal said," After these acquisitions, the difference between a global innovator company and an Indian generic company is getting blurred. While one arm is filling patents, the other arm is busting them."

***Source:*** *The Economic Times, 3rd August 2009*

## NPPA may fine pharma cos Rs. 2k crore for over-pricing

Drug manufacturing companies such as Cipla, Ranbaxy, Johnson & Johnson and Dr. Reddy's Laboratories (DRL) may have to pay over Rs. 2,038 crore to the government for over-charging consumers on price-controlled medicines. Through a nation-wide survey and others tools of inspection, the drug price regulator National Pharmaceutical Pricing Authority (NPPA) has found that these pharmaceutical companies were overcharging consumers for several medicines or selling them without a price approval from NPPA.

The NPPA controls prices of 74 bulk drugs used as raw material to make medicines. Prices of all medicines containing one or more of these bulk drugs are also directly controlled by the pricing authority. Unlike decontrolled drugs, the prices of which can he hiked by up to 10% annually, manufacturers do not have the liberty to increase prices of drugs under price control on their own. Several essential medicines such as antibiotics, pain killers and ones for treating ailments such as cancer and asthma are part of the list of medicines where the pricing authority believes manufacturers have indulged in over-charging.

Out of the total Rs. 2,038 crore estimated by NPPA as "overcharged" amount, Cipla alone accounts for nearly Rs. 1,282 crore, a notification said. The pricing authority has also served over charging notices for around Rs. 136 crore to Ranbaxy, of which it has recovered merely Rs. 30 crore till july 2009. Johnson & Johnson has paid Rs.20.86 crore out of Rs. 40.65 crore that it wa asked tto pay for overcharging consumers the statement said. Similarly, the pricing authority has recovered around Rs. 11 crore from DRL out of Rs. 38 crore that it had fined the company on account of overcharging.

According to the statement, Cipla is accused of overcharging consumers for medicines such as salbutamol prescribed for treatment of asthma and antibiotics such as cloxacillin and ciprofloxacin used to treat a wide variety of infections. The pricing authority has also fined Ranbaxy for over charging consumers for medicines such as antibiotic Gramoneg and painkiller pentazocine apart from cloxacillin and ciprofloxacin. Several of the companies accused of over-charging including Cipla and Wyeth have already taken NPPA to court over the issue. The overcharged amount stuck in litigation is around Rs. 1, 905 crore. The findings of the statement are based on samples collected by NPPA analysis of the dta recevesd by the pricing autority from ORG-IMS and the complaints received from consumers, doctors and chemists from across the country.

The drug price regulator issues to pharmaceutical companies whenever evidence of overcharging is found against them.

***Source:*** *The Economic Times 21 August 2009*

## Pharma outsourcing to cross $2.3 b by'10

Riding over lower manufacturing cost coupled with availability of quality manpower with technical capabilities, the Indian pharmaceutical outsourcing industry is expected to reach $2.3 billion by the end of 2010, according to a report.

The report jointly prepared by global consultancy firm Ernst & Young and industry body OPPI (The Organization of Pharmaceutical Producers of India) said Indian Pharmaceutical contract manufacturing industry is growing at thrice the rate of the global outsourcing market, and is expected to reach $2.3 billion from $1.1 billion in 2008.

"India scores well on its ability to create a differentiating cost value proposition, powered by its lower manufacturing costs and manpower and technical capabilities, but it needs to improve on its culture of environment and health safety compliance and infrastructure," the report said.

India's share of the total global outsourcing market is also estimated to increase from 2.8% in 2007 to 5.5% in 2010, it added. Ernst & Young OPPI report said the outsourcing industry is undergoing a paradigm shift with the rise of a number of new players from emerging economies who offer global capabilities a substantial cost advantage.

***Source:*** *The Economic Times, 15th August, 2009*

# EVENTS

## Seminar on recent trends in Pharmaceutical Sciences


The Alumni Association of Sri Ramachandra College of Pharmacy had organized a one day seminar on "Recent trends in pharmaceutical sciences" on 31/8/09 at Sri Ramachandra University. The seminar was inaugurated by our Pro-Chancellor Prof. Dr. T. K. Parthasarathy, SRU. Our Principal Prof. Dr. C. Uma Maheswara Reddy welcomed the gathering and Prof. Dr. P. Soundarajan, HOD, Dept.of Nephrology, SRU, presided over the function. Prof. Dr.Vasantha Janardhan, HOD, Dept. of Pharmacy Practice, SRU, gave an overview, Prof. Dr. K. Chitra and Prof. Dr. D. Chamundeeswari, Vice Principals, Sri Ramachandra College of Pharmacy, Dr. Uma Maheswari, President, Alumni Association, did the felicitations. A new website for the Alumni Association of Sri Ramachandra College of Pharmacy was inaugurated by our Associate Dean of Administration, Prof. Dr. T.R. Gopalan. The Inaugural function ended with the Vote of Thanks by Ms. N. Vanitha Rani, Secretary, Alumni Association, and was followed by scientific sessions. Speakers from both Academics and Industry delivered scintillating lectures on emerging trends in pharmaceutical sciences.

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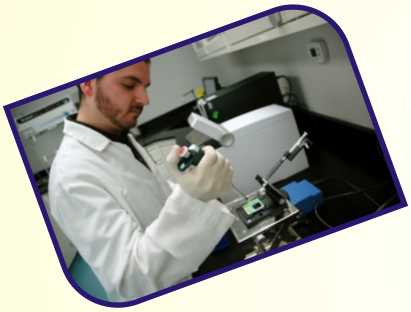

Phone No: 0452 - 2424652, 2423454

Fax No: 0452 - 2423415

E-mail: kmcp@sancharnet.in

Website: www.kmcp.ac.in

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