INTELLECTUAL PROPERTY RIGHTS AND DRUG REGULATORY AFFAIRS

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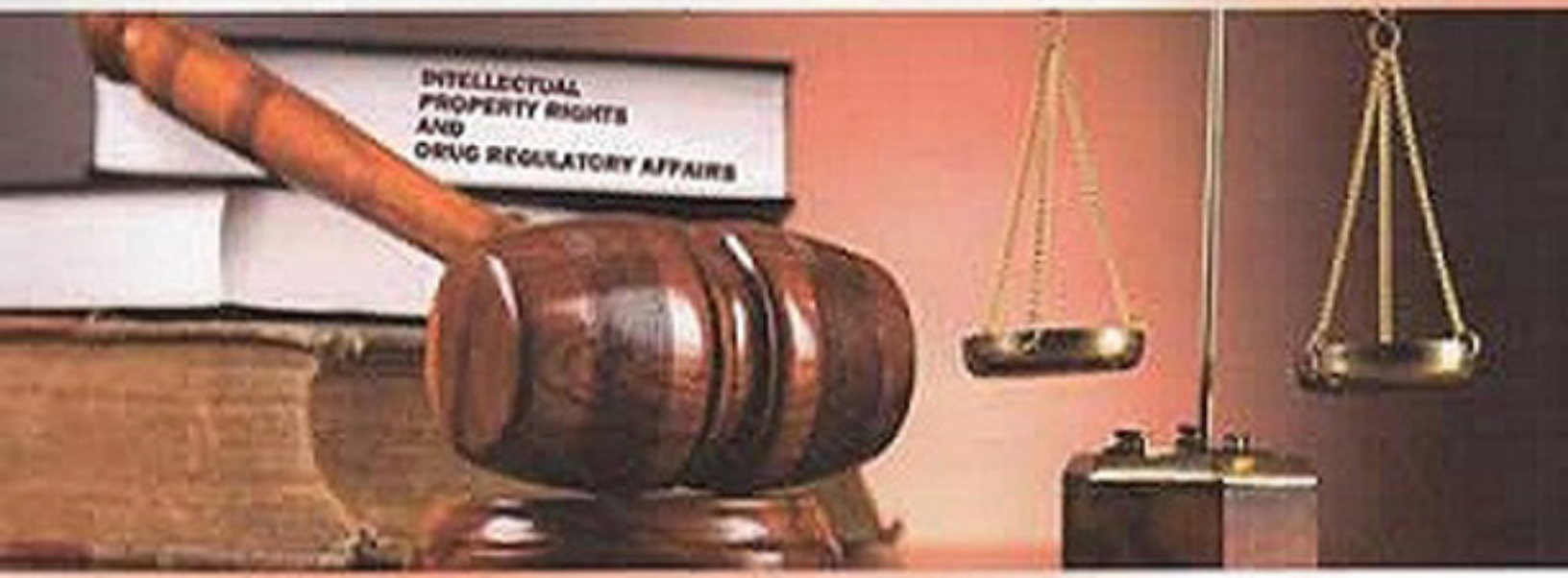

NIRALI PRAKASHAN

INTELLECTUAL PROPERTY RIGHTS AND DRUG REGULATORY AFFAIRS

FOR
UNDERGRADUATE AND POST GRADUATE PHARMACY STUDENTS AND STUDENTS OF LAW

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Dedicated to

My Daughter Saanvi

&

Beloved Ones

PREFACE

The laws and regulations governing the pharmaceutical industry were adopted to protect the consuming public by attempting to provide drugs of constituent quality, purity, and efficacy. The Food, Drug and Cosmetic Act (the Act) is a living document in that it is amended frequently and interpreted constantly. The act may be imperfect, but careful attention to its provisions plus an effort of good faith by all persons concerned with drug manufacturing can produce the type of product for which the Act and its regulations strives. Even though the applicable laws and regulations may change with regard to specifics, there are, nonetheless, many constant applicable generally. This book serves an overview of the more significant laws, regulations and Acts related to the Regulatory requirements for Therapeutical, Medicinal and Biological products, Product development and Clinical Trials. This book describes the Food, Drug and Cosmetic Act, treats briefly regulations bearing on pharmaceutical manufacturing, looks at the structure, powers, and duties of the Food and Drug administration (FDA), describes state and local laws and regulations, and finally, covers the protection of industrial property and product liability.

This book consists of 24 chapters. A topic includes and focuses on Current Good Manufacturing Practices (cGMPs), Good Clinical Practices (GCPs), intellectual property rights, trade marks, different schedules, regulatory requirement for packaging material, ICH Guidelines for stability and safety, specifications for clinical trials and the corresponding documentation requirements, and enforcement options as per revised curriculum of various universities. Written in a jargon-free style, it draws information from a wide range of resources. It demystifies the inner workings of the DRA and facilitates an understanding of how it operates with respect to compliance and product approval. Book contains lots of diagrammatic presentation to make laws easier to understand and memorize. The major objective of writing this book is to provide key information about the drug regulatory affairs, various schedules and related acts for graduate and postgraduate students of pharmacy as well as law.

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AUTHORS

CONTENTS

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INTRODUCTION

INTELLECTUAL PROPERTY RIGHTS (IPR)

The term *Intellectual Property (IP)* means product of the mind or the intellect. In our day-to-day life we come across various forms of Intellectual property such as television, personal computer, gas stove, microwave oven, refrigerator, vehicles, weighing machine, cereals for breakfast, pasteurized milk in tetra pack, paints and even a design on the bed sheet. Practically, everything that we use is a product of man's ingenuity, knowledge and skill, besides labor and capital and it falls under some kind of IP that has to be recognized before it could be lawfully commercialized.

The concept of Intellectual Property will be well appreciated if we understand what is meant by the term property. Legally speaking, the term '*Property'* essentially means a bundle of rights flowing from the concept of '*ownership'* and '*possession'*. The right of ownership and possession is an integral part of the property that assures the owner, the right to dispense with the property in a manner he or she deems fit, whether to use or not to use, exclude others from using, or to transfer the ownership.

With this concept in the mind, *Intellectual Property Right (IPR)* can be defined as the right held by a person over the creation of his mind. Intellectual Property acquires legal rights in the form of patent, copyright, trademark, industrial design etc. It gives the creator an exclusive right over the use of his/her creations for a certain period of time.

DRUG REGULATORY AFFAIRS (DRA)

The pharmaceutical biotechnology and medical device research and development industries are among the most highly regulated industries in the country. As India is growing very rapidly in pharmaceutical sector, there is a need of regulatory affairs professionals to cater the current needs of industries for the global competition. Regulatory affairs professionals are the link between pharmaceutical industries and world wide regulatory agencies. They are required to be well versed in the laws, regulations, guidelines and guidance of the regulatory agencies. There is a growing need to incorporate the current requirements of pharmaceutical industries in the standard curriculum of pharmacy colleges to prepare the students with the latest developments to serve the industries. The present article discusses the regulatory education and its need, learning resources, courses available, syllabus contents, and job opportunities in regulatory affairs.

As the pharmaceutical industries throughout the world are moving ahead towards becoming more and more competitive, these are realizing that the real battle of survival lies in executing the work by understanding the guidelines related to various activities

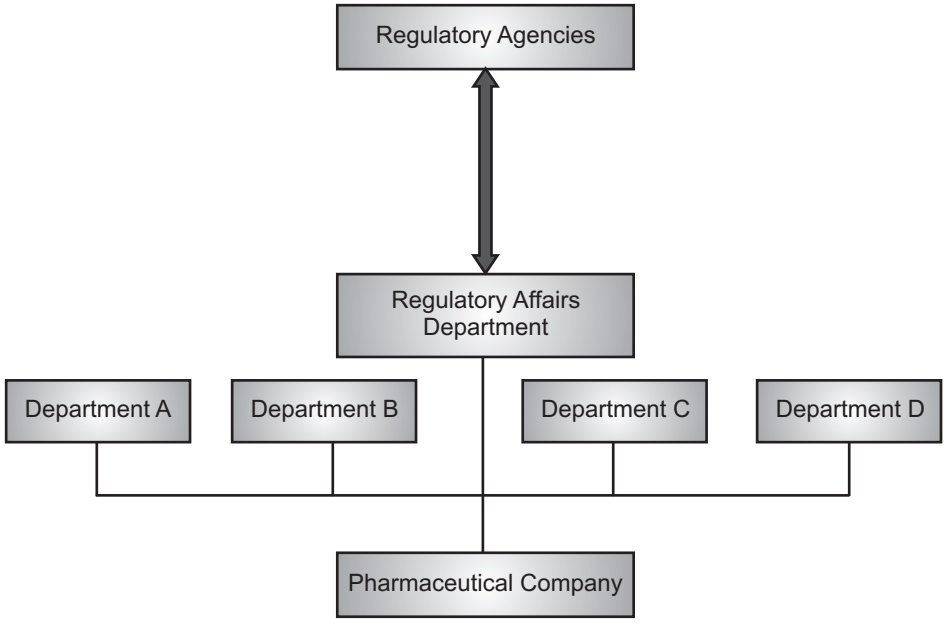
carried out to give an assurance that the process is under regulation. Pharmaceutical Industry, being one of the highly regulated industries, is in immense need of people than ever before who are capable of handling issues related to regulatory affairs in a comprehensive manner.

Regulatory Affairs is a profession within regulated industries namely-pharmaceuticals, medical devices, energy and banking. It has specific meaning within healthcare industries namely-pharmaceuticals, medical devices, biologics and functional foods. (In this blog, I am going to deal about Regulatory Affairs related to pharmaceuticals meant for human use).

Regulatory Affairs in the pharma industry may be defined as "**The interface between the pharmaceutical company and the regulatory agencies across the world.**"

The person indulging in the regulatory affairs must be familiar with all the guidelines, guidance and regulatory documents. He should have thorough understanding of a particular regulatory document which has been drafted. Such people are the primary communication link between the company and worldwide regulatory agencies such as USFDA (United States Food and Drug Administration) and European Union of Drug Regulatory Affairs (EUDRA) In the above presentation, we are conveying the fact that among all the departments of a pharma company Regulatory Affairs Department acts as the interface between the pharmaceutical company and the regulatory agencies across the world.

Regulatory agency in the present context may be defined as "**The competent government agency which is responsible for ensuring that medicines work and are acceptably safe**."



Origin of Regulatory Affairs

- Elixir Sufanilamide, prepared using DEG (a poison) as solvent resulted in the death of more than 100 people in the USA in 1937. This incident led to the passing of the 1938 Federal Food, Drug and Cosmetic act in USA.
- Thalidomide use by pregnant women for treating morning sickness was linked to the cause of birth deformities in more than 10,000 children in late 1950's and early 1960's. This incident led to the **Kefauver-Harris Amendment** in USA-it is a 1962 amendment to the Federal Food, Drug and cosmetic act.

Similarly, other tragic incidents led to various acts/amendments.

The purpose of writing this book is to provide graduate/post graduate level education in the important aspects of legal and regulatory issues that are critical to the pharmaceutical industries. The book focuses on key legal concepts such as intellectual property and the range of regulatory affairs and provide strategic, tactical and operational direction and support for working within regulations to expedite the development and delivery of safe and effective healthcare products to individuals around the world.

These individuals are new or relatively new to the profession with limited or no regulatory affairs knowledge. Many have education and/or experience in science, clinical studies or engineering and understand specific aspects of the healthcare product arena. Throughout the book, these individuals develop basic knowledge and understanding of the regulatory and legal frameworks, regulatory requirements, legislation, processes and procedures.

This book is structured in six different parts. These parts are as follows:

Part I describes different schedules considered under the syllabus i.e., Schedule Y, Schedule M and Schedule T. These schedules come under Drug and cosmetics Act, 1945. Schedules from the Drug and cosmetics Act, 1945 are as follows:

- **Schedule A:** Applications for licenses for import, manufacturing, and sale of drug and cosmetics, the forms in which the licenses are granted and renewed and other forms.
- **Schedule B:** Fees for analysis of drug and cosmetics that have to be paid to the Central Drug Laboratories or other Govt. Laboratories.
- **Schedule C:** List of Biological and Immunological Products, Antibiotics and Ophthalmic lotions and Ointments and all products for parenteral use (Injections).
- **Schedule C (I):** List of drugs, from biological origin, namely Alkaloids, Hormones, Vitamins and Antibiotics for oral use.
- **Schedule D:** Exemptions that have been granted to drugs and importers of drugs from complying with the requirements of import of drugs and also the conditions for such exemptions.

- **Schedule E:** List of poisons for which labelling and other requirements were to be complied with. This schedule has been deleted.
- **Schedule E(I):** List of poisonous substances under the Ayurvedic, Siddha and Unani Systems of medicines.
- **Schedule F:** Special provisions to be complied with, for the manufacture, testing and labelling of biological products for human use like Sera and Vaccines. These provisions have now been deleted. The requirements for running Blood Banks and other requirements are now includes in this schedule.
- **Schedule F (I):** Special provisions to be complied with for the manufacture, testing and labelling of Veterinary Biological Products.
- **Schedule F (II):** Standards for Surgical Dressings.
- **Schedule F (III):** Standards for Umbilical Tapes.
- **Schedule FF:** Additional standards for ophthalmic preparations.
- **Schedule G:** List of drugs which should be used by patient under medical supervision and which shall be labelled with the words "Caution – It is dangerous to take this preparation except under medical supervision".
- **Schedule H:** List of drugs which are to be sold by retail against the prescription of Registered Medical Practitioner and which shall be labelled with words "Schedule H Drug-Warning: to be sold by retail on the prescription of a Registered Medical Practitioner only."
- **Schedule I:** List of poisons of particulars about the proportion of poison in certain cases. Schedule I was linked with Schedule E. When schedule E was deleted in 1982, Schedule I was also deleted.
- **Schedule J:** Names of diseases and ailments (by whatever name described) which a drug may not purpose to prevent or cure by means of claims made on the label of the container of the drug.
- **Schedule K:** Names of drugs or classes of drugs which are exempted from complying with the provisions for manufacture, sale and standards of drugs and the conditions of such exemption.
- **Schedule L:** List of drugs which were required to be sold by retail against the prescription of Registered Medical Practitioner. Subsequently the drugs listed in Schedule L were transferred to Schedule H. Schedule L was deleted in 1982.
- **Schedule M :** Good Manufacturing Practices (GMP) and the requirements of premises, plant and equipments for manufacture of drugs.
- **Schedule M(I):** Requirements for factory premises of Homeopathic Medicines.
- **Schedule M(II):** Requirements for factory premises of Cosmetics.

- **Schedule M(III):** Requirements of factory premises for manufacture of Medical Devices.
- **Schedule N:** List of minimum equipments, requirements of premises for the effective running of a pharmacy.
- **Schedule O:** Standards for Disinfectant fluids.
- **Schedule P:** Life Period and Conditions of Storage of Drugs.
- **Schedule P(I):** Pack sizes of Drugs.
- **Schedule Q:** List of Coal Tar colours permitted to be used in cosmetics.
- **Schedule R:** Standards and labelling requirements of Condoms, Copper T and Contraceptive Tube Rings.
- **Schedule R(I):** Standards to be complied with by medical devices.
- **Schedule S:** Standards for Cosmetics.
- **Schedule T:** Requirements of factory premises and hygienic conditions to be complied with by the manufacturer of Ayurvedic, Siddha and Unani Drugs.
- **Schedule U:** Particulars to be shown in the manufacturing records, record of raw materials and in the analytical records of drugs.
- **Schedule V:** Standards for patient and proprietary medicines and the maximum and minimum quantities of vitamins that are permitted to be added in such preparations for oral use.
- **Schedule W:** Names of drugs which shall be marketed under generic names only.
- **Schedule X:** Names of psychotropic drugs for which special control measures have been laid down.
- **Schedule Y:** Requirements and guidelines on clinical trials for import and manufacture of new drugs.

Part II emphasizes on GCP (Good Clinical Practices), GLP (Good Laboratory Practices), GMP (Good Manufacturing Practices), USFDA-NDA/ANDA (U S Food and Drug Administrations - New Drug Approval/Abbreviated New Drug Approval) and TQM (Total Quality Management).

GCP (Good Clinical Practices) : GCP is an international quality standard that is provided by International Conference on Harmonization (ICH), an international body that defines standards, which governments can transpose into regulations for clinical trials involving human subjects. Good Clinical Practice guidelines include protection of human rights as a subject in clinical trial. It also provides assurance of the safety and efficacy of the newly developed compounds. Good Clinical Practice Guidelines include standards on how clinical trials should be conducted, define the roles and responsibilities

of clinical trial sponsors, clinical research investigators, and monitors. In the pharmaceutical industry monitors are often called Clinical Research Associates.

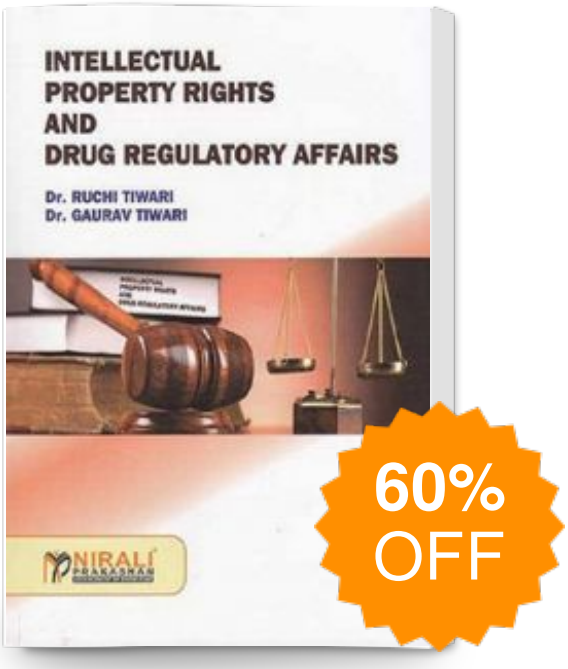
GLP (Good Laboratory Practices) : GLP deals with the organization, process and conditions under which laboratory studies are planned, performed, monitored, recorded and reported. GLP practices are intended to promote the quality and validity of test data. Published GLP regulations and guidelines have a significant impact on the daily operation of an analytical laboratory.

GMP (Good Manufacturing Practices) : Manufacturing relies on the ability to reproduce exactly a single product hundreds, if not thousands, of times. To make this possible, guidelines have been drawn up in most countries that are similar to the FDA ones described here that define GMPs. Diagnostic companies, including those manufacturing and distributing biosensors, cannot sell their products for either public or professional use unless they have been approved on the basis of these guidelines.

USFDA-NDA/ANDA (U S Food and Drug Administration - New Drug Approval/ Abbreviated New Drug Approval). The **New Drug Application** (NDA) is the vehicle in the United States through which drug sponsors formally propose that the Food and Drug Administration (FDA) approve a new pharmaceutical for sale and marketing. When the sponsor of a new drug believes that enough evidence on the drug's safety and effectiveness has been obtained to meet FDA's requirements for marketing approval, the sponsor submits to FDA a **New Drug Application (NDA).** The application must contain data from specific technical viewpoints for review, including chemistry, pharmacology, medical, biopharmaceutics, and statistics. If the NDA is approved, the product may be marketed in the United States. For internal tracking purposes, all NDA's are assigned an NDA number. **Abbreviated New Drug Application (ANDA).** An Abbreviated New Drug Application (ANDA) contains data that, when submitted to FDA's Center for Drug Evaluation and Research, Office of Generic Drugs, provides for the review and ultimate approval of a generic drug product. Generic drug applications are called "abbreviated" because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and effectiveness. Instead, a generic applicant must scientifically demonstrate that its product is bioequivalent (i.e., performs in the same manner as the innovator drug). Once approved, an applicant may manufacture and market the generic drug product to provide a safe, effective, low cost alternative to the American public.

Total Quality Management (TQM) : Concept of quality control can be extended to cover all aspects of a company's operation by the implementation of a total quality management (TQM) scheme. This involves the implementation of quality systems through every part of the operation. Once companies realize the advantages of TQM and adopt it as their normal working practice, the chances of subsequent product failure will drop and confidence in the industry will increase.

Intellectual Property Rights & Drug Regulatory Affairs



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