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Participant Handbook

Sector
Life Sciences

Sub-Sector
Pharmaceutical, Biopharmaceutical

Occupation
Research and Development

Reference ID: **LFS/Q0509, Version 1.0**
NSQF level: 3

Lab Technician/Assistant

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"Skilling is building a better India. If we have to move India towards development then Skill Development should be our mission."

Shri Narendra Modi
Prime Minister of India

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Certificate

COMPLIANCE TO QUALIFICATION PACK – NATIONAL OCCUPATIONAL STANDARDS

is hereby issued by the

LIFE SCIENCES SECTOR SKILL DEVELOPMENT COUNCIL

for

SKILLING CONTENT : PARTICIPANT HANDBOOK

Complying to National Occupational Standards of

Job Role/ Qualification Pack: **"Lab Technician/Assistant"** QP No. **"LFS/Q0509 , NSQF Level 3"**

Date of Issuance:
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*Valid up to the next review date of the Qualification Pack or the 'Valid up to' date mentioned above (whichever is earlier)

Authorised Signatory
(Life Science Sector Skill Development Council)

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We would like to thank Dr. Vinay Umesh Rao, Mr. Sanjeev Kumar Sharma, Dr. M Saharyar, Mr. P K Gupta and all those who provided inputs to put together this manual— which we believe will make an invaluable contribution to Life Sciences sector.

We are grateful to organizations like Cadila Pharmaceuticals Limited, Glenmark Pharmaceuticals Limited, RPG Life Sciences Limited, Centaur Lab Pvt. Limited, Belco Pharma, Crystal Pharma, Systole Remedies Pvt. Limited for their efforts in reviewing and endorsing this Participant Manual.

About this book

Life Sciences Sector is one of the primary engines of growth in the manufacturing space, and a leading player in the recently launched 'Make in India' campaign. With revenue in excess of $30 bn, Life Sciences sector has been growing at over 16% per annum in the past few years. The sector currently provides employment to around 800,000. The Manufacturing job roles, comprise around 384,000 (approx. 48% of the total job volume).

Life Sciences Sector Skill Council is aiming for skilling about 30,000 Lab Assistant in next 3 years. This participant manual dovetails with the National Occupation Standards for Lab Assistant- Life Sciences, also developed by LSSSDC with Industry. The Manual will prove to be a vital tool in the skilling process. It will also be a boon for all fresh aspirants who wish to join the Life Sciences sector as Lab Assistant. It is designed to enable theoretical and practical skilling on Lab Assistant- Life Sciences Qualification Pack which mandates the below four Occupation Standards for the job role:

- Help the lab/QC Chemists/ Research Associates in performing the experiments and analysis.
- Carry out washing, processing and drying of the glassware/plastic ware for experimentation
- Carry out preparation of solution and reagents
- Ensure appropriate measures are taken while opening of chemicals to be used in analysis
- Maintain records of lab usage, storage of chemicals, labels, date of opening and closing
- Reprocess the instruments before carrying out experiments
- Maintain a healthy, safe and secure working environment in the life sciences facility
- Ensure cleanliness in the work area

The above four occupational standards are covered under various units in the participant manual which comprehensively binds knowledge and skills related to these. It.

The book is designed keeping in mind the minimum education qualification of Lab Assistant- Life Sciences to be 10th class Pass as stipulated by Industry. However, as part of this book, efforts have been made to put focus on practical learning in addition to all technical and manufacturing concepts required for the role. The Key Learning Objectives and the skills gained by the participant are defined in their respective units.

The contents of this book are in simple language. It is envisaged that this participant manual will provide the participants with the knowledge and skills required for Job role of Lab Assistant- Life Sciences. It should enable participants to become effective and responsible Lab Assistant for Life Sciences Industry.

Symbols used in the book have been listed below.

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1. Orientation Module

Unit 1.1 - Orientation Module

Key Learning Outcomes

At the end of the module, you will be able to:

1. Familiarse with Life Sciences Industry in Indian and Global Context.
2. Explain pharmaceutical & biopharmaceutical sub-sector of Life Sciences Industry including relevant Govt. Scheme, social security benefits, and manufacturing basics and requirements.
3. Brief introduction of Regulatory Authorities and Government Policies, rules and Regulations and their impact on manufacturing organizations, its structure.
4. Describe the knowledge, understanding and skills required for a Lab Assistant.

UNIT 1.1: Orientation Module

Unit Objectives

At the end of the unit, you will be able to:

1. Familiarse with Life Sciences Industry in Indian and Global Context.
2. Explain pharmaceutical & biopharmaceutical sub-sector of Life Sciences Industry including relevant Govt. Scheme, social security benefits, and manufacturing basics and requirements.
3. Brief introduction of Regulatory Authorities and Government Policies, rules and Regulations and their impact on manufacturing organizations, its structure.
4. Describe the knowledge, understanding and skills required for a Lab Assistant.

1.1.1 Sub-Sectors in Life Sciences Industry

The Indian Life Sciences industry currently tops the chart amongst the Indian There is a huge range of science based industries with capacity of expanding in drug manufacture and technology sector. With recent advances in scientific knowledge and technological breakthrough discoveries, Life Sciences industry has gained the central platform with global giants and industry experts getting involved in research and development of new products.

Life Sciences being a diverse and vibrant global industry encompasses a wide range of activities. The activities range from drug discovery, research & development and manufacture of therapeutics, medical devices, diagnostics and platform technologies. It also includes the specialist suppliers of products and services necessary for the functioning of various organizations related to Life Sciences. The increasingly aging global population and their demand for improved longevity offers a very strong growth potential to Life Sciences industry

The life sciences industry in India is huge and has able to incorporate pharmaceutical companies, biopharmaceutical and contract research organization (CROs) with the support of specialized suppliers and organization. The pharmaceutical industry develops, produces, and markets drugs for use as medications.

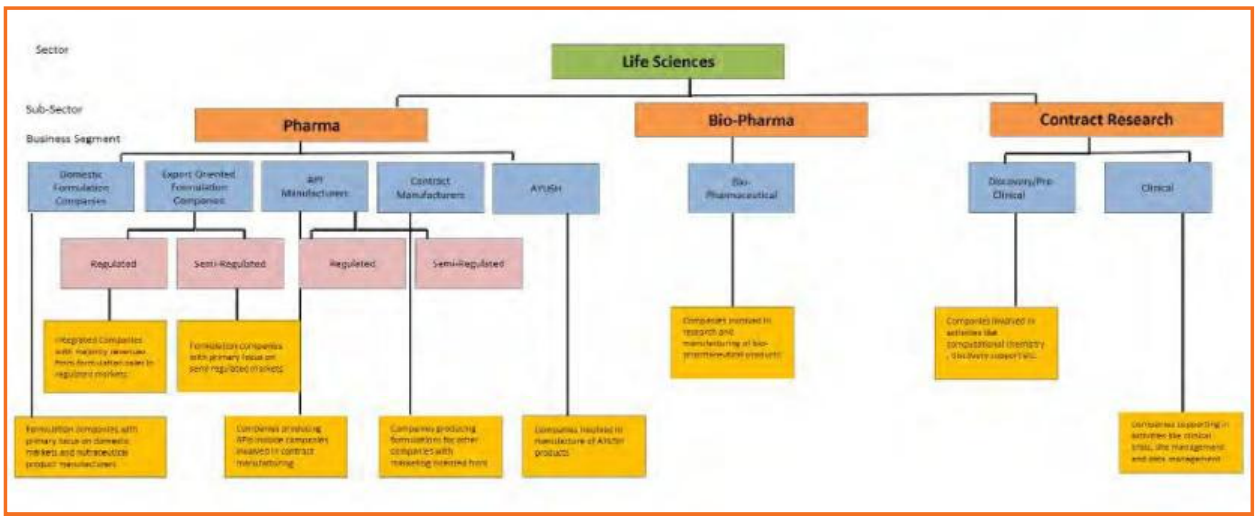


Fig:1.1.1: Life Sciences Sector

1.1.1.1 Pharmaceuticals

Fig:1.1.2: Medicines

- **Domestic Formulation companies:** Formulation is the process that combines different chemical substances including the active drug in order to produce a final medicinal product. Tablets, capsules, liquid form, lyophilized, etc. are a few different forms of Pharmaceutical Formulations. A large number of companies are involved in processing and supplying of different types of pharmaceutical medicines across the domestic sector.
- **Export Oriented Formulation companies:** These integrated companies are engaged in exporting formulation to other parts of the globe. The global trade liberalisation and capacity building by Indian companies have enables India to export to a large number of markets and earn substantial revenue. These export oriented formulation companies target both regulated and semi-regulated markets. There has been a current benefaction in the healthcare sector in which the Indian generics have provided aide in fighting AIDS and are being recognized worldwide.
- **API manufacturers:** Companies producing Active Pharmaceutical Ingredients (APIs) includes companies involved in contract manufacturing. API is manufactured from raw materials through both chemical and physical means. Synthesis of any APIs might need multi-step complex chemistry utilizing a range of processing technologies. This may depend on the complexity of the molecule required. A few names to mention include Dr Reddy's, Teva Active Pharmaceutical Ingredients (TAPI)Aurobindo Pharma, Cadila Pharma.
- **Contract manufacturing of formulations:** These companies produce formulations for other companies with a marketing front-end. Contract manufacturing involves production of goods by firm, which can be The contract manufacturers render such services to various firms purely based on their own setup or by the consumers preferences, designs , formulas and specifications. Services offered by such companies include pre-formulation, formulation development, stability studies, method development, pre-clinical and Phase I clinical trial materials, late-stage clinical trial materials, formal stability, scale-up, registration batches and commercial production. Some leading names in this area include Orion Corporation, Saneca Pharmaceuticals, Wockhardt.

1.1.1.2 Biopharmaceuticals

Biopharmaceutical business is engaged in discovering, developing and delivering innovative medicines to patients with serious diseases.

Biopharmaceuticals are medical medication created victimization biotechnology.

Biologics is composed of a mixture of sugars, proteins, or Nucleic acids or is also living cells or tissues. They're isolated from Natural sources—human, animal, or organism. Some leading Companies operating during this space embrace Biocon, Bodily Fluid Institute of India, Nostrum Biotec, Piramal care, GlaxoSmithKline.

Fig:1.1.3: Biopharmaceutical

1.1.1.3 Contact Research

- A Contract analysis Organization (CRO) role within the trade is to supply clinical trials and support to the pharmaceutical, biotechnology, and medical devices industries. These organizations area unit employed for specific expertise on contract basis within the style of outsourced analysis services.

- Discovery / Pre-clinical are those firms that are concerned in activities like procedure chemistry and discovery support.
- Clinical firms support in activities like clinical trials, site management, information management Some well-known Clinical
- Research Organizations within the company and Biotech business
- include Quintiles, Covance, PAREXCEL.

Fig:1.1.4: CRO

1.1.2 Drug Regulatory Agencies

Life sciences domain cater to lives of humans, thus they are available below rigorous restrictive laws. The restrictive affairs departments of life-science firms make sure that the businesses fit all of the rules and laws regarding their business. Restrictive Affairs is actively concerned in each stage of development of a replacement medicine and within the post-marketing activities with authorized healthful product.

Country	Regulatory Agency
United States of America	• FDA • Center for Drug Evaluation and Research (CDER)
European Union	• European Medicines Agency (EMA)
Canada	• Health Canada • Health Products and Food Branch (HPFB) • Therapeutic Products Directorate (TPD)
Australia	• Therapeutics Goods Administration(TGA)
India	• Central Drugs Standard Control Organization (CDSCO)

Fig:1.1.5: Regulatory Agency

1.1.3 Major Drugs and Pharmaceuticals Regulating Bodies

The responsibility of safeguarding the consent, production and marketing of the quality drugs with the support of the regulatory bodies at reasonable cost.

The Central Drug Standards and Control Organization (CDSCO) which is under the supervision of the Ministry of Health and Family Welfare. The CDSCO prescribes standards and measures for:

- Ensuring the safety, efficacy and quality of drugs, cosmetics, diagnostics and devices in the country.
- Regulating the market authorization of new drugs and clinical trials standards

- Supervising drug imports and approves licenses to manufacture the above-mentioned products.

Another authority is the National Pharmaceutical Pricing Authority (NPPA), which works under the Department of Chemicals and Petrochemicals. The main areas of work include:

The CDSCO laid down the standards and measures for:

- To insure the security, proficiency and quality of drugs, cosmetics, diagnostics and devices in the country
- The new drugs and clinical trial standards should be monitored at Market Dominion
- Inspect the drug imports and acknowledge the license to manufacture the above mentioned products

The Department of Chemicals and Petrochemicals also oversees policy, planning, development and regulatory activities pertaining to the chemicals, petrochemicals and pharmaceutical sector. As compared to other two bodies, this agency has responsibilities that are relatively broader and varied in comparison to the other two bodies. The prices of decontrolled bulk drugs and formulations at judicious intervals:

- Periodically update the list under price control through inclusion and exclusion of drugs in accordance with established guidelines.
- Maintain data on production, exports and imports and market share of pharmaceutical firms.
- Enforce and monitor the availability of medicines in addition to imparting inputs to parliament in issues pertaining to drug pricing.
- The cost of the decontrolled bulk drugs and formulations should be adjusted and amended at profound intervals.
- Augment the listing under the price control through encompassment and elimination of drugs with the conformed guidelines at regular intervals.
- The data on production, exports and market share of pharmaceutical firms should be validated.
- Administer and oversee the availability of medicines to impart with inputs to parliament in issues with relation to the drug pricing.
- The main aspects of pharmaceutical regulation are divided between the two ministries:
- The Ministry of Health and Family Welfare examines pharmaceutical issues within the larger context of public health.
- The Ministry of Chemicals and Fertilizers focuses on industrial policy.

However, some other ministries also play a role in the regulation process such as the Ministry of Environment and Forests, Ministry of Finance, Ministry of Commerce and Industry and the Ministry of Science and Technology. The process for drug approval entails the coordination of different departments, in addition to the DCGI, depending on whether the application in question is for a biological drug or one based on recombinant DNA technology.

The prime conditions of pharmaceutical regulation are divided between two ministries:

- The pharmaceutical issues are being reviewed by the Ministry of Health and Family Welfare within the larger frame of reference of public health.
- The Ministry of Chemicals and Fertilizers fixate itself on the industrial policy.

Anyhow, some ministries also perform a part in the regulation process such as the Ministry of Environment and Forests, Ministry of Finance, Ministry of Commerce and Industry and the Ministry of Science and Technology. The process for the drug approval leads to the gradation of the different departments, in addition with the DCGI contingent upon whether the proposal in inquest is for the fundamental drug or on recombinant DNA

Technology.

The Department of commercial Policy and Promotion and board of directors General of Foreign Trade, each underneath the aegis of Ministry of Commerce and trade and also the Ministry of Chemicals and Fertilizers govern the problems related to industrial policy like the regulation of patents, drug exports and government support to the industry.

- The Central Drug Controller, Ministry of Health and Family Welfare, Department of Biotechnology, Ministry of Science and Technology (DST) and Department of atmosphere, Ministry of atmosphere and Forests regulate licensing and management internal control problems and market authorization.
- State drug controllers have the supremacy to issue licenses for the manufacture of approved medicine and oversee quality control, beside the Central Drug Standards management Organization (CDSCO).

In India, drug producing, quality and promoting is regulated in accordance with the medicine and Cosmetics Act of 1940 and Rules 1945 that have witnessed many amendments over the previous couple of decades. The Drugs Controller General of Bharat (DCGI), United Nations agency heads the Central medicine Standards management Organization (CDSCO),assumes responsibility for the amendments to the Acts and Rules. different major connected Acts and Rules include:

The Pharmacy Act of 1948

- The Drugs and Magic Remedies Act of 1954
- Drug Prices Control Order (DPCO) 1995

Some of the important schedules of the Drugs and Cosmetic Acts include:

- Schedule D: dealing with exemption in drug imports.
- Schedule M: which, deals with Good Manufacturing Practices involving premises and plants.
- Schedule Y: which, specifies guidelines for clinical trials, import and manufacture of new drugs.

1.1.4 Social Security Benefits

Employees operating in factories or different institution, India have a social insurance system that provides for retirement and insurance advantages to those workers. The system is ruled by the Employees' Provident Fund and Miscellaneous Provisions Act, 1952 ('PF Act') and therefore the schemes created there beneath, namely the Employees' Provident Fund theme ('EPF') and therefore the Employees 'Pension theme ('EPS'). The EPFO, a statutory body established by the government of Asian country, administers the social insurance laws in India.

Fig:1.1.6: Social Security Benefits

1.1.4.1 Covered Persons

Every institution in India is using twenty persons or a lot of is mandate by law to register with the social insurance authorities unless it qualifies as an exempted institution. An institution using fewer than twenty persons can voluntarily favor to register with the authorities for the welfare of its workers. Upon voluntarily registration, the provisions of the Indian social insurance laws apply in barely a similar approach as if such registration were compulsory.

1.1.4.2 Contributions

Workers are required to contribute 12% of their salary to the EPF contribution. The term salary' is broad and covers basic wages (all emoluments paid or collectable in money whereas on duty or on leave/ holiday), expense allowances, retention allowances and therefore the money worth of any food concessions. Equal contribution is made by employers. The accumulated balance within the Provident Fund earns interest at nominal rate that is proclaimed by the govt from time to time.

Withdrawal benefits

The EPF and the EPS lay down detailed rules for withdrawals. The withdrawal can be possible at the time of leaving the job or at the time or retirement.

Provident fund: International employees can forgo their accumulated balance from the Provident Fund within the following conditions:

- Retirement from service in the establishment or after attaining 58 years of age, whichever is later.
- Retirement on account of permanent and total incapacity for work due to bodily or mental infirmity as certified by an accredited medical officer/registered practitioner.
- When suffering from certain diseases detailed in the terms of the scheme.
- On ceasing to be associate worker of a distinguished institution, wherever the international employee is from associate degree SSA country. India Social Security systems round the globe 167 In cases wherever the international employee is from an SSA country, withdrawal from the Provident Fund shall be due within the payee's checking account directly or through the leader. Altogether different cases, the quantity withdrawn are attributable to the international worker's Indian checking account. Amendments are created within the Indian restrictive framework to allow international employees to open Indian bank accounts so as to receive Provident Fund cash. Any payment withdrawn by international employees from the Provident Fund on retirement or otherwise once finishing five years of continuous service in a very coated institution in India or below different such that circumstances is exempt from tax. Altogether different cases, the employer's contribution and interest attained on it contribution (on each the leader and employee's share) is nonexempt within the year of withdrawal. What is more, where an international employee has claimed a deduction on his/her own contribution in previous years, the deduction is nonexempt within the year within which the withdrawal is formed.

Pension fund: Accumulated sums within the pension fund square measure would not pay a pension to staff upon retirement or in bound circumstances as laid out in the EPS. International staff blank not entitled to pension have the benefit of the pension fund unless they need rendered eligible service for an amount of 10 years. Wherever international staff are lined beneath AN Social Security Administration, earlier withdrawal from pension fund is feasible. However, identical is totally dutiable in their hands within the year of withdrawal. The monthly pension received from the pension fund on retirement is taxable as attained financial gain.

However, commutation of pension payments is exempt from tax, subject to the following conditions:

- In cases of a receipt of a gratuity, the commuted value of one third of the pension is exempt from tax.
- In other cases, the commuted value of one half of the pension is exempt from tax.

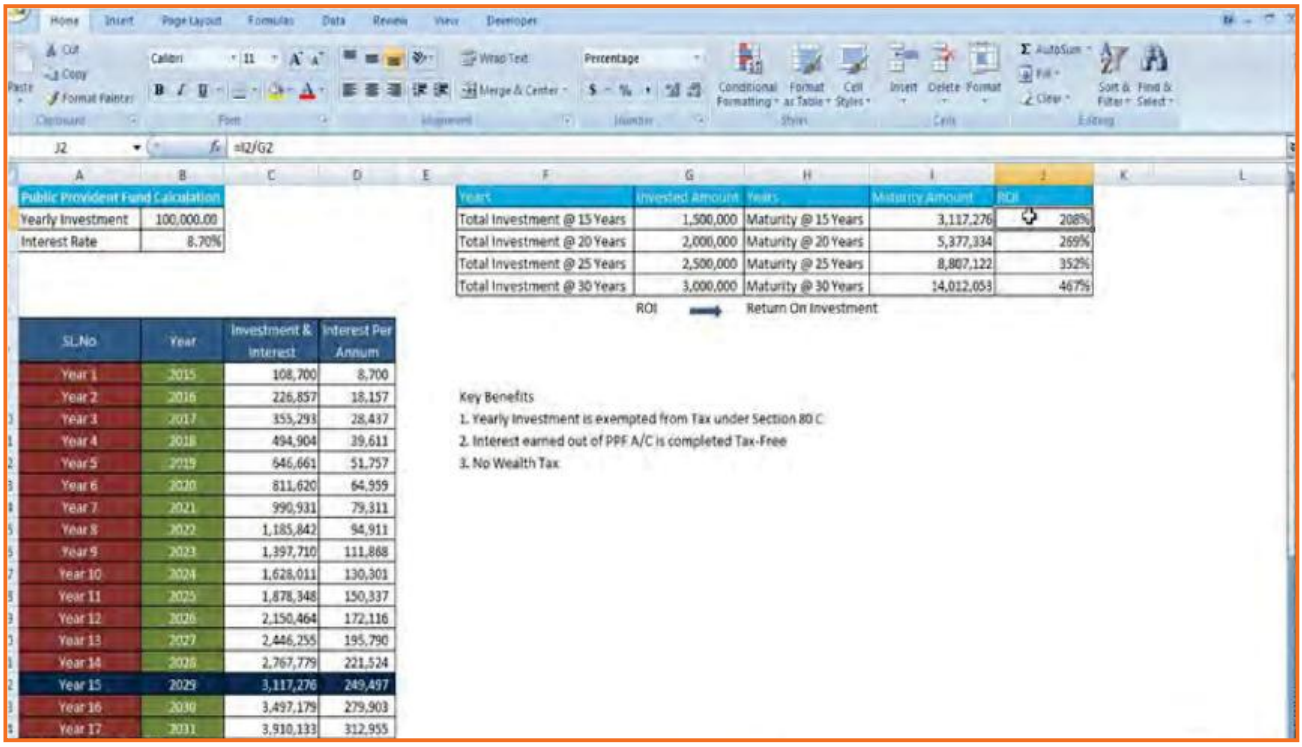
Insurance benefit: During the period of service, a nominal contribution is made by the employer and/or government to provide insurance benefit to family members (nominees) if the employee dies whilst in employment.

SSA benefits

SSAs are bilateral agreements between India and other countries designed to protect the interests of cross-border workers. They provide for avoidance of 'no coverage' or 'double coverage' and equality of treatment of

the workers of both countries. An SSA generally provides for the following:

- **Detachment:** Applies to employees posted to the other country provided they comply with the social security requirements of their home country.
- **Exportability of pension:** Provision for payment without any reduction in the employee's home country or any other country.
- **Totalisation:** The period of service in a foreign country is counted on a pro rata basis when determining eligibility linked to length of service. As on date India has entered in to a SSA with 17 countries out of which the SSA with Denmark, France, Germany, Hungary, Luxembourg, Netherlands, South Korea, Switzerland and Belgium have been ratified while the agreements with Austria, Canada, Czech Republic, Finland, Japan, Norway , Portugal and Sweden are still pending.



SL.No	Year	Investment & Interest	Interest Per Annum
Year 1	2015	108,700	8,700
Year 2	2016	226,857	18,157
Year 3	2017	355,293	28,437
Year 4	2018	494,904	39,611
Year 5	2019	646,661	51,757
Year 6	2020	811,620	64,959
Year 7	2021	990,931	79,311
Year 8	2022	1,185,842	94,911
Year 9	2023	1,397,710	111,868
Year 10	2024	1,628,011	130,301
Year 11	2025	1,878,348	150,337
Year 12	2026	2,150,464	172,116
Year 13	2027	2,446,255	195,790
Year 14	2028	2,767,779	221,524
Year 15	2029	3,117,276	249,497
Year 16	2030	3,497,179	279,903
Year 17	2031	3,910,133	312,955

Fig:1.1.7: Pension Benefits

1.1.5 Regulatory Authority and Government Policies

The main functions of the regulatory bodies are to ensure a healthy supply of quality drugs at affordable prices to the Indian masses. The regulatory concerns in the Indian life sciences industry are affected by the fast growth and rapidly evolving and maturing process guidelines globally, with reference to good manufacturing practices (GMP), good clinical practices (GCP) and good laboratory practices (GLP).

The main regulatory bodies responsible for ensuring the approval of production and marketing of quality drugs in India at reasonable prices are:

- Central Drug Standards and Control Organization (CDSCO)
- National Pharmaceutical Pricing Authority (NPPA).

The CDSCO prescribes standards and measures for ensuring the safety, efficacy and quality of drugs, cosmetics, diagnostics and devices in the country; regulates the market authorization of new drugs and clinical trials standards; supervises drug imports and approves licenses to manufacture the above mentioned products.

National Pharmaceutical Pricing Authority (NPPA), which was instituted in 1997 under the Department of Chemicals and Petrochemicals, which fixes or revises the prices of decontrolled bulk drugs and formulations at judicious intervals; periodically updates the list under price control through inclusion and exclusion of drugs in accordance with established guidelines; maintains data on production, exports and imports and market share of pharmaceutical firms; and enforces and monitors the availability of medicines in addition to imparting inputs to Parliament in issues pertaining to drug pricing.

The Department of Chemicals and Petrochemicals also oversees policy, planning, development and regulatory activities pertaining to the chemicals, petrochemicals and pharmaceutical sector. The main aspects of pharmaceutical regulation are thus divided between the above two ministries. The Ministry of Health and Family Welfare examines pharmaceutical issues within the larger context of public health while the focus of the Ministry of Chemicals and Fertilizers is on industrial policy.

With respect to licensing and quality control issues, market authorization is regulated by the Central Drug Controller, Ministry of Health and Family Welfare, Department of Biotechnology, Ministry of Science and Technology (DST) and Department of Environment, Ministry of Environment and Forests. State drug controllers have the authority to issue licenses for the manufacture of approved drugs and monitor quality control, along with the Central Drug Standards Control Organization (CDSCO).

In India, drug manufacturing, quality and marketing is regulated in accordance with the Drugs and Cosmetics Act of 1940 and Rules 1945. This act has witnessed several amendments over the last few decades. The Drugs Controller General of India (DCGI), who heads the Central Drugs Standards.

Control Organization (CDSCO), assumes responsibility for the amendments to the Acts and Rules. Other major related Acts and Rules include the Pharmacy Act of 1948, The Drugs and Magic Remedies Act of 1954 and Drug Prices Control Order (DPCO) 1995 and various other policies instituted by the Department of Chemicals and Petrochemicals.

In accordance with the Act of 1940, there exists a system of dual regulatory control or control at both Central and State government levels. The central regulatory authority undertakes approval of new drugs, clinical trials, standards setting, control over imported drugs and coordination of state bodies' activities. State authorities assume responsibility for issuing licenses and monitoring manufacture, distribution and sale of drugs and other