Skill India
कौशल भारत-कुशल भारत

सत्यमेव जयते
GOVERNMENT OF INDIA
MINISTRY OF SKILL DEVELOPMENT
& ENTREPRENEURSHIP

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LSSSDC

Participant Handbook

Sector
Life Science

Sub-Sector
Pharmaceutical, Biopharmaceutical

Occupation
Manufacturing

Reference ID: **LFS/Q 0207, Version 1.0**
NSQF Level 4

Production/Machine Operator - Life Sciences

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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: **"Machine Operator - Life Science"** QP No. **"LFS/Q0207, NSQF Level 4"**

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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.

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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 Production/ Machine Operator- Life Sciences in next 3 years. This participant manual dovetails with the National Occupation Standards for Production/ Machine Operator 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 Production/ Machine Operator. It is designed to enable theoretical and practical skilling on Production/ Machine Operator- Life Sciences Qualification Pack which mandates the below six (6) Occupation Standards for the job role:

- Prepare machines and accessories for the manufacturing process
- Perform manufacturing operations
- Ensure cleanliness in the work area
- Carry out reporting and documentation
- Carry out broad level quality checks before, in-processand post manufacturing
- Maintain a healthy, safe and secure working environment in the life sciences facility

The above six (6) 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 Production/ Machine Operator- Life Sciences to be 10+2 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 Production/ Machine Operator- Life Sciences. It should enable participants to become effective and responsibleProduction/ Machine Operatorfor Life Sciences Industry.

Symbols used in the book have been listed below.

Symbols Used

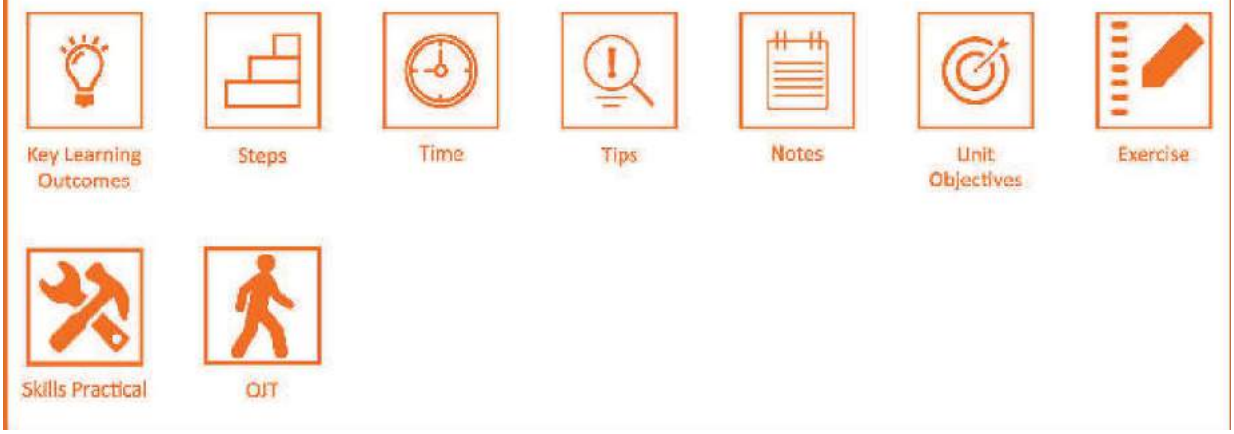

Table of Content

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Skill India
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1. Orientation Module

Key Learning Outcomes

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

1. Gain brief knowledge about Life Sciences industry and its sub-sectors.
2. Gain knowledge about Regulatory Authorities and Government policies, rules and regulations and their impact on manufacturing in Life Sciences industry in India and emerging markets.
3. Know the standards for manufacturing in Life Sciences (cGMP and ISO).
4. Acquire knowledge about the organization structure in Life Sciences industry (Large / Medium / Small Enterprises).
5. Discuss on typical manufacturing function in a Life Sciences organization.
6. Learn about the role of a Machine Operator in Life Sciences industry.

UNIT 1.1: Life Sciences Industry and Its Sub-Sectors

Unit Objectives

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

1. Know about Life Sciences Industry, its sub-sectors

1.1.1 General Instructions for the Participants

- Always be punctual for every class.
- Be regular. Candidates who fall short of the required attendance will not be certified.
- Inform your instructor if, for any reason, you need to miss class.
- Pay careful attention to what your instructor is saying or showing.
- In case you do not understand something do not hesitate to put up your hand and seek clarification.
- Make sure you do all the exercises in your workbook. It will help you understand the concept better.
- Practice any new skills you have learnt as many times as possible. Seek the help of your Trainer or co-participant for practice.
- Make sure you are neatly attired and presentable at all times.
- Participate actively in all the activities, discussions and games during training. It will make you more confident and help in the learning process.
- Always take bath, wear clean clothes and comb your hair before you come to class.
- The three most important words you must always remember and use in your daily conversation are PLEASE, THANK YOU and SORRY.

1.1.2 Introduction to Indian Life Sciences Industry

The Indian Life Sciences industry currently tops the chart amongst the Indian science-based industries with wide ranging capabilities in the complex field of drug manufacture and technology. 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 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 ageing global population and their demand for improved longevity offers a very strong growth potential to Life Sciences industry.

1.1.3 Sub-Sectors in Life Sciences Industry

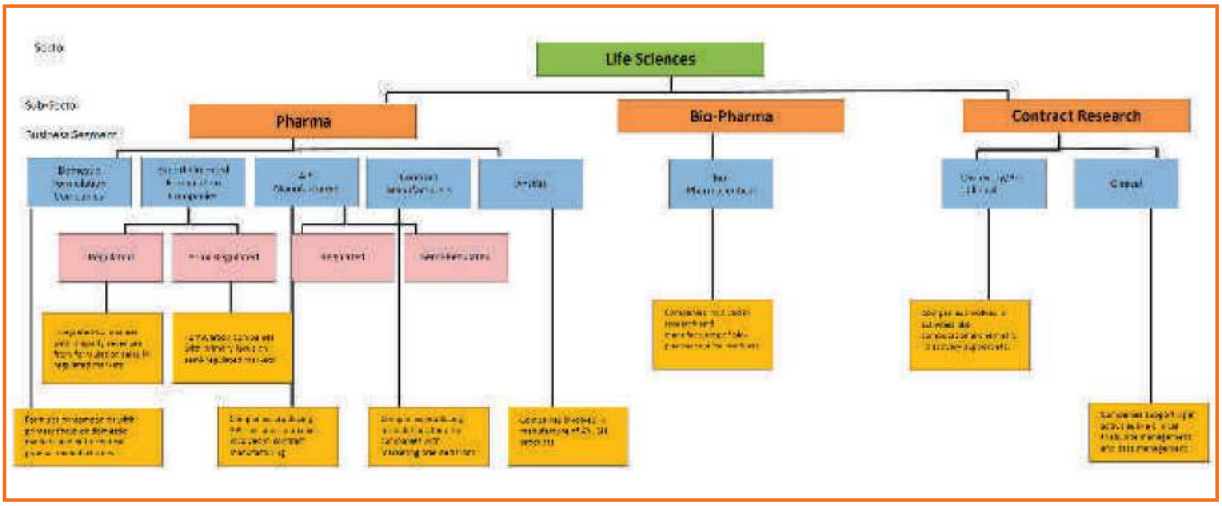

Fig 1.1.1: Overview of Life sciences industry

The Life Sciences industry in India is diverse and encompasses pharmaceutical companies, biopharmaceutical companies and contract research organisations (CROs) along with specialist suppliers and support organisations.

1.1.3.1 Pharmaceuticals

The pharmaceutical industry develops, produces, and markets drugs for use as medications.

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. The recent contribution of Indian generics in fighting AIDS and its contribution to affordable healthcare in the US and elsewhere is widely acknowledged.
- **API manufacturers:** Companies producing Active Pharmaceutical Ingredients (APIs) includes companies involved in contract manufacturing. API is manufactured from raw materials through both chemical and biochemical 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, 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 under the label or brand of another firm. Contract manufacturers provide such service to several firms based on their own or consumers' designs, formulas, and or 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.

1.1.3.2 Biopharmaceuticals

Biopharmaceutical industry is engaged in discovering, developing and delivering innovative medicines to patients with serious diseases. Biopharmaceuticals are medical drugs produced using biotechnology. Biologics can be composed of a combination of sugars, proteins, or nucleic acids or may be living cells or tissues. They are isolated from natural sources —human, animal, or microorganism. Some leading companies working in this area include Biocon, Serum Institute of India, Panacea Biotec, Piramal Healthcare, GlaxoSmithKline.

Fig 1.1.3: Biopharmaceutical

1.1.3.3 Contact Research

A Contract Research Organization (CRO) role in the industry is to provide clinical trials and support to the pharmaceutical, biotechnology, and medical devices industries. These organizations are hired for specific expertise on contract basis in the form of outsourced research services.

- Discovery / Pre-clinical are those companies which are involved in activities like computational chemistry and discovery support.
- Clinical companies support in activities such as clinical trials, site management, data management

Fig 1.1.4: CRO

Some well-known Clinical Research Organisations in the Pharma and Biotech industry include Quintiles, Covance, PAREXCEL.

1.4.1 Organization Structure

Organizations need structuring, so that lines of authority along with individual duties and responsibilities can be understood by every member of an organization. The life sciences industry is a complex organisations. Under its roof, a team of scientists, technicians and other specialists come together for representing virtually all the sciences. Some other people who contribute for the viability of this unique business enterprise include management executives, lawyers, accountants, engineers, system analysts and many others. There may be a different organizational structure for a large scale, medium or small scale life sciences company.

Formal organization structure regulates all relevant questions referred to organization:

- It connects people and resources in closer and wider groups (workplaces, work units, company).
- It allocates and connects organizational tasks.
- It defines people status in a company (managers and employees).
- It sets rules and behavioural norms in an organization.

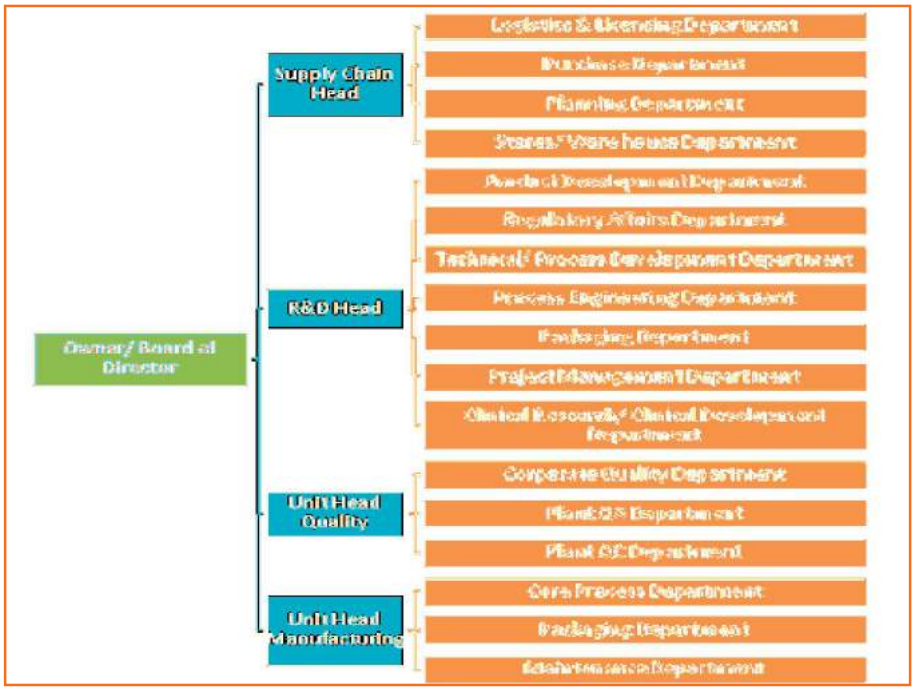

Fig.1.5.1: Organization Structure of Life Science

Organisation structure is a formal system of task and authority relationships that controls how people are to cooperate and use resources to achieve organization's goals.

Organization Charts is a pictorial record showing the formal relations among the various employees. The organization charts of large firms are far more complex and include individuals at many levels where as small and medium enterprises generally have fewer layers of management and fewer managers in general. Small business organizational charts have two or three stacked rows of post with one or two post on top where as large organizational structures, look like pyramids, with several management layers that reflect a more complex reporting structure.

Exercise

1. Name any two activities of Life Sciences

   .....

   .....

2. Formulation is the process that combines different chemical substances including the active drug in order to produce a final medicinal product.

   a) True

   b) False

3. What is the full form of API?

   .....

   .....

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

   a) True

   b) False

5. What is the full form of CRO?

   .....

   .....

UNIT 1.2: Drug Regulatory Agencies

Unit Objectives

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

- Know about the drug regulatory agencies and authorities.

1.2.1 Drug Regulatory Agencies

Manufacturing and sales of Drugs and Pharmaceuticals is governed by government regulatory bodies of different countries. The Regulatory Affairs Department of Life Science companies should make it a point that the companies ought to follow the rules and laws regarding their business. The Regulatory Affairs are strongly concerned about every stages of advancement of a new medication and also within the post marketing activities

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

Fig.1.2.1: Countries and its Regulatory Agency

1.2.1.1 India

Fig.1.2.2: CDSCO India

- Medicines in India are regulated by Central Drugs Standard Control Organization (CDSCO), under Ministry of Health and Family Welfare, headed by Directorate General of Health Services.
- CDSCO regulates the Pharmaceutical Products through DCGI - Drugs Controller General of India at Chair.
- Pharmaceutical products are regulated under the Drugs & Cosmetics Act,1940.
- To ensure drugs manufactured, imported, sold and distributed are safe and efficacious.

Fig.1.2.3: Organizational structure of CDSCO

Exercise

1. Which regulatory authority does India come under?

   .....

   .....

2. Which is the regulatory authority of US?

   .....

   .....

3. Mention any one thing FDA is responsible for?

   .....

   .....

4. Name any two elements the FDA regulates?

   .....

   .....

5. What is the full form of CDER?

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   .....

6. Mention any two roles of the agency?

   .....

   .....

7. What is TGA?

   .....

   .....

8. Name any two industries the TGA doesn't regulate?

   .....

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