**APPRENTICESHIP CURRICULUM (OPTIONAL TRADE)**

**Life Sciences**

**Research Associate- Pharma and Biological Products: Biological Product Development**

**Course Code: CO022500012**

**NAPS Non-NAPS**

**NSQF Level: 5.5**

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# Course Details

|  |  |  |
| --- | --- | --- |
|  | **Course Name** | **Research Associate- Pharma and Biological Products: Biological Product Development** |
|  | **Course Code** | **CO022500012** |
|  | **Apprenticeship Training Duration:**  *(2 to 4 weeks of BT is embedded in this duration as per the requirement of the establishment)* | **Months: 6 Months** |
| **Remarks** |  |
|  | **Credit** | 20 |
|  | **NSQF Level** (*Mandatory for NAPS*) | 5.5 **NSQC Approval Date:** 29th September 2023 |
|  | **Related NSQF aligned qualification details** | |  |  |  |  | | --- | --- | --- | --- | | **S. No.** | **Instantiated QP Name** | **Instantiated QP Code & Version** | **NQR Code** | | 1. | **Research Associate- Pharma, Biological Products: Biological Product Development** | **LFS/Q0514-SI003 (v1.0)** | **QG-5.5-LS-00997-2023-V1-LSSSDC** | |
|  | **Brief Job Role Description** | Research Associate- Pharma and Biological Products: Biological Product Development is responsible for assisting in biological product development, API synthesis, medicinal chemistry-based research, carrying out research related activities along with also assists in technology transfer and process development activities to large scale manufacturing. The jobholder is also responsible for reporting and documentation, problem solving and decision-making, Co-ordinate with manager and team members and maintaining healthy and safe working environment. |
|  | **NCO-2015 Code & Occupation** (*Access the NCO 2015 volumes from:* [*https://labour.gov.in/organizationsofmole/directorate-general-employment-training-dget*](https://labour.gov.in/organizationsofmole/directorate-general-employment-training-dget) ) | NCO-2015/2131.1300  Research and Development |
|  | **Minimum Eligibility Criteria**  *(Educational and/ or Technical Qualification)* | Pursuing Final Year of post-graduation -M Sc. In relevant science field  Or  Pursuing Final Year of post-graduation M. Pharma  Or  Pursuing Final Year of post-graduation M.Tech Biotechnology |
|  | **Entry Age for Apprenticeship** | 21 Years |
|  | **Any Licensing Requirements** (*wherever applicable*) | NA |
|  | **Is the Job Role amenable to Persons with Disability** | **Yes  No**  **If yes, check the applicable type of Disability**   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Locomotor Disability** | **Leprosy Cured Person** | **Cerebral Palsy** | **Dwarfism** | **Muscular Dystrophy** | | **Acid Attack Victims** | **Blindness** | **Low Vision** | **Deaf** | **Hard of Hearing** | | **Speech and Language Disability** | **Intellectual Disability** | **Specific Learning Disabilities** | **Autism Spectrum Disorder** | **Mental Illness** | | **Multiple Sclerosis** | **Parkinson's Disease** | **Hemophilia** | **Thalassemia** | **Sickle Cell Disease** | | **Multiple Disabilities** |  |  |  |  | |  | |
|  |  | **Remarks:** |
|  | **Submitting Body Details** | **Name:** Life Sciences Sector Skill Development Council  **E-mail ID:** info@lsssdc.in  **Contact Number:** 011-41042407/8 |
|  | **Certifying Body** | Life Sciences Sector Skill Development Council |
|  | **Employment Avenues/Opportunities** | **Quality Control Analysis or Analytical R&D in Pharmaceutical/Bio Pharma/Chemical/Food Processing/Agriculture companies**  Jobs Opportunities in private companies  The trainees can get a job in a corporate as a Research Associate- Pharma and Biological Products: Biological Product Development |
|  | **Career Progression** | **Vertical progression**  1. Research Scientist- Pharma, Biological Products and Medical Devices) |
|  | **Trainer’s Qualification & Experience:** | M.Pharma (with Pharmacognosy Subject) OR M.Tech in (Relevant Field) with 7 years of industry relevant experience in Research Associate- Pharma and Biological Products specification and 2 year experience On the job assessment/ Training experience/ Vocational assessment/ Academic assessment with Certification for Job Role: “Research Associate- Pharma and Biological Products” mapped to the Qualification Pack: “LFS/Q0514, V1.0” with minimum accepted score of 80%.  Or  M. Sc. (with relevant Subjects) with 5 years of industry relevant experience in biologist specification and 2-year experience on the job assessment/ Training experience/ Vocational assessment/ Academic assessment with Certification for Job Role: “Research Associate- Pharma and Biological Products” mapped to the Qualification Pack: “LFS/Q0514, V1.0” with minimum accepted score of 80%.  Or  NSQF Level 5.5 Certified under Research Associate- Pharma and Biological Products with 3 years of industry relevant experience and 1 year of experience in experience On the job assessment/ Training experience/ Vocational assessment/ Academic assessment with Certification for Job Role: “Research Associate- Pharma and Biological Products” mapped to the Qualification Pack: “LFS/Q0514, V1.0” with minimum accepted score of 80%.  Recommended that the Trainer is certified for the Job Role: “Trainer(VET and Skills)”, mapped to the Qualification Pack: ““MEP/Q2601,v2.0”” with minimum score of 80% |
|  | **Curriculum Creation Date** | 05 February 2025 |
|  | **Curriculum Valid up to Date** | 29 September 2026 |

# Module Details

| **S. No** | **Module/NOS Name, Code, Version** | **Outcomes** | **Assessment Marks** | | **Passing Percentage** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Th.** | **Pr.** | **Th.** | **Pr.** |
|  | **Ensure adherence to Environment, health and safety guidelines in a production facility and GMP controlled areas: LFS/N0111, v2** | * Adhere to health and personal hygiene- related protocols as per WHO standards and cGMP guidelines. * Ensure to wash the hands before entering in the production area as per SOP. * Check any allergy, sickness, or any other environment related breach and inform the supervisor. * Follow gowning procedures while entering an environment- controlled work area. * Adhere to safety and security policies, and procedures. * Use appropriate safety gears, like headgear, mask, gloves and other accessories as mentioned in the guidelines. * Maintain discipline for material segregation and 5S system is followed at the storage area under supervision * Report the alarm and notify the designated person immediately for action in cases of spill, fall, injury, toxic inhalation, fire, explosion, or any hazards. * Assist supervisor to implement preventive and corrective actions for identified deviations in safety and security policies and for reported hazards in consultation with EHS personnel. * Follow emergency procedures efficiently under supervision. | 30 | 70 | 70% | 70% |
|  | **Coordinate and communicate with supervisor/production chemist, research teams and auditors: LFS/N0129, v1** | * Assist manager to communicate process- flow improvements, production defects received from the previous process, repairs and maintenance of equipment to reporting supervisor/ production chemist. * Notify the supervisor/ Production chemist in case of planned absence, illness or critical issues requiring intervention. * Assist to communicate work- related and behavioral feedback with the supervisor for continuous improvement. * Assist manager to guide the manufacturing and packaging assistants during production process. * Perform the process of receiving, documenting and delivering clear and accurate handover, ensuring the effective transfer of essential operational information between shift operators under the supervision of a senior. * Follow the instructions provided by the reporting supervisor to ensure compliance with work requirements. * Assist the maintenance team for preventive and corrective maintenance break down and calibration errors under the supervision of senior. * Engage with quality control team for sample collection and batch release under supervision. * Assist with QA team for machine/ equipment validation at a routine interval as per SOP. * Respect all the genders, religions, and caste. * Ensure to adhere with the guidelines laid in Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act. * Report any violation of prevention of sexual harassment (POSH) rules immediately to the manager. | 30 | 70 | 70% | 70% |
|  | **Maintain experiment records ensuring data integrity and intellectual property rights: LFS/N0572,v 1** | * Assist manager in reviewing and updating the test methods and procedures as per the schedule. * Learn how to fill the logbooks worksheet (an analytical record), reference standard entries, calibration records, parameters of column, reagent, volumetric solution and working standards under the guidance of manager. * Ensure any defects/problem/incidents/quality issues/test results and report to the supervisor. * Assist manager in preparing analytical reports for detailed findings and recommendations as per SOPs. * Manage lab records in LNB and eLNB under supervision. * Check that the all original and controlled document files and quality records in a timely and accurate manner following ALCOA PLUS principles under the guidance of senior. * Help manager in daily monitoring, logging, prioritizing assessment requests. * Assist manager to ensure that all titles and asset information is reviewed thoroughly and in-dept. * Manage the confidentiality of the research projects and processes under the guidance of a senior. | 30 | 70 | 70% | 70% |
|  | **Employability Skills: DGT/VSQ/N 0103** | * Comprehend the importance of employability skills in fulfilling the current demands of the job market and the future of work. * Learn strategies for navigating learning and employability platforms effectively. * Delve into the significance of legal values, encompassing civic rights and responsibilities, citizenship, and societal obligations. * understand personal values and ethics like integrity, honesty, respect, and empathy. * Apply 21st Century Skills such as self-awareness, interpersonal skills, time management, critical and adaptive thinking, problem-solving, creative thinking, cultural and social awareness, emotional intelligence, and continuous learning in both personal and professional spheres. * Read and comprehend routine information, notes, instructions, emails, letters, etc., presented in English. * Practice basic English communication for everyday conversations in various contexts, both in person and over the telephone. * Write concise messages, notes, letters, and emails in English. * Differentiate between a job and a career and grasp their distinctions. * Demonstrate respectful and appropriate communication and behavior when interacting with individuals of all genders and persons with disabilities (PWD). * Discuss the protocol for reporting instances of sexual harassment in the workplace according to the guidelines set out in the POSH Act. * Identify the key components of a salary, calculate income, expenses, taxes, and potential investments. * Explore relevant rights and laws and utilize legal resources to combat instances of exploitation. * Recognize and enumerate various forms of entrepreneurship and enterprises, and evaluate potential business opportunities through research. * Identify potential sources of funding, and anticipate and address potential financial or legal challenges in pursuing a business opportunity. * Explain the process of identifying different customer types and understanding their needs. * Identify available apprenticeship opportunities and complete the registration process following the provided guidelines and requirements. * Prepare a sample career development plan with short- and long-term goals, based on aptitude. * Practice following verbal and nonverbal communication etiquette and active listening techniques in various settings. * Practice how to carry out offline and online financial transactions, safely and securely. * Operate digital devices and carry out basic internet operations securely and safely. * Demonstrate the use of e- mail and social media platforms and virtual collaboration tools to work effectively. * Practice the of use basic features of word processor, spreadsheets, and presentations. * Develop a sample business plan and a work model, considering the 4ps of marketing product, price, place, and promotion. * follow appropriate hygiene and grooming standards. * Create a sample professional curriculum vitae (résumé) * Practice how to search for suitable jobs using reliable offline and online sources such as employment exchange, recruitment agencies, newspapers etc. And job portals, respectively * Identify job openings using offline /online methods as per requirement | 20 | 30 | 70% | 70% |
|  | **Assist in new biological product development: LFS/N0576, v1** | * Assist manager to develop the exploratory development proposals for new innovation products. * Learn how to perform a literature search for the new product development. * Help manager in carrying out technical feasibility analysis on the NPD ideas. * Support manager to collect and analyze current development plans, new scientific developments and competitive activities. * Check reaction work-up and extraction process for new biological product synthesis. * Learn how to use appropriate measuring instruments, equipment, tools, accessories, MSDS, and relevant personal protective equipment (PPE) as required under supervision. * Demonstrate all the experimentation in adherence to safety, GRP and GLP guidelines under the supervision of senior. * Assist manager in identifying issues on projects and report to higher authorities. * Help manager in monitoring and conducting regular checks on equipment and instrument conditions, document calibrations. * Support manager in execution of product (innovation) development related activities. * Learn how to demonstrate standardization, optimization, and scale-up of new biological product synthesis. | 30 | 70 | 70% | 70% |
| **Total Marks** | | | **140** | **310** | **70%** | |

# Glossary

|  |  |
| --- | --- |
| **Term** | **Description** |
| Declarative Knowledge | Declarative knowledge refers to facts, concepts, and principles that need to be known and/or understood to accomplish a task or to solve a problem. |
| Key Learning Outcome | The key learning outcome is the statement of what a learner needs to know, understand, and be able to do to achieve the terminal outcomes. A set of key learning outcomes will make up the training outcomes. Training outcome is specified in terms of knowledge, understanding (theory), and skills (practical application). |
| OJT (M) | On-the-job training (Mandatory); trainees are mandated to complete specified hours of training on-site |
| Procedural Knowledge | Procedural knowledge addresses how to do something, or how to perform a task. It is the ability to work or produce a tangible work output by applying cognitive, affective, or psychomotor skills. |
| Training Outcome | Training outcome is a statement of what a learner will know, understand, and be able to do upon the completion of the training. |
| Terminal Outcome | The terminal outcome is a statement of what a learner will know, understand, and be able to do upon the completion of a module. A set of terminal outcomes helps to achieve the training outcome. |

# Acronyms

|  |  |
| --- | --- |
| **Acronym** | **Description** |
| AA | Assessment Agency |
| AB | Awarding Body |
| ISCO | International Standard Classification of Occupations |
| NCO | National Classification of Occupations |
| NCrF | National Credit Framework |
| NOS | National Occupational Standard(s) |
| NQR  NSQF | National Qualification Register  National Skills Qualifications Framework |
| OJT | On the job Training |
| SOP | Standard Operating Procedure |
| GMP | Good Manufacturing Practices |
| GLP | Good Laboratory Practices |
| ALCOA | Attributable, Legible, Contemporaneous, Original, and Accurate |
| BPR | Batch Packaging Record |
| BMR | Batch manufacturing Record |
| CAPA | Corrective and Preventive Actions |
| GDP | Good Documentation Practices |
| SME | Subject Matter Experts |

# Annexure 1: Tools and Equipment

## List of Tools and Equipment

The tools and equipment required are:

|  |  |  |
| --- | --- | --- |
| **S. No.** | **Tool / Equipment Name** | **Specification** |
|  | Autoclave | As per Industry Requirements |
|  | Laboratory Microscopes(40X and 100X) | As per Industry Requirements |
|  | pH meter | As per Industry Requirements |
|  | Hot plate with magnetic stirrer | As per Industry Requirements |
|  | analytical balance with printer (sensitivity 0.001 mg, 0.01 mg,0.1 mg,1 mg sensitivity) | As per Industry Requirements |
|  | water bath | As per Industry Requirements |
|  | Vortex Mixer | As per Industry Requirements |
|  | Micropipette (20 to 200 microlitre) | As per Industry Requirements |
|  | Micropipette (100 to 1000 microlitre) | As per Industry Requirements |
|  | Micropipette (0.5 ml to 5 ml) | As per Industry Requirements |
|  | Biosafety Cabinet | As per Industry Requirements |
|  | Laminar air flow (Vertical) | As per Industry Requirements |
|  | Dry Heat Air Oven | As per Industry Requirements |
|  | Depyrogenation oven | As per Industry Requirements |
|  | Refrigerator | As per Industry Requirements |
|  | Deep freezer | As per Industry Requirements |
|  | CO2 Incubator | As per Industry Requirements |
|  | Laboratory incubator for different temperature range | As per Industry Requirements |
|  | Shaker incubator | As per Industry Requirements |
|  | Garment cubicle | As per Industry Requirements |
|  | Needle burner | As per Industry Requirements |
|  | Hygrometer | As per Industry Requirements |
|  | Heat sealing machine | As per Industry Requirements |
|  | Glass slides | As per Industry Requirements |
|  | Self- Contained Breathing Apparatus | As per Industry Requirements |
|  | Co2 type Fire Extinguisher | As per Industry Requirements |
|  | ABC Type Fire Extinguisher | As per Industry Requirements |

## Classroom Aids

The aids required to conduct sessions in the classroom are:

1. Projector
2. Computer/laptops
3. Internet connectivity
4. Whiteboard
5. Marker pen
6. Scanner
7. Computer speaker

# Annexure 2: Assessment Strategy

This section includes the processes involved in identifying, gathering, and interpreting information to evaluate the Candidate on the required competencies of the program.

1. **Assessment System Overview:**

The assessment for the Training will be conducted toward the end of the training duration. The assessment of the qualification shall be carried out by NCVET approved assessment agencies empaneled by LSSSDC after a defined evaluation process. For Execution of the assessment for training for the qualification, LSSSDC will be engaging more than one NCVET approved assessment agency/ body.

* 1. **Criteria of selection of assessment body/agency:**

The assessment body/agency is selected based on:

* + - Prior experience and understanding of Life Sciences or similar sector.
    - Experience in conducting assessments for similar job roles.
    - Manpower and Technical capabilities.
    - Geographical reach
    - Existing Network in the Life Sciences Sector
    - Agencies internal policies to maintain standards, quality & professional Integrity
    - Agencies policy and practices in assessor management
    - NCVET approval
  1. **Assessment tool development for assessment of Training:**

For the Training assessment, the assessment instrument development is done by the selected assessment body with close monitoring and support of LSSSDC at every stage.

* + 1. ***Digital Written test for knowledge assessment:***

**Scope –** Is used to test the knowledge component of the QP.

**Tools –**computer or tab based online or offline.

**Method –** objective type questions, match the columns, fill in the blanks, tick the odd man out, choose the correct option, choose the best answer, True or false, Identify the object, tool or machinery, arrange in proper sequence, case study, scenario-based responses.

**Analysis –** Question paper is divided into sections. Each Section intends to assess a particular knowledge field of the trainee. Thus, section-wise calculation of marks gives a clear idea of the areas of improvement or expertise of the trainee. While a consolidated mark gives the overall rating of the trainee.

* + 1. ***Digital Written test for skill assessment:***

**Scope –** Is used to test primarily the Skill component of the QP. Trainee’s expertise in handling and managing the situation is tested.

**Tools –** computer or tab based online or offline questions

**Method –** A situation is narrated or created in the question posed to the trainee and he is asked objective type questions to select the correct reaction to the situation. The selected situations are based on real situations.

**Analysis –** Question paper is divided into sections. Each Section intends to assess a particular skill field of the trainee. Thus, section-wise calculation of marks gives a clear idea of the areas of improvement or expertise of the trainee. While a consolidated mark gives the overall rating of the trainee.

* 1. **Steps for assessment tool development:**
     + The selection of assessment tool(s) is done as per the assessment criteria prescribed in Qualification Pack
     + For Research Associate- Pharma and Biological Products: Biological Product Development assessment a blueprint of the question paper is part of the assessment tool for training.
     + Development of layout of Question paper is such that the entire PCs (Performance Criteria) of that QP are covered.
     + Score per question maps with the weightage given to that PC, in the assessment criteria, and the level of difficulty of the question.
     + An expert from industry is selected who is called “Subject Matter Expert” (SME). This SME must have over 13-15 years of experience in the industry in manufacturing occupation.
     + SME is screened and approved by LSSSDC. He/she is oriented by both LSSSDC and Assessment agency on – creating question Bank, level of questions, end the desired outcome of the assessment.
  2. **Execution of Training Assessment/ RPL Assessment:**
     + Once the assessment date for training is decided with common agreement of Industry/ Vocational Training Centre and LSSSDC, LSSSDC allocates the batch to an NCVET approved and LSSSDC empaneled assessment body/agency.
     + Assessment agency ensures
       - the availability of required infrastructure
       - the availability of validated assessment tools for the assessment of training for the assigned qualification
       - the availability of assessor as per assessor eligibility criteria of the qualification
     + Assessment agencies send the assessment confirmation to VTP/TC looping SSC
     + Assessment agency deploys LSSSDC certified assessor for executing the assessment
     + LSSSDC monitors the assessment process & records
     + The assessment is executed in two possible ways depending on the choice of the industry:
     1. Tab based assessment using physical proctoring
     2. Smartphone-based assessment using e-proctoring
     3. **Tab-based assessment using physical proctoring**
        + A representative from the Assessment agency is present on the day of assessment to executing the assessment at the venue in case of physical proctoring.
        + The assessment agency representative carries an identity card and letter from the council authorizing to conduct the assessment.
        + Assessment agency representative ensures the authenticity of Trainee’s identity by verifying the documents (any document issued by GOI, such as Ration card, Aadhaar Card, Driving License, Passport, Election card, etc)
        + The assessment agency representative maintains the records of attendance, verified documents, and tablet instruments used in the assessment.
        + Assessment agency representative collects evidence of the assessment in the best possible way (videos, pictures, voice recordings, etc)
        + Assessment agency representative transfers the assessment scores from tab to assessment agency server, using a secure, encrypted web-based program.
        + The assessment agency after processing the results and putting them in standard format hands over to LSSSDC within 7 days of assessment.
     4. **Smartphone-based assessment using e-proctoring**
        + All trainees enrolled in the batch due for assessment, are registered on an assessment tool application using their unique mobile number and e-mail ID along with a Govt. ID issued proof.
        + An assessment link is sent to the mail ID of each trainee with a defined expiry date of the link.
        + Trainee at any location can click on the link using his/her smartphone or a web camera-enabled computer system
        + Using the unique credentials and Govt ID number, the trainee logs in for the start of assessment and completes the assessment.
        + The authenticity of Trainee’s identity is done by assessment application by verifying the documents (any document issued by GOI, such as Ration card, Aadhaar Card, Driving Licence, Passport, election card, etc.) and a live photo capture
        + A live video of the candidate during the assessment is captured to collect the evidence of the assessment
        + Once the assessment is complete, the assessment application automatically assessment scores to the assessment agency server, using a secure, encrypted web-based program.
        + The assessment agency after processing the results and putting them in standard format hands over to LSSSDC within 7 days of assessment.

1. **Testing Environment:**

* The Centre/ location of the assessment is pre decided and geo tagged in case of physical assessment
* The assessment of LSSSDC qualifications are 99% done in digital environment while 1% pen and paper is used ONLY in business exigencies
* Based on the size of batch the assessment duration/ no. of required assessors are decided to ensure detailed assessment without any negative impact on quality of assessment
* The system driven automated assessment management system ensures uniform time allocation to each student, unique logins for each students and automated randomization of questions for developing multiple sets of question paper for single batch.
* Identity check of the student is mandated

1. **Assessment Quality Assurance levels/Framework:**

* Question bank is created by the Subject Matter Experts (SME) of Assessment Agency are verified by the other SME of LSSSDC
* All Questions are mapped to the specified assessment criteria
* Assessor eligibility criteria are structured to ensure quality and knowledge credentials of an assessor like-wise the trainer’s quality and knowledge credentials.
* Eligible Assessor must be certified by LSSSDC for the respective and relevant qualification
* The tools used for assessment are validated for relevance and feasibility for skill assessment of the qualification in consideration

1. **Types of evidence or evidence-gathering protocol:**

* Time-stamped & geotagged reporting of the assessor from assessment location
* ID Proof of the students
* Educational qualification of students
* Certificate of Trainer
* In case of Physical assessment, geotagged photographs of the students undergoing assessment
* While students are undergoing assessment on the digital assessment platform the system captures random photos of the student which is audited by LSSSDC

1. **Method of verification or validation:**

* Surprise visit to the assessment location
* ID Proof of the students for identity verification
* Educational qualification verification of students for validation of entry level criteria
* Certificate of Trainer to verify the credential of vocational educator
* Random photos taken by the digital system are verified during audit by the assessment team

1. **Method for assessment documentation, archiving, and access**

* Hard copies and digital copies (whichever is applicable) of the assessment evidences are stored with assessment agency team for 5 years
* Assessment transcripts are stored in the server space of assessment agency for 5 years
* Assessment question banks and validation records are stored with assessment agency and LSSSDC digitally
* Assessment records are archived with assessment agency archive server after 5 years for another 5 years
* Access of assessment records are controlled with restricted access to concerned department and stakeholders and is shared on demand after due approval of Head of Assessment and Certification-LSSSDC

**7.On the Job Training Assessment (applicable for OJT/ Apprenticeship):**

* 1. Each module/ NOS will be assessed separately.
  2. The candidate must score minimum percentage as per assessment criteria laid out in qualification in each module to successfully complete the OJT exam.
  3. Tools of OJT Assessment that will be used for assessing whether the candidate is having desired skills and competence, including Soft Skills effectively:
* Videos of Trainees during OJT (wherever possible)
* Observation based mark sheet from Supervisor or OJT examiner
* Simulated question paper
* XR practice module analytics wherever possible
  1. Assessment of each Module will ensure that the candidate is able to:
* Meet minimum performance criteria of the expected outcome/ skill set for each module/ NOS
* Understand and know the required concepts and its application at workplace
* Has gained the required employability skills

# Annexure 3: Not Applicable