

QUALIFICATIONS PACK - OCCUPATIONAL STANDARDS FOR LIFE SCIENCES INDUSTRY



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What are Occupational Standards (OS)?

- OS describe what individuals need to do, know and understand in order to carry out a particular job role or function
- OS are performance standards that individuals must achieve when carrying out functions in the workplace, together with specifications of the underpinning knowledge and understanding

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Introduction

Qualifications Pack - Production/ Manufacturing Chemist – Life Sciences

SECTOR: LIFE SCIENCES

SUB-SECTOR: PHARMACEUTICAL

OCCUPATION: MANUFACTURING

REFERENCE ID: LFS/Q1201

ALIGNED TO: NCO-2004/ 2113.0701

Production Chemist, also known as Manufacturing Chemist, is responsible for effective production of sustainable, compliant, quality products.

Brief Job Description: Production Chemist directs factory workers and supervises the defined production process to ensure that the desired product yield is achieved. They utilize their technical expertise on the manufacturing process, machine operation and support in as well as record deviations, incidents, OOS, OOT and change control and coordinate with QA and QC team for reports. They provide feedback to the production operators and assist in developing new methods to work in a more efficient manner.

Personal Attributes: The individual should have good knowledge of production process, GMP and must demonstrate attention to detail and proactive behaviour. The individual should have good planning and execution skills and should be able to anticipate and identify any bottlenecks for the production process.

Qualifications Pack For
Production/ Manufacturing Chemist – Life Sciences

Job Details

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|--------------------------|---|------------------|----------|
| Qualifications Pack Code | LFS/Q1201 | | |
| Job Role | Production/ Manufacturing Chemist – Life Sciences | | |
| Credits(NSQF) | TBD | Version number | 1.0 |
| Sector | Life Sciences | Drafted on | 23/06/14 |
| Sub-sector | Pharmaceutical | Last reviewed on | 15/05/15 |
| Occupation | Manufacturing | Next review date | 01/06/16 |
| NSQF Clearance on | 18/06/2015 | | |

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| Job Role | Production/ Manufacturing Chemist – Life Sciences |
| Role Description | Responsible for effective production of sustainable, compliant, quality products. |
| NSQF level | 5 |
| Minimum Educational Qualifications | B.Pharma preferable/ Graduate in Science (chemistry specialization preferable for Pharmaceuticals)/ B.Tech in chemistry |
| Maximum Educational Qualifications | M. Pharma / Masters in science (chemistry specialization preferable for Pharmaceuticals) |
| Training (Suggested but not mandatory) | On the job training (1 year of training for entry level chemist is mandatory), GMP training (Mandatory) |
| Minimum Job Entry Age | 19 Years |
| Experience | Fresher, no prior experience required for B. Pharma / M.Pharma / M.Sc. 1-3 years of experience for others |
| Applicable National Occupational Standards (NOS) | <p>Compulsory:</p> <ol style="list-style-type: none"> LFS/N0203 Supervise production process LFS/N0101 Maintain a healthy, safe and secure working environment in the life sciences facility LFS/N0204 Coordinate with Shift Supervisor, cross functional teams and within the team <p>Optional: N.A.</p> |

*Qualifications Pack For
Production/ Manufacturing Chemist – Life Sciences*

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| | |
| Performance Criteria | As described in the relevant OS units |

Qualifications Pack For
Production/ Manufacturing Chemist – Life Sciences

| Definitions | Keywords /Terms | Description |
|--------------------------|---|--|
| | Core Skills/Generic Skills | Core Skills or Generic Skills are a group of skills that are key to learning and working in today's world. These skills are typically needed in any work environment. In the context of the NOS, these include communication related skills that are applicable to most job roles. |
| | Description | Description gives a short summary of the unit content. This would be helpful to anyone searching on a database to verify that this is the appropriate NOS they are looking for. |
| | Function | Function is an activity necessary for achieving the key purpose of the sector, occupation, or area of work, which can be carried out by a person or a group of persons. Functions are identified through functional analysis and form the basis of NOS. |
| | Job role | Job role defines a unique set of functions that together form a unique employment opportunity in an organisation. |
| | Knowledge and Understanding | Knowledge and Understanding are statements, which together specify the technical, generic, professional and organisational specific knowledge that an individual needs in order to perform to the required standard. |
| | National Occupational Standards (NOS) | NOS are Occupational Standards, which apply, uniquely in the Indian context. |
| | Occupation | Occupation is a set of job roles, which perform similar/related set of functions in an industry. |
| | Organisational Context | Organisational Context includes the way the organisation is structured and how it operates, including the extent of operative knowledge managers have of their relevant areas of responsibility. |
| | Performance Criteria | Performance Criteria are statements that together specify the standard of performance required when carrying out a task. |
| | Qualifications Pack(QP) | Qualifications Pack comprises the set of NOS, together with the educational, training and other criteria required to perform a job role. A Qualifications Pack is assigned a unique qualification pack code. |
| Qualifications Pack Code | Qualifications Pack Code is a unique reference code that identifies a qualifications pack. | |
| Scope | Scope is the set of statements specifying the range of variables that an individual may have to deal with in carrying out the function which have a critical impact on the quality of performance required. | |
| Sector | Sector is a conglomeration of different business operations having similar businesses and interests. It may also be defined as a distinct subset of the economy whose components share similar characteristics and interests. | |

Qualifications Pack For
Production/ Manufacturing Chemist – Life Sciences

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|------------------------|---|
| Sub-Sector | Sub-sector is derived from a further breakdown based on the characteristics and interests of its components. |
| Sub-functions | Sub-functions are sub-activities essential to fulfil the achieving the objectives of the function. |
| Technical Knowledge | Technical Knowledge is the specific knowledge needed to accomplish specific designated responsibilities. |
| Unit Code | Unit Code is a unique identifier for an NOS unit, which can be denoted with an 'N'. |
| Unit Title | Unit Title gives a clear overall statement about what the incumbent should be able to do. |
| Vertical | Vertical may exist within a sub-sector representing different domain areas or the client industries served by the industry. |
| Keywords /Terms | Description |
| NOS | National Occupational Standard(s) |
| NSQF | National Skill Qualifications Framework |
| NCO-2004 | National Classification of Occupations-2004 |
| OS | Occupational Standard(s) |
| QP | Qualifications Pack |
| GMP | Good Manufacturing Practices |
| MHRA | The Medicines and Healthcare Products Regulatory Agency |
| USFDA | US Food and Drug Administration |
| CCF | Change Control Form |
| BMR | Batch Manufacturing Record |
| BPR | Batch Production Record |
| CDSCO | The Central Drugs Standard Control Organization |
| OOS | Out of Specification |
| OOT | Out of Trends |
| CAPA | Corrective and Preventive Action |

Acronyms

LFS/N0203: Supervise Production Process

National Occupational Standard



Overview

This Occupational Standard describes the knowledge, understanding and skills required for a Production Chemist to supervise the production process.

LFS/N0203: Supervise Production Process

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|--------------------------------|---|--|
| National Occupational Standard | Unit Code | LFS/N0203 |
| | Unit Title (Task) | Supervise Production Process |
| | Description | This NOS is about a Production Chemist performing the required activities to effectively supervise the production process |
| | Scope | <p>This unit / task covers the following: Supervise production activities</p> <ul style="list-style-type: none"> • Provide the production schedule and necessary guidelines to production operators to handle production activities on a daily basis to achieve target • Communicate directions basis defined SoPs for junior chemists/ production operators that include the proper ingredients, temperatures, pressure and mixing times for each step in the production process as per defined SoPs • Review documentation of all activities to ensure compliance to the process for future reference • Record the production output for each shift operation in the Batch Process Report as per the approved guidelines of respective Drug Administration Body (MHRA, USFDA, CDSCO, IDRA, India FDA etc.) • Ensure that all the in-process checks are carried out and quality of the product is ensured at each stage as per the Standard Operating Procedures and other statutory requirements • Communicate any equipment breakdown to maintenance team without any delay including monitoring the status and type of breakdown, CAPA if required. • Maintain GMP standards at shop floor and conditions suitable for production of quality products as per requirement <p>Manage staff and inventory</p> <ul style="list-style-type: none"> • Train junior chemists/ production operators on procedures and provide assistance to them when needed • Coordinate to maintain sufficient stock of raw materials and chemicals for production activities as per production schedule • Plan and source materials from the stores as per daily production schedule • Ensure that all the materials are released and labeled properly, used in defined quantities and returned to stores after use, including inventory of production accessories • Develop standard operating procedures to improve efficiency • Check the raw material for name , code, conditions, batch no., shelf life and quantities <p>Participate as a team member during audits</p> <ul style="list-style-type: none"> • Facilitate the audit as a production team member |
| | Performance Criteria (PC) w.r.t. the Scope | |
| Element | Performance Criteria | |

LFS/N0203: Supervise Production Process

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| Supervise production activities | <p>To be competent, the user/individual on the job must be able to:</p> <p>PC1. execute day-wise/shift-wise allocated work as per defined plan to ensure adherence to production schedule and document the same (including online documentation)</p> <p>PC2. follow-up on Reaction set up/ Distillation/ Separation/ Dispensing/ Mixing / Granulation/ Compression/ Coating/ Filling/ Encapsulation/ Visual Inspection/ any other production activity as per Good Manufacturing Practices (GMP)</p> <p>PC3. fill up batch manufacturing records and log books (including online)</p> <p>PC4. follow-up of manufacturing activity as per standard operating procedures and batch manufacturing records</p> <p>PC5. monitor batch mixing and other production activity and conditions required as per SoP and maintain BMR / BPR</p> <p>PC6. co-ordinate with stores, quality assurance ,quality control, engineering & packing department</p> <p>PC7. raise the incidents/deviations/change control to quality assurance</p> <p>PC8. plan the equipment for idle condition to prepare for preventive maintenance and cleaning as per schedule</p> <p>PC9. ensure that the work area is clean, dry and in a sanitized condition</p> <p>PC10. fill the CCF (Change Control Form) for changes as mandated and create planned deviation report</p> <p>PC11. communicate any equipment breakdown to the maintenance team as per defined organization procedure without time delay, get maintenance date and shutdown dates from maintenance team, ensure that the issues are resolves as per desired level and plan batches accordingly in order to meet the production schedules</p> <p>PC12. online monitoring of environment conditions in the process area, quarantine area and other as defined by SOP (including necessary escalations in case of observed abnormalities)</p> <p>PC13. calibration and verification of the equipment and balances used in the process area</p> <p>PC14. coordinate for line clearance activities</p> <p>PC15. carry out error free documentation of the production activities</p> <p>PC16. minimize wastage</p> <p>PC17. ensure optimal usage of resources by effective deployment of the same, including identification of process optimization opportunities and reducing breakdowns</p> <p>PC18. coordinate with maintenance teams for planning preventive maintenance activities in order resolve all machine –related issues</p> <p>PC19. execute the work as per risk control procedure</p> |
| Manage staff and inventory | <p>PC20. check the availability of dispensed raw material, packaging material and finished goods for ideal conditions, batch number and quantities</p> <p>PC21. train down the line staff on various processes and controls (including on best practices)</p> <p>PC22. manage manpower</p> |
| Participate as a team member during audits | <p>PC23. ensure that the production area is always audit ready</p> <p>PC24. provide necessary response to audit query via appropriate channel</p> |
| Knowledge and Understanding (K) | |
| A. Organisational Context | The user/individual on the job needs to know and understand: |

LFS/N0203: Supervise Production Process

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| <p>(Knowledge of the Company/ Organisation and its processes)</p> | <p>KA1. company's Quality policy KA2. production norms of the company KA3. safety and hygiene norms KA4. roles and responsibilities of others in the production area all relevant standard operating procedures(SOP) of the company KA5. organization's whistle blowing policy</p> |
| <p>B. Technical Knowledge</p> | <p>The user/individual on the job needs to know and understand:</p> <p>KB1. Knowledge of Fundamental Science in API Production including Size Separation, Mixing and homogenization Process, Mass Transfer, Fluid Flow, Heat Transfer, Size Reduction, Basics of Formulations including Route of Drug Administration and Various Dosage Forms like Oral Solid Dosage, Liquid Oral Dosage, Sterile Dosage, Dermatological Dosage and their relevant benefits, Assay calculation procedure and assay role in formulation, Standard weight procedure or standard quantity effect in formulation</p> <p>KB2. conceptual and practical skills about Production process of Oral Solid Dosage including Process of Granulation, Compression, Coating, Capsule Filling; production process of Liquid Oral Dosage, Sterile Dosage and Dermatological Formulations</p> <p>KB3. knowledge of production equipment and operations (RMG, FBD, Vibro sifter, Multimill, Paste kettle, Compression Machine, Capsule Machine, Coating Machine, Blister Machine, Countec Machine Liquid - Filter Press, Inline Homogeniser Cum Mixer, Preparation vessel, reactor & Storage Tank, Dispo Homogenizer, Skid CIP-WIP System, Colloid Mill, Automatic Filling Machine, Semi-Automatic Cap Sealing Machine, Induction machine, Washing Machine, On Line Inspection, Turn Table, Labelling machine; Ointment – Planetary, Preparation vessel, reactor & Storage Tank, Vacuum Homogenizer Mixer, Agitator- Stirrer, Colloid Mill, Inline Homogenizer, Skid CIP-WIP System, Tube Filling Machines For Laminated / Plastic Tubes Injection – Multicolumn, Rectangular Steriliser, D.M. storage Tank, Dry Heat Sterilizer, Filling / Pressure Vessel, Automatic Filling Machine, Monoblock Rotary Dry Powder Filling & Sealing Machine, Semi-Automatic Cap Sealing Machine, Semi-Automatic Ropp Cap Sealing Machine & Screw Capping Machine, Automatic Single Head Ropp Cap Sealing Machine, Washing Machine, On Line Inspection, Automatic Self Adhesive Vertical Labelling Machine API- Various type of reactors, separation and distillation equipment etc</p> <p>KB4. health and safety requirements of the production area KB5. standard operating procedures of the entire production unit KB6. good manufacturing practices and good documentation practices KB7. ideal conditions for working of equipment KB8. maintenance schedule of equipment KB9. importance of maintaining cleanliness in the production area KB10. calibrations & inspection of equipment KB11. knowledge of ethical compliance/ code of ethics</p> |
| <p>Skills (S)</p> | |
| | <p>Writing skills</p> |

LFS/N0203: Supervise Production Process

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| A. Core Skills/ Generic Skills | The user/ individual on the job needs to know and understand how to: SA1. do legible entries with the permanent ink SA2. write detailed reports for investigation SA3. pay attention to detail while recording production parameters |
| | Reading skills |
| | The user/individual on the job needs to know and understand how to: SA4. read important documents, reports and procedures accurately SA5. read the guidelines and interpret them correctly |
| | Oral Communication (Listening and Speaking skills) |
| | The user/individual on the job needs to know and understand how to: SA6. Interact with people to effectively gather information, including through shopfloor visits and daily / weekly operational meetings SA7. Listen effectively and orally communicate information accurately SA8. Ask for clarification and advice from others |
| B. Professional Skills | Decision making |
| | The user/individual on the job needs to know and understand how to: SB1. make decisions on a suitable course of action or response SB2. make decisions in a team considering the ideas of the team |
| | Plan and Organise |
| | The user/individual on the job needs to know and understand how to: SB3. make line/process specific production plan from the overall production plan after considering all the parameters like manpower, preventive maintenance schedule, validation schedule, time, availability of materials etc. SB4. plan work assigned on a daily basis and provide estimates of time required for each piece of work and update the status of the assigned work SB5. place and ensure all the things are arranged in an organised manner easy to locate and accessible |
| | Problem solving |
| | The user/individual on the job needs to know and understand how to: SB6. seek clarification on problems from others SB7. use effective problem solving techniques for root cause identification SB8. discuss with team about the problem and try to solve SB9. evaluate and solve the problem in shortest period of the time |
| | Analytical thinking |
| | The user/individual on the job needs to know and understand how to: SB10. analyse data and activities SB11. pass on relevant information to others SB12. analyse the batch documents SB13. check the working approach of other individuals, including adherence to GMP |
| | Critical thinking |

LFS/N0203: Supervise Production Process

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| | <p>The user/individual on the job needs to know and understand how to:</p> <ul style="list-style-type: none">SB14. provide opinions on work in a detailed and constructive waySB15. apply balanced judgments to different approachesSB16. understand the depth of the issue and apply a proactive approach |
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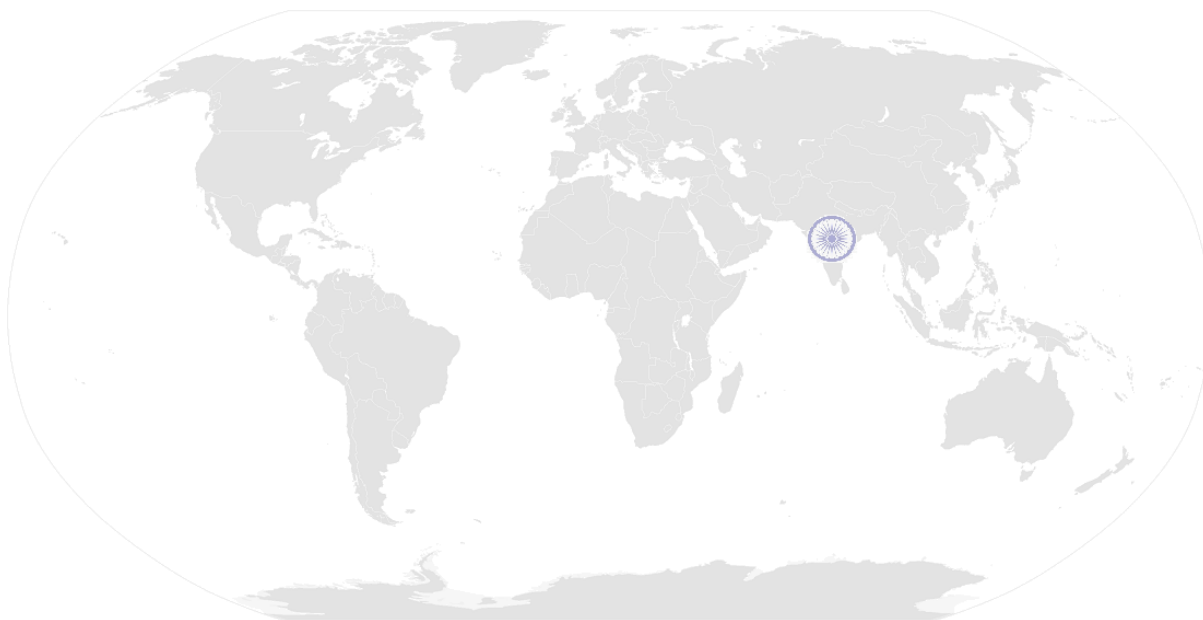
LFS/N0203: Supervise Production Process
NOS Version Control

| NOS Code | LFS/N0203 | | |
|---------------------|----------------|------------------|----------|
| Credits(NSQF) | TBD | Version number | 1.0 |
| Industry | Life Sciences | Drafted on | 23/06/14 |
| Industry Sub-sector | Pharmaceutical | Last reviewed on | 15/05/15 |
| Occupation | Manufacturing | Next review date | 01/06/16 |



LFS/N0101: Maintain a healthy, safe and secure working environment in the life sciences facility

National Occupational Standard



Overview

This Occupational Standard is about the knowledge, understanding and skills required by a Production Chemist to ensure healthy, safe and secure working environment in the life sciences facility.

LFS/N0101: Maintain a healthy, safe and secure working environment in the life sciences facility

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| National Occupational Standard | Unit Code | LFS /N0101 |
| | Unit Title (Task) | Maintain a healthy, safe and secure working environment in the life sciences facility |
| | Description | This NOS unit is about a Production Chemist monitoring the working environment and making sure that it meets the requirements for health, safety and security in the pharmaceutical/contract research/biopharmaceutical facility/ manufacturing/ testing/ analysis/ research laboratory. |
| | Scope | <p>This unit / task covers the following:</p> <p>Ensuring healthy, safe and secure working environment:</p> <ul style="list-style-type: none"> • self monitor and adhere to safety principles and standards • ensure behavioural safety by workmen to cGMP and applicable safety standards on the shop floor/ laboratory • report any identified breaches in health, safety, and security policies and procedures to the designated person <p>Managing emergency procedures:</p> <ul style="list-style-type: none"> • illness • accidents • fires • other reasons to evacuate the premises • breaches of security |
| Performance Criteria (PC) wrt the Scope | | |
| Element | Performance Criteria | |
| Ensuring healthy, safe and secure working environment | <p>To be competent, the user/individual on the job must be able to:</p> <p>PC1. observe and comply with the company's current health, safety and security policies and procedures</p> <p>PC2. while carrying out work, use appropriate safety gears like head gear, masks, gloves and other accessories as mentioned in the guidelines</p> <p>PC3. report any identified breaches in health, safety, and security policies and procedures to the designated person</p> <p>PC4. responsible for maintaining discipline at the shop-floor/ production area</p> <p>PC5. identify and correct any hazards that the individual can deal with safely, competently and within the limits of their authority</p> <p>PC6. adhere and comply to storage and handling guidelines for hazardous material</p> <p>PC7. identify and recommend opportunities for improving health, safety, and security to the designated person</p> <p>PC8. complete any health, safety and security activities like safety drills and prepare records legibly and accurately</p> | |
| Managing emergency procedures | <p>PC9. report any hazards that the individual is not competent to deal with to the relevant person in line with organizational procedures and warn other people who may be affected</p> <p>PC10. follow the company's emergency procedures promptly, calmly, and efficiently</p> | |

LFS/N0101: Maintain a healthy, safe and secure working environment in the life sciences facility

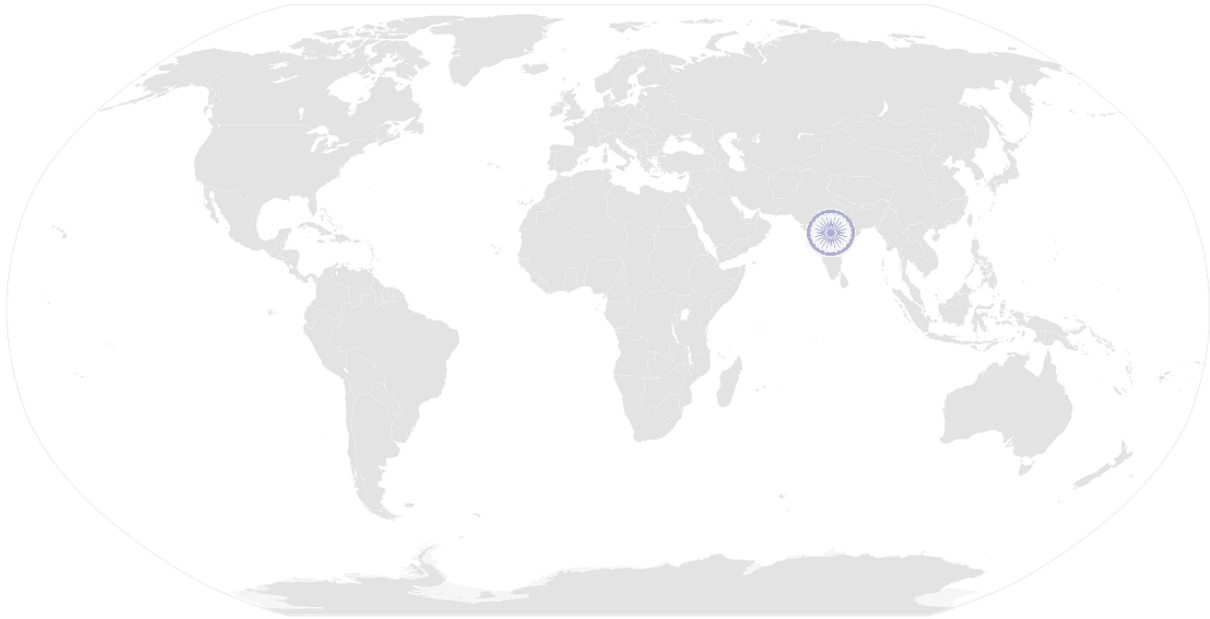
| Knowledge and Understanding (K) | |
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| <p>A. Organisational Context (Knowledge of the Company/ Organisation and its processes)</p> | <p>The user/ individual on the job needs to know and understand:</p> <p>KA1. legislative requirements and company’s procedures for health, safety and security and individual’s role and responsibilities in relation to this</p> <p>KA2. what is meant by a hazard, including the different types of health and safety hazards that can be found in the workplace</p> <p>KA3. how and when to report hazards</p> <p>KA4. limits of individual responsibility for dealing with hazards</p> <p>KA5. the organization’s emergency procedures for different emergency situations and the importance of following these</p> <p>KA6. the importance of maintaining high standards of health, safety and security</p> <p>KA7. implications that any non-compliance with health, safety and security may have on individuals and the organization</p> <p>KA8. health hazards and its implications if any in the production process</p> |
| <p>B Technical Knowledge</p> | <p>The user/ individual on the job needs to know and understand:</p> <p>KB1. different types of breaches in health, safety and security and how and when to report these</p> <p>KB2. evacuation procedures for workers and visitors</p> <p>KB3. how to summon medical assistance and the emergency services, where necessary</p> <p>KB4. how to use the health, safety and accident reporting procedures and the importance of these</p> <p>KB5. different types of occupational health hazards</p> <p>KB6. knowledge of chemical substances, their characteristics and required precaution and safety measures</p> |
| Skills (S) | |
| <p>A. Core Skills/ Generic Skills</p> | <p>Writing skills</p> |
| | <p>The user/ individual on the job needs to know and understand how to:</p> <p>SA1. complete accurate, well written work with attention to detail</p> |
| | <p>Reading skills</p> |
| | <p>The user/ individual on the job needs to know and understand how to:</p> <p>SA2. read instructions, guidelines, procedures, rules and service level agreements</p> |
| | <p>Oral Communication (Listening and Speaking skills)</p> |
| | <p>The user/ individual on the job needs to know and understand how to:</p> |

LFS/N0101: Maintain a healthy, safe and secure working environment in the life sciences facility

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| | SA3. listen effectively and orally communicate information accurately |
| B. Professional Skills | Decision making |
| | The user/ individual on the job needs to know and understand how to: |
| | SB1. make decisions on suitable courses of action |
| | Plan and Organise |
| | The user/ individual on the job needs to know and understand how to: |
| | SB2. plan and organize work to meet health, safety and security requirements |
| | Problem solving |
| | The user/ individual on the job needs to know and understand how to: |
| | SB3. apply problem solving approaches in different situations |
| | Analytical thinking |
| The user/ individual on the job needs to know and understand how to: | |
| SB4. analyse data and activities | |
| Critical thinking | |
| The user/ individual on the job needs to know and understand how to: | |
| SB5. apply balanced judgments to different situations | |

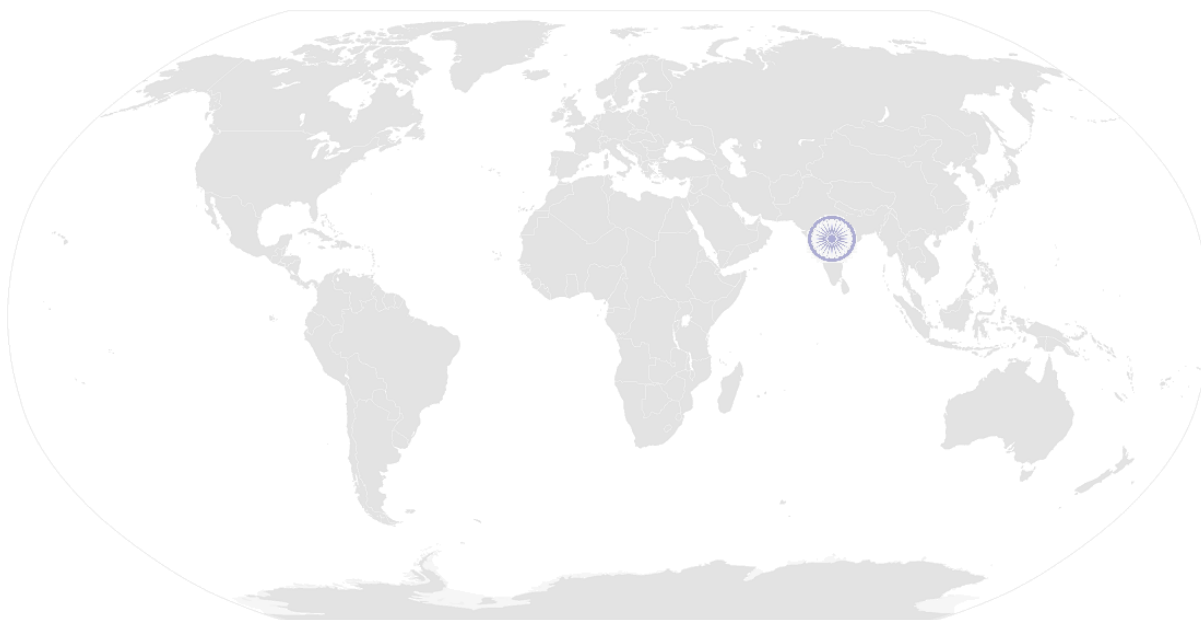
LFS/N0101: Maintain a healthy, safe and secure working environment in the life sciences facility
NOS Version Control

| NOS Code | LFS /N0101 | | |
|---------------------|--|------------------|----------|
| Credits(NSQF) | TBD | Version number | 1.0 |
| Industry | Life Sciences | Drafted on | 26/06/14 |
| Industry Sub-sector | Pharmaceuticals, Bio Pharmaceuticals | Last reviewed on | 15/05/15 |
| Occupation | Manufacturing, Quality, Supply Chain, R&D | Next review date | 01/06/16 |



LFS/N0204 : Coordinate with Shift Supervisor, cross functional teams and within the team

National Occupational Standard



Overview

This Occupational Standard describes the knowledge, understanding and skills required of a Production Chemist to work as a team member and multi-task in order to achieve production on schedule and meeting the quality requirements.

LFS/N0204 : Coordinate with Shift Supervisor, cross functional teams and within the team

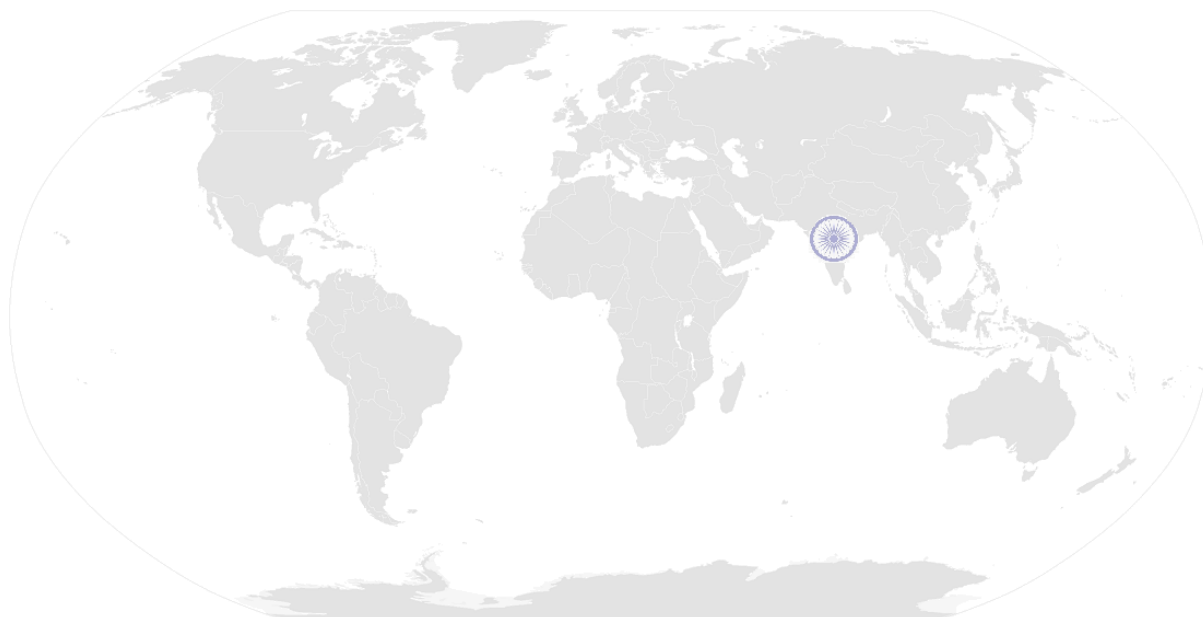
| | | |
|--|--|--|
| National Occupational Standard | Unit Code | LFS/N0204 |
| | Unit Title (Task) | Coordinate with Shift Supervisor, cross functional teams and within the team |
| | Description | This NOS unit is about communicating with colleagues (both within team & cross-functional) and seniors in order to achieve smooth and hazard-free work flow during production |
| | Scope | <p>This unit/task covers the following:</p> <p>Interact with Immediate Supervisor</p> <ul style="list-style-type: none"> • receive work instructions from reporting supervisor • communicate to reporting supervisor about process-flow improvements and production defects received from previous process • communicate any potential hazards or expected process disruptions • communicate maintenance and repair schedule proactively to the supervisor • handover completed work to supervisor <p>Interact with colleagues within the team</p> <ul style="list-style-type: none"> • work as a team with colleagues and share work as per their or own work load and skills • communicate and discuss work flow related difficulties in order to find solutions with mutual agreement <p>Interact with colleagues from cross functional teams</p> <ul style="list-style-type: none"> • receive feedback from Quality Control and Quality Assurance and rework in order to complete work on time • provide support to Quality Assurance team during audits • coordinate with maintenance team for any breakdowns and for preventive and corrective maintenance • Coordinate with Stores to receive material in time |
| Performance Criteria (PC) w.r.t. the Scope | | |
| Element | Performance Criteria | |
| Interact with Immediate Supervisor | <p>To be competent, the user/individual on the job must be able to:</p> <p>PC1. understand the work output requirements</p> <p>PC2. understand the quality standards to be maintained</p> <p>PC3. proactively inform supervisor on issues requiring intervention</p> <p>PC4. comply with company policy and rule</p> | |
| Interact with colleagues within the team | <p>PC5. deliver quality work on time and report any anticipated reasons for delays</p> <p>PC6. be able to resolve conflicts</p> | |
| Interact with colleagues from cross functional teams | <p>PC7. multi-task relevant activities to align with team goals</p> <p>PC8. put team over individual goals</p> | |

LFS/N0204 : Coordinate with Shift Supervisor, cross functional teams and within the team

| Knowledge and Understanding (K) | |
|--|---|
| A. Organisational Context (Knowledge of the Company/ Organisation and its processes) | The user/individual on the job needs to know and understand: KA1. company's vision, policies on: preferred language of communication, reporting and escalation policy, quality delivery standards, and personnel management KA2. reporting structure |
| B. Technical Knowledge | The user/individual on the job needs to know and understand: KB1. communicate effectively KB2. build team coordination |
| Skills (S) | |
| A. Core Skills/ Generic Skills | Writing skills |
| | The user/ individual on the job needs to know and understand how to: SA1. read job sheets and interpret technical details mentioned in the jobsheet |
| | Reading skills |
| | The user/individual on the job needs to know and understand how to: SA2. read notes/comments from the supervisor |
| | Oral Communication (Listening and Speaking skills) |
| | The user/individual on the job needs to know and understand how to: SA3. Interact (speak and listen) with team members to work efficiently SA4. be clear and concise in communicating |
| B. Professional Skills | Decision making |
| | The user/individual on the job needs to know and understand how to: SB1. spot and communicate potential areas of disruptions to work process and report the same SB2. when to report to supervisor and when to deal with a colleague individually, depending on the type of concern |
| | Plan & Organize |
| | The user/individual on the job needs to know and understand how to: SB1. plan and organize assigned work in order to achieve specified targets and deadlines |

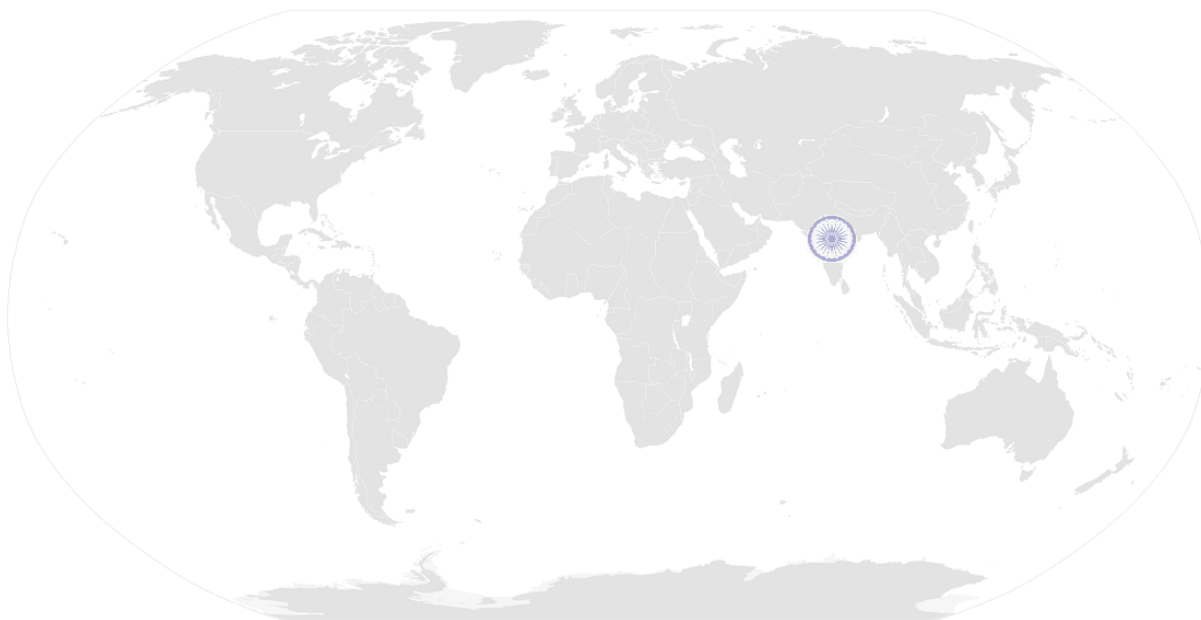
LFS/N0204 : Coordinate with Shift Supervisor, cross functional teams and within the team

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| | SB2. multi-task and adapt to meet work timelines |
| | SB3. establish rapport and effective working relationships with different team members and other teams to deliver planned work |
| | Analytical thinking |
| | The user/individual on the job needs to know and understand how to: |
| | SB3. improve work processes by interacting with others and adopting best practices |
| | Critical thinking |
| | The user/individual on the job needs to know and understand how to: |
| | SB4. spot process disruptions and delays and report and communicate with solutions |



LFS/N0204 : Coordinate with Shift Supervisor, cross functional teams and within the team
NOS Version Control

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|---------------------|---|------------------|----------|
| NOS Code | LFS/N0204 | | |
| Credits(NSQF) | TBD | Version number | 1.0 |
| Industry | Life Sciences | Drafted on | 23/06/14 |
| Industry Sub-sector | Pharmaceuticals, Bio Pharmaceuticals | Last reviewed on | 15/05/15 |
| Occupation | Manufacturing | Next review date | 01/06/16 |



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Annexure

Nomenclature for QP and NOS

Qualifications Pack

9 characters

LFS/ Q 0101

LFS



QP Number (2 numbers)

Q denoting Qualification Pack



Occupation (2 numbers)

Occupational Standard

An example of NOS with 'N'

9 characters

LFS/ N 0101

LFS



OS Number (2 numbers)

N denoting National Occupational Standard



Occupation (2 numbers)

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The following acronyms/codes have been used in the nomenclature above:

| Sub-Sector | Range of Occupation Numbers |
|--|-----------------------------|
| Pharmaceutical and Biopharmaceutical and Contract Research | 01-10 |
| Pharmaceutical | 11-20 |
| Biopharmaceutical | 21-30 |
| Contract Research | 31-40 |

| Sequence | Description | Example |
|------------------|-------------------|---------|
| Three letters | Industry name | LFS |
| Slash | / | / |
| Next letter | Whether QP or NOS | Q/N |
| Next two numbers | Occupation code | 01 |
| Next two numbers | OS number | 01 |

Qualifications Pack For Production/ Manufacturing Chemist – Life Sciences

CRITERIA FOR ASSESSMENT OF TRAINEES

Job Role Production/ Manufacturing Chemist – Life Sciences

Qualification Pack LFS/Q1201

Sector Skill Council Life Sciences Sector Skill Development Council

Guidelines for Assessment:

1. Criteria for assessment for each Qualification Pack will be created by the Sector Skill Council. Each Performance Criteria (PC) will be assigned marks proportional to its importance in NOS. SSC will also lay down proportion of marks for Theory and Skills Practical for each PC.
2. The assessment for the theory part will be based on knowledge bank of questions created by the SSC.
3. Individual assessment agencies will create *unique question papers for theory part for each candidate at each examination/training center* (as per assessment criteria below)
4. Individual assessment agencies will create *unique evaluations for skill practical for every student at each examination/training center* based on this criteria
5. To pass the Qualification Pack , every trainee should score a minimum of 70% in every NOS
6. In case of successfully passing only certain number of NOS's, the trainee is eligible to take subsequent assessment on the balance NOS's to pass the Qualification Pack.

| | | Marks Allocation | | | |
|---|--|-------------------|--------|--------|------------------|
| | | Total Marks (300) | Out Of | Theory | Skills Practical |
| LFS/N0203 (Supervise production process) | PC1. execute day-wise/shift-wise allocated work as per defined plan to ensure adherence to production schedule | 100 | 4 | 2 | 2 |
| | PC2. follow-up on Dispensing/ Mixing / Granulation/ Compression/ Coating/ Filling/ Encapsulation/ Visual Inspection/ any other production activity as per Good Manufacturing Practices (GMP) | | 4 | 2 | 2 |
| | PC3. fill up batch manufacturing records and log books (including online) | | 5 | 2 | 3 |
| | PC4. follow-up of manufacturing activity as per Standard Operating Procedures and Batch Manufacturing Records | | 4 | 2 | 2 |
| | PC5. monitor batch mixing and other production activity and conditions required as per SoP/ and maintain BMR/ BPR | | 4 | 2 | 2 |

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| | | | |
|--|---|---|---|
| PC6. co-ordinate with quality assurance ,quality control & packing department | 5 | 2 | 3 |
| PC7. raise the incidents/deviations/change control to Quality Assurance | 4 | 2 | 2 |
| PC8. plan the equipment for idle condition to prepare for preventive maintenance and cleaning as per schedule | 3 | 1 | 2 |
| PC9. ensure that the work area is clean, dry and in a sanitized condition | 4 | 2 | 2 |
| PC10. fill the CCF (Change Control Form) for changes as mandated and create planned deviation report | 5 | 2 | 3 |
| PC11. communicate any equipment breakdown to the maintenance team as per defined organization procedure without time delay, get maintenance date and shutdown dates from maintenance team, ensure that the issues are resolves as per desired level and plan batches accordingly in order to meet the production schedules | 4 | 2 | 2 |
| PC12. online monitoring of environment conditions in the process area, quarantine area and other as defined by SoP (including necessary escalations in case of observed abnormalities) | 4 | 2 | 2 |
| PC13. calibration and verification of the balances and equipment used in the process area | 4 | 2 | 2 |
| PC14. coordinate for line clearance activities | 4 | 2 | 2 |
| PC15. carry out error free documentation of the production activities | 4 | 2 | 2 |
| PC16. minimize wastage | 4 | 2 | 2 |
| PC17. ensure optimal usage of resources by effective deployment of the same, | 4 | 2 | 2 |

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| | | | | | |
|--|---|-----|-----|----|----|
| | including identification of process optimization opportunities and reducing breakdowns | | | | |
| | PC18. coordinate with maintenance teams for planning preventive maintenance activities in order to resolves machine-related issues | | 4 | 2 | 2 |
| | PC19. execute the work as per risk control procedure | | 4 | 1 | 3 |
| | PC20. check the availability of dispensed raw material, packaging material and finished goods for ideal conditions, batch number and quantities | | 2 | 1 | 1 |
| | PC21. train down the line staff on processes and controls (including on best practices) | | 4 | 2 | 2 |
| | PC22. manage manpower | | 6 | 3 | 3 |
| | PC23. ensure that the production area is always audit ready | | 5 | 2 | 3 |
| | PC24. provide necessary response to audit query via appropriate channel | | 5 | 3 | 2 |
| | Total | | 100 | 47 | 53 |
| LFS/N0101 (Maintain a healthy, safe and secure working environment in the life sciences facility) | PC1. observe and comply with the company's current health, safety and security policies and procedures | 100 | 10 | 5 | 5 |
| | PC2. while carrying out work, use appropriate safety gears like head gear, masks, gloves and other accessories as mentioned in the guidelines | | 10 | 5 | 5 |
| | PC3. report any identified breaches in health, safety, and security policies and procedures to the designated person | | 10 | 5 | 5 |
| | PC4. responsible for maintaining discipline at the shop-floor/ production area | | 10 | 5 | 5 |
| | PC5. identify and correct any hazards that the individual can deal with safely, competently and within the limits of their authority | | 10 | 5 | 5 |

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|---|---|-------|-----|----|----|
| | PC6. adhere and comply to storage and handling guidelines for hazardous material | | 10 | 5 | 5 |
| | PC7. identify and recommend opportunities for improving health, safety, and security to the designated person | | 10 | 5 | 5 |
| | PC8. complete any health, safety and security activities like safety drills and prepare records legibly and accurately | | 10 | 4 | 6 |
| | PC9. report any hazards that the individual is not competent to deal with to the relevant person in line with organizational procedures and warn other people who may be affected | | 10 | 4 | 6 |
| | PC10. follow the company's emergency procedures promptly, calmly, and efficiently | | 10 | 5 | 5 |
| | | Total | 100 | 48 | 52 |
| LFS/N0204 (Coordinate with Shift Supervisor, cross functional teams and within the team) | PC1. understand the work output requirements | 100 | 12 | 6 | 6 |
| | PC2. understand the quality standards to be maintained | | 12 | 6 | 6 |
| | PC3. proactively inform supervisor on issues requiring intervention | | 12 | 6 | 6 |
| | PC4. comply with company policy and rule | | 13 | 6 | 7 |
| | PC5. deliver quality work on time and report any anticipated reasons for delay | | 13 | 6 | 7 |
| | PC6. be able to resolve conflicts | | 12 | 6 | 6 |
| | PC7. multi-task relevant activities to align with team goals | | 12 | 6 | 6 |
| | PC8. put team over individual goals | | 14 | 6 | 8 |
| | | Total | 100 | 48 | 52 |