

TRANSNATIONAL SKILL STANDARDS FOR LIFE SCIENCES INDUSTRY

Scope		Overview	science related work activities. This could include individuals working in hospitals, scientific laboratories, schools and universities.
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Competency Mapping

Performance Criteria - Indian NOS	Performance Criteria - UK NOS	Gaps in Indian NOS
Assist in technology transfer / process development: To be competent, the user/individual on the job must be able to-	Plan and monitor small scale processing activities within life sciences: You must be able to-	
PC1. devise ways to produce the new product on a large scale with standardized protocols and support in technology transfer	P1. ensure that your life sciences related work activity is carried out in accordance with workplace procedures	None
PC2. research and develop ways to manufacture products and monitor existing processes and products for quality and efficiency		None
PC3. asses the manufacturer's information like raw materials, critical process parameters, performing equipment and comparisons	P4. establish the conditions for small scale processing and take the appropriate action to maintain them	None
	P5. detail the calibration status of equipment and the preparations required for the processing operation	None
PC4. evaluate the process development for its robustness		None
PC5. review packaging line trials, e.g. if a product is a new SKU to the plant/site it is crucial to perform line trials for filling the product into the proposed bottle/ container		None

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PC6. review stability indicating methods to enable onsite transfer against the protocol signed off by the client/manufacturer/ R&D team	P7. use the agreed plans to start, monitor and control delivery of small scale processing activities	None
PC7. review validation records for the small scale batch produced		None
PC8. crosscheck safety handling protocols for the product		None
PC9. devise ways to make improvements in methods and technology by reviewing and interpreting technical test results and data	P9. gather information from implementation of the small processing plan to assist in the preparation of future plans	None
PC10. use sophisticated technology to monitor and identify faults in the production process		None
PC11. work closely with cross functional teams from Operations, Tech Operations, CMC, Supply Chain, Analytical, Quality, R&D etc.		None
PC12. Identification/verification of CPPs and CQAs and other important parameters.	P8. evaluate variances between what was planned and what actually happened on the activities and take action in accordance with organization policies and procedures	None
PC13. verify design space and understand set of input ranges (CPPs) that provide high probability that CQAs will meet specification		None
PC14. support the control strategy to assure focus on critical points		None
PC15. assurance of clear documentation of all process/product knowledge		None
PC16. work with the integrated interdisciplinary team of	P3. evaluate available information and consult with	None

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experts: Operations, Tech Operations, CMC, Supply Chain, Analytical, Quality, R&D etc.	others to prepare plans for small scale processing activities	
		P2. use safe practices and the appropriate personal protection equipment where scientific or technical activities are performed
		P6. submit proposed plans to the relevant people in the organization for approval and to assist the overall planning
		P10. present the results of the work done to the appropriate people, in accordance with departmental and organisational procedures
Knowledge & Understanding- Indian NOS: Organisational Context- Indian NOS	Knowledge Statements- UK NOS	
KA1. the reason and impact of the occurrence of problems during research work	K21. common problems that can occur and solutions	None
KA2. measures, steps and possible solutions that have been taken/identified to address the previous problems	K21. common problems that can occur and solutions	None
KA3. the correct method for carrying out corrective actions outlined for each problem		None
KA4. knowledge of competitor products		None
KA5. in-depth knowledge of organisation products and their benefits vis-à-vis competition	K1. why it's important to understand the latest technological developments in the life sciences industry and how to keep up-to-date with them	None

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Knowledge & Understanding- Indian NOS: Technical Knowledge	Knowledge Statements- UK NOS	
KB1. understanding of prior knowledge from similar products		None
KB2. manufacturer's information: from raw materials through critical process parameters, followed by performing equipment, backside, and comparisons	K15. the range of equipment used for small scale processing	None
	K19. the range of resources needed for small scale processing	None
Knowledge & Understanding- Indian NOS: Technical Knowledge	Knowledge Statements- UK NOS	
KB4. need and relevance for technology transfer	K1. why it's important to understand the latest technological developments in the life sciences industry and how to keep up-to-date with them	None
KB5. Scale-Up and Post-Approval Change (SUPAC) guidelines along with FDA guidelines which identify the types of equipment available for different pharmaceutical manufacturing functions	K5. the implications of not taking account of legislation, regulations, standards and guidelines when conducting scientific or technical activities	None
KB6. ideal technology transfer conditions where equipment should stay within the same class or sub-class, eliminating unnecessary variables	K13. the operating conditions that are necessary to conduct the small scale processing, and how to maintain them	None
KB7. broad reasons for questioning during FDA pre-approval reviews and annual reports		None

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KB8. Critical Process Parameters (CPPs), Critical Quality Attributes (CQAs)	K3. how to ensure cost effectiveness does not affect quality	None
	K12. the essential features of a process plan and how to establish it	None
KB9. process parameters and process capability	K12. the essential features of a process plan and how to establish it	None
KB10. manufacturing and process control technologies along with quality systems infrastructure	K6. the scientific or technical techniques and processes you must use correctly in the workplace	None
	K10. the consequences of breaches of quality procedures	None
KB11. concept of pilot vs. manufacturing scale	K2. why it's important to ensure your activities are cost effective	None
	K11. the principles and procedures for small scale processing	None
Knowledge & Understanding- Indian NOS: Technical Knowledge	Knowledge Statements- UK NOS	
KB12. product/process/analytical method knowledge between development and manufacturing sites		None
KB13. knowledge of SOPs and protocols	K14. why it is important to establish set procedures	None
KB14. product life cycle knowledge and understanding		None
KB15. knowledge of manufacturing process		None
KB16. technical reasons for manufacturing defects		None

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KB17. Uni/Multivariant Design of experiments		None
KB18. validation requirements/strategy		None
Core Skills/ Generic Skills- Indian NOS: The user/ individual on the job needs to know and understand how to:- Indian NOS	Knowledge Statements- UK NOS	
SA1. make complete and accurate notes of the information and data gathered		None
SA2. record and communicate details of work done to appropriate people		None
SA3. excellent report writing skills both offline (pen and paper) and online using computer based system		None
SA4. follow guidelines/procedures/rules and service level agreements		None
SA5. Read and interpret memos/ instructions. SOPs		None
Core Skills/ Generic Skills- Indian NOS: The user/ individual on the job needs to know and understand how to:- Indian NOS	Knowledge Statements- UK NOS	
SA6. communication with upstream and downstream teams	K23. the reasons why effective communication is important, and the methods used for communicating effectively	None
SA7. listen effectively and orally communicate information accurately		None
Professional Skills- Indian NOS: The user/ individual on the job needs to know and understand how to:	Knowledge Statements- UK NOS	

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SB1. make decisions on a suitable course of action or response		None
SB2. apply balanced judgments to different approaches		None
SB3. plan work assigned on a daily basis to complete the work in time and provide estimates of time required for each piece of work		None
SB4. seek clarification on problems from supervisors		None
SB5. use effective problem solving techniques		None
SB6. analyse data and activities		None
SB7. pass on relevant information to other departments		None
SB8. give attention to detail		None
Professional Skills- Indian NOS: The user/ individual on the job needs to know and understand how to:	Knowledge Statements- UK NOS	
		K4. the health and safety requirements of the area in which you are carrying out the life sciences related work activities
		K7. the importance of correct identification, and any unique workplace coding system
		K8. the lines of communication and responsibilities in your department, and the links with the rest of the organisation
		K9. the limits of your own authority and to whom you should report if you have problems that you cannot resolve

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		K16. why it is important to establish data recording and reporting procedures for activities
		K17. the methods that can be used for dealing with the handling, storage and disposal of materials
		K18. the cleaning materials and methods that should be used
		K20. the reporting procedure in the event of deviations from processing plans
		K22. the document control and reporting procedures that should be used

***General Note:** In the LSSSDC NOS, Range statement is not separated out. It is integrated holistically into the PCs and organizational context knowledge and technical knowledge within the QPs.