

**SKILLS FRAMEWORK FOR FOOD MANUFACTURING
TECHNICAL SKILLS & COMPETENCIES (TSC) REFERENCE DOCUMENT**

TSC Category	Quality Management					
TSC	Process Validation					
TSC Description	Verify that a process is reproducible and consistent in delivering quality products according to specifications and standards					
TSC Proficiency Description	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6
		FMF-QUA-2028-1.1	FMF-QUA-3028-1.1	FMF-QUA-4028-1.1-14	FMF-QUA-5028-1.1-14	
		Collect data required for process validation activities	Evaluate data to establish whether a process is reproducible and capable of consistently delivering quality product	Develop process validation procedures and evaluate validation results	Formulate process validation strategy to ensure quality of integrated systems across the manufacturing process chain	
Knowledge		<ul style="list-style-type: none"> Purpose of process validation Definition of process variables, parameters and conditions Types of data required for process validation Methods of data collection Procedures for quality assurance and control in the food manufacturing plant Types, causes and consequences of process deviations Importance of following standard operating procedures (SOPs) Good manufacturing practices (GMPs) 	<ul style="list-style-type: none"> Design of experiment (DOE) studies Laboratory, pilot-scale and commercial models of production Product and ingredient attributes impacting on quality Process, operating and equipment parameters Functionality and limitations of commercial manufacturing equipment Predictors of and contributors to production variability Risk and impact analysis procedures and tools for screening variables Principles of statistical control, including but not limited to deviation analysis and process control limits Procedures for quality control in a food manufacturing facility Documenting investigations and reporting out-of-specification attributes and parameters 	<ul style="list-style-type: none"> Approaches to process control Effects of scale on commercial processes Application of statistical metrics Purpose and applications of various process validation tests and procedures Potential risks of process deviation Production efficiency and quality metrics 	<ul style="list-style-type: none"> End-to-end processes in food manufacturing Procedures of food manufacturing processes Parameters for testing viability of food manufacturing processes Principles of process development Techniques to project long term impact of process deviations Local and global industry standards and best practices in process validation 	

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<p>Abilities</p>		<ul style="list-style-type: none"> Identify collection methodology to be applied based on critical validation characteristics to be studied Follow work plans and schedules to complete collection work on-time Collect data on critical validation characteristics according to SOPs Store data in appropriate format Support in the identification of process deviations Submit data for evaluation 	<ul style="list-style-type: none"> Evaluate data on performance of manufacturing processes and production outputs Detect and evaluate deviations of process variables from the steady state condition of a process plant to determine cause Identify and record deviations in production attributes and parameters Identify possible sources of variability in product and process quality Evaluate re-usability of materials to establish usable lifetimes of materials Document the investigation and data analysis performed as per organisational procedures 	<ul style="list-style-type: none"> Plan process validation tests, procedures and schedules in accordance with regulations and good manufacturing practices (GMPs) Establish production attributes and parameters deviation detection, control, and mitigation procedures Monitor the status of process validation analysis to evaluate the analytical methods used Describe statistical methods to be used in analysing data collected Assess impact of changes in a process production efficiency and validation requirements Evaluate key results and findings from process validation tests and analyses Confirm uniformity of product and process quality Draft process performance qualification (PPQ) reports 	<ul style="list-style-type: none"> Liaise with relevant departments to develop an organisation-wide process validation plan, Inclusive of a process performance qualification (PPQ) protocol Determine optimal manufacturing conditions for operating parameters, processing limits and raw material inputs Determine data collection and evaluation requirements Determine acceptance criteria for each processing step Develop a sampling plan assuring statistical confidence of quality within and between batches Develop strategies for addressing deviations from expected conditions and handling of nonconforming data Direct the implementation of process controls during process design and qualification phases Communicate key insights from process validation analysis to senior stakeholders Review PPQ reports to conclude whether the process meets validation criteria Provide detailed justification in cases where validation 	
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					approval is denied, outlining specific aspects of the design stage through the process qualification stage	
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