

TSC Category	Quality Assurance and Quality Control Management					
TSC	Analytical Method Validation					
TSC Description	Verify analytical methods used to ensure accuracy, validity and reliability					
TSC Proficiency Description	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6
		ECM-QAM-2001-1.1	ECM-QAM-3001-1.1	ECM-QAM-4001-1.1	ECM-QAM-5001-1.1	
		Apply procedures in data collection to support analytical method validation	Perform critical method validation characteristics studies	Establish and oversee analytical method validation processes and activities	Lead analytical method validations to ensure consistency of processes	
Knowledge		<ul style="list-style-type: none"> Purpose of analytical method validation Types of data required for analytical method validation Methods of data collection Importance of following Standard Operating Procedures (SOPs) Procedures for Quality Assurance and Quality Control (QA&QC) 	<ul style="list-style-type: none"> Principles of analytical method validation Importance of analytical method validation Types of quality control tests Analytical method validation characteristics 	<ul style="list-style-type: none"> Timing and frequency requirements for analytical method validation Application of different analytical methods Impact of different analytical methods on accuracy, validity and reliability of analytical results Methods of troubleshooting inaccuracies, invalidities and unreliability within analytical methods and results Quality control (QC) management procedures Regulatory agency inspections and audit procedures 	<ul style="list-style-type: none"> Importance of analytical test method validation throughout manufacturing process steps in the energy and chemicals industry Importance of cross-functional collaboration in validating quality control (QC) testing procedures and analyses 	
Abilities		<ul style="list-style-type: none"> Identify data collection methodologies 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 	<ul style="list-style-type: none"> Identify critical method validation characteristics to be studied, based on specific analytical methods Prepare lead-time, resources and schedules, based on specific analytical methods Perform critical method validation characteristics 	<ul style="list-style-type: none"> Develop analytical method validation plans Articulate objectives, and key indicators, of analytical method validation Specify quality control test requirements to be validated Evaluate impact of QC test process changes on 	<ul style="list-style-type: none"> Advise on critical process steps requiring QC testing and analysis Collaborate with key stakeholders across functions to approve validation of analytical methodologies Drive analytical method validation improvements 	

**SKILLS FRAMEWORK FOR ENERGY AND CHEMICALS
TECHNICAL SKILLS AND COMPETENCIES (TSC) REFERENCE DOCUMENT**

		<ul style="list-style-type: none"> • Store data in appropriate formats • Clean up data to remove incomplete, duplicated and/or incorrect data • Support identification of process deviations • Submit data for evaluation 	<p>studies, according to Standard Operating Procedures (SOPs)</p> <ul style="list-style-type: none"> • Analyse method validation results • Document method validation results 	<p>analytical methods required</p> <ul style="list-style-type: none"> • Develop internal analytical method validation Standard Operating Procedures (SOPs) and documentation • Review method validation results • Evaluate validation reports to identify areas for improvement • Recommend changes to QC testing procedures and analysis 		
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