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| **TSC Category** | Development and Implementation | | | | | |
| **TSC Title** | Process Validation | | | | | |
| **TSC Description** | Verify that processes are reproducible and consistent in delivering quality products according to specifications, and in line with international regulations | | | | | |
| **TSC Proficiency Description** | **Level 1** | **Level 2** | **Level 3** | **Level 4** | **Level 5** | **Level 6** |
|  |  | **ICT-QUA-3028-1.1** | **ICT-QUA-4028-1.1** | **ICT-QUA-5028-1.1** |  |
|  |  | Evaluate data to establish whether processes are reproducible and capable of consistently delivering quality products | Develop process validation procedures and evaluate validation results | Formulate process validation strategies to ensure quality integrated systems across the manufacturing process chain |  |
| **Knowledge** |  |  | * Design of experiment studies * Laboratory-scale, pilot-scale and commercial models of production * Quality, product and raw material attributes * Process, operating and equipment parameters * Functionalities 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 biopharmaceutical manufacturing plants * Methods of documenting investigations and reporting out-of-specification attributes and parameters | * Approaches to process control * Effects of scale on commercial processes * Application of statistical metrics * Purpose and applications of various process validation tests and procedures * Types of Process Analytical Technology (PAT) tools and their applications * Potential risks of process deviations * Production efficiency and quality metrics | * End-to-end processes in biopharmaceutical manufacturing * Procedures of biopharmaceutical manufacturing processes * Parameters for testing the viability of biopharmaceutical manufacturing processes * Principles of process development * Principles of integrating Process Analytical Technology (PAT) into process validation procedures * Techniques to project the long-term impact of process deviations * Local and global industry standards and best practices in process validation |  |
| **Abilities** |  |  | * Evaluate data on the performance of manufacturing processes and production outputs * Detect and evaluate deviations of process variables from process plants’ steady state condition to determine root causes * Identify and record deviations in production attributes and parameters * Identify possible sources of variability in product and process quality * Perform impact analysis for identified root causes * Evaluate the re-usability of materials to establish usable lifetimes of materials * Document investigations and data analyses performed as per organisational procedures | * Plan process validation tests, procedures and schedules in accordance with regulations and Current Good Manufacturing Practices (CGMPs) * Establish procedures for production attributes and parameters deviation detection, control, and mitigation * Evaluate the analytical methods used in process validation analysis * Describe the statistical methods to be used process validation to analyse data collected * Facilitate the integration of PAT into process validation procedures * Assess the impact of changes in processes on production efficiency and validation requirements * Evaluate key results and findings from process validation tests and analyses * Confirm the uniformity of product and process quality * Draft Process Performance Qualification (PPQ) reports | * Liaise with relevant departments to develop organisation-wide process validation plans, which incorporate Process Performance Qualification (PPQ) protocols * Determine optimal manufacturing conditions for required operating parameters, processing limits and raw material inputs * Determine data collection and evaluation requirements * Determine acceptance criteria for each process step * Develop sampling plans, assuring statistical confidence of quality within and between batches * Develop strategies for addressing deviations from expected conditions and managing non-conforming data * Direct the implementation of process controls during the process design and qualification phases * Communicate key insights from process validation analyses to relevant stakeholders * Review PPQ reports to conclude whether processes meet validation criteria * Provide detailed justification in cases where validation approval is denied, outlining specific aspects of the design stage through the process qualification stage to meet approval requirements |  |
| **Range of Application** |  | | | | | |