COGBENG-02

Develop a Maintenance and Testing Programme for a Biomanufacturing Process

Overview

This standard identifies the competences you need for planning the effective testing, calibration and maintenance programmes for the equipment used within the biomanufacturing environment.

Based on the control strategy for the bioprocess you will be required to identify appropriate testing, calibration and maintenance programmes for the equipment used in the biomanufacturing process to ensure that bioproduction meets all regulatory and quality requirements. You will be required to work to the relevant standard operating procedures, legislation and organisational policy, and to follow Good Manufacturing Practice (GMP). You will also be required to ensure that records are kept of the testing, calibration and maintenance activities and are accessible to the relevant people.

This activity is likely to be undertaken by someone whose work role carries out process engineering work activities in a biochemical environment. This could include individuals working in the following industries, Chemical, Pharmaceutical and Life Science industries.

Performance criteria

You must be able to:

P1 review and interpret the regulations, directives and guidelines relevant for a bioprocess testing, calibration and maintenance programme
P2 determine the specific equipment tests, sequence and timings based on the control strategy and the use of criticality analysis that will enable the bioprocess to be compliant with the continuing regulations, directives and guidelines
P3 determine the specific maintenance requirements, sequence and timings based on the control strategy that will enable the bioprocess to be compliant with the continuing regulations, directives and guidelines
P4 incorporate the recommended manufacturers calibration and maintenance schedules within protocols and procedures for servicing and maintenance as appropriate
P5 produce and update relevant testing, calibration and maintenance schedules and plans in the agreed format
P6 review the results of the testing and maintenance activities and implement further tests if necessary
P7 resolve any instances where the testing, calibration or maintenance activities cannot be fully met or where there are identified defects outside the planned schedule
P8 set up measures to check the planned maintenance is effective and up-to-date
P9 make improvements to the testing, calibration and maintenance programme where appropriate and gain approval for the improvements
P10 maintain full, accurate and legible records of information and store in line with current legislation, guidelines, local policies and protocols
P11 work within your level of competence, responsibility and accountability
P12 deal effectively with problems within your control and report those that cannot be solved

Knowledge and understanding

You need to know and understand:

K1 the biochemical manufacturing process from raw materials through to final product
K2 the regulations, directives and guidelines relevant for a bioprocess testing, calibration and maintenance programme
K3 the control strategy designated for the biomanufacturing process
K4 how to perform a criticality analysis to determine specific equipment requirements
K5 the importance of a risk-based planned maintenance, testing and calibration programme for biomanufacturing equipment and potential impact on safety, product quality and regulatory infringement
K6 how to interpret technical manuals, drawings, instructions and other equipment information relevant in the planning of the work activities
K7 the principles of operation of the instrumentation and control equipment being tested/calibrated, its intended use, capabilities and limitations
K8 where maintenance is supported by an external contractor, how to obtain and check suitability of their quantitative and qualitative measures for the maintenance service
K9 the equipment failure modes and the identification of which failure modes might effectively be reduced by appropriate preventive maintenance
K10 methods of checking and calibrating instruments, and the type and range of equipment that can be used
K11 how to set up and apply the appropriate test and calibration equipment
K12 the impact on production affecting decisions on the bioprocess maintenance activity
K13 the specific precautions to be taken when carrying out instrument testing and calibration activities within a biomanufacturing environment
K14 the correct procedures for handling and testing of the equipment and related technology during maintenance procedures
K15 how to create or update Standard Operating Procedures (SOP's) maintenance schedules and plans
K16 how to monitor the testing, calibration and maintenance programme and identify specific performance issues
K17 how to analyse the test and calibration results
K18 how to verify the compliance to statutory requirements for both equipment testing/calibration and planned maintenance
K19 what to do if instruments do not meet the required calibration parameters and how to recommend appropriate improvement actions
K20 hazards associated with carrying out testing and calibrating activities on instrumentation and control systems and how to minimise them and reduce any risks

K21 the importance of completing and maintaining accurate and clear testing, calibration and maintenance records, in the correct format and location to meet organisation and regulatory requirements
K22 the information and documentation systems that are in use within the organisation
K23 the documentation required, and the procedures to be followed, at the end of the testing and calibrating to record data to the system
K24 how to verify that accurate monitoring records are maintained and retained
K25 how the testing, calibrating and manufacturing activities may affect the work of others, and the procedure for informing them of the activities
K26 the extent of your own authority and to whom you should report if you have problems that you cannot resolve

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