COGSCIM4_13

Contribute to team feasibility review for product development in a biomanufacturing environment

Overview

This standard identifies the competences you need to contribute to a team feasibility review for existing/new development in a biomanufacturing environment, in accordance with approved procedures. You are required to evaluate the design with other member of the new/existing product development and introduction team in the context of your area of responsibility. You will also be required to identify and recommend improvements to the design from the perspective of your area of responsibility. 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 present records and details of your biomanufacturing work to the appropriate people.

Your responsibilities will require you to comply with organisational policy and procedures for ensuring, through your technical support of the new/existing product development and introduction team, the successful review of the existing/new product. You will also report any problems that you cannot personally resolve to the relevant authority.

Your responsibilities will require you to comply with health and safety requirements and organisational policy and procedures for the team review work that is undertaken. You will be required to report any problems with the biomanufacturing activities that you cannot personally resolve, or that are outside your permitted authority, to the relevant people. You will be expected to work to verbal/written instructions and standard operating procedures, and to report against your departmental goals set by senior management, taking personal responsibility for your own actions and for the quality and accuracy of the work that you carry out.

Your underpinning knowledge will be sufficient to provide a sound basis for your work, and will enable you to adopt an informed approach to existing/new product development and introduction procedures. You will have an understanding of the team review principles used, in adequate depth to provide a sound background for carrying out the biomanufacturing activities to the required specification.

You will understand the safety precautions required when carrying out the biomanufacturing activities for scientific operations and processes. You will be required to demonstrate safe working practices throughout, and will understand your responsibility for taking the necessary safeguards to protect yourself and others in the workplace.

This activity is likely to be undertaken by someone whose work role carries out Science/Bio manufacturing work activities. This could include individuals working in the following industries, Chemical, Pharmaceutical and Life Science industries.

COGSCIM4_13

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Performance criteria

You must be able to:

P1 ensure that your work is carried out in accordance with standard operating procedures
P2 wear the appropriate personal protection equipment (PPE) when working in the biomanufacturing environment
P3 review the team meeting agenda and identify actions
P4 prepare data and information for the team review of the new product
P5 evaluate the design specification in the context of your area of responsibility
P6 make recommendations as to where improvements/changes can be made to the design/product
P7 record the results of the feasibility exercise, according to agreed procedures
P8 execute and communicate agreed actions, following the feasibility exercise, in the agreed timescales
P9 communicate the required information about the work done, to senior management and other authorised people, in accordance with organisational procedures

COGSCIM4_13

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Knowledge and understanding

You need to know and understand:

K1 the health and safety requirements of the area in which you are carrying out the biomanufacturing activities
K2 the implications of not taking account of legislation, regulations, standards and guidelines when conducting biomanufacturing activities
K3 the standard operating procedures, as set down in local biomanufacturing operating manuals
K4 the importance of following equipment manufacturers' operating instructions
K5 the principles of Good Manufacturing Practice (GMP) applied in the workplace
K6 the importance of wearing protective clothing, gloves and eye protection when handling materials (including biochemical substances, biological pathogens and/or antigens), and the equipment used to contain and process them
K7 the manufactured product and batch process tracking and records system
K8 the types of handling and sorting system, and the procedures used for products undergoing processing in the manufacturing facilities
K9 the importance of correct identification, and any unique organisational or manufacturing numbers
K10 the organisational requirements for maintaining the security of the workplace
K11 the lines of communication and responsibilities in your department, and their links with the rest of the organisation
K12 the limits of your own authority and to whom you should report if you have problems that you cannot resolve
K13 how to identify and minimise potential risks to health and safety that could occur during implementation of the new product development and introduction programme
K14 the organisational procedures and information systems for storing product review data
K15 the organisational activities required for the new product development and introduction team's product review process
K16 the importance of establishing and recording responsibilities for new product review and analysis process
K17 who should have responsibility for the different parts of the review process
K18 the various procedures that can be used in the product review process
K19 the principles and techniques used in a structured new product review
K20 the factors to be taken into account for disseminating information before and after a review process
K21 the types of problem that could occur during the team review process
K22 the methods and techniques used to evaluate new products
K23 how to use decision making and creativity techniques to generate ideas for improvement
K24 how to prioritise and rank improvement ideas
K25 why it is important to have new product review exercises
K26 what should be included in plans for team reviews of new products
K27 how to prioritise and schedule review activities

Scope/range

1. carry out all of the following activities:
1.1. identify important characteristics of the manufacturing design
1.2. provide technical evaluation and recommend strategies
1.3. identify potential strengths, weakness and opportunities for the new product manufacture, in the context of your area of responsibility
1.4. communicate information to the appropriate people and to the quality management system

2. establish the criteria and procedures for feasibility review of the design, including six of the following:
   2.1. functionality
   2.2. performance/specification
   2.3. aesthetics
   2.4. materials
   2.5. cost
   2.6. regulatory requirements
   2.7. weight
   2.8. recycling
   2.9. manufacturability
   2.10. durability
   2.11. safety
   2.12. other (please specify)

3. evaluate product manufacturing activity against all of the following:
   3.1. comparisons between the new product and existing product processes
   3.2. comparison data and information systems
   3.3. identify new technologies that are being included in the new product manufacturing process
   3.4. identify effective methods and techniques for meeting the manufacturing requirements
   3.5. generate ideas for improved manufacturing performance

4. contribute technical advice and recommendations to two of the following:
   4.1. mixing
   4.2. fermentation
   4.3. filtration
   4.4. packaging
   4.5. quality control
   4.6. other (please specify)

5. record details of the work done and communicate the details to the appropriate people, using:
   5.1. verbal report
   Plus one method from the following:

5.2. written or typed report
5.3. specific company documentation
5.4. computer-based record
5.5. electronic mail

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