

Overview

This unit identifies the competences you need to provide leadership to members of your biomanufacturing team, in accordance with approved procedures. You are required to motivate and support them to achieve the objectives of the team and their personal work objectives. 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 be required to present records and details of your biomanufacturing work to the appropriate people.

You will be required to plan the work of your team, and to set and agree individual objectives. You will help them solve technical problems, monitor their progress against the objectives you set, and provide feedback and guidance for improvements in their performance

Your responsibilities will require you to comply with organisational policy and procedures for the leadership activities undertaken, and to report any problems with the activities, materials or equipment 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, with a minimum of supervision, taking personal responsibility for your own actions and for the quality and accuracy of the work that you and your team 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 team building/leading procedures. You will have an understanding of the leadership skills 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.

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 set out and positively communicate the purpose and objectives of your biomanufacturing team
- P4 involve team members in planning how your biomanufacturing team will achieve its objectives
- P5 ensure that each member of your biomanufacturing team has personal work objectives and understands how achieving these will contribute to achievement of the team's objectives
- P6 encourage and support your biomanufacturing team members to achieve their personal work objectives and those of the team, and provide recognition when objectives have been achieved
- P7 steer your biomanufacturing team successfully through difficulties and challenges, including conflict within the team
- P8 encourage and recognise creativity and innovation within your biomanufacturing team
- P9 give your biomanufacturing team members support and advice when needed
- P10 monitor activities and progress against objectives across your biomanufacturing team, and encourage responsibility in individuals for their own actions
- P11 communicate the required information about the work of your biomanufacturing team to authorised people, in accordance with departmental and organisational procedures

Knowledge and understanding

You need to know and understand:

Sector specific

- 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 principles of Good Manufacturing Practice (GMP) applied in the workplace

Organisation specific

You need to know and understand:

- K4 the importance of wearing protective clothing, gloves and eye protection when handling materials (such as biochemical substances, biological pathogens and/or antigens), and the equipment used to contain and process them
- K5 the manufactured product and batch process tracking and records system
- K6 the types of handling and sorting system, and the procedures used for products undergoing processing in the manufacturing facilities
- K7 the importance of correct identification, and any unique organisational or manufacturing numbers
- K8 the organisational requirements for maintaining the security of the workplace
- K9 the lines of communication and responsibilities in your department, and their links with the rest of the organisation
- K10 the limits of your own authority and to whom you should report if you have problems that you cannot resolve

Equipment/Process specific

You need to know and understand:

- K11 different ways of communicating effectively with members of your team
- K12 how to set objectives which are SMART (Specific, Measurable, Achievable, Realistic and Time-bound)
- K13 how to plan the achievement of team objectives, and the importance of involving team members in this process
- K14 the importance of, and being able to show team members how personal work objectives contribute to the achievement of team objectives
- K15 how to allocate work objectives and delegate responsibility to individuals in your team
- K16 how to select and successfully apply a limited range of different methods for motivating, supporting and encouraging team members, and for recognising their achievements
- K17 difficulties and challenges that may arise (including conflict within the

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- team), and ways of identifying and overcoming them
- K18 the importance of encouraging others to take the lead, and ways in which this can be achieved
- K19 the benefits of, and how to encourage and recognise creativity and innovation within a team
- K20 who the biomanufacturing team members are, their purpose, objectives and plans for them
- K21 the types of support and technical advice that your biomanufacturing team are likely to need, and how to provide these

Additional Information

**Scope/range
related to
performance
criteria**

You must be able to:

1. carry out **all** of the following leadership activities:
 - 1.1 identify and utilise the expertise and skills of individual team members
 - 1.2 obtain and give the relevant information to achieve team goals and objectives
 - 1.3 plan tasks and objectives for the team to accomplish set goals
 - 1.4 represent the team at meetings and in communications with senior colleagues and customers
 - 1.5 improve the knowledge, skills and attitude of the team
2. use **three** of the following types of protective clothing and equipment:
 - 2.1 laboratory coat/overalls
 - 2.2 gloves
 - 2.3 head/hair covers
 - 2.4 safety shoes/shoe covers
 - 2.5 safety glasses/visors
 - 2.6 other (please specify)
3. record and communicate to the appropriate people, using **all** of the following:
 - 3.1 verbal report
 - 3.2 company documentation
 - 3.3 electronic mail
 - 3.4 written or typed report
 - 3.5 computer-based record
 - 3.6 graphs/charts

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