Unit 208  Assist with the manufacture and assembly of medicinal products

Element 1  Assist with the preparation and packaging of medicinal products
Element 2  Assist with the completion of the manufacturing and assembly process
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Element 2  Assist with the completion of the manufacturing and assembly process

Background

Pharmaceutical manufacturing is a highly specialised area of practice. Regardless of where a product is manufactured, the controls and standards that apply to its preparation should be the same. As these processes become more specialised, they are being concentrated into fewer hospital manufacturing units. The Medicines Control Agency (MCA) licenses some of these units; others operate as unlicensed units on a small scale for named patient use.

In a manufacturing unit work is usually undertaken in batches, which may include non-sterile and sterile products. This is done for several reasons, e.g.

- Batch production makes more effective use of staff time
- The manufacture of products in batches ensures the necessary quality
- Control of ingredients/raw materials and final products takes place
- Batch production allows the product to be produced in advance of demand and put into stock
- Being able to put the product into the stock control system
- Operators become skilled and this helps it to make sure the product is made to the same standards every time
- Products are made to set procedures and working practices, which are recorded and this confirms that quality is maintained

You will need to become familiar with the general standards associated with manufacturing such as the EC Directive on Good Manufacturing Practice for Human Medication; Rules and Guidance for Pharmaceutical Manufacturers and Distributors (current edition).

As with other areas of pharmacy practice you need to make sure you work to Standard Operating Procedures (SOPs). With manufacturing it is absolutely essential and any deviation from an SOP must not occur unless the authorised person within the unit has approved it in writing.

When working according to Standard Operating Procedures, it must be recorded on the batch documentation who undertook each stage so that in the unlikely event of a fault appearing at a later date, an investigation can be undertaken to attempt to find the cause of the problem. This will help to prevent it from happening again.

Your role within a pharmacy batch production or manufacturing unit will be concerned with ensuring that the environment, equipment and containers for manufacturing are clean and ready to make the required batch, as well as packing and labelling some batches that you may prepare.
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Key words and concepts

These definitions are provided to explain how key words and concepts are used in this unit.

**Standard Operating Procedures**

These are referred to as SOPs and include written protocols or procedures. They state the way your organisation requires tasks to be carried out to ensure a quality pharmacy service is provided, this would include, for example, how you should order stock, when stock should be ordered and where it should be stored.

**Stock rotation**

This is the process of ensuring the shortest dated stock is used first, care must be taken when receiving, storing or issuing stock.

**Special orders**

These include special orders for customers, named patient drugs, clinical trials stock.

**Health and safety**

This includes correct moving and handling procedures, safe handling of stock, safe storage of stock and COSHH regulations.
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You must show that you know and understand:

*For the whole unit*

**K1**  The basic principles of GMP.

**K2**  The criteria for licensed and unlicensed units.

**K3**  Current, relevant Health and Safety Legislation and how it applies to the working Environment.

**K4**  The importance of SOPs and why you must always work within these procedures.

**K5**  Basic hygiene and the importance of maintaining a clean working environment.

**K6**  The importance of personal hygiene and the correct use of protective clothing.

**K7**  The reasons for using and keeping the correct, accurate documentation.

**K8**  The basic principles of sterilisation.

**K9**  The sources of contamination, microbiological and cross-contamination, and the methods of prevention

*Preparation and packaging of medicinal products*

**K10**  The difference between the various types of products.

**K11**  How and when you must use the different processes.

**K12**  The correct handling of hazardous materials and how to minimise the risks.

**K13**  The importance of label and product reconciliation.

**K14**  The methods and materials used for packaging.

*Completing the process*

**K15**  The procedures for dismantling equipment.

**K16**  The different methods of cleaning equipment and work areas.

**K17**  How to store equipment safely and in a condition ready for use.

**K18**  The procedures for the disposal of waste materials and cleaning products.

**K19**  The storage requirements for all products manufactured or assembled including any quarantine requirements.
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Activities

1. Find out where your procedures for the manufacture and assembly of medicinal products are kept. Read the procedures listed above before training. Discuss key points with your Trainer/Assessor.

2. Draw a 'family tree' and add in the name of all the staff in your manufacturing unit. Record the job titles of all staff identified on the 'family tree'. Discuss with your Trainer/Assessor your role, your limits and responsibilities of your work. Find out who you should refer to if you need advice, help or guidance on any part of your work.

3. Draw and label a plan of your unit. Indicate on your plan what the term 'workflow' means. Find out and list the workflow arrangements relating to your plan.

4. Find out what is meant by non-sterile products and batches and sterile products and batches. Discuss with your Trainer/Assessor what is meant by 'sterilisation'. Identify the different methods of sterilisation used in your unit.

5. Identify what types of products are made in your unit. Describe the different environments that the products you identified above would be made in. Discuss this with your Trainer/Assessor and describe your role in making these products.

6. Find out what the term 'GMP' means. Discuss with your Trainer/Assessor the role of GMP in the manufacturing unit. Briefly describe the points covered.

7. Obtain copies of the following documents and write on them what they are used for:
   a) Worksheet
   b) Environment monitoring records
   c) The production diary/planner
   d) Raw materials/container records
   e) Cleaning records
   f) Quarantine records/bond document
   g) Final release document
   h) Recall procedure

8. Find out what an unlicensed and licensed unit are. List the differences between them. Find out and record what type of unit you work in.
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Activities

9. Obtain a copy of a product label. Write on the label what details are on it and why they must be included. Put this in your portfolio.

10. Find out how master worksheets and batch worksheets are produced. Observe the process involved in producing a batch worksheet and labels. Identify who is responsible for this.

11. Find out what batch numbers are and why they are important. Find out what expiry dates are and why they are important.

12. Describe what the abbreviation QA means. List the QA checks that are carried out before batch production begins. Identify what types and how often inspections are carried out by others external to your manufacturing unit.

13. Ask your Trainer/Assessor to provide you with a worksheet and observe you undertaking the following:
   a) Selecting the required raw materials.
   b) Entering the necessary details required.
   c) Ensuring checks that need to be performed are carried out by the relevant person before continuing.
   d) Ensuring all information is recorded on the worksheet.

14. Find out how you would prepare yourself for entry to the manufacturing area. Describe the protective clothing required and when it would be used in your manufacturing unit. Identify where the protective clothing is stored. Ask your Trainer/Assessor to observe how you prepare your environment and equipment in order to batch manufacture. Identify and list what environmental monitoring is required throughout the process.

15. Demonstrate to your Trainer/Assessor how you carry out and record environmental monitoring. Ask your Trainer/Assessor to record their observations.

16. After training, ask your Trainer/Assessor to observe you preparing a range of routine products made in your unit. Keep all documentation for your portfolio.

17. List and date the batch products your Trainer/Assessor supervised you making.

18. Identify the checks that must be carried out before starting the labelling of your product. After training, ask your Trainer/Assessor to observe how you label the following products:
   a) Syringe
   b) Tube
Activities

c) Carton
d) Jar
e) Ampoule
f) Vial
g) Suppository mould
h) Liquid bottle
i) Tablet bottle

Find out why it is important that products are labelled correctly.

19. Find out what is meant by and what might cause contamination. Identify how your working practice might help avoid contamination. Find out what cleaning needs to take place during and after batch manufacturing.

20. Discuss your knowledge of the following with your Trainer/Assessor:
   a) The different types of cleaning solutions that you use in your unit and when they are used
   b) Cross-contamination
   c) Why cleaning is important in the prevention of cross-contamination.
   d) the sources of cross-contamination.
   e) Why you need to ensure that no clutter or rubbish builds up in your work area.

21. Identify what reconciliations are carried out and describe why they are important. Get copies of all the documentation that needs to be completed at the end of the manufacturing process and write on each piece of documentation what it's purpose is.

22. Find out what quarantine means and why batches are put into quarantine. Observe samples being taken and find out what they are testing for. Find out what other checks need to be performed whilst the product is in quarantine. Identify who releases the products from quarantine. Describe what happens to the product after release. Find out how the completed batch documentation is stored.

23. Identify which products that you may help prepare that are considered 'hazardous'. Describe how COSHH regulations are followed to minimise danger from these products. Describe how spillages from these products would be dealt with. Describe the general COSHH documentation process for your unit. Describe how to dispose of ' sharps'.

24. Ask your Trainer/Assessor to observe you disposing of all waste generated by making your product.
Questions

The limits of your own role and the referral procedures
(from the NVQ Level 2 Knowledge and Understanding Framework for unit 208)

- What are your roles and responsibilities relating to the manufacture and assembly of medicinal products?

- What are the roles and responsibilities of the other members of your team who are involved in the manufacture and assembly of medicinal products?

- Under what circumstances would you refer to each of these team members when manufacturing and assembling medicinal products?
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Questions

**K1** The basic principles of Good Manufacturing Practice (GMP).

- What are the basic principles of Good Manufacturing Practice (GMP)?

- How does GMP apply to your working environment?

- Why is it important that you follow the principles of GMP at all times in your working environment?

- What could happen if you did not follow the principles of GMP?
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Questions

K2  The criteria for licensed and unlicensed units.

- What are the criteria for licensed units?

- What are the criteria for unlicensed units?

- What are the differences between licensed and unlicensed units?

- What type of unit do you work in?
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Questions

K3 Current, relevant Health and Safety Legislation and how it applies to the working environment.

• What are the key points covered in the Control of Substances Hazardous to Health (COSHH) Regulations 2002?

• How does this COSHH legislation apply to your working environment?

• Why is it important that you follow this COSHH legislation?
• What could happen if you did not follow this COSHH legislation?
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(continued)

K3  Current, relevant Health and Safety Legislation and how it applies to the working environment.

- What other Health and Safety Legislation is in place in your organisation and department, which is relevant to your working environment?
- What are the key points covered in this legislation?

- Why is it important that you follow this legislation?
- What could happen if you did not follow this legislation?
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Questions

K4 The importance of SOPs and why you must always work within these procedures.

- What procedures are in place in your department relating to the manufacture and assembly of medicinal products?

- What are the key points covered in these procedures?

- Why is it important that you follow these procedures?
  - What could happen if you did not follow these procedures?
Questions

**K5** Basic hygiene and the importance of maintaining a clean working environment.

- Why is it important to maintain a clean working environment?

- What could happen if a clean working environment was not maintained?

- How is the cleanliness of your working environment maintained?
K5  Basic hygiene and the importance of maintaining a clean working environment.

- What are your roles and responsibilities in maintaining a clean working environment?

- What are the roles and responsibilities of the other members of your team in maintaining a clean working environment?
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Questions

K6  The importance of personal hygiene and the correct use of protective clothing.

• What procedures are in place covering personal presentation and hygiene in your workplace?

• What are the key points covered in these procedures?

• Why is it important that you follow these procedures?
  • What could happen if you did not follow these procedures?
K6 The importance of personal hygiene and the correct use of protective clothing.

- What protective clothing are you required to wear in your workplace?

- Under what circumstances must you wear this protective clothing?

- Why is it important that you wear this protective clothing in these circumstances?
- What could happen if you did not wear this protective clothing?
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Questions

K7 The reasons for using and keeping the correct, accurate documentation.

- What pieces of documentation do you use in your workplace?

- What are the purposes of these pieces of documentation?
- Under what circumstances do you use these pieces of documentation in your workplace?
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(continued)

K7 The reasons for using and keeping the correct, accurate documentation.

• What records must be kept in your workplace?

• Why is it important that these records are accurately maintained?
  • What could happen if these records were not accurately maintained?

• What are your roles and responsibilities in maintaining these records?

• What are the roles and responsibilities of the other members of your team in maintaining these records?
Questions

K8 The basic principles of sterilisation.

- Why are some products sterilised?

- What different methods can be used to sterilise products?
  - How do these methods ensure that products are sterilised?
  - Under what circumstances are these methods used?
K8 The basic principles of sterilisation.

- Which products are sterilised in your unit?
- Which methods are used to sterilise these products?
- What is the reason for using these methods?
Questions

K9  The sources of contamination, microbiological and cross-contamination, and the methods of prevention.

- What is meant by the following?
  - Contamination
  - Microbiological contamination
  - Cross-contamination
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(continued)

K9 The sources of contamination, microbiological and cross-contamination, and the methods of prevention.

• What are the basic causes of contamination in your workplace?

• How can these sources of contamination be avoided?

• How should you deal with areas that are contaminated?
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Questions

K10 The difference between the various types of products.

- What different types of products are made in your unit?

- What are the differences between these types of products?

- What is your role in making these products?
Questions

K11 How and when you must use the different processes.

- What procedures and techniques are used to measure volumes of liquids in your unit?
- Under what circumstances are these different processes used?
- What is the reason for using these processes in these circumstances?
- What are the units of measurement for volumes of liquids?
- Why is it important to measure volumes of liquids accurately?
- What could happen if volumes of liquids are not measured accurately?
K11 How and when you must use the different processes.

- What procedures and techniques are used to weigh solids in your unit?
- Under what circumstances are these different processes used?
- What is the reason for using these processes in these circumstances?
- What are the units of measurement for solids?
- Why is it important to weigh solids accurately?
- What could happen if solids are not weighed accurately?
K11 How and when you must use the different processes.

- What are the functions of Inspectors of weights and measures?

- What other processes are used in the manufacture of products in your unit?

- Under what circumstances are these different processes used?
  - What is the reason for using these processes in these circumstances?
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Questions

K12 The correct handling of hazardous materials and how to minimise the risks.

- What hazardous materials do you come into contact with in your job role?

- How can you identify these materials?

- How should these materials be handled?

- What precautions must you take to minimise the risks associated with these hazardous materials?
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Questions

K13 The importance of label and product reconciliation.

• Why is it important to reconcile all labels that have been generated?
• What could happen if this did not occur?

• Why is it important to reconcile all products that have been used in the manufacture or assembly process?
• What could happen if this did not occur?
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Questions

K14 The methods and materials used for packaging.

- What types of containers and packaging are commonly used to hold pharmaceutical products?
- What are the features of these types of containers and packaging?

- Which of these containers are used in your workplace?
- For which pharmaceutical products are they used?
- Why are these containers used for these products?

- How should containers be labelled?
- Why is it important to label containers in this way?
- What could happen if containers were not labelled in this way?
K14 The methods and materials used for packaging.

- What types of closures are commonly used in the manufacture and assembly of pharmaceutical products?
- What are the features of these types of closures?
- What are the legal requirements which govern the type of closure used?
- Which of these closures are used in your workplace?
- For which pharmaceutical products are they used?
- Why are these closures used for these products?

- How should medicines be packaged for safe postage and transport?
- What are the legal requirements for safe transport of pharmaceutical products?
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**Questions**

**K15  The procedures for dismantling equipment.**

- What procedures are in place in your department relating to the dismantling of equipment after use?

- What are the key points covered in these procedures?

- Why is it important that you follow these procedures?
- What could happen if you did not follow these procedures?
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Questions

K16  The different methods of cleaning equipment and work areas.

• What procedures are in place in your department relating to cleaning equipment and work areas after use?

• What are the key points covered in these procedures?

• Why is it important that you follow these procedures?
  • What could happen if you did not follow these procedures?
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Questions

K17  How to store equipment safely and in a condition ready for use.

• What procedures are in place in your department on how to store equipment safely and in a condition ready for use?

• What are the key points covered in these procedures?

• Why is it important that you follow these procedures?
  • What could happen if you did not follow these procedures?
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Questions

K18 The procedures for the disposal of waste materials and cleaning products.

- What procedures are in place in your department relating to the disposal of waste materials and cleaning products?

- What are the key points covered in these procedures?

- Why is it important that you follow these procedures?
  - What could happen if you did not follow these procedures?
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Questions

K19 The storage requirements for all products manufactured or assembled including any quarantine requirements.

- What procedures are in place in your department relating to the storage of products which have been manufactured or assembled?

- What are the key points covered in these procedures?

- Why is it important that you follow these procedures?
- What could happen if you did not follow these procedures?
K19 The storage requirements for all products manufactured or assembled including any quarantine requirements.

- What procedures are in place in your department relating to the quarantine requirements for products which have been manufactured or assembled?

- What are the key points covered in these procedures?

- Why is it important that you follow these procedures?
- What could happen if you did not follow these procedures?