## Module 1: The WHO Quality Management Programme

<table>
<thead>
<tr>
<th>Title</th>
<th>Teaching Aim</th>
<th>Core Topics</th>
<th>Key Points</th>
<th>Teaching Focus</th>
<th>Learning Outcomes</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>QMT 1.1</td>
<td>WHO strategy for blood safety Presentation</td>
<td>To introduce course participants to the WHO strategy for blood safety</td>
<td>• WHO strategy for global blood safety</td>
<td>• The WHO strategy for blood safety defines requirements for the safety, adequacy and accessibility of national blood supplies</td>
<td>Participants should be able to:</td>
<td>Participants should be able to:</td>
</tr>
<tr>
<td>QMT 1.2</td>
<td>WHO Quality Management Programme (QMP) for Blood Transfusion Services Presentation</td>
<td>To introduce course participants to the WHO Quality Management Programme (QMP) and Quality Management Training (QMT)</td>
<td>• Quality Management Programme • Quality Management Training</td>
<td>• The WHO QMP aims to assist Member States in improving the safety and adequacy of national blood supplies • QMT courses are held in each region to support the establishment of quality systems in blood transfusion services in all Member States • QMT course participants will play a central role in establishing national quality systems</td>
<td>• Explain the purpose of the QMP and QMT</td>
<td>½ hour</td>
</tr>
<tr>
<td>Title</td>
<td>Teaching Aim</td>
<td>Core Topics</td>
<td>Key Points</td>
<td>Teaching Focus</td>
<td>Learning Outcomes</td>
<td>Time</td>
</tr>
<tr>
<td>-------</td>
<td>--------------</td>
<td>-------------</td>
<td>------------</td>
<td>----------------</td>
<td>------------------</td>
<td>------</td>
</tr>
</tbody>
</table>
| QMT 1.3 | Introduction to the WHO QMT course Presentation | To introduce the WHO QMT course | • Modular approach  
• Role of the facilitators  
• Role of the participants | • The overall structure of the course is modular  
• The course will help participants to implement quality systems in their BTS/blood centre  
• The role of the facilitators is to ensure that there is active learning | • Ensure participants understand the course objectives and structure  
• Ensure participants recognize the active role they are expected to take in the learning process  
• Encourage participants to ask questions about the course | • Outline the structure and content of the course  
• Identify their role and responsibilities in the QMT course | ½ hour |
| QMT 1.4 | Participants’ expectations Activity | To find out what course participants expect to gain from the QMT course | • Discussion of the objectives and structure of the QMT course  
• Identification of participants’ specific interests and learning needs in relation to quality management | • QMT is not designed to provide technical training  
• Follow-up and support will be provided after the course  
• If identified as a need, technical training will be provided after the course | • Help to keep participants’ expectations realistic and focused on quality rather than on technical issues | • Explain how the QMT course will assist them in applying the principles of quality in their own BTS | 2 hours |
| QMT 1.5 | Pre-course assessment Activity | To determine participants’ current levels of knowledge and understanding about quality | • Assessment of participants’ knowledge and understanding of quality  
• Determination of the range of knowledge within the group in order to plan an appropriate level of training | • The pre-course assessment aims to generate baseline information about participants  
• It will help facilitators to focus the course on areas of particular weakness or need | • Emphasize that the pre-course assessment is not an examination | • Assess their own level of knowledge and understanding of quality issues | ¾ hour |
**Module 2**

**Introduction to Quality**

<table>
<thead>
<tr>
<th>Title</th>
<th>Teaching Aim</th>
<th>Core Topics</th>
<th>Key Points</th>
<th>Teaching Focus</th>
<th>Learning Outcomes</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>QMT 2.1</td>
<td>The importance of quality in the blood transfusion service</td>
<td>To introduce the overall concept of quality in the blood transfusion service</td>
<td>• The need for quality in the BTS&lt;br&gt;• Factors affecting quality&lt;br&gt;• Results of quality</td>
<td>• Quality is essential to ensure that blood transfusion is safe and efficacious&lt;br&gt;• Quality applies to all BTS activities&lt;br&gt;• Quality involves all staff&lt;br&gt;• Quality benefits all&lt;br&gt;• Quality improvement is achievable, even when resources are limited</td>
<td>• Encourage participants to identify additional positive outcomes of quality&lt;br&gt;• Emphasize that quality is everybody’s responsibility</td>
<td>• Explain the importance of quality in blood transfusion&lt;br&gt;• Identify the positive outcomes of quality in the BTS</td>
</tr>
<tr>
<td>QMT 2.2</td>
<td>The consequences of poor quality in the blood transfusion service</td>
<td>To contrast the consequences of poor quality with the benefits of good quality</td>
<td>• The consequences of poor quality for blood donors, recipients, staff and the BTS</td>
<td>• Poor quality:&lt;br&gt;• Endangers patients’ lives&lt;br&gt;• Undermines the credibility of the BTS&lt;br&gt;• Creates a negative attitude towards blood donation and transfusion&lt;br&gt;• Contributes to poor staff morale and job insecurity</td>
<td>• Encourage participants to discuss some examples of poor quality in relation to blood transfusion and the reasons why they may occur&lt;br&gt;• Do not force reluctant participants to reveal deficiencies in their own BTS at this early stage of the course&lt;br&gt;• Acknowledge the problems and constraints posed by limited staff and resources&lt;br&gt;• Emphasize that the QMT course will focus in a practical way on how every BTS can work towards quality</td>
<td>• Identify some of the reasons for poor quality in the transfusion process&lt;br&gt;• Identify the consequences of poor quality</td>
</tr>
<tr>
<td>Title</td>
<td>Teaching Aim</td>
<td>Core Topics</td>
<td>Key Points</td>
<td>Teaching Focus</td>
<td>Learning Outcomes</td>
<td>Time</td>
</tr>
<tr>
<td>-------------------------------------------</td>
<td>--------------------------------------------------</td>
<td>------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------</td>
<td>---------</td>
</tr>
<tr>
<td>QMT 2.3 Introducing quality Presentation</td>
<td>To introduce the concept of quality</td>
<td>• What is quality? • Benefits of quality • Quality as a process of continuous improvement • Basic quality principles • Basic quality definition • Fitness for purpose • Quality characteristics</td>
<td>• Quality is a continual process of striving for improvement to ensure consistently high quality • Quality products and services are fit for their purpose</td>
<td>• Ensure all participants have a clear understanding of basic principles of quality</td>
<td>• Demonstrate an understanding of the broad concepts of quality • Recognize the importance of quality in everyday life and in the BTS</td>
<td>¾ hour</td>
</tr>
<tr>
<td>QMT 2.4 Quality characteristics Activity</td>
<td>• To demonstrate how the term ‘fitness for purpose’ is a broad definition of quality • To demonstrate how quality applies to common, everyday situations • To introduce the concept of quality characteristics</td>
<td>• Quality is “fitness for purpose” • Quality extends beyond simply producing a product • Quality relates to products, production, packaging and service</td>
<td>• Customers want a high quality product/service • Everything about a product defines its quality</td>
<td>• Ensure that the aim of the activity is clear • Ensure an understanding of defining and meeting customer needs</td>
<td>• Identify the quality characteristics of a product • Demonstrate an understanding of fitness for purpose and customer needs</td>
<td>1 hour</td>
</tr>
<tr>
<td>QMT 2.5 Tour of the Blood Transfusion Centre (BTC) Activity</td>
<td>To familiarize participants with the layout and activities of the BTC</td>
<td>• Familiarization with the building • Opportunity to observe a working blood transfusion centre (BTC) • Introduction to a working quality system</td>
<td>• Quality is visible • Quality is a continuing process • Quality involves all staff</td>
<td>• Point out areas of particular interest in relation to quality • Do not get drawn into specifics about the way in which the BTS works</td>
<td>• Identify elements of a quality system that lead to consistency and fitness for purpose</td>
<td>1½ hours</td>
</tr>
<tr>
<td>Title</td>
<td>Teaching Aim</td>
<td>Core Topics</td>
<td>Key Points</td>
<td>Teaching Focus</td>
<td>Learning Outcomes</td>
<td>Time</td>
</tr>
<tr>
<td>-----------------------</td>
<td>------------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------</td>
<td>---------</td>
</tr>
</tbody>
</table>
| QMT 3.1 Quality Systems Presentation | To introduce the concept of quality systems | • Quality and quality systems  
• Key elements of a quality system:  
  — Organizational management  
  — Standards for quality systems  
  — Documentation  
  — Training  
  — Assessment | • Quality systems are designed to control processes  
• There are five key elements in a quality system:  
  — Organizational management  
  — Standards for quality systems  
  — Documentation  
  — Training  
  — Assessment | • Use examples of simple, generic quality systems to ensure understanding  
• Where appropriate, encourage participants to discuss their own quality systems | • List the key elements of a quality system  
• Demonstrate an understanding of the interrelationship between these key elements | ½ hour |
| QMT 3.2 Processes and procedures Presentation | To introduce the concept of processes, procedures and their control | • Processes  
• Procedures  
• Critical control points  
• Indicators | • An organization’s operations consist of processes and procedures  
• Critical control points need to be identified in each procedure  
• Indicators for measuring control of the procedure must be identified and analysed | • Check for understanding of the concepts of processes and procedures  
• Emphasize that there are critical control points in every process | • Define processes and procedures  
• Define critical control points and indicators  
• List the characteristics of indicators | ½ hour |
<table>
<thead>
<tr>
<th>Title</th>
<th>Teaching Aim</th>
<th>Core Topics</th>
<th>Key Points</th>
<th>Teaching Focus</th>
<th>Learning Outcomes</th>
<th>Time</th>
</tr>
</thead>
</table>
| QMT 3.3                    | Flowcharting as a tool for mapping processes                                  | • Main elements of the analysis of processes and procedures                  | • Processes and procedures must be analysed in order to identify critical control points  
  • Several important questions should be asked when analyzing a process:  
  ─ Is the task critical to the outcome?  
  ─ Can the task – or the outcome of the task – be measured?  
  • Flowcharting provides a simple picture (map) of the overall process | • Use simple examples of processes  
  • Use conventional flowcharting symbols and terminology | • List factors that need to be considered in process analysis  
  • Design a flowchart of a process                                                                                     | 1 hour |
|                            | Presentation                                                                  | • Preparing flowcharts                                                        | • Processes are made up of individual procedures  
  • Flowcharts help to clarify the individual elements of processes and procedures, including critical control points | • Focus on the basic processes, from raw materials to final product and distribution  
  • Emphasize the need for simplicity  
  • Provide a specimen flowchart for the process                                                                 |                                                                                                   |       |
| QMT 3.4                    | Developing a process flowchart                                               | • Breakdown of a specific process                                             | • Processes are made up of individual procedures  
  • Flowcharts help to clarify the individual elements of processes and procedures, including critical control points | • Focus on the basic processes, from raw materials to final product and distribution  
  • Emphasize the need for simplicity  
  • Provide a specimen flowchart for the process                                                                 | • Identify the individual elements in a specific process  
  • Develop a simple process flow chart                                                                                  | 1½ hours |
<table>
<thead>
<tr>
<th>Title</th>
<th>Teaching Aim</th>
<th>Core Topics</th>
<th>Key Points</th>
<th>Teaching Focus</th>
<th>Learning Outcomes</th>
<th>Time</th>
</tr>
</thead>
</table>
| QMT 4.1                | Management responsibility for quality  Presentation                         | • Quality management terminology  
• Organizational responsibility for quality  
• Quality policy as a part of the organization’s strategic plan  
• Planning and implementing a quality system  
• Managing a quality system | • Commitment by management to quality is essential  
• Responsibility for quality should be outlined in the quality policy and plan  
• Quality must first be planned by management  
• The involvement and commitment of all staff is essential to develop a “culture of quality” | • Emphasize the importance of top-level support and action  
• Emphasize the role of all staff in ensuring quality | • Define management’s responsibilities for quality  
• Define commonly used quality management terminology  
• List the key elements of a quality policy | ½ hour |
| QMT 4.2                | Developing a quality policy Activity                                           | • Full and active support from senior management  
• Formal approval and acceptance of the policy  
• Key quality principles upon which the policy is based  
• Identifying appropriate standards | • The quality policy must reflect the needs of the organization’s customers as well as its own structure and capabilities  
• Whatever standards are adopted, they must be appropriate to the organization  
• The support of senior management is central to successful implementation of the quality policy | • Ensure that the policies reflect the organization and its customers  
• Focus on simplicity and the use of simple wording  
• Ensure there is a section for top management to sign the policy | • Write a quality policy for a generic organization  
• Apply the general principles and ultimately write a quality policy for their own BTS | 1½ hours |
<table>
<thead>
<tr>
<th>Title</th>
<th>Teaching Aim</th>
<th>Core Topics</th>
<th>Key Points</th>
<th>Teaching Focus</th>
<th>Learning Outcomes</th>
<th>Time</th>
</tr>
</thead>
</table>
| **QMT 4.3**  
Organizational structure and role of the quality manager  
**Presentation** | To highlight the importance of a reporting structure in an organization and the role of the quality manager | • Authority and responsibility for the organization's activities  
• Importance of a clear definition of all activities and responsibilities in an organization  
• Role and responsibilities of the quality manager | • Every organization needs a formal structure  
• A clear organizational structure is essential for smooth functioning  
• Authority and responsibility within the organization must be defined  
• Structures should be developed that maintain and strengthen the organization as a whole  
• The quality manager is responsible for the implementation and maintenance of the quality system  
• The quality manager must be independent of operational activities  
• The quality manager reports to the head of the organization or institution | • Emphasize that organizational structures need not be complex to be effective  
• Ensure participants understand the definitions of authority and responsibility and how the two are related in an organization | • Explain why a clear organizational structure is an important part of a quality system  
• Prepare a basic organizational chart (organigram)  
• List the responsibilities of the quality manager | ½ hour |

| **QMT 4.4**  
Developing an organigram  
**Activity** | To provide practice in preparing a simple organizational chart (organigram) | • Preparation of organizational charts  
• Consolidation of the use of organigram | • Organigrams simplify the presentation of organizational structures | • Ensure the participants keep to a simple organizational structure for generic organization | • Draw an organizational chart  
• Demonstrate their knowledge of lines of responsibility and reporting structures | 1 hour |
<table>
<thead>
<tr>
<th>Title</th>
<th>Teaching Aim</th>
<th>Core Topics</th>
<th>Key Points</th>
<th>Teaching Focus</th>
<th>Learning Outcomes</th>
<th>Time</th>
</tr>
</thead>
</table>
| QMT 4.5        | Job descriptions, responsibility and delegation                             | • Job descriptions                                                          | • All organizations must ensure that they employ the right person for the right job  
• Staff should be well-trained and competent  
• Job descriptions and person specifications set out precisely what a job involves and the kind of person needed  
• Responsibility must come with authority  
• Delegation enables managers to make the best use of their time and develop junior staff  
• Delegation is the sign of a good manager and a good quality system | • Emphasize the importance of clear and specific job descriptions and person specifications  
• Reinforce the importance of the delegation of authority | • List the key elements of job descriptions and person specifications  
• Identify the importance of authority and responsibility  
• Explain the importance of delegation | 1 hour |
|                | Presentation                                                                  | • Person specifications                                                      | | | | |
|                |                                                                              | • Competence                                                                 | | | | |
|                |                                                                              | • Authority/responsibility                                                  | | | | |
|                |                                                                              | • Effective personnel management                                            | | | | |
|                |                                                                              | • Delegation                                                                | | | | |
| QMT 4.6        | Writing a job description to a given format                                 | • The job description as a structured document                              | • All job descriptions in an organization should have the same format and should include the key elements of the job | • Ensure key elements are included in the job descriptions  
• Emphasize the quality manager’s role in ensuring a standardized approach to the development of job descriptions | • Prepare a simple job description and person specification  
• Include the appropriate duties and responsibilities in the job description | 1½ hours |
|                | Activity                                                                      | • Key elements of a job description                                          | | | | |
|                |                                                                              | • Appropriate responsibilities and duties for a job                         | | | | |
|                |                                                                              | • The job description as a structured document                              | | | | |
| QMT 4.7        | The cost of quality saves money                                              | • Definition of the cost of quality                                          | • Poor quality leads to failures and rejected products  
• Poor quality increases operational costs  
• Poor quality costs more | • Give a range of examples where the actual cost is higher than expected due to poor quality | • Analyse processes and procedures to identify where poor quality increases costs | ½ hour |
<p>|                | Presentation                                                                  | • Cost of quality                                                            | | | | |
|                |                                                                              | • Elements of quality costs                                                 | | | | |
|                |                                                                              | • Poor quality costs more                                                    | | | | |</p>
<table>
<thead>
<tr>
<th>Module 5</th>
<th>Standards for Quality Systems</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Title</strong></td>
<td><strong>Teaching Aim</strong></td>
</tr>
</tbody>
</table>
| QMT 5.1  | Introduction to standards for quality systems | To introduce various quality standards that may be used by blood transfusion services | • Quality standards  
• National and international standards  
• Regulatory standards  
• Quality standards and audits | • Quality standards are key elements of the quality system  
• Quality standards help ensure a systematic and consistent approach to the development of quality systems  
• Quality standards must be relevant to the BTS | • Explain the usefulness of quality standards to the BTS  
• Emphasize the importance of identifying appropriate standards for the particular BTS | Explain the role of quality standards  
Describe the benefits to the BTS of using quality standards  
Explain the role of the quality manager in ensuring that relevant quality standards are identified and implemented | ½ hour |
| QMT 5.2  | Principles of good manufacturing practice | To introduce the principles of Good Manufacturing Practice (GMP) within the quality system | • The BTS as a manufacturer  
• GMP as a part of the quality system  
• Key elements of GMP | • BTSs are manufacturers of therapeutic products  
• Implementing GMP is essential to assure good quality products  
• Focus on the BTS as a manufacturer  
• Ensure an understanding of the concept of manufacture applied to blood/blood products | • Describe the role of GMP within the quality system  
• List the elements of GMP | 1 hour |
<table>
<thead>
<tr>
<th>Module 6</th>
<th>Documentation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Title</strong></td>
<td><strong>Teaching Aim</strong></td>
</tr>
</tbody>
</table>
| QMT 6.1 Documentation in quality systems Presentation | To explain the key role of documentation in quality systems | - Definitions relating to documentation  
- Basic types of documents  
- Relationship between documents  
- Dangers of too much documentation | - Documentation is key to a quality system  
- Documentation helps to ensure consistency of processes and procedures  
- Documentation gives traceability  
- Good documentation indicates a good quality system  
- Training is easier if there is good documentation to train to | - Illustrate the importance of documentation by using examples from your own experience  
- Use scenarios where a lack of documentation may have/has caused problems  
- Ensure that participants understand the value of documentation | - Explain the role and need for documentation in a quality system  
- List different types of documents used in a quality system | ½ hour |
| QMT 6.2 Standard operating procedures Presentation | To describe how to plan and write an effective SOP | - Planning and writing SOPs  
- Validation of SOPs  
- Use of SOPs | - SOPs are an essential part of the quality system  
- SOPs should be written for all the key procedures in an organization  
- SOPs must be clear, concise and easy to follow  
- SOPs should be used for staff training  
- SOPs should be validated  
- SOPs should be living documents  
- Staff must have easy access to the SOPs  
- SOPs must be followed | - Focus on the value and use of SOPs generically  
- Do not be too prescriptive about layout and design of SOPs | - Identify key characteristics of an effective SOP  
- Describe how to plan SOPs  
- Prepare SOPs  
- Explain the use of SOPs | 1 hour |
<table>
<thead>
<tr>
<th>Title</th>
<th>Teaching Aim</th>
<th>Core Topics</th>
<th>Key Points</th>
<th>Teaching Focus</th>
<th>Learning Outcomes</th>
<th>Time</th>
</tr>
</thead>
</table>
| QMT 6.3 Writing an SOP Activity | To provide practice in preparing an SOP for a simple, familiar activity | • Identifying the components of the activity  
• Preparation of a usable SOP | • SOPs define the way in which a procedure is to be carried out  
• SOPs must be written to be used | • Ensure the SOPs follow the principles taught  
• Keep the SOPs focused on simply making the coffee  
• Ensure that SOPs reflect the actual procedure | • Write an SOP of a simple familiar activity  
• List the key components of an SOP | 1½ hours |
| QMT 6.4 Validating an SOP Activity | To demonstrate how SOPs are validated | • Creating a validation protocol for an SOP  
• Identifying and understanding any problems with the validation of SOPs  
• Correcting any problems identified | • No SOP should be introduced without first being validated  
• The procedure must result in an acceptable outcome | • Ensure that the SOPs are followed as written  
• Ensure that all aspects of the SOPs are reviewed | • Validate an SOP  
• Identify missing steps in an SOP through the validation process | 1 hour |
| QMT 6.5 Document control Presentation | To introduce the mechanisms and reasons for control of documents | • The importance of document control  
• Mechanisms of document control  
• Distribution of documents  
• Document revisions | • All documents related to quality should be controlled  
• Control mechanisms cover:  
  • Distribution  
  • Review  
  • Change | • Emphasize the kind of problems likely without a document control system  
• Stress the need for simplicity in document control systems  
• Make clear the distinction between revision and a new document | • Identify the key aspects of document control  
• State which documents must be controlled and how | ½ hour |
| QMT 6.6 Controlling a document Activity | To illustrate the process of document control | • Identifying a simple revision required to an SOP  
• Incorporating the revision into a new version of the SOP  
• Correct annotation of the revised SOP  
• Ensuring document control procedures have been followed | • Revision of documents is an ongoing activity  
• Document control systems ensure that the correct document is in use  
• Revisions must be validated before the release of the document | • Ensure that the revision is correctly identified  
• Ensure that the key changes needed have been identified  
• Ensure the control system is simple and easy to follow  
• Review the difference between the revision of a document and need for a new document | • Identify the errors that result from lack of document control  
• Identify how to take corrective action | 1½ hours |
<table>
<thead>
<tr>
<th>Module 7</th>
<th>Training</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Title</strong></td>
<td><strong>Teaching Aim</strong></td>
</tr>
</tbody>
</table>
| QMT 7.1 | Training in the quality system | To highlight the importance of training in the quality system | • Importance of training  
• Organization’s responsibility for training  
• Types of training | • Staff are a major variable in processes  
• Training of staff is essential to ensure consistent performance of duties  
• Every organization should take responsibility for the continuing training of its staff  
• The organization benefits from having a skilled and motivated workforce | • Emphasize that quality problems are likely if staff are not trained  
• Reinforce the value of training to the organization and the individual | ½ hour |
| QMT 7.2 | Training needs and plans | To examine the importance of assessing training needs of all categories of staff and preparing training plans | • Identifying the need for job-specific training  
• Planning the training  
• Resources required  
• The trainer and the trainee  
• Training materials  
• How to impart training  
• The distance learning approach | • Training must be well planned  
• The required resources must be provided:  
  • Funds  
  • Appropriate trainers  
  • Materials  
• The trainer must be able to impart his/her knowledge to trainees | • Highlight the need to identify all job-specific training  
• Emphasize the need to ensure training plans are realistic | ½ hour |
| QMT 7.3 | Creating a training plan | To provide practice in preparing a training plan | • Identifying key skills required for the job  
• Developing an appropriate, effective and deliverable training programme  
• Reviewing training plans to ensure that all aspects have been covered | • Training plans must be designed to meet identified needs  
• Review and assessment of training plans are essential | • Check that training plans are appropriate and comprehensive  
• Ensure that they are deliverable  
• Check that training plans are effective and complete | 1 hour |
<table>
<thead>
<tr>
<th>Title</th>
<th>Teaching Aim</th>
<th>Core Topics</th>
<th>Key Points</th>
<th>Teaching Focus</th>
<th>Learning Outcomes</th>
<th>Time</th>
</tr>
</thead>
</table>
| QMT 7.4 Monitoring and evaluation of training Presentation | To establish the importance of documentation and records in training and the need to monitor and evaluate training | • Documenting the training program  
• Training records  
• Monitoring the effectiveness of training | • Quality principles apply to training as much as any other BTS process  
• All training should be documented  
• Training procedures should be defined, agreed on and documented  
• Both the overall training plan and the actual training need to be monitored and evaluated  
• Evaluation should be used to improve training in the future | • Emphasize the importance of training records  
• Highlight the importance of regular reviews of training and their documentation | • Demonstrate an understanding of the need for documentation and training records  
• Produce effective documentation covering the training syllabus and its delivery  
• Develop a training programme that includes monitoring and evaluation | ½ hour |
<table>
<thead>
<tr>
<th>Module 8</th>
<th>Assessment within the Quality System</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Title</strong></td>
<td><strong>Teaching Aim</strong></td>
</tr>
</tbody>
</table>
| **QMT 8.1** Assessment within quality systems  
Presentation | To introduce assessment of the quality system | • The need for assessment  
• Elements of assessment  
  ─ Evaluation  
  ─ Validation  
  ─ Monitoring  
• Quality assessment schemes  
• Errors and error management  
• Audits | • Continual assessment is essential for the maintenance and improvement of the quality system  
• There are a number of interrelated tools that should be used for quality assessment | • Emphasize the value and importance of monitoring and evaluation in the maintenance of a quality system | • List key elements of assessment and their use within quality systems | ½ hour |
| **QMT 8.2** Validation  
Presentation | To explain the importance of validation within the quality system | • Basic principles of validation  
• Principles for the validation of processes, equipment, reagents and software  
• Planning validations | • Validation ensures:  
  ─ Everything to be used in a process, including the process itself, is working to documented specifications before use  
  ─ Everything used remains within specifications (re-validation)  
• Validation controls the impact of change | • Emphasize the risks of a failure to validate new activities or changes  
• Clarify the distinction between validation and evaluation | • Describe the main purposes of validation  
• Develop a validation plan | 1 hour |
| **QMT 8.3** Preparing a validation plan  
Activity | To provide practice in producing an effective and appropriate validation plan | • Identifying critical validation points  
• Appropriate validation  
• The difference between validation and evaluation  
• Examples of validation plans | • Planning is essential  
• No matter how small the change, validation is needed | • Focus on validation, not evaluation  
• Ensure participants keep validation plans simple  
• Ensure understanding of the difference between validation and evaluation | • Describe the main activities when validating reagents, processes, equipment and software  
• Identify the use of documentation in validation procedures | 2 hours |
<table>
<thead>
<tr>
<th>Title</th>
<th>Teaching Aim</th>
<th>Core Topics</th>
<th>Key Points</th>
<th>Teaching Focus</th>
<th>Learning Outcomes</th>
<th>Time</th>
</tr>
</thead>
</table>
| QMT 8.4 | Maintenance and calibration of equipment | Presentation | To introduce the reasons for and the basic principles of maintenance and calibration of equipment | • Need for equipment maintenance  
• Organizational and user responsibilities  
• Principles of calibration  
• Action in the event of calibration failure  
• Records and documentation | • Prevention is better than cure  
• An effective maintenance and calibration programme is required for all equipment that has any impact on the quality of the final product  
• Maintenance and calibration should be regular, appropriate and comprehensive  
• Staff must be trained in the correct use, maintenance and calibration of equipment  
• All maintenance and calibration must be documented | • Emphasize the value of preventive maintenance  
• Discuss in depth the action to be taken in the event of calibration failure  
• Discuss the importance of the reliability of previous results obtained with that equipment | • List the main reasons for the maintenance and calibration of equipment  
• Discuss the value of preventive maintenance  
• Outline the basic principles of calibration and how to apply them  
• Develop documentation for the maintenance and calibration of equipment | ¾ hour |
| QMT 8.5 | Designing a maintenance and calibration plan | Activity | To provide practice in producing appropriate maintenance and calibration plans | • Identifying the maintenance and calibration needs of equipment  
• Determining appropriate calibration methods | • There are different approaches to maintenance and calibration  
• Maintenance and calibration plans must be sustainable | • Emphasize the importance of designing simple and appropriate maintenance and calibration plans  
• Ensure participants understand the value and use of documentation and records for maintenance and calibration | • Produce an appropriate maintenance and calibration schedule  
• Identify key documentation for the maintenance and calibration of equipment | 1½ hours |
<table>
<thead>
<tr>
<th>Title</th>
<th>Teaching Aim</th>
<th>Core Topics</th>
<th>Key Points</th>
<th>Teaching Focus</th>
<th>Learning Outcomes</th>
<th>Time</th>
</tr>
</thead>
</table>
| QMT 8.6 | Quality monitoring tools Presentation | To introduce quality monitoring and some examples of quality monitoring tools | • Monitoring performance  
• Monitoring tools  
• Benchmarking | • Quality monitoring is a way of looking at what is actually happening  
• Looking at key indicators can identify trends and help prevent problems occurring  
• Monitoring is an active process that requires appropriate data analysis to make best use of the monitoring system  
• Visualization of data is one of the best ways of looking at what is going on | • Emphasize that there are different approaches to quality monitoring  
• Encourage participants to try different methods | • List some simple tools for data analysis  
• Describe how these simple tools may be used to monitor performance | ¾ hour |
| QMT 8.7 | Analysing data and monitoring performance Activity | To illustrate the value of monitoring the data that are generated | • Using different types of data  
• Appropriate analysis of data  
• Critical analysis of data  
• Recognizing potential problems  
• Statistical process control (SPC)/(SPM)  
• Identifying and monitoring trends | • Many BTS activities generate data  
• Not all data are a measure of performance  
• Monitoring focuses on what is actually happening  
• Visual presentation of data is an effective method of analysis and understanding | • Explain why certain data have limited monitoring value  
• Give examples of different types of analysis and their advantages and disadvantages  
• Keep the work focused on a simple analysis of the data  
• Explore possible reasons for trends in data | • Analyse some typical laboratory data  
• Prepare simple charts to monitor and evaluate performance  
• Use SPC (SPM) to demonstrate and monitor trends | 1½ hours |
<table>
<thead>
<tr>
<th>Title</th>
<th>Teaching Aim</th>
<th>Core Topics</th>
<th>Key Points</th>
<th>Teaching Focus</th>
<th>Learning Outcomes</th>
<th>Time</th>
</tr>
</thead>
</table>
| QMT 8.8 Error management Presentation | To demonstrate the importance of putting systems in place to deal with errors | • Defining errors  
• Error policy  
• Error reporting  
• Error analysis  
• Correction, corrective action and preventive action | • Errors (quality incidents) must be defined clearly  
• Systems to report quality incidents need to be in place so that they can then be investigated  
• Systems of correction, corrective and preventive action need to be in place  
• All staff and users of products/services must be aware of these systems  
• Incidents must be used to improve processes/procedures, not punish staff | • Define "errors"  
• Discuss the boundary between mistakes and errors  
• Discuss the differences between mistakes, errors and non-compliance | • Demonstrate an understanding of errors and their reporting  
• Explain the importance of taking action to correct errors and prevent further occurrences | ¾ hour |
| QMT 8.9 Preparing an SOP on error reporting Activity | To provide practice in preparing an SOP on dealing with errors | • Identifying errors  
• Reporting and recording errors  
• Analysing errors  
• Corrective and preventive action | • Reporting of errors is essential  
• Staff need to feel able to report errors without fear of punishment | • Focus on the benefits of error reporting  
• Ensure feedback mechanisms are included  
• Reinforce the definition of errors and their reporting  
• Emphasize the need for corrective and preventive action | • Write an SOP on error reporting for their BTS  
• Clearly define errors, reporting mechanisms and action required | 1½ hours |
<table>
<thead>
<tr>
<th>Title</th>
<th>Teaching Aim</th>
<th>Core Topics</th>
<th>Key Points</th>
<th>Teaching Focus</th>
<th>Learning Outcomes</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>QMT 8.10 Audits and auditing Presentation</td>
<td>To introduce the importance of audits within the quality system</td>
<td>• Audits and auditing  • Audit definitions  • Audit planning  • Benefits and value of audits</td>
<td>• Audits are essential to maintain and improve quality  • Audits must be performed and received as positive events  • Audits should be viewed as “improvement opportunities”  • Appropriate and relevant standards must be used  • All staff should become involved and be able to contribute to the audit and its outcome</td>
<td>• Reinforce the importance and value of audits  • Stress the importance of preparing for audits  • Consider any relevant national standards</td>
<td>• Define quality audit  • List the different types of quality audit  • Describe the audit planning process  • Outline the benefits and value of an audit</td>
<td>1 hour</td>
</tr>
<tr>
<td>QMT 8.11 The audit process Presentation</td>
<td>To describe the audit process and how to report on the findings</td>
<td>• Audit process  • Audit reports</td>
<td>• The audit process involves the following steps:  ─ Preparation  ─ Performance  ─ Conclusion  ─ Report  ─ Follow-up  • Audit findings must be documented in the form of a report which should be controlled and follow a defined format  • The audit is incomplete until any corrective action required is taken</td>
<td>• Emphasize the need for auditors to prepare carefully before an audit  • Stress the importance of auditing to the standards  • Emphasize the importance of making the audit a positive experience</td>
<td>• Describe the steps in the audit process  • State the main elements of an audit report</td>
<td>¾ hour</td>
</tr>
<tr>
<td>QMT 8.12 Developing an audit plan Activity</td>
<td>To provide participants with practice in preparing an audit plan</td>
<td>• Types of audit  • Using standards as a basis for an audit</td>
<td>• Audit plans should be simple  • Audit plans should reflect the standards being used  • Pre- and post-audit meetings are essential</td>
<td>• Remember that the course does not aim to train auditors, but to give participants a tool for monitoring their quality system  • Ensure the plans are simple and appropriate</td>
<td>• Design an audit plan</td>
<td>1 hour</td>
</tr>
<tr>
<td>Title</td>
<td>Teaching Aim</td>
<td>Core Topics</td>
<td>Key Points</td>
<td>Teaching Focus</td>
<td>Learning Outcomes</td>
<td>Time</td>
</tr>
<tr>
<td>---------------------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>-------</td>
</tr>
</tbody>
</table>
| QMT 8.13 Identifying non-compliances against a set of standards | To illustrate a typical audit situation  
To provide practice in identifying non-compliances and observations in an audit situation | • Identifying non-compliances  
• Relating non-compliances to audit standards  
• Defining observations | • The auditor must be able to identify and understand the key quality elements in a procedure  
• It is important to be very specific about any non-compliances identified and document them carefully | • Ensure that participants understand the aim of the activity  
• Encourage questions about the players’ audit technique  
• Ensure all non-compliances are identified | • Identify non-compliances from observations made during an audit | 1½ hours |
| QMT 8.14 Audit of a work area | To illustrate the experience of an audit from the perspective of an auditor | • Using an audit plan to conduct an audit  
• Identifying non-compliances | • Audits must be performed in a professional, sensitive and positive way  
• Successful audits are systematic  
• It is essential to have pre- and post-audit meetings to outline the process and review the findings | • Control the audit  
• Ensure that all members of the groups are involved  
• Reinforce the importance of recording observations  
• Invite the auditees to participate in the review of the audit | • Demonstrate an understanding of the audit process | 1½ hours |
| QMT 8.15 Analysing quality system failures | To illustrate the problems that can occur without good quality systems | • System failures affect quality  
• Minor errors can combine to create one serious failure in the quality system | • The consequences of a quality failure can be serious  
• An analysis of failures often identifies a number of minor errors as the cause | • Explain the activity clearly  
• Ensure all participants take part  
• Keep the role play light-hearted and fun  
• Ensure that all the quality failures are identified | • Explain how quality failures can affect the quality of products and services  
• Demonstrate an ability to identify errors and potential errors in processes | 1½ hours |
| QMT 8.16 Mid-course assessment | To assess participants’ broad understanding of Modules 1–8 | • Participants should have achieved improved knowledge and competence in the topics covered in Modules 1–8 | • Demonstrate improved knowledge and understanding of the topics covered in Modules 1–8 | | | 1 hour |
# Module 9: Quality Management in the BTS

## QMT 9.1: Applying quality management in the BTS
### Presentation
- **Teaching Aim**: To introduce how quality systems are applied to blood transfusion processes
- **Core Topics**:
  - WHO strategy for blood safety
  - Quality systems for blood safety
  - Introduction to Part 2 of the course
- **Key Points**:
  - Modules 9–14 will demonstrate how to apply knowledge about quality systems to the BTS:
    - Quality management in the BTS
    - Hygiene and safety
    - Donor management and blood collection
    - Laboratory testing
    - Blood component production and management
    - The clinical interface
- **Teaching Focus**: Ensure participants understand that Part 2 of the course will assist them in applying what they have learned to the various areas of the BTS
- **Learning Outcomes**:
  - Explain the WHO strategy for blood safety
  - Define the key elements of the WHO Aide-Mémoire: Quality Systems for Blood Safety
- **Time**: ½ hour

## QMT 9.2: Identifying critical control points and preparing flowcharts for BTS activities
### Activity
- **Teaching Aim**: To analyse some activities within the transfusion process and identify critical control points
- **Core Topics**:
  - Analysing processes and procedures in the transfusion process
  - Identifying critical control points in BTS activities
  - Using flowcharts to analyse BTS processes and procedures
- **Key Points**:
  - An understanding of processes and procedures is vital to ensure quality
  - Critical control points can be identified for all BTS activities
  - Flowcharts assist in analysing activities
- **Teaching Focus**: Use common BTS processes
- **Learning Outcomes**:
  - Review processes in BTS activities
  - Identify critical control points
  - Produce accurate and consistent flowcharts of BTS processes and procedures
- **Time**: 1½ hours
<table>
<thead>
<tr>
<th>Title</th>
<th>Teaching Aim</th>
<th>Core Topics</th>
<th>Key Points</th>
<th>Teaching Focus</th>
<th>Learning Outcomes</th>
<th>Time</th>
</tr>
</thead>
</table>
| QMT 9.3 | Steps in developing and implementing a quality system in the BTS | Presentation | To highlight the steps in developing and implementing a quality system in the BTS | • Commitment and support  
• Quality working group  
• Quality policy:  
  — National  
  — Local  
• Standards  
• Documentation  
• Activity plan  
• Training  
• Assessment | • Commitment from all concerned is essential for success  
• Finalize a quality policy  
• Develop a quality plan ensuring:  
  — All processes and their appropriate quality needs are identified  
  — Monitoring and evaluation are built into the plan  
• The plan must be documented, followed and monitored | • Focus on achievable steps in developing and implementing a quality system in the BTS  
• Be sensitive to the varying situations of the participants | • List the steps in developing and implementing a quality system in the BTS | ½ hour |
| QMT 9.4 | Costing activities in a blood transfusion service | Presentation | To highlight the importance of costing all BTS activities | • Definition of costing  
• Benefits of costing  
• WHO manual “Costing Blood Transfusion Services”  
• Basic cost analysis of BTS activities | • The quality manager needs to understand the principles of costing  
• Accurate costing of BTS activities enables accurate budget planning and resource mobilization  
• Sustainability of the BTS is not achievable without costing procedures  
• Costing BTS activities contributes to quality monitoring | • Focus on simplicity  
• Concentrate on basic principles and practice rather than trying to identify specific costs  
• Give a range of examples where the actual cost is higher than expected due to poor quality | • Explain the value of comprehensive costing of all BTS activities  
• Define key factors that need to be taken into account in costing the activities of a BTS | ¾ hour |
<table>
<thead>
<tr>
<th>Title</th>
<th>Teaching Aim</th>
<th>Core Topics</th>
<th>Key Points</th>
<th>Teaching Focus</th>
<th>Learning Outcomes</th>
<th>Time</th>
</tr>
</thead>
</table>
| **QMT 9.5**<br>Principles of stock control<br>Presentation | To highlight the importance of stock control and correct storage conditions | • Stock control and ordering  
• Perishable and non-perishable materials  
• Delivery checks  
• Quarantine of materials  
• Inspection of incoming materials  
• Correct storage of perishable materials  
• Monitoring correct storage conditions  
• Documentation | • All BTSs need a good stock management system  
• Sufficient stocks of critical items must be maintained at all times  
• All incoming materials must be appropriately checked before use  
• Quarantine and release procedures must be in place for certain items  
• Monitoring of usage can help ensure adequate stock levels are maintained | • Highlight the problems of stock control when delivery times cannot be guaranteed  
• Stress the importance of correct storage conditions  
• Emphasize the need for contingency plans for refrigerator/freezer failure  
• Reinforce the importance of documenting the monitoring of storage conditions | • Describe methods of monitoring the stock control system  
• Identify the factors that can influence storage conditions  
• Explain the principles of quarantine/release procedures  
• List essential documentation and records for stock control | ¾ hour |
| **QMT 9.6**<br>Quality aspects of contingency planning<br>Presentation | To encourage the development of contingency plans to ensure an adequate supply of safe blood products at all times | • Maintaining the safety and adequacy of the blood supply  
• Plans and procedures  
• Major disasters or incidents  
• Responsibility: role of the quality manager  
• Planning to minimize adverse outcomes  
• Co-ordination with other agencies | • Things do go wrong  
• Disasters do happen  
• The continuity of the blood supply is essential  
• Contingency planning is essential  
• Documented procedures need to be in place, available to all staff and reviewed at appropriate intervals  
• BTS plans need to be incorporated into appropriate national and local contingency plans | • Provide examples of different situations in which the safety and adequacy of the blood supply may be compromised | • Identify situations that may threaten the safety and adequacy of the blood supply  
• Develop a contingency plan for the BTS | ½ hour |
<table>
<thead>
<tr>
<th>Title</th>
<th>Teaching Aim</th>
<th>Core Topics</th>
<th>Key Points</th>
<th>Teaching Focus</th>
<th>Learning Outcomes</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>QMT 9.7</td>
<td>Quality status analysis Activity</td>
<td>To assist participants to assess the quality status of their BTS</td>
<td>• The use of the Quality Status Questionnaire as a tool for education and monitoring</td>
<td>• The Quality Status Questionnaire will help participants to begin the process of preparing their action plans</td>
<td>• If necessary, assist participants in answering the questions</td>
<td>• Use the information in the questionnaire to monitor their own progress</td>
</tr>
<tr>
<td>QMT 9.8</td>
<td>Preparing an action plan Presentation</td>
<td>To introduce participants to the preparation of their individual action plans</td>
<td>• Introduction to preparing an action plan</td>
<td>• The action plan should include all the main elements of a quality management system</td>
<td>• Emphasize that the suggested steps are only examples and that participants’ plans will vary considerably depending on their own situation</td>
<td>• List the main areas to consider when preparing the first draft of a basic plan of action</td>
</tr>
<tr>
<td>QMT 9.9</td>
<td>Preparing a draft action plan Activity</td>
<td>To assist participants in drafting their individual action plans</td>
<td>• The first draft of the action plan will be refined at the end of the course</td>
<td>• Participants should initially focus on the next 6–12 months</td>
<td>• Encourage participants to be honest and realistic about what is achievable</td>
<td>• Identify priority areas from the quality status questionnaire</td>
</tr>
<tr>
<td>Module 10</td>
<td>Hygiene and Safety in the BTS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>-----------</td>
<td>-----------------------------</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Title</td>
<td>Teaching Aim</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>QMT 10.1</td>
<td>Introduction to hygiene and safety in the BTS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>To review the elements of a quality system in relation to hygiene and safety in the BTS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Core Topics</td>
<td>Key Points</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Hygiene and safety as quality issues</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Safety policy and procedures</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Biosafety</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Other safety issues - Mechanical/electrical/chemical/fire/radiation safety</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Disposal of waste</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Responsibilities for safety</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• A safety policy is an essential component of the elements of the quality system</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• The safety policy should reflect the commitment by the organization to hygiene and safety issues</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Responsibilities for hygiene and safety should be defined</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Emphasize that the quality manager is responsible for ensuring a hygiene and safety policy is in place</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Provide examples of safety policies</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Teaching Focus</td>
<td>Learning Outcomes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Identify quality issues in relation to hygiene and safety in the BTS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Define key elements of a safety policy for a BTS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Identify the responsibilities of the organization and staff for hygiene and safety</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Identify the role of the quality manager in ensuring hygiene and safety in the BTS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Time</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>½ hour</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<p>| QMT 10.2  | Hygiene in the BTS |
|           | To demonstrate the importance of hygiene and cleanliness in the BTS |
| Core Topics | Key Points                          |
|           | • Hygiene in work areas as a quality requirement |
|           | • Personal hygiene                   |
|           | • Good hygiene requires cleanliness and tidiness |
|           | • Cleanliness and tidiness of the work area is a quality requirement to protect donors, staff and products |
|           | • Personal hygiene is essential      |
|           | • Emphasize the importance of hygiene for the quality of the product and the protection of staff and donors |
|           | • Emphasize the need for the continual cleaning of surfaces, equipment, etc. |
|           | • Ensure participants understand that cleaning is the responsibility of all staff |
| Teaching Focus | Learning Outcomes            |
|           | • Explain why hygiene is a quality requirement |
|           | • Identify the actions required to ensure hygiene in the BTS |
|           | Time                              |
|           | ¾ hour                            |</p>
<table>
<thead>
<tr>
<th>Title</th>
<th>Teaching Aim</th>
<th>Core Topics</th>
<th>Key Points</th>
<th>Teaching Focus</th>
<th>Learning Outcomes</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>QMT 10.3</td>
<td>To demonstrate the importance of biological and chemical safety in the BTS</td>
<td>• Types of hazardous material&lt;br&gt;• Universal safety precautions&lt;br&gt;• Safe handling of hazardous material&lt;br&gt;• Safe disposal of hazardous waste</td>
<td>• Universal safety precautions must be followed at all times for the protection of staff, the environment and the general public&lt;br&gt;• Potentially hazardous material must be handled safely and disposed of in the correct manner&lt;br&gt;• Biohazardous material must be appropriately labelled and transported in appropriate containers&lt;br&gt;• All hazardous spills must be contained and decontaminated</td>
<td>• Ensure that participants are familiar with universal safety precautions&lt;br&gt;• Discuss the role of the quality manager in ensuring there is a system for the correct handling and disposal of hazardous waste</td>
<td>• Identify the actions required to ensure biological and chemical safety in the BTS</td>
<td>¾ hour</td>
</tr>
<tr>
<td>QMT 10.4</td>
<td>To provide participants with practice in identifying safety issues and how to resolve them</td>
<td>• Identification of key safety issues&lt;br&gt;• Creating awareness of safety issues&lt;br&gt;• Actions needed to minimize risks</td>
<td>• An analysis of the safety aspects of all processes and procedures is essential</td>
<td>• Give examples of the types of potential risk to staff, donors and the public&lt;br&gt;• Ensure that safety plans are feasible and cover key areas</td>
<td>• Identify key BTS safety issues&lt;br&gt;• List the key elements of maintaining a safe workplace&lt;br&gt;• Design a plan for safety checks in the BTS</td>
<td>1½ hours</td>
</tr>
<tr>
<td>Module 11</td>
<td>Quality Systems in Blood Donor Management</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>------------</td>
<td>------------------------------------------</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Title</strong></td>
<td><strong>Teaching Aim</strong></td>
<td><strong>Core Topics</strong></td>
<td><strong>Key Points</strong></td>
<td><strong>Teaching Focus</strong></td>
<td><strong>Learning Outcomes</strong></td>
<td><strong>Time</strong></td>
</tr>
</tbody>
</table>
| QMT 11.1   | Introduction to quality systems in blood donor management | • Elements of a quality system as applied to blood donor management  
• Quality issues in donor management:  
  — Recruitment  
  — Selection  
  — Blood collection  
  — Documentation  
  — Donor care, satisfaction and retention  
• Role of the quality manager | • The quality system in blood donor management should focus on the activities of:  
  — Recruitment  
  — Selection  
  — Collection  
  — Documentation  
  — Donor care, satisfaction and retention | • Acknowledge and expand on the differences in approach by different BTSS  
• Regular low-risk blood donors are the foundation of a safe and adequate blood supply  
• Discuss the role of the quality manager in ensuring quality in blood collection | • Identify the actions required to ensure quality in blood donor management  
• Identify the role of the quality manager in ensuring quality in blood donor management | ½ hour |
| QMT 11.2   | Donor recruitment and selection | • Donor recruitment  
• Donor selection  
• Assessment | • Applying quality to donor recruitment ensures that:  
  — The lowest risk blood donor populations are identified  
  — The safest donors are recruited and retained | • Explain the importance of an analysis of populations to identify groups to target or avoid  
• Emphasize that quality means meeting and exceeding the customer’s expectations  
• Ensure that all relevant WHO recommendations and guidelines are included in the presentation | • Identify the quality issues related to the processes of donor recruitment and selection  
• Identify the action required to ensure quality in blood donor recruitment and selection  
• Identify the role of the quality manager in blood donor recruitment and selection | 1 hour |
| QMT 11.3   | Donor recruitment and selection | • Quality awareness training of the staff in donor recruitment and selection  
• Donor recruitment staff should understand the impact of quality on the BTS | • Discuss the adverse affect of poor donor recruitment strategies and attitudes | • Explain the importance of quality in blood donor recruitment and selection | 1 hour |
<table>
<thead>
<tr>
<th>Title</th>
<th>Teaching Aim</th>
<th>Core Topics</th>
<th>Key Points</th>
<th>Teaching Focus</th>
<th>Learning Outcomes</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>QMT 11.4</td>
<td>Blood collection Presentation</td>
<td>To demonstrate how to apply quality to blood collection</td>
<td>• Pre-donation checks of equipment and materials&lt;br&gt;• Donor identification&lt;br&gt;• Donor arm cleansing&lt;br&gt;• Venepuncture and collection&lt;br&gt;• Care of the donor&lt;br&gt;• Handling of donations and samples&lt;br&gt;• Quality issues at mobile donor sessions</td>
<td>• Quality in blood collection protects the donor and the recipient&lt;br&gt;• Quality in blood collection ensures the quality of the product</td>
<td>• Introduce the topic in a very broad way&lt;br&gt;• Be aware of significant differences between countries in the way in which blood is collected&lt;br&gt;• Keep the focus on quality aspects of blood collection&lt;br&gt;• Discuss the additional problems in applying quality in mobile donor sessions</td>
<td>• Identify the quality issues related to the process of blood collection&lt;br&gt;• Identify specific quality issues related to blood collection at mobile donor sessions&lt;br&gt;• Identify the role of the quality manager in ensuring quality in blood collection</td>
</tr>
<tr>
<td>QMT 11.5</td>
<td>Blood collection Activity</td>
<td>To enable participants to examine the benefits of introducing a quality system to blood collection activities</td>
<td>• The role of the quality manager in blood collection&lt;br&gt;• Monitoring of blood collection activities</td>
<td>• Applying standard procedures to collection activities&lt;br&gt;• Training of blood collection staff</td>
<td>• Ensure the participants clearly understand the role of the quality manager in blood collection</td>
<td>• Explain the importance of good quality in blood collection&lt;br&gt;• Explain the role of the quality manager in blood collection</td>
</tr>
<tr>
<td>QMT 11.6</td>
<td>Developing a documentation system for blood donor management Presentation</td>
<td>To demonstrate how to develop an effective documentation system for blood donor management</td>
<td>• Types and levels of documents required&lt;br&gt;• Traceability – donor to donation&lt;br&gt;• Confidentiality&lt;br&gt;• Monitoring and evaluation</td>
<td>• Each activity in the donor clinic, and the outcome of each activity, should be documented&lt;br&gt;• A documentation system enables the BTS to manage the blood donor programme e.g.&lt;br&gt;  ─ Assists in donor recall and retention&lt;br&gt;  ─ Ensures traceability&lt;br&gt;  ─ Records and analyzes successes and failures&lt;br&gt;  ─ Assists in error analysis</td>
<td>• Keep the focus on the need for simplicity of all records&lt;br&gt;• Discuss why traceability is essential&lt;br&gt;• Emphasize the importance of confidentiality</td>
<td>• Apply the principles of documentation in quality systems to blood donor management&lt;br&gt;• Explain the need for traceability</td>
</tr>
<tr>
<td>Title</td>
<td>Teaching Aim</td>
<td>Core Topics</td>
<td>Key Points</td>
<td>Teaching Focus</td>
<td>Learning Outcomes</td>
<td>Time</td>
</tr>
<tr>
<td>-------</td>
<td>--------------</td>
<td>-------------</td>
<td>------------</td>
<td>----------------</td>
<td>-------------------</td>
<td>------</td>
</tr>
</tbody>
</table>
| **QMT 11.7**  
Donor care, satisfaction and retention  
Presentation | To emphasize the importance of high quality donor care in ensuring donor satisfaction and retention | • Donor care  
• Donor satisfaction  
• Donor retention  
• Donor complaints | • The quality system should ensure that the donor is treated as an important customer  
• Donor satisfaction and retention are directly influenced by the quality of donor care  
• Complaints must be formally investigated both to satisfy the donor and to critically examine BTS practice | • Introduce the concept of the donor as a customer  
• Emphasize the importance of recognizing and understanding donors' needs | • Explain how high quality donor care promotes donor satisfaction which leads to retention  
• Identify the actions required to ensure high quality donor care  
• Explain the role of the quality manager in ensuring donor satisfaction | ½ hour |
| **QMT 11.8**  
Donor satisfaction  
Activity | • To encourage participants to examine any aspects of the donor selection and blood collection process that may lead to donor dissatisfaction  
• To assist participants to examine those aspects of a quality system that would promote donor satisfaction | • The importance of donor satisfaction  
• Communication between the donor and the BTS  
• Donor satisfaction is essential to achieve retention of voluntary donors  
• All staff need to be aware of the importance of donor satisfaction | • Emphasize that donor satisfaction can be very dependent upon staff attitude and responsiveness  
• Acknowledge the need for specialized communication skills in the blood donor clinic | • Explain how a quality focused approach can play a major part in ensuring blood donor satisfaction | | ½ hour |
| **QMT 11.9**  
Identifying and monitoring critical control points in blood donor management  
Activity | To identify the critical control points for assessing the processes in blood donor management | • Using flowcharts to identify critical control points in the process of blood donor management  
• Identifying indicators and tools for monitoring and controlling the blood donor management process  
• The selection of donors is the first step in ensuring the safety of the blood supply  
• The quality of the blood collection process may directly affect the quality of the raw material | • Emphasize the reasons for monitoring  
• Ensure that appropriate monitoring tools are identified  
• Focus on the key indicators | • Identify the critical control points in the process of blood donor management  
• Identify indicators and appropriate tools for monitoring the critical control points in the process of blood donor management | | 1½ hour |
<table>
<thead>
<tr>
<th>Title</th>
<th>Teaching Aim</th>
<th>Core Topics</th>
<th>Key Points</th>
<th>Teaching Focus</th>
<th>Learning Outcomes</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>QMT 12.1 Introduction to quality systems in laboratory testing</td>
<td>To review the elements of a quality system in relation to laboratory testing</td>
<td>• Elements of a quality system as applied to laboratory testing • Quality issues in laboratory testing: — Equipment — Samples — Selection and use of reagents and test kits — Quality control — Laboratory documents — Handling of test results</td>
<td>• A quality system is essential in the laboratory to ensure the correct results for the correct donation/donor and patient • The quality system in the laboratory should cover: — Organization and staff — Facilities and equipment — Reagents/test kits — Documentation — Samples — Handling of test results — Quality control — Assessment</td>
<td>• Emphasize that all laboratories have similar quality needs</td>
<td>• Identify the actions required to ensure quality in laboratory testing • Identify the role of the quality manager in ensuring quality in laboratory testing</td>
<td>½ hour</td>
</tr>
<tr>
<td>QMT 12.2 Evaluation and use of immunohaematology reagents</td>
<td>To demonstrate how to apply quality to the evaluation and use of immunohaematology reagents</td>
<td>• Definitions • Selection and evaluation • Validation • Control during routine use</td>
<td>• Selection of immunohaematology reagents is a process that needs to be planned carefully • The characteristics that should be examined include specificity, sensitivity, potency, avidity • Overall performance depends upon a number of factors, including methodology and staff • Testing needs and the resources available to meet those needs must be taken into account in selection of reagents</td>
<td>• Be aware of the limitations on procurement in different countries • Promote the ideal with an acceptance of the reality</td>
<td>• Identify the actions required to ensure quality in the evaluation and use of immunohaematology reagents • Identify the role of the quality manager in the evaluation and use of immunohaematology reagents</td>
<td>¾ hour</td>
</tr>
<tr>
<td>Title</td>
<td>Teaching Aim</td>
<td>Core Topics</td>
<td>Key Points</td>
<td>Teaching Focus</td>
<td>Learning Outcomes</td>
<td>Time</td>
</tr>
<tr>
<td>-------</td>
<td>--------------</td>
<td>-------------</td>
<td>------------</td>
<td>----------------</td>
<td>------------------</td>
<td>------</td>
</tr>
<tr>
<td>QMT 12.3</td>
<td>Evaluation and use of test kits for transfusion-transmissible infections</td>
<td>To demonstrate how to apply quality to evaluation and use of test kits for transfusion-transmissible infections (TTIs)</td>
<td>• Definitions</td>
<td>• The basic principles of selection and evaluation apply to all assays used in the BTS</td>
<td>• Be aware of the limitations on procurement in different countries</td>
<td>• Identify the actions required to ensure quality in the evaluation and use of TTI test kits</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Selection and evaluation</td>
<td>• Batch testing is essential</td>
<td>• Promote the ideal with an acceptance of the reality</td>
<td>• Identify the role of the quality manager in the evaluation and use of TTI test kits</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Validation</td>
<td>• Other factors influence choice</td>
<td>• Demonstrate the potential false economy of using cheap test kits</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Control during routine use</td>
<td>— Constraints</td>
<td>— Resources</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>QMT 12.4</td>
<td>Selecting reagents and test kits</td>
<td>To provide practice in selecting reagents and test kits for specified activities</td>
<td>• General criteria for selecting reagents and test kits</td>
<td>• Importance of selecting high quality, cost-effective reagents and test kits</td>
<td>• Emphasize the balance between what is needed and what is available</td>
<td>• Analyse requirements and list key criteria for selecting test kits and/or reagents</td>
</tr>
<tr>
<td>Activity</td>
<td></td>
<td></td>
<td>• Identifying the correct reagents and test kits to use</td>
<td>• Constraints on the selection of ideal reagents and test kits</td>
<td>• Encourage discussion over different ways to solve problems</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Selection is deciding “fitness for purpose”</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>QMT 12.5</td>
<td>Developing a documentation system for the laboratory</td>
<td>To demonstrate how to develop an effective documentation system in the laboratory</td>
<td>• Essential documentation in the laboratory</td>
<td>• Laboratory documentation is essential for traceability</td>
<td>• Clarify the information that needs to be documented</td>
<td>• Identify the types of documents that are required in the laboratory</td>
</tr>
<tr>
<td>Presentation</td>
<td></td>
<td></td>
<td>• Laboratory records</td>
<td>• Laboratories produce large amounts of data</td>
<td>• Give examples of different types of documentation</td>
<td>• List the essential laboratory records that should be maintained</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Recording and analysing laboratory data</td>
<td>• Data should be analysed and used to improve laboratory performance</td>
<td></td>
<td>• Identify the data that should be analysed to ensure continuous improvement</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>QMT 12.6</td>
<td>External Quality Assessment (EQA) schemes</td>
<td>To promote the participation of BTS laboratories in appropriate EQA schemes</td>
<td>• Principles of EQA</td>
<td>• External quality assessment provides confidence in the overall performance in the laboratory</td>
<td>• Give examples of national and international schemes</td>
<td>• List the objectives and benefits of EQA</td>
</tr>
<tr>
<td>Presentation</td>
<td></td>
<td></td>
<td>• Objectives of EQA</td>
<td>• EQA is one of the tools used to monitor and improve quality</td>
<td>• Encourage participation in EQA schemes</td>
<td>• Define the role of EQA in a quality system</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Benefits of EQA</td>
<td></td>
<td></td>
<td>• Identify the role of the quality</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Organization and process of EQA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• WHO EQA schemes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Title</td>
<td>Teaching Aim</td>
<td>Core Topics</td>
<td>Key Points</td>
<td>Teaching Focus</td>
<td>Learning Outcomes</td>
<td>Time</td>
</tr>
<tr>
<td>--------------------------------------------</td>
<td>------------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------</td>
<td>----------</td>
</tr>
</tbody>
</table>
| QMT 12.7                                   | To identify the critical control points for assessing and controlling the processes in the testing laboratory | • Using flowcharts to identify critical control points in the processes in the testing laboratory  
• Indicators and tools for monitoring and controlling the processes in the laboratory | • Ensuring a well-defined flow of work in the laboratory leads to improved quality  
• The laboratory environment provides much data for analysis and use as indicators  
• Indicators in the laboratory should be monitored through the use of SPC | • Emphasize the need for well-defined flowcharts  
• Emphasize the reasons for monitoring and analysing data in the laboratory  
• Focus on the key indicators | • Identify the critical control points in the processes in the testing laboratory  
• Identify indicators and appropriate tools for monitoring the critical control points | 1½ hours |
<table>
<thead>
<tr>
<th>Module 13</th>
<th>Quality Systems in Component Production and Management</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Title</strong></td>
<td><strong>Teaching Aim</strong></td>
</tr>
<tr>
<td>QMT 13.1</td>
<td>To review the elements of a quality system in relation to blood component production and management</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<p>| QMT 13.2  | To demonstrate how to apply quality monitoring in blood component production and management | • Specifications | • The purpose of monitoring is to answer the basic question – are we producing what we are meant to be producing? | • Keep the emphasis on GMP | • Identify what needs to be monitored to ensure quality in blood component production and management | ¾ hour |
|          | | • Incoming blood units | • The parameters to be monitored need to be matched to the product and its intended use | | • Identify the role of the quality manager in quality monitoring | |
|          | | • Product monitoring | • Monitoring is a tool to generate data – positive or negative – to feed back into the process | | | |
|          | | • Monitoring plans | • Monitoring is an integral part of any production process | | | |
|          | | • Analysis and use of results | | | | |</p>
<table>
<thead>
<tr>
<th>Title</th>
<th>Teaching Aim</th>
<th>Core Topics</th>
<th>Key Points</th>
<th>Teaching Focus</th>
<th>Learning Outcomes</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>QMT 13.3 Evaluation and monitoring of blood component production activities</td>
<td>To provide practice in analysing component production activities and identifying appropriate monitoring methods</td>
<td>• Identifying the monitoring points available&lt;br&gt;• Identifying monitoring strategies and evaluation methods</td>
<td>• Critical control points in the process need to be identified</td>
<td>• Ensure that the terms &quot;monitoring&quot; and &quot;evaluation&quot; are clearly understood&lt;br&gt;• Ensure the plans are feasible&lt;br&gt;• Ensure the plans do not interfere with the workflow</td>
<td>• Outline the principles of monitoring and evaluation of component production&lt;br&gt;• Prepare a plan for monitoring and evaluation of components</td>
<td>1½ hours</td>
</tr>
<tr>
<td>QMT 13.4 Quarantine and release</td>
<td>To demonstrate how to develop systems for quarantine and release</td>
<td>• Principles&lt;br&gt;• Quarantine&lt;br&gt;• Release&lt;br&gt;• Responsibility&lt;br&gt;• Concessions&lt;br&gt;• Documentation</td>
<td>• All donated blood should be placed in quarantine on receipt from collection teams&lt;br&gt;• There should be clear physical segregation of tested and untested products&lt;br&gt;• Responsible persons need to be identified who can authorize the release of products&lt;br&gt;• A concession system may be needed in defined circumstances</td>
<td>• Explore the issue of responsibility for release</td>
<td>• Explain the importance of quarantine and release&lt;br&gt;• List the key elements of an effective quarantine and release system&lt;br&gt;• Identify the role of the quality manager in quarantine and release</td>
<td>¾ hour</td>
</tr>
<tr>
<td>QMT 13.5 Storage and transportation of blood components</td>
<td>To demonstrate how to apply quality in the storage and transportation of blood components</td>
<td>• Storage&lt;br&gt;• Packaging&lt;br&gt;• Transportation&lt;br&gt;• Maintenance of the blood cold chain&lt;br&gt;• Documentation</td>
<td>• Storage and transportation need to be controlled to ensure the quality of products is maintained from donor to patient, from &quot;vein to vein&quot;&lt;br&gt;• The blood cold chain needs to be maintained&lt;br&gt;• Transportation conditions are especially important&lt;br&gt;• Monitoring is essential</td>
<td>• Focus on the need to protect the product from &quot;vein to vein&quot;&lt;br&gt;• Explore different methods of transporting products to maintain the blood cold chain</td>
<td>• Identify the actions required to ensure quality in storage and transportation&lt;br&gt;• Explain what is meant by the blood cold chain&lt;br&gt;• Describe the elements of an effective blood cold chain&lt;br&gt;• Identify the role of the quality manager in ensuring quality in storage and distribution</td>
<td>½ hour</td>
</tr>
<tr>
<td>Title</td>
<td>Teaching Aim</td>
<td>Core Topics</td>
<td>Key Points</td>
<td>Teaching Focus</td>
<td>Learning Outcomes</td>
<td>Time</td>
</tr>
<tr>
<td>-------</td>
<td>-------------</td>
<td>-------------</td>
<td>------------</td>
<td>----------------</td>
<td>------------------</td>
<td>------</td>
</tr>
</tbody>
</table>
| QMT 13.6 | Storage and transportation of blood components Activity | To provide practice in developing standards and policies for the storage, transportation and distribution of blood components | • Quarantine and release procedures  
• Blood cold chain maintenance  
• Security during transportation | • All staff should be made aware of the impact of poor quality during storage, transportation and distribution of blood products | • Explore all possible scenarios, keeping in mind that many countries do not have the resources available to countries in the developed world  
• List the documents required to ensure a quality approach | 1 hour |
| QMT 13.7 | Blood stock management Presentation | To demonstrate how to apply quality to blood stock management | • Importance of blood stock management  
• Managing blood stocks  
• Managing fluctuations in supply and demand  
• Minimum blood stock levels  
• Documentation | • The proper management of stock is essential for the BTS to be able to provide clinical users with sufficient products  
• Stock management includes the management of the other factors that can affect the stocks of blood  
• Minimum stock levels and actions to be taken to replenish stocks need to be defined | • Stress the importance of managing stocks to ensure the availability of desired components or particular blood groups at all times  
• Explore the issue of returning blood for re-use  
• Highlight the importance of minimizing the number of blood units that expire  
• Explain the importance of managing blood stocks  
• Identify the actions required to ensure that blood stocks are managed effectively  
• Identify the role of the quality manager in ensuring effective blood stock management | ¾ hour |
| QMT 13.8 | Developing a documentation system for blood component production Presentation | To demonstrate how to develop an effective documentation system for blood component production | • What to document  
• Types of documents  
• Labelling  
• Traceability | • A documentation system is an essential requisite  
• GMP guidelines should be followed  
• All processing and associated activities need to be documented  
• The labelling of products is a critical area with the potential for major errors if not effectively controlled | • Clarify the information that needs to be documented  
• Give examples of the different types of documentation  
• Identify the information that needs to be documented  
• Identify the basic labelling requirements on blood products | ½ hour |
<table>
<thead>
<tr>
<th><strong>Title</strong></th>
<th><strong>Teaching Aim</strong></th>
<th><strong>Core Topics</strong></th>
<th><strong>Key Points</strong></th>
<th><strong>Teaching Focus</strong></th>
<th><strong>Learning Outcomes</strong></th>
<th><strong>Time</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>QMT 13.9</td>
<td>To identify the critical control points for monitoring blood component production</td>
<td>• Using flowcharts to identify critical control points in blood component production&lt;br&gt;• Indicators and tools for monitoring and controlling blood component production</td>
<td>• The principles of quality systems and GMP should be applied to the production of blood components&lt;br&gt;• SPC assists in monitoring and controlling the processes in blood component production</td>
<td>• Emphasize the reasons for monitoring&lt;br&gt;• Ensure the appropriate monitoring tools are identified&lt;br&gt;• Focus on the key indicators</td>
<td>• Identify the critical control points in the processes at which monitoring should take place&lt;br&gt;• Identify indicators and tools for monitoring</td>
<td>1½ hours</td>
</tr>
</tbody>
</table>
### Module 14 | Quality Systems and the Clinical Interface

<table>
<thead>
<tr>
<th>Title</th>
<th>Teaching Aim</th>
<th>Core Topics</th>
<th>Key Points</th>
<th>Teaching Focus</th>
<th>Learning Outcomes</th>
<th>Time</th>
</tr>
</thead>
</table>
| **QMT 14.1** | **Introduction to quality systems at the clinical interface** | **Presentation** | To review the elements of a quality system in relation to the clinical interface | • Definition of the clinical interface  
• Elements of a quality system as applied to the clinical interface  
• Quality issues at the clinical interface:  
  — Importance of an effective clinical interface  
  — Role of the BTS/hospital blood bank  
  — Hospital transfusion process  
  — Appropriate clinical use of blood | • The need for quality continues after the blood leaves the BTS  
• The BTS has an important role in ensuring the quality of the clinical transfusion process  
• The needs of both the patient and the clinician must be considered in determining how to ensure customer satisfaction  
• The quality system of documentation extends to the clinical interface  
• All staff involved in the clinical interface require training  
• Effective communication is required between the BTS and the hospital | • Acknowledge the different relationships between BTSSs and hospitals in different countries  
• Refer to WHO recommendations and learning materials on the clinical use of blood  
• Identify the actions required to ensure quality at the clinical interface  
• Identify the role of the quality manager in ensuring quality at the clinical interface | ½ hour |

| **QMT 14.2** | **Policy and guidelines on the clinical use of blood** | **Presentation** | To demonstrate how a policy and guidelines on the clinical use of blood can improve the quality of clinical transfusion practice | • Policy on the clinical use of blood  
• Guidelines on the appropriate clinical use of blood  
• The role of the BTS in the development of a national policy and guidelines on the appropriate clinical use of blood  
• The role of a hospital transfusion committee | • The BTS should play a key role in the development of a national policy and guidelines on the clinical use of blood, in collaboration with national health authorities and clinical specialists  
• Transfusion committees, both national and hospital-based, need to be formed to ensure effective policy making and monitoring  
• Refer to WHO recommendations and other relevant material, including learning materials: The Clinical Use of Blood  
• Provide examples of national policies | • Explain the importance of the appropriate clinical use of blood for safe transfusion  
• Identify the actions required to promote the appropriate clinical use of blood  
• Identify the role of the BTS in promoting the appropriate clinical use of blood | ⅓ hour |
<table>
<thead>
<tr>
<th>Title</th>
<th>Teaching Aim</th>
<th>Core Topics</th>
<th>Key Points</th>
<th>Teaching Focus</th>
<th>Learning Outcomes</th>
<th>Time</th>
</tr>
</thead>
</table>
| QMT 14.3 | Role of the BTS at the clinical interface | To explore the role of the BTS at the clinical interface | • The BTS has an important role to play in the appropriate clinical use of blood  
• Ensuring the appropriate clinical use of blood requires effective collaboration between the BTS and prescribers of blood | • Discuss different approaches to ensure the “quality” use of blood products | • Describe the role of the BTS at the clinical interface  
• List the players in establishing quality at the clinical interface | 1 hour |
| QMT 14.4 | Documentation in the hospital transfusion process | To demonstrate how an effective documentation system can be used to improve the hospital transfusion process | • Information to be recorded  
• The importance of documentation in the hospital transfusion process  
• Using documentation in the hospital transfusion process for improvement of all aspects of blood transfusion | • Emphasize the importance of full traceability of donations  
• Focus on the lack of traceability if records are incomplete or inaccurate | • Identify the information that needs to be documented in relation to the hospital transfusion process  
• Identify the actions required to establish an effective system for documenting the hospital transfusion process  
• Identify the role of the BTS in developing an effective system for documenting the hospital transfusion process | ½ hour |
| QMT 14.5 | Designing a blood request form | To determine the key information required to identify a patient and his/her blood needs | • Relevant clinical information  
• Simplifying documentation to focus only on that which is needed  
• Identifying who should design a blood request form | • Transfusion should only occur when clinically indicated  
• Patient details must be completed accurately to ensure correct identification | • Remind participants of the importance of the basic information required  
• Emphasize the importance of legibility  
• Discuss relevant and irrelevant information | • List the essential information required on a blood request form  
• Explain why this information is required  
• Produce an appropriate and effective blood request form | 1 hour |
<table>
<thead>
<tr>
<th>Title</th>
<th>Teaching Aim</th>
<th>Core Topics</th>
<th>Key Points</th>
<th>Teaching Focus</th>
<th>Learning Outcomes</th>
<th>Time</th>
</tr>
</thead>
</table>
| QMT 14.6                                   | To identify the role of the BTS in ensuring quality in the hospital transfusion process | • Hospital transfusion process  
  • Positive identification  
  • Storage of blood components  
  • Requests for blood  
  • Responsibilities of the compatibility testing laboratory  
  • Administration of blood  
  • Role of the BTS/blood bank | • The BTS has a responsibility to ensure that hospitals using its products meet quality standards in transfusion practice  
  • The BTS should assist hospitals to develop policies and SOPs for each stage of the clinical transfusion process | • Stress the importance of the role of the BTS in the transfusion process  
  • Emphasize the role of a documentation system in ensuring patient, specimen and product identification | • Identify the actions required to ensure quality in the hospital transfusion process  
  • Identify the role of the BTS/blood bank in ensuring quality in the hospital transfusion process  
  • Identify the role of the quality manager in ensuring quality in the hospital transfusion process | ¾ hour |
| QMT 14.7                                   | To identify key quality aspects of transfusion requests and administration of blood products | • Sample identification  
  • Patient identification  
  • Product identification | • The BTS has an active role in ensuring quality at the bedside  
  • Correct sample from the correct patient  
  • Correct product for correct patient | • Discuss the different approaches to ensuring quality at the bedside | • List the documents needed to ensure quality at the bedside | 1 hour |
| QMT 14.8                                   | To demonstrate how monitoring and evaluation can be used to improve the quality of the hospital transfusion process | • Monitoring and evaluation  
  • Indicators  
  • Analysing and using data for improvement in all aspects of blood transfusion | • All aspects of the process of transfusion should be monitored and the results analysed and acted on  
  • A hospital transfusion committee should be established in every hospital  
  • The BTS and hospital blood bank should be represented on the hospital transfusion committee  
  • The clinical use of blood should be monitored using defined indicators | • Illustrate the importance of monitoring and feedback with reference to crossmatch : transfusion ratios  
  • Emphasize the importance of using monitoring data to reduce unnecessary transfusions  
  • Give examples of national monitoring and reporting systems | • Explain how data from monitoring and evaluation can be used to improve hospital transfusion practice  
  • Identify the actions required to develop a system for the monitoring and evaluation of the hospital transfusion process  
  • Identify the role of the BTS in the monitoring and evaluation of the hospital transfusion process | 1 hour |
<table>
<thead>
<tr>
<th>Title</th>
<th>Teaching Aim</th>
<th>Core Topics</th>
<th>Key Points</th>
<th>Teaching Focus</th>
<th>Learning Outcomes</th>
<th>Time</th>
</tr>
</thead>
</table>
| QMT 14.9 Haemovigilance Presentation | To promote the development of a national reporting system for adverse transfusion events | • Definition  
• Principle  
• Requirements  
• Benefits  | • To be effective haemovigilance requires open and honest reporting and investigation  
• Haemovigilance depends upon traceability in the hospital and the BTS  
• Haemovigilance is an essential part of the quality system in BTS/clinical interface  
• Information is fed back into the transfusion system to improve the overall safety and quality of transfusion practice in the BTS and the hospital  | • Emphasize the importance of using the information gathered to improve blood safety  | • Explain how a haemovigilance system can help to improve the quality of every aspect of blood transfusion  
• Describe the elements of a haemovigilance system  
• Identify the actions required to establish a national haemovigilance system  
• Identify the role of the quality manager in developing a national haemovigilance system and utilizing the data to improve transfusion practice  | ¾ hour |
| QMT 14.10 Identifying and monitoring critical control points for the clinical interface and the administration of blood Activity | To identify critical control points at the clinical interface and plan systems for monitoring | • Identifying the monitoring points available  
• Identifying the monitoring strategies and evaluation methods  | • Critical control points in the process must be identified  | • Emphasize the importance of good communication between the BTS/blood bank and the hospital  
• Emphasize the role of the hospital transfusion committee in ensuring the safety of the patient requiring transfusion  | • Identify the critical control points in the process at which monitoring should take place  
• Identify the kind of monitoring that should take place  | 1 hour |
<table>
<thead>
<tr>
<th>Module 15</th>
<th>Finalization of Participants’ Action Plans and Completion of the Course</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Title</strong></td>
<td><strong>Teaching Aim</strong></td>
</tr>
<tr>
<td>QMT 15.1</td>
<td>Review of the course</td>
</tr>
<tr>
<td>Activity</td>
<td>Activity</td>
</tr>
<tr>
<td>QMT 15.2</td>
<td>Laboratory/clinic visits in BTS</td>
</tr>
<tr>
<td>Activity</td>
<td>Activity</td>
</tr>
<tr>
<td>QMT 15.3</td>
<td>Completing individual action plans</td>
</tr>
<tr>
<td>Activity</td>
<td>Activity</td>
</tr>
<tr>
<td>QMT 15.4</td>
<td>Discussion of individual action plans</td>
</tr>
<tr>
<td>Activity</td>
<td>Activity</td>
</tr>
<tr>
<td>QMT 15.5</td>
<td>Review of quality systems</td>
</tr>
<tr>
<td>Presentation</td>
<td></td>
</tr>
<tr>
<td>Title</td>
<td>Teaching Aim</td>
</tr>
<tr>
<td>---------------------------</td>
<td>------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>QMT 15.6</td>
<td>Post-course assessment Activity</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>QMT 15.7</td>
<td>Course evaluation Activity</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>QMT 15.8</td>
<td>Final discussions Activity</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Closing Ceremony**