Arranging a date:
Once your hospital blood bank has been highlighted for inspection an MHRA inspector will ring to arrange a date which will be confirmed in writing. When arranging a date for a routine inspection there will normally be a minimum of two weeks notice. In most instances there will be one inspector unless there is a trainee inspector undergoing tuition. The hospital blood bank inspection will usually be completed in one day. Where possible the following persons are required to meet the inspector:

**MUST**
- Blood Bank Manager
- Quality Manager

**COULD**
- Consultant Haematologist
- General Pathology Manager
- Transfusion practitioner
- Senior members of staff
- Estates staff if fridges are serviced internally
- Laboratory IT Manager

**Hospital Preparation**
Ensure all paperwork is in place.
Ensure the lab is clean and tidy
Review the answers given on the compliance form. Where processes, systems etc. have progressed since the completion of the compliance form ensure this information is made available for the inspectors.
Where you know you are not compliant have a prepared project implementation plan. For example if you have no training records in place the plan could include:

<table>
<thead>
<tr>
<th>Title</th>
<th>Training Record Implementation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project Objective</td>
<td>Training records for all staff to comply with the Blood Safety and Quality Regulations 2005</td>
</tr>
</tbody>
</table>
| What is required    | 1. Identify the training records which need to be developed linked to all processes undertaken in Blood Bank  
                        2. Identify who needs to be trained (all staff working at any time in Blood Bank)  
                        3. Develop the training records  
                        4. Develop competency assessments |
| Project leader      | Training Manager (Name)                                            |
| Time scale          |                                                                     |
| Identify who needs training | Time for trainers  
                        To develop training records | Time for trainees  
                        Develop competency assessment | Printing/stationery  
                        Deliver training | |
| Resources required  | Time for trainers  
                        Time for trainees  
                        Printing/stationery                                |
| Exclusions          | None                                                                |
| Constraints         | Staff time with shift pattern  
                        Staff working nights and weekends  
                        Only one part-time training officer                  |

Be realistic when identifying the time required to plan and deliver the project.
The inspector arrives
Ensure there is some room the inspector(s) can use with hot and cold drinks available, a table and chair(s) and where there is some peace and quiet to review paperwork.

Opening meeting
Introduction of inspection team and laboratory staff
Information gathering, reviewing paperwork
Tentative schedule of how the inspection may be conducted
Overview of the laboratory working practices

The Inspection
Obtaining Information
Witnessing Tasks being performed
Reviewing Documented Procedures
Investigating Issues - Why?

System Inspection based upon:
Quality management system to include:-
  • Personnel
  • Premises and Equipment
  • Documentation
  • Complaints/component recall
  • Self Inspection
  • Training records
  • Validation and calibration documents

The inspector will also want to review the systems and processes in place for:-
  • Traceability
  • Storage and distribution
  • Review of Serious Adverse event/reaction reporting
  • Crossmatching / automation

This list is not exhaustive and the inspectors may wish to look at any system/laboratory process.

Closing meeting
• Closing meeting by inspector
• Presentation of findings
• Opportunity for establishment to provide further information
• Acceptance of findings
• Notification of next steps

Post Inspection
The laboratory will review the report from the MHRA and respond to the areas where there may be
  Critical
  Major
  Significant other deficiencies
  Responses from the hospital blood bank should be received by the inspector 28 days after delivery of the post inspection letter.
  The corrective action to be taken including the timescale will be reviewed
  Further information may be requested and you may be required to provide evidence of satisfactory correction of the deficiency
  Close-out letter sent when inspector assured that the deficiencies have been adequately addressed