Q1: What do the initials GMP stand for? *(please tick)*

- Good Manufacturing Procedure
- Good Manufacturing Practice *(1 point)*
- Great Manufacturing Procedure

Q2. GMP/BSQR compliance is audited by:

- MHRA *(1 point)*

Q3. The key EU Directive for Blood is: *(tick the most accurate statement)*

- 2006/98/EC *(1 point)*
- 2002/98/EC
- 2003/94/EC

Q4. Name 3 of the 9 Chapters in the GMP “Orange Book” Guide

- Quality Management
- Personnel
- Premises & Equipment
- Documentation
- Processes/Procedures
- Quality Control
- Contract Manufacture
- Complaints & Product Recall
- Self Inspection *(3 points)*

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Q5: Following a regulatory inspection, any observations made are categorised into Tick the correct option)
- critical, major and minor
- critical, major and other   (1 point)
- Priority 1,2,3

Q6: (Please answer True or False to the following statements)
The Blood safety & Quality regulations require:

- A quality system based upon Good Practices  T/F
- Reporting of all serious adverse events  T/F
- Record keeping for 10 years  T/F

(3 points)

Q7: List two things you need to consider to ensure your premises meet GMP design standards.

- design, layout, workflow, heating, lighting, ventilation,
- adequate storage, quarantine, security  (2 points)

Q8: All equipment should …………… (please circle Yes or No)

- Have an individual identification number  Y/N
- Have identified cleaning and maintenance procedures  Y/N
- Have maintenance fault logs  Y/N

(3 points)

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Q9: *(Please Answer True or false to the following statements)*

All complaints must be reviewed according to written procedures  
**True/False**

Recall Operations can only be performed during the normal working day  
**True/False**

Recall operations must be able to be initiated promptly at any time  
**True/False**

Written recall procedures are not necessary as long as everyone knows what they are doing  
**True/False**  
(4 points)

Q10: What do the initials .......... Stand for.

- **IQ:** Installation Qualification  
- **OQ:** Operational Qualification  
- **PQ:** Performance Qualification  

(3 points)