GMP Assessment

Name: ____________________________ Date: _______________

Designation: ______________________  Org: ______________

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

– Good Manufacturing Procedure
– Good Manufacturing Practice
– Great Manufacturing Procedure

Q2. GMP/BSQR compliance is audited by:

________________________________________

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

- 2006/98/EC
- 2002/98/EC
- 2003/94/EC

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

________________________________________

________________________________________

________________________________________
Q5: Following a regulatory inspection, any observations made are categorised into Tick the correct option)

- critical, major and minor
- critical, major and other
- 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

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

i) ____________________________

ii) ____________________________

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
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**

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

- **IQ:** ____________________________
- **OQ:** ____________________________
- **PQ:** ____________________________