Your answers should be specific to the questions asked.
Draw neat labeled diagrams wherever necessary.

LONG ESSAY (Answer any Three) **3 X 10 = 30 Marks**

1. Discuss the scope and applications of ICH Q8 in pharmaceutical development.
2. What are deviations? Explain how CAPA helps prevent deviation in pharmaceutical process.
3. Discuss the process of NABL accreditation.
4. What are the categories cost of poor quality and discuss methods of optimizing cost of poor quality?

SHORT ESSAY (Answer any Nine) **9 X 5 = 45 Marks**

5. Differentiate various types of benchmarking.
6. What are the benefits of Statistical Process Control and what ''causes'' do they address?
7. What are the principles of TQM?
8. Discuss briefly about electronic records and electronic signatures, and its advantages?
9. How do you handle customer complaints?
10. Explain the concept of FMECA for risk assessment.
11. What are OSHAS guidelines?
12. How does process variability impact manufacturing? How is it minimized?
13. Discuss the significance of benchmarking process.
14. Explain change control process in pharmaceutical industry.

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