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GUJARAT TECHNOLOGICAL UNIVERSITY

M. Ph. - SEMESTER -1 - EXAMINATION – SUMMER -2018

Subject Code: MRA101T **Date: 03/05/2018**

Subject Name: Good Regulatory Practices

Time: 02:30PM TO 05:30PM **Total Marks: 80**

Instructions:

1. **Attempt any five questions.**
2. **Make suitable assumptions wherever necessary.**
3. **Figures to the right indicate full marks.**

Q.1	**(a)**	Discuss general classification system for IVD medical device as per GHTF.	**06**
	(b)	Write a note on Validation master plan.	**05**
	(c)	Enlist the different types of Validation Qualification. Explain the Operational Qualification with suitable example.	**05**
Q.2	**(a)**	Discuss the principle of Good Distribution Practices.	**06**
	(b)	Discuss general criteria for SOPs as per GALP.	**05**
	(c)	Discuss the change control protocol for validation.	**05**
Q.3	**(a)**	Discuss the goals of Laboratory Quality Audit.	**06**
	(b)	Discuss the importance of documentation in GLP.	**05**
	(c)	Discuss the procedure for cleaning validation.	**05**
Q.4	**(a)**	Discuss about premises and storage condition as per GDP guidelines.	**06**
	(b)	Discuss checklist of 21 CFR Part 11 for GALP.	**05**
	(c)	Write a note on Audit report.	**05**
Q.5	**(a)**	Discuss quality management system as per ISO 13485.	**06**
	(b)	Describe subpart B as per USFDA GLP regulations.	**05**
	(c)	Discuss concept of Total Quality Management.	**05**
Q. 6	**(a)**	Define and explain the terminology of Precision, Specificity and Ruggedness.	**06**
	(b)	Describe Rational, purpose and scope of medical device GHTF guidelines.	**05**
	(c)	Discuss principles of Quality by Design.	**05**
Q.7	**(a)**	Define Quality Audit and Discuss the tools of Audit.	**06**
	(b)	Write a note on QCI Standards.	**05**
	(c)	Describe briefly about GAMP-5 guidelines.	**05**

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