CERTIFICATION COURSE IN DRUG REGULATORY AFFAIRS

CONTENT	DURATION
1) Schedule M and basic principles of GMP	3Hrs
2) Indian regulatory systems	3Hrs
3) Introduction to DMF and dossier	3Hrs
4) Design and study of specification	3Hrs
5) Process validation and method validation	3Hrs
6) International Regulatory systems -ROW	3Hrs
7) International Regulatory systems-US	3Hrs
8) International Regulatory systems- Europe, Australia, New Zealand	3Hrs
9) Demonstration of regulatory software usage MSDS writing, SmPC writing	3Hrs
10) cGMP principles data integrity and ALCOA + principal	3Hrs

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