

Annex 3. References to the requirements in each Chapter

In this summary there are referrals to all requirements treated in the different Chapters of the book. The fourth column refers to the equivalent requirements in the ISO 9001 standard to show what relations there are to a more general quality system.

1. Quality work and Quality management (and introduction)

EU Part I	EU Part II	21 CFR 210/211	ISO9000
1. Quality Management	1.Introduction	210 General	1. Scope
1	1.1-1.2	210.1	1.1
1.1-1.5	2. Quality Management	210.2	1.2
2. Personnell	2.10-2.18	210.3	1.3
2.3-2.7	2.20-2.22	A. General Provisions	4. General Requirements
4. Documentation	2.41	211.1	4.1
4.24	2.50-2.51	211.3	4.2
6. Quality Control	6. Documentation and Records	B. Organization and Personnel	5. Management Responsibility
6.1-6.4	6.10, 6.40	211.22	5.1
6.31	6.52-6.53	E. Control of Components and Drug Product Containers and Closures	5.2
6.33	6.70-6.73		5.3
7. Contract Manufacture and analysis	7. Materials Management	211.84	5.4
7.11	7.11-7.12	F. Production and Process Controls	5.5
8. Complaints and Product Recall	8. Production and In-Process Controls	211.100	5.6
8.1-8.3	8.15, 8.20	211.110	6. Resource Management
8.9	8.32-8.33	211.111	6.1
9. Self Inspection	9. Packaging and Identification Labelling of APIs and Intermediates	211.115	6.2
9.1-9.3		G. Packaging and Labeling Control	7. Product Realization
-----		211.125	7.1
	9.31		7.2

1. Quality work and Quality management (cont.)

EU Part I	EU Part II	21 CFR 210/211	ISO9000
-----	10. Storage and distribution	I. Laboratory Controls	8. Measurement, analysis and improvement
	10.20	211.160	
	11. Laboratory Controls	211.165	8.1
	11.10, 11.12	211.170	8.2
	11.14-11.15	J. Records and Reports	8.3
	11.22, 11.43	211.180	8.4
	12. Validation	211.192	8.5
	12.10, 12.20	K. Returned and Salvaged Drug Products	-----
	12.23, 12.60		
	13. Change Control	211.204	
	13.12, 13.17	211.208	
	14. Rejection and Reuse of Materials	-----	
	14.31		
	15. Complaints and Recalls		
	15.10, 15.15		
	16. Contract Manufacturers (including Laboratories)		
	16.10-16.16		
	17. Agents, Brokers, Traders, Distributors, Repackers, and Relabellers		
	17.30		
	17.60-17.63		
