

Table: Time Frames for Completing the Various Sections of Chapter 797

Compliance Areas	Specific Details to Consider	Recommended Completion Date
Quality Assurance (QA) Program	Formalized in writing	July 2005
	Describes specific monitoring and evaluation activities (measures identified)	July 2005
	Reporting and evaluation of results	January 2006
	Identification of follow-up activities when thresholds are exceeded	January 2006
	Delineation of individual responsibilities for each aspect of the program	January 2006
QA Practices	Routine disinfection of direct compounding environment	Current
	Quality testing of direct compounding environment	January 2006
	Visual confirmation of personnel processes regarding gowning, etc.	January 2005
	Review of orders and packages of ingredients to assure correct identity and amounts of ingredients	Current
	Visual inspection of compounding sterile products (CSP)	Current
Reports/Documents	Adverse event reporting	Current
	Complaint procedures	Current
	Periodic review of quality control documents	January 2005
Patient and Caregiver Training (Home Care only)	Formalized program that includes the following: –Understanding of the therapy provided –Handling and storage of the CSP –Appropriate administration techniques –Use and maintenance of any infusion device involved –Use of printed material –Appropriate follow-up	Current
Maintaining Product Quality and Control once the CSP leaves the Pharmacy (both institutional-based and NICPs)	Packaging, handling, and transport –Policies and procedures including the packaging, handling, and transport of chemotoxic/hazardous CSPs	July 2005
	Use and Storage –Policies and procedures	July 2005
	Administration –Policies and procedures dealing with such issues as hand washing, aseptic technique, site care, etc.	Current
	Education/Training –Policies and procedures dealing with proper education of patients and staff ensuring all of the above	July 2005
Storage Conditions and Beyond—Use Dating	Specific labeling requirements	January 2005
	Specific beyond-use dating policies, procedures, and requirements	January 2005
	Policies regarding storage	July 2005
Finished Product—Release Checks and Tests	Policies and procedures that address the following: –Physical inspections –Compounding accuracy checks	July 2005
Finished Product—Release Checks and Tests	Policies and procedures that address the following: –Sterility testing –Pyrogen testing –Potency testing	July 2005

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Table: Time Frames for Completing the Various Sections of Chapter 797 (continued)

Compliance Areas	Specific Details to Consider	Recommended Completion Date
CSP Work Environment	Appropriate solid surfaces	Approved facility renovation plan by January 2005 for completion in 3 years. Interim safety measures required by July 2005
	Limited (but necessary) furniture, fixtures, etc.	
	Anteroom area	
	Buffer zone	
Equipment	Policies and procedures that address calibration, routine maintenance, personnel training	July 2005
Components	Policies and procedures that address sterile components	July 2005
Processing: Aseptic Technique	Policies and procedures that address specific training and performance evaluation	July 2005
Environmental Control	Policies and procedures that address the following: –Cleaning and sanitizing the workspaces (DCCA) –Personnel and gowning –Standard operating procedures	July 2005
Sterility Testing of Non-Sterile Products	Sterility, pyrogen, and potency testing completed on sample from each batch	Current
Verification Procedures—Environmental Monitoring	Certification of laminar air flow workbench (hood) and barrier isolates every six (6) months	If new—before use, if current by January 2005
	Certification of the buffer room/zone and anteroom/zone every six (6) months	If new—before use, if current by January 2005
	Bacterial monitoring using an appropriate manner	January 2006
Verification Procedures—Personnel Training and Education	Initially and annually thereafter –Didactic review –Written testing –Media-fill testing	January 2005