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Current Good Manufacturing Practices for Finished Pharmaceuticals Services Action Items

Services	Areas	Programs/Policies/Procedures/Forms/ Lessons	Action Items
All Inclusive – customized to the Code of Federal Regulations	Subpart A - General Provisions -Scope: 1. Inclusion: Current Good Manufacturing Practice to Drug Products for administration to humans or animals 1a. Biological products for human use 1b. Human cells, tissues, and cellular and tissue-based products (HCT/Ps)	Current Good Manufacturing Practice for Finished Pharmaceuticals	Collect/Provide Records
			Assess
			Develop
			Review
			Approve
			Implement
	Subpart B - Organization and Personnel - Program (Documentation of training, including the date of the training, the type of training, and the person(s) trained) -Responsibilities of quality control unit -Personnel qualifications -Personnel responsibilities -Consultants	Management Responsibility	Collect/Provide Records
			Assess
			Develop
			Review
			Approve
			Implement
			Verify
			Validate
		Personnel Qualification	Collect/Provide Records
			Assess
			Develop
			Review
			Approve
			Implement
			Verify
			Validate
		Training	Collect/Provide Records
			Assess
			Develop
			Review
			Approve
			Implement
			Verify
			Validate
		Job Description	Collect/Provide Records
			Assess
			Develop
			Review
			Approve
			Implement
			Verify
			Validate
	Subpart C - Buildings and Facilities - Program -Design and construction features -Lighting -Ventilation, air filtration, air heating and cooling -Plumbing -Sewage and refuse -Washing and toilet facilities -Sanitation -Maintenance	Premises Location	Collect/Provide Records
			Assess
			Develop
			Review
			Approve
			Implement
			Verify
			Validate
		Grounds and Roadways	Collect/Provide Records
			Assess
			Develop
			Review
			Approve
			Implement
			Verify
			Validate
		Cleaning and Sanitation	Collect/Provide Records
			Assess
			Develop
			Review
			Approve
			Implement
			Verify

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Services	Areas	Programs/Policies/Procedures/Forms/ Lessons	Action Items
			Validate
		Sanitation Standard Operating Procedures	Collect/Provide Records
			Assess
			Develop
			Review
			Approve
			Implement
			Verify
			Validate
		Building Materials	Collect/Provide Records
			Assess
			Develop
			Review
			Approve
			Implement
			Verify
			Validate
		Lighting and Light Fittings	Collect/Provide Records
			Assess
			Develop
			Review
			Approve
			Implement
			Verify
			Validate
		Ventilation	Collect/Provide Records
			Assess
			Develop
			Review
			Approve
			Implement
			Verify
			Validate
		Repairs and Maintenance	Collect/Provide Records
			Assess
			Develop
			Review
			Approve
			Implement
			Verify
			Validate
	Subpart D - Equipment Program -Equipment design, size, and location -Equipment construction -Equipment cleaning and maintenance -Automatic, mechanical, and electronic equipment -Filters	Equipment - Maintenance	Collect/Provide Records
			Assess
			Develop
			Review
			Approve
			Implement
			Verify
			Validate
		Equipment - Calibration	Collect/Provide Records
			Assess
			Develop
			Review
			Approve
			Implement
			Verify
			Validate
		Equipment - Cleaning and Sanitation	Collect/Provide Records
			Assess
			Develop
			Review

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Services	**Areas**	**Programs/Policies/Procedures/Forms/ Lessons**	**Action Items**
			Approve
			Implement
			Verify
			Validate
		Sanitation Standard Operating Procedures	Collect/Provide Records
			Assess
			Develop
			Review
			Approve
			Implement
			Verify
			Validate
	Subpart E - Control of Components and Drug Product Containers and Closures - Program -Receipt and storage of untested components, drug product containers, and closures -Testing and approval or rejection of components, drug product containers, and closures -Use of approved components, drug product containers, and closures -Retesting of approved components, drug product containers, and closures -Rejected components, drug product containers, and closures -Drug product containers and closures	Receipt, Storage and Handling	Collect/Provide Records
			Assess
			Develop
			Review
			Approve
			Implement
			Verify
			Validate
		Receiving Log	Collect/Provide Records
			Assess
			Develop
			Review
			Approve
			Implement
			Verify
			Validate
		Receiving Protocol	Collect/Provide Records
			Assess
			Develop
			Review
			Approve
			Implement
			Verify
			Validate
		Non Conforming Materials and Products	Collect/Provide Records
			Assess
			Develop
			Review
			Approve
			Implement
			Verify
			Validate
		Product Release Monitoring	Collect/Provide Records
			Assess
			Develop
			Review
			Approve
			Implement
			Verify
			Validate
		Loading, Transport and Unloading Practices	Collect/Provide Records
			Assess
			Develop
			Review
			Approve
			Implement
			Verify
			Validate
	Subpart F - Production and Process Controls - Program	Corrective and Preventative Action	Collect/Provide Records

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Services	Areas	Programs/Policies/Procedures/Forms/ Lessons	Action Items
	-Written procedures; deviations -Charge-in of components -Calculation of yield -Equipment identification -Sampling and testing of in-process materials and drug products -Time limitations on production -Control of microbiological contamination -Reprocessing		Assess
			Develop
			Review
			Approve
			Implement
			Verify
			Validate
		Standard Operating Procedures	Collect/Provide Records
			Assess
			Develop
			Review
			Approve
			Implement
			Verify
			Validate
		Product Formulation and Realization	Collect/Provide Records
			Assess
			Develop
			Review
			Approve
			Implement
			Verify
			Validate
		Product Sampling	Collect/Provide Records
			Assess
			Develop
			Review
			Approve
			Implement
			Verify
			Validate
		Production/Batch Monitoring Report	Collect/Provide Records
			Assess
			Develop
			Review
			Approve
			Implement
			Verify
			Validate
		Product Testing Protocol	Collect/Provide Records
			Assess
			Develop
			Review
			Approve
			Implement
			Verify
			Validate
		Reprocessing Procedure	Collect/Provide Records
			Assess
			Develop
			Review
			Approve
			Implement
			Verify
			Validate
	Subpart G - Packaging and Labeling Control - Program -Materials examination and usage criteria. -Labeling issuance. -Packaging and labeling operations. -Tamper-evident packaging requirements for over-the-counter (OTC) human drug products. -Drug product inspection. -Expiration dating	Specifications - Packaging and Labeling Materials	Collect/Provide Records
			Assess
			Develop
			Review
			Approve
			Implement

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Services	Areas	Programs/Policies/Procedures/Forms/ Lessons	Action Items
	-Expiration dating.		Verify
			Validate
		Label Verification/Reconciliation	Collect/Provide Records
			Assess
			Develop
			Review
			Approve
			Implement
			Verify
			Validate
	Subpart H - Holding and Distribution - Program -Warehousing procedures. -Distribution procedures.	Good Warehousing Procedures/ Standard Operating Procedures	Collect/Provide Records
			Assess
			Develop
			Review
			Approve
			Implement
			Verify
			Validate
		Stock Rotation Procedure	Collect/Provide Records
			Assess
			Develop
			Review
			Approve
			Implement
			Verify
			Validate
	Subpart I - Laboratory Controls - Program -Specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms	Stability Testing Procedure	Collect/Provide Records
			Assess
			Develop
			Review
			Approve
			Implement
			Verify
			Validate
		Product Identification - Reserved Sample Procedure	Collect/Provide Records
			Assess
			Develop
			Review
			Approve
			Implement
			Verify
			Validate
		Laboratory Testing Protocol	Collect/Provide Records
			Assess
			Develop
			Review
			Approve
			Implement
			Verify
			Validate
	Subpart J - Records and Reports - Program -Production, control, and/or distribution records -Production record review	Equipment Cleaning and Use Log	Collect/Provide Records
			Assess
			Develop
			Review
			Approve
			Implement
			Verify
			Validate
		Inventory - Component, Drug product container, Closure, and Labeling forms/records	Collect/Provide Records
			Assess
			Develop

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Services	**Areas**	**Programs/Policies/Procedures/Forms/ Lessons**	**Action Items**
			Review
			Approve
			Implement
			Verify
			Validate
		Master Production and Control forms/records	Collect/Provide Records
			Assess
			Develop
			Review
			Approve
			Implement
			Verify
			Validate
		Laboratory and Testing forms/records	Collect/Provide Records
			Assess
			Develop
			Review
			Approve
			Implement
			Verify
			Validate
		Distribution forms/records	Collect/Provide Records
			Assess
			Develop
			Review
			Approve
			Implement
			Verify
			Validate
		Complaint forms/records	Collect/Provide Records
			Assess
			Develop
			Review
			Approve
			Implement
			Verify
			Validate
	Subpart K - Returned and Salvaged Drug Products - Program -Returned drug products -Drug product salvaging	Returned Drug Products	Collect/Provide Records
			Assess
			Develop
			Review
			Approve
			Implement
			Verify
			Validate
		Destroying and or Disposal of Expired, Damaged, Recalled, Rejected Returned and Non-conforming Drug Procedure	Collect/Provide Records
			Assess
			Develop
			Review
			Approve
			Implement
			Verify
			Validate
		Returned Drugs Quality Evaluation Procedure	Collect/Provide Records
			Assess
			Develop
			Review
			Approve
			Implement
			Verify
			Validate

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Services	**Areas**	**Programs/Policies/Procedures/Forms/ Lessons**	**Action Items**
21 CFR 111 Dietary Supplement cGMP (Storage and Distribution) Services			
All Inclusive – customized to the Code of Federal Regulations	Subpart M - Holding and Distributing - Holding Conditions Program	Receipt, Storage and Handling of Goods	Collect/Provide Records
			Assess
			Develop
			Review
			Approve
			Implement
			Verify
			Validate
			Verify
			Validate
		Corrective and Preventative Action	Collect/Provide Records
			Assess
			Develop
			Review
			Approve
			Implement
			Verify
			Validate
			Verify
			Validate
	Subpart M - Holding and Distributing Program - Reserved Samples Procedure	Product Sampling	Collect/Provide Records
			Assess
			Develop
			Review
			Approve
			Implement
			Verify
			Validate
			Verify
			Validate
		Non Conforming Materials and Products	Collect/Provide Records
			Assess
			Develop
			Review
			Approve
			Implement
			Verify
			Validate
			Verify
			Validate
	Subpart M - Holding and Distributing - Distribution Conditions Program	Loading, Transport and Unloading Practices	Collect/Provide Records
			Assess
			Develop
			Review
			Approve
			Implement
			Verify
			Validate
			Verify
			Validate
	Subpart P - Records and Recordkeeping Program	Label Artwork/Reference	Collect/Provide Records
			Assess
			Develop
			Review
			Approve
			Implement
			Verify
			Validate
			Verify
			Validate

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Services	**Areas**	**Programs/Policies/Procedures/Forms/ Lessons**	**Action Items**
		Shipping Records	Collect/Provide Records
			Assess
			Develop
			Review
			Approve
			Implement
			Verify
			Validate
			Verify
			Validate
		Distribution Records	Collect/Provide Records
			Assess
			Develop
			Review
			Approve
			Implement
			Verify
			Validate
			Verify
			Validate
		Import Documentation	Collect/Provide Records
			Assess
			Develop
			Review
			Approve
			Implement
			Verify
			Validate
			Verify
			Validate
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