Records, Documents and Change Controls Series

GxP Responsibilities Procedure Template

For Pharmaceutical and Medical Devices

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ISBN:
Edition 1.0,

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Purpose

The purpose of this document to provide the instructions and guide to designate the responsibilities for each record and activities contained in the GxP document approved. Besides, this procedure must guarantee:

- The duties are valid, reasonable, written and approved under the consent and agreement of the company management and involved parties.
- The responsibilities are clear, specific, accurate and described appropriately annotated in English.
- The responsibilities designation is properly addressed, documented and satisfactorily established after considering all affected applications and documents.

Scope

The scope of this document aims to all GxP documents generated by the corporate during the system development life cycle, including, but not limited to: software design specification documents, manuals, procedures, testing, and validation related documents.

The responsibilities designation also aims to ensure the project completion on the expected due date and to accomplish the commitment on each task and activities under consideration by the correct responsible person(s).

The responsibilities designation are divided into two (2) primary groups:

- The responsibilities of the document originator that is designated to prepare, execute, and close a particular GxP document.
- The responsibilities of the document reviewer or approver that is designated to double-check everything, including but not limited to: guarantee that the document complies with all requirements established in the company procedures.

Additional responsibilities groups or roles can be defined and used as needed by each particular GxP document.

Appendix 1. Avoid Mistakes Assigning GxP Responsibilities.

Review your actual procedures and policies of Good (GMP, GDP, GLP, etc) Practices and evaluate the responsibilities of each individual position based on their role in terms of cGMP documentation and requirements that needs attention of a person(s) responsible for its execution.

Moreover, also consider the frequency that GMP data and information is controlled and documented in your records, evaluate all previous errors, incorrect documentation, risks and how fast you need to control each cGMP document accurately.

Visit www.ciqa.net/shop to download **Quality Management Procedure Templates** in .pdf format or a fully editable in MS Word format, ready to fill, and use according to the cGMPs, 21 CFR Part 211 and 820.

ONLINE QMS SOP's PROCEDURES TEMPLATES AVAILABLE	
Audit Management Procedure Template - QMS	EHS Procedure Template – Environ. Health & Safety
BCP Business Contingency Planning Procedure Template	Employee's Manual Procedure Template
BCP Disaster Recovery Procedure Template	GxP Responsibilities Procedure Template
BCP Exercising and Testing Procedure Template	Pest Control Procedure Template - EHS
BCP Performance Evaluation Procedure Template	Preventive Maintenance Procedure Template - PM
Calibration Management Procedure Template	Quality Management Review Procedure Template
CAPA Management Procedure Template	Quality Manual Procedure Template
cGMP and GDP Procedure Template	Risk Analysis Assessment & FMEA Procedure Template
Change Control Management Procedure Template	Sampling Plan Procedure Template to Collect Data
Cleaning Validation Procedure Template - Medical Devices	Suppliers Certification & Monitoring Procedure Template
Cleaning Validation Procedure Template - Pharma	Validation and Qualification Procedure Template
Complaints Management Procedure Template	Work Orders and Testing Metrics Procedure Template
Document Records Control Management Procedure Template	Many Others Documents.

Appendix 2. Quality Management System (QMS) Software Application

Try the best Cloud-based QMS Software Application to handle all your documentation records from anywhere at any time. *CSV Validated and Ready to use immediately.*

- Secure All-in-One QMS Software Application with all modules included free.
- Cloud Software Application 21 CFR Part 11 compliance.
- Software as a Service -SaaS.
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QMS Modules	Future Modules - Coming Soon
Annual Product Review Management	Accounts Receivable & Payable Management
Design Control, Specs, and P&ID's Management	Audits Management
EHS - Environmental Health & Safety Mngt	Calibrations Management
Experimental Projects & Pilot Lots Management	CAPA & Non-Conformances Management
Manufacturing Instructions Management	Change Control Management
Media Fills Management	Cleaning and Sanitization Management
Pest Control Management	Complaints Management
Regulatory Compliance Submissions Mngt	Human Resources – Management
Pest Control Management	Laboratory Management
Standard Operating Procedures SOPs Mngt	Machine Setup and Configuration Management
Training Management	Manufacturing Scheduling & Inventory Controls
Validation & Qualification Management	MES Manufacturing Execution System Mngt
Core System: Features	Preventive Maintenance Management
Security, Privacy and Data Encryption,	Recalls, Containments, Shipping Holds Mngt
Audit Trail – 21 CFR Part 11	Reprocessing / Reworks Management
Backup and Restore Functionalities	Retained Samples Management
Access Controls: Serialized records controls	Returned Goods Management
Controlled Forms, Downloads & Prints	Risk Analysis & FMEA Assessment Management
Fully CSV Computer System Validated	Suppliers Management – SCARS Management

Appendix 3. The Series: All You Need to Know About…Validations

The Series called All You Need to Know About… is intended to provide more information about basic principles as validations and other documentation activities for cGMP-and GDP related areas.

The purpose of these Series is to bring more detailed information to increase your knowledge and capabilities in different Quality System Regulations for your company at affordable prices.

ONLINE VALIDATION PROTOCOL TEMPLATES AVAILABLE	
Clean Steam Sterilization Validation Protocol Template	Gamma Irradiation Validation Protocol Template
Cleaning Validation Plan Protocol Template - Medical Devices	IQ/OQ Qualification Protocol Template - Freezer
Cleaning Validation Plan Protocol Template - Pharma	IQ/OQ Qualification Protocol Template - Incubator
Cleaning Validation Protocol Template - Equipment Surfaces	Installation Qualification Protocol Template - Equipment
Cleaning Validation Protocol Template - Medical Devices	Lyophilization Process Validation Protocol Template
Cleaning Validation Protocol Template - Pharma	Media Fills Validation Protocol Template
Cleaning Validation Risk Assessment Protocol Template	Operational Qualification Protocol Template - Equipment
Component Qualification Protocol Template	Performance Qualification Protocol Template - Equipment
CSV Installation Qualification Protocol Template - IQ	Test Method Validation Protocol Template
CSV Operational Qualification Protocol Template - OQ	Thermal Mapping Protocol Template
DOE Design of Experiment Protocol Template -Taguchi Method	Training Management Procedure Template
Environmental Cleanroom Qualification Protocol Template	URS User Requirement Specifications Protocol Template
EO Ethylene Oxide Sterilization Validation Protocol Template	Validation Master Plan Protocol Template - VMP
Facilities Qualification Protocol Template	Validation Plan Protocol Template - VP
FRS Functional Requirement Specifications Protocol Template	Many Others Protocol Documents

Appendix 4. About The Author

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Bachelor and Master Degree in Chemical Engineering from the University of Puerto Rico in 1989.

30+ years of experience in Quality System Regulations serving more than 1,000 clients in over 100 multinational companies related to the pharmaceutical, biotechnology, food & medical devices.

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Author of over 250 Quality Management Procedures and Validation Protocols.

United States & European Citizen. Speak English & Spanish.

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