



THE GMP QUALITY GROUPS

Presents:



CAPA MANAGER

Your FDA, EMA & ISO Compliance Partners.

Providing CAPA Managers with the Education,
Training, Background & Experience, you require.

We have the full support of the Worlds largest
Compliance Auditing, Remediation SMEs and
Regulations Teams through The Quality Groups.



- REQUIRE QUALITY RESOURCES?
 - PROCEDURAL DEVELOPMENT?
 - PROJECT MANAGEMENT?
 - AUDIT READINESS?

Your Quality Resources

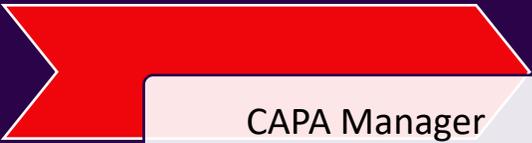
With decades of combined project management experience, our SMEs assist with ensuring that your tasks are completed, on time, and in a controlled quality driven process.



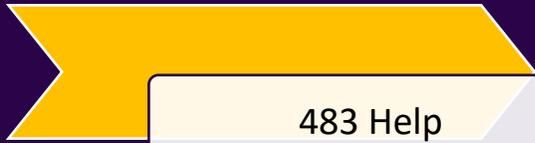
CAPA Managers Protects:

- Reduced and Prevent Legal Liability.
- Improve product quality.
- Improve Customer Satisfaction.
- Prevent major financial losses.
- Strengthen a company's reputation.
- Verification of resolution/deviation

THE SINGLE SOURCE SOLUTION



CAPA Manager



483 Help



Audit & Training



Proactivity

CAPA Management

The CAPA Manager Role is to provide Project Management Support for your Remediation Efforts, to resolutions, and Compliance Readiness.

483 Help

483 Help provides the Templates, Tools, Procedures, and Process Support, to assist your Company's Quality initiatives. CAPA Managers are there when you need the FDA Back Office and Front Office Support.

The Auditing Group

Continual Audit and Training readiness is the key to satisfying your FDA Audit requirements. The Auditing Group and GMP Boot Camps are there to support your ongoing commitment to FDA readiness and compliance.

Changing Patterns

Compliance is the goals of every Company. They are achieved when FDA's GMP Regulations become a 'Lifestyle' shared by everyone! GMP is about changing of attitudes and behavior patterns because it makes Good Business Practice and protects the company from liability!



CAPA MANAGEMENT & CAPA MANAGERS

- **Three (3) day GMP Audit (1 Draft and 1 Final Report)*.**
- **Weekly scheduled up to 4-hour remote CAPA Manager meetings.**
- **Monthly One (1) day onsite Quality Meeting – Remediation verification**
- **GANTT and Project Manager – Review and Quality Meeting Minutes**
- **Update and provide missing procedures as per Gap Analysis****
- **Protected QMS Spreadsheet with Reports supporting:**
 - CAPA (Corrective and Preventive Actions)
 - Nonconformance
 - Deviations
 - Complaints
 - Change Control
 - Audit Management
 - Documentation Control
 - Vendor Qualification Management
 - Equipment Asset Management, Planned Maintenance and Calibration
- **Audit – Follow up onsite 1-day GMP Audit – 6th Month.**
- **FDA Emergency onsite Back Office Audit Support 2 days**
- **One (1) day onsite GXP Training – 6th or 12th Month.**

GMP AUDIT CERTIFICATE OF COMPLIANCE

*Or 3rd Month Mock Audit

**Up to 25 Procedures

Meeting Objectives



Monthly Onsite



Weekly Remote

- Corrective and Preventive Actions (CAPAs)
- Deviations
- Nonconformances
- Out of Specifications/Out of Trend
- Complaints
- Changes & Change Controls
- Recalls, Returns & Warranty Claims
- Vendors/Supplier/Contractor – QTA*
- Audits – Agency/Internal/External Follow up
- Safety – Product and Regulatory Affairs
- Training Requirements
- Validation Requirements
- 21 CFR Part 11 Compliance
- Components, Packaging & Finished Materials
- Environmental, Health and Safety (EHS)

GOOD PROJECT MANAGEMENT PRACTICE

ID	Task Mod	Report Nr.	Task Name	Duration	Start	Finish	T	F	S
1		3.1 (f)	Develop Remediation Project Plan Enter Tasks into CAPA						
2		3.1 (b)	Review, Challenge and Revise Quality Manual						
3		3.1 (c)	Review and Revise Procedures						
4		3.1 (c)	Develop and Challenge SOP on SOPs						
5		3.1 (d) 3.3(c)	Review, Challenge and Revise SOP/OP Procedures						
6		3.1 (d) 3.3(c)	Review, Challenge and Revise Forms assoc. with SOPs						
7		3.8 (b)	Develop IT SOPs (Approx. 20)						
8			Review, Challenge and Revise Business Continuity Plan						
9			Create Additional Procedures (As Required)						
10		3.8 (f)	Develop Part 11 Initiative						
11		3.8 (c)	IT Infrastructure Manual Review						
12		3.8 (d)	Lack of Validation Plans for Systems						
13		3.5 (e)	Device History File Issues						
14		3.1 (g)	Risk Management Issue						
15			Quality Issues						
16			Challenge Supplier / Vendor Audit Reports						
17			Challenge Internal Audit Requirements						
18			Conduct formal Quality Critical Document Audit						
19			Validation Issues - Marketed Products						
20		3.7(a) 3.8(d)	No Single Formal VMP						
21		3.7(a) 3.8(d)	Develop Software/Systems Life Cycle Practice						
22		3.7(c)	No formal DQ for DSX						
23		3.7(c)	No formal DQ for DS2						

Task		Inactive Summary		External Tasks
Split		Manual Task		External Milestone
Milestone		Duration-only		Deadline
Summary		Manual Summary Rollup		Progress
Project Summary		Manual Summary		Manual Progress
Inactive Task		Start-only		
Inactive Milestone		Finish-only		

Project: RemediationPlan
Date: Mon 3/30/15

Page 1

- Assigning Tasks
- Expected Completion Dates
- Assigning Predecessors
- Defining Roles & Responsibilities
- Prioritize based upon Risk & Applicability
- Writing Deviations when Applicable
- Writing Reports & Providing Records

AutoSave Off | QMSSpreadsheet-22... | Saved to this PC | Search | Comments | Share

Deviation No.	Form No.	Date Entered	Description	Type	Risk	CAPA Filed?	Responsible Person	Resolution
22-00001	QAFM-006	6/30/2022	FDA Observation 1 - 2021_0722-FDA483 - Due Date Extension	FDA 483	High		John Cusplilich	7/15/2022 - Extension
22-00002	QAFM-006	6/30/2022	FDA Observation 2 - 2021_0722-FDA483 - Due Date Extension	FDA 484	High		John Cusplilich	7/15/2022 - Extension
22-00003	QAFM-006	6/30/2022	FDA Observation 3 - 2021_0722-FDA483 - Due Date Extension	FDA 485	High		John Cusplilich	7/15/2022 - Extension
22-00004	QAFM-006	6/30/2022	FDA Observation 4 - 2021_0722-FDA483 - Due Date Extension	FDA 486	High		John Cusplilich	7/15/2022 - Extension
22-00005	QAFM-006	6/30/2022	FDA Observation 5 - 2021_0722-FDA483 - Due Date Extension	FDA 487	High		John Cusplilich	7/15/2022 - Extension
22-00006	QAFM-006	6/30/2022	FDA Observation 6 - 2021_0722-FDA483 - Due Date Extension	FDA 488	High		John Cusplilich	7/15/2022 - Extension
22-00007	QAFM-006	6/30/2022	FDA Observation 7 - 2021_0722-FDA483 - Due Date Extension	FDA 489	High		John Cusplilich	7/15/2022 - Extension

Navigation: CAPA | Deviations | Non-Conformance | Change Control | OOS | OOT | Complaints | Plannecc

CAPA MANAGEMENT & CAPA MANAGERS

Protect your Company!

Turn-Key GMP & QMS Readiness

Turn-key solutions to get your company up and running within a CGMP Controlled Environment, avoiding FDA violations or Warning Letters.

- Get your products to the market faster.
- Avoid Company Liability
- Envision Your Return On the Investment (ROI)
- Operate in a State of Control with Confidence!

Free Quote!

FDA Subject Matter Experts

Seeking a quick resolution to your 483s or Warning Letters? Let us help, fast and discretely.

Contact:

Email: info@capamanager.com

www.capamanager.com

www.auditing.com

www.thequalitygroups.com

For more information about CAPA Management Services Call 856-437-5880



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