### Totally editable documentation package for quick process improvement

Complete editable document tool kit on ISO 22716- Cosmetic GMP (GMP manual, system procedures, Exhibits, Process Approach, SOP, formats, audit checklist, etc.) prepared as per ISO 22716:2007, Cosmetic-Good Manufacturing Practices (GMP)

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Chapter - 1.0 CONTENTS OF ISO 22716 Cosmetic GMP DOCUMENTATION KIT (More than 95 document files)

#### A. This editable documentation kit has 8 main directories in MS Word/excel, as below:

| Sr.<br>No. | Directory  | Details of Documents                        |
|------------|--|---|
| 1.         | ISO 22716 Manual   | 01 File in MS Word                          |
| 2.         | Procedures   | 10 Procedures in MS Word                    |
| 3.         | Exhibits   | 06 Exhibits in MS Word                      |
| 4.         | Process Approach   | 09 Process approach in MS Word              |
| 5.         | Standard Operating Procedures  | 28 Standard operating procedures in MS Word |
| 6.         | Blank Formats /Templates Name of departments   | 42 Blank Formats in MS Word                 |
|            | Engineering (ENG)  | 06 formats in MS Word                       |
|            | Marketing (MKT)  | 04 formats in MS Word                       |
|            | Purchase (PUR)   | 05 formats in MS Word                       |
|            | Stores (ST)  | 02 formats in MS Word                       |
|            | System (SYS)   | 14 formats in MS Word                       |
|            | Housekeeping (HKC)   | 04 formats in MS Word                       |
|            | Training (TRG)   | 07 formats in MS Word                       |
| 7.         | ISO 22716 Audit checklist  | More than 180 questions                     |
| 8.         | ISO 22716 document compliance matrix (Requirement wise reference documented information) | 01 File in MS Excel                         |

Total 95 files in editable form; Quick Download by e-delivery

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# Buy at: www.documentationconsultancy.com B. Documented information package:

Our documentation kit contains sample documents required for ISO 22716certification as listed below. All documents are in MS-Word/Excel files and you can edit them. You can make changes as per your organization's need and within few days your entire documents with all necessary controls will be ready. In the ISO 22716, documented information (procedures, SOPs, etc.) are required a few places only. But for making the system better, we have provided many editable templates from which a user can select templates as per their own requirement and make some minor changes in them to make own system. Two types of documented information are provided in this kit, as listed below:

- 1. Maintain documented information (Scope, Manual, etc.)
- 2. Retain documented information (Forms / Templates)

Under the main directories, further files are provided in MS Word document as per the details given below.

#### 1. ISO 22716 Manual:

It is a sample copy of ISO 22716 manual having clause-wise details of how ISO 22716 system is implemented. The ISO 22716 manual is tier-1 of ISO 22716 documents and covers list of procedures as well as overview of organization. This manual has covering company profile, amendment sheet, index, clause-wise details as per ISO 22716 for implementation, sample policy and organization chart.

### (A) Table of Contents

| Chapter<br>No. | Subject  | Page<br>No. | ISO 22716 Clause reference              |  |  |  |
|----------------|--|-------------|---|--|--|--|
|                | Section – 1  |             |   |  |  |  |
| 1.             | Introduction and table of contents                                       |             |   |  |  |  |
| 2.             | Control and distribution   |             |   |  |  |  |
|                | Section – 2  |             |   |  |  |  |
| 3 to 17        | Details requirements for COSMETIC GMP based on the standard requirements | ==          | 3 to 17                                 |  |  |  |
| Annexure       |  |             |   |  |  |  |
| ANX-I          | List of Quality Procedures   |             | =========                               |  |  |  |
| ANX-II         | Glossary of Terms  |             | ========                                |  |  |  |
| ANX-III        | Process Flow Chart   |             | =========                               |  |  |  |
| ANX-IV         | Quality Policy   |             |   |  |  |  |
| ANX-V          | Organization Structure   |             | ======================================= |  |  |  |

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### 2. Procedures (10 procedures):

Sample copies of mandatory procedures as per ISO 22716 are provided, which cover all the details like purpose, scope, responsibility, how procedure is followed as well as the list of exhibits, reference documents and formats. The list of sample procedures provided in the kit is given below.

#### **List of Procedures**

- Procedure for Management review
- 2. Procedure for Document and Data Control
- 3. Procedure for Control of records
- 4. Procedure for Internal Audit
- 5. Procedure for Training
- 6. Procedure For Corrective and Preventive Action
- 7. Procedure For Control of Monitoring and Measuring Equipment
- 8. Procedure for Purchasing
- 9. Procedure for Control of Non-Conforming Products
- 10. Procedure for identification of products

#### 3. Exhibits (06 exhibits)

Exhibits cover It covers Skill Requirements, Disposal of Non-conforming Products, Quality Plan, Raw materials Specifications, Document codification system, Housekeeping schedule etc. as per ISO 22716 standard.

#### **List of Exhibits**

- 1. Skill Requirements
- 2. Disposal of Non–conforming Products
- Quality Plan
- 4. Raw materials Specifications
- 5. Document codification system
- 6. Housekeeping schedule

### 4. Process flow charts (09process flow charts)

Sample copies of process flow chart as per ISO 22716are provided. The list of sample process flow chart provided in the kit is given below.

#### List of process flow chart

- Process flow chart of Customer Service
- 2. Process flow chart of Despatch
- Process flow chart of Engineering

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- 4. Process flow chart of Marketing
- 5. Process flow chart of Production
- 6. Process flow chart of Purchase
- 7. Process flow chart of Quality Control
- 8. Process flow chart of Stores
- 9. Process flow chart of Training

#### 5. Standard operating procedures (28SOPs)

It covers sample copy of standard operating procedure as per ISO 22716. It takes care of all such issues and used as a training guide as well as to establish control and make system in the organization. The samples given are as a guide and not compulsory to follow and organization is free to change the same to suit own requirements.

#### **List of Standard operating procedures**

- 1. SOP for SOP
- 2. SOP for Control of Version, Archival and Retrieval of Data
- 3. SOP for Receipt and Handling of Market Complaints
- 4. SOP for Product recall
- 5. SOP for Handling of market returns
- 6. SOP for Change control system
- 7. SOP for Deviation and Investigation
- 8. SOP for Vendor quality audit
- 9. SOP for Out of Calibration (OOC)
- 10. SOP for Out of specification (OOS)
- SOP for Batch release of Finished
- '' Products
- 12. SOP for Rework procedure
- 3. SOP for In-process Inspection During
- Manufacturing
- 14. SOP for Handling and storage of controlled samples

- 15. SOP for Retain samples and its disposal
- 16. SOP for Mock recall
- 17. SOP for Receipt of Raw & Packaging Materials
- 18. SOP for Receipt, Storage& Dispatch of Finished Goods
- 19. SOP for Waste management
- 20. SOP for Cleaning and sanitization
- 21. SOP for Pest control
- 22. SOP for Line clearance
- 23. SOP for Equipment cleaning and sanitization
- 24. SOP for General housekeeping
- 25. SOP for Entry / Exit procedure Personnel hygiene
- 26. SOP for Floor cleaning
- 27. SOP for Cleaning of doors, Windows, Walls and tube light and fan
- 28. SOP for Incident reporting

#### 6. Blank sample formats for all the departments (42 sample formats)

This directory includes sample copy of blank forms that are required to maintain records as well as establish control and create system in the organization. The samples are given for the users as a guide to follow. The organization is free to change the same to suit their own requirements. The blank formats can be used as templates. A total of 42 blank formats are provided as per the list given below.

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### **List of blank formats**

| 1.  | Purchase order                                    | 22. | Audit plan / schedule                         |
|-----|---|-----|---|
| 2.  | Indent cum Incoming inspection report             | 23. | Internal Audit Non–Conformity Report          |
| 3.  | Approved Vendor list cum open purchase order      | 24. | Clause-wise Document-wise Audit Review Report |
| 4.  | Supplier Registration form                        | 25. | Continual Improvement Plan                    |
| 5.  | Open purchase order                               | 26. | Corrective Action Report                      |
| 6.  | Daily stock statement                             | 27. | Preventive Action Report                      |
| 7.  | Gate pass   | 28. | Qualitative Process Monitoring Report         |
| 8.  | Breakdown history card                            | 29. | Vendor Rating                                 |
| 9.  | Preventive maintenance schedule                   | 30. | List of license/certificate                   |
| 10. | Equipment Wise preventive maintenance checkpoints | 31. | Training Calendar                             |
| 11. | Daily pm check point                              | 32. | Training Need Cum Records Sheet               |
| 12. | PM Checkpoints for Building & civil work          | 33. | Induction Training Report                     |
| 13. | Order form/ confirmation                          | 34. | Job Description and Specification             |
| 14. | Customer Complaint report                         | 35. | Skill Matrix                                  |
| 15. | Customer feedback form                            | 36. | Training Report                               |
| 16. | Customer property monitoring register             | 37. | Skill Matrix for QC Personnel                 |
| 17. | Master list cum distribution list of documents    | 38. | Housekeeping record                           |
| 18. | Change note                                       | 39. | Visitor gate pass                             |
| 19. | Calibration status of instrument / equipment      | 40. | Incident Reporting form                       |
| 20. | Master list of records                            | 41. | Rodent trapping record                        |
|     |   |     |   |

#### 7. ISO 22716 Audit Checklists (More than 180 Questions)

This covers audit questions based on the ISO 22716 requirements. It will be a very good tool for the auditors to make audit questionnaire for auditing. It will bring effectiveness in auditing. A total of more than 180 questions are prepared on the basis of ISO 22716.

42. Sanitation report

#### 8. ISO 22716 compliance matrix

Quality objective monitoring report

21.

This compliance matrix contains ISO 22716 requirement wise list of documented information for easy reference of users and to understand how this system is made.

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### **Chapter - 2.0 ABOUT COMPANY**

Documentation Consultancy is a progressive company promoted by a group of qualified engineers and management graduates having rich experience of over 25 years in ISO consultancy and management areas. The company serves the global customers through on-site and off-site modes of service delivery systems. We offer a full range of consulting services geared towards helping all types of organizations to achieve competitiveness, certifications and compliance to international standards and regulations. So far, we have more than 2700 clients in more than 36 countries. Our readymade training kit and editable documentation kit help the clients in making their documents with ease and complying with the related ISO standard faster.

- Our promoters and engineers have rich experience of providing management training and ISO series consultancy for more than 2700 companies globally. We have clients in more than 36 countries.
- 2. We are a highly qualified team of 80 members (M.B.A., Degree Engineers). Our Director has rich professional experience in this field (since 1991).
- 3. We have 100% success rate in ISO series certification for our clients from reputed certifying bodies. We possess a branded image and are a leading name in the global market.
- 4. We suggest continual improvement and cost reduction measures as well as provide highly informative training presentations and other products that give you payback within 2 months against our cost.
- 5. So far, we have trained more than 50000 employees in ISO series certification.
- 6. We have spent more than 60000 man-days (170 man-years) in the preparation of ISO documents and training slides.

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- 3. Professional approach
- 4. Hard work and updating the knowledge of team members
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### **Chapter - 3.0 USER FUNCTION**

### 3.1 Hardware and Software Requirements

#### A. Hardware

- Our documentation kit can better perform with the help of P4 and higher computers with a minimum of 10 GB hard disk space.
- For better visual impact, you may keep the setting at high color.

#### **B. Software**

• Documents are written in MS-Office 2007 and Windows XP programs. You are, therefore, required to have MS-Office 2007 or higher versions with Windows XP.

#### 3.2 Features of Documentation kit

- The kit contains all necessary documents as listed, and complies with the requirements of system standards.
- The documents are written in easy to understand English language.
- This kit will save much time in typing and preparing your documents at your own.
- The kit is user-friendly to adopt and easy to learn.
- The contents of this kit are developed under the guidance of experienced experts.
- The kit provides a model of the management system that is simple and free from excessive paperwork.

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### **Chapter - 4.0 BENEFITS OF USING OUR DOCUMENTATION KIT**

- 1. By using these documents, you can save a lot of your precious time while preparing the ISO documents.
- 2. The kit takes care of all the sections and sub-sections of ISO 22716 standards and helps you to establish better system.
- 3. This documentation kit enables you to change the contents and print as many copies as you need. The users can modify the documents as per their industry requirements and create their own ISO 22716 documents for their organization.
- 4. It will save much cost in document preparation.
- 5. You will get a better control in your system due to our proven formats.
- 6. You will also get a better control in your system as our proven documents and templates are developed under the guidance of experts and globally proven consultants. The team has a rich experience of more than 25 years in the ISO consultancy.
- 7. Our products are highly sold across the globe and are used by many multinational companies. They have got total satisfaction as well as experienced value for money.
- 8. In the preparation of documentation kit, our team has verified and evaluated the entire content at various levels. More than 1000 hours have been spent in the preparation of this documentation kit.
- 9. The entire kit is prepared by a globally proven team of leading ISO consultants.

### **Chapter - 5.0 METHOD OF ONLINE DELIVERY**

On completion of the secured purchase, we provide a username and password to download the product from our FTP server. We provide instant online delivery of our products to the user by sending an e-mail of username and password.

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