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~~Quality Management~~

~~System Basics ISO 9001~~

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*Create a Quality*

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~~Management principles~~

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~~*Management System*~~

~~*(QMS)? Why write a*~~

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*examples* **ISO 9000**

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*1.1 QMS Documentatio*

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document is important

because it will assist

you in maintaining

quality standards at your

work place and helps

you to decide the quality

of products or services

you are offering.

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[www.iso9001help.co.uk](http://www.iso9001help.co.uk)

ISO 9001:2015 Quality  
Management System

Document Ref. Page 8

of 51 4 Context of the  
Organization 4.1

Organizational Context

Your organization is  
committed to defining

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our position in the  
marketplace and  
understanding how  
relevant

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General Quality Manual

Template The quality

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laboratory quality

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training toolkit, Module

16 - Documents and

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based on internationally-accepted standards, and provides guidance for public health and

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11.11.2016 1 Practice

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~~[Operation / User  
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Regulation or Standard

Site Master File Quality

Manual EU GMP Yes

(Chapter 4) Yes

(Chapter 1) PIC/S GMP

version 11 (2017) Yes

(Chapter 4) Yes

(Chapter 1) WHO

GDRP (2016) No Yes

EU and PIC/S SMF

guidance document Yes

No specific requirement

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ISO 9001 (2015) No  
Yes (2013), No (2015)  
now more general ICH  
Q10 No Yes Adapted  
from Tang, S. 2013.

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12 5.4 Management

Review - Management

reviews the quality

system to ensure its

continuing suitability,

adequacy and

effectiveness.

~~QUALITY MANUAL~~

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A Data Quality Policy

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ISO 9001 Quality

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contains the quality manual, quality policy, scope, objectives,

procedures, forms,

reports, process maps,

audit checklists -

whether this is your

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are transitioning from

9001:2008 to

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helpful. A business  
normally consists of  
various departments to  
run and manage

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business operations  
professionally and in a  
best way to create a  
visible position in  
market as well as in  
eyes of potential  
customers.

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designed to develop the document that reflect their own policy and systems of control. This is a document that is used to highlight the important factors which are involved in improving the quality of products or services.

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Logo XXXX

ISO9001:2015 Quality

Manual Reviewed by:

Approved by: Version:

Quality is about

processes and data Page

20 Quality is shared

responsibility within an

organization 9

Performance evaluation

9.1 Monitoring,

measurement, analysis

and evaluation 9.1.1

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determine below about  
monitoring,  
measurement, analysis  
and evaluation

activities: What needs to  
be monitored &  
measured The ...

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QMS Manual In  
compliance with  
standards listed in

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Quality 2.0, the Quality Management System Manual contains Net Safety Monitoring policies for quality.

It covers the purpose and scope, responsibilities and further descriptions of activities to support the policy, and interaction between processes. 2

**QUALITY**

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~~MANAGEMENT~~  
~~Quality Manual~~  
~~SYSTEM MANUAL~~  
~~Emerson~~

ISO 9001 document  
template: Quality  
Manual. The Quality  
Manual organization  
and demonstrates the  
capability of the  
organization to  
continuously provide  
products and services  
that address customer  
requirements.

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5.1.1 General 13 5.1.2

Customer Focus 13 5.2

Policy 14 5.2.1

Developing the Quality  
Policy 15 ... This quality  
manual defines the  
policies and principles  
applied against each of  
the requirements of ISO  
9001:2008 and relates to

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all activities carried out  
in the company that  
determine quality, and  
lays down ...

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