

OVERVIEW OF ISO 9001 2015 QUALITY MANAGEMENT STANDARD

4. CONTEXT

1. UNDERSTAND YOUR ORGANIZATION'S CONTEXT

2. CLARIFY EXPECTATIONS OF INTERESTED PARTIES

3. DEFINE SCOPE OF QUALITY MANAGEMENT SYSTEM (QMS)

4. DEVELOP A QUALITY MANAGEMENT SYSTEM

5. LEADERSHIP

1. PROVIDE LEADERSHIP BY FOCUSING ON QUALITY AND CUSTOMERS

2. PROVIDE LEADERSHIP BY ESTABLISHING A QUALITY POLICY

3. PROVIDE LEADERSHIP BY DEFINING QMS ROLES AND RESPONSIBILITIES

6. PLANNING

1. DEFINE ACTIONS TO MANAGE RISKS AND ADDRESS OPPORTUNITIES

2. SET QUALITY OBJECTIVES AND DEVELOP PLANS TO ACHIEVE THEM

3. PLAN AND CONTROL CHANGES TO YOUR QUALITY MANAGEMENT SYSTEM

7. SUPPORT

1. PROVIDE NEEDED RESOURCES FOR QMS

2. ENCOURAGE AND EXPECT COMPETENCE

3. ASK PERSONNEL TO HELP WITH QMS

4. MANAGE QMS COMMUNICATIONS

5. CONTROL QMS INFORMATION

8. OPERATIONS

1. DEVELOP PROCESSES

2. DETERMINE REQUIREMENTS

3. CARRY OUT DESIGN

4. MONITOR SUPPLIERS

5. MANAGE PRODUCTION

6. CONTROL PRODUCTS

7. DOCUMENT YOUR ACTIONS

9. EVALUATION

1. MONITOR, MEASURE, AND ANALYZE QUALITY MANAGEMENT SYSTEM (QMS)

2. SET UP INTERNAL AUDIT PROGRAM AND USE IT TO EXAMINE YOUR QMS

3. REVIEW YOUR ORGANIZATION'S QMS AT PLANNED INTERVALS

10. IMPROVEMENT

1. IDENTIFY AND SELECT QMS IMPROVEMENT OPPORTUNITIES

2. CONTROL NONCONFORMITIES AND TAKE SUITABLE CORRECTIVE ACTIONS

3. ENHANCE QMS SUITABILITY, ADEQUACY, AND EFFECTIVENESS

Iso 9001 Procedures Manual

Anthony S. Fauci



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