IJPPR
INTERNATIONAL JOURNAL OF PHARMACY & PHARMACEUTICAL RESEARCH
An official Publication of Human Journals
ISSN 2349-7203
HUMAN

Human Journals
**Review Article**
November 2019 Vol.:16, Issue:4


# Quality Risk Assessment in Pharmaceutical Industry an Overview of Regulatory Guidelines

IJPPR
INTERNATIONAL JOURNAL OF PHARMACY & PHARMACEUTICAL RESEARCH
An official Publication of Human Journals
ISSN 2349-7203
HUMAN

**Soumen Pattanayek*[1], S.B.Puranik[2]**

*[1]Teva Pharmaceuticals 1776 Aspen Ln Weston, FL, 33327*

*[2]Drishti Institute of Distance Learning, Bangalore, Karnataka, India.*

**Submission:** 27 October 2019
**Accepted:** 02 November 2019
**Published:** 30 November 2019



**Keywords:** WHO, Schedule M. USFDA, TGA, Personnel, Regulatory requirements

**ABSTRACT**

Quality Risk Management is a systematic process for the assessment, control, communication and review of risks to the quality of the medicinal product. It can be applied both proactively and retrospectively. The Quality risk assessment tools can be used in various sectors apart from the pharmaceutical industry to assess the risk with its mitigation plans like Engineering industries, Financial sectors, Academics, Hospitals, etc. In the pharmaceutical industry, the Quality risk assessment is regularized through various regulatory bodies, In detail, the Quality risk assessment is briefed in ICH Q9 whereas in other regulatory guidelines is linked to the ICH Q9 Requirements, presently to evaluate as per various regulatory guidelines other than ICH Q9.

## INTRODUCTION

Currently, the study is aimed at requirements of Quality Risk Assessment as per the different regulatory guidelines viz., WHO, Schedule M of D and C Act, USFDA, MHRA, TGA.

Each of the selected guidelines describes the requirement of QRM under the different chapters as below.

**WHO** describes the Quality risk assessment in Annexure 3 WHO good manufacturing practices for pharmaceutical products: 1. Quality assurance.

Schedule M does not describe the QRM in the Act.

USFDA describes the Risk assessment in PART 211— Current Good Manufacturing Practice for Finished Pharmaceuticals Guidance for Industry Quality Systems Approach to Pharmaceutical CGMP Regulations — Risk assessment IV. THE QUALITY SYSTEMS MODEL D. Evaluation Activities 3. Quality Risk Management.

**MHRA** describes the Quality Risk Assessment in Section II – 2EU Guidance on Good Manufacturing Practice (GMP) - QUALITY RISK MANAGEMENT.

**TGA/PICS** describes the Quality Risk Assessment in CHAPTER 1 Quality Management - Risk assessment.

Detailed comparison of the selected guidelines concerning QRM is made in below:

**Table No. 1: Comparison of regulatory guidelines for Risk assessment in the pharmaceutical industry**

| WHO [1] | Schedule M [2] | USFDA [3] | MHRA [4] | TGA[5]/PICS[6] |
|---|---|---|---|---|
| **WHO** describes the Risk assessment in Annexure 3 **WHO good manufacturing practices for pharmaceutical products:** | **Schedule M** describes the Risk assessment in **PART 1 Good Manufacturing Practices And Requirements Of Premises, Plant And Equipment For Pharmaceutical Products** | **USFDA describes the Risk assessment in PART 211—Current Good Manufacturing Practice for Finished Pharmaceuticals Guidance for Industry Quality Systems Approach to Pharmaceutical CGMP Regulations — Risk assessment** | **MHRA** describes the Risk assessment in **Section II – 2EU Guidance On Good Manufacturing Practice (GMP) - Risk assessment** | **TGA/PICS** describes the Risk assessment in **CHAPTER 1 Quality Management - Risk assessment** |
| **1. Quality assurance** **1.4** QRM is a systematic process for the assessment, control, communication and review of risks to the quality of the medicinal product. It can be applied both proactively and retrospectively. **1.5** QRM should ensure that: — the evaluation of the risk to quality is based | Schedule M does not cover in detail about the Quality Risk Management. | **IV. THE QUALITY SYSTEMS MODEL** **D. Evaluation Activities** **3. Quality Risk Management** Effective decision-making in a quality systems environment is based on an informed understanding of quality issues. Elements of risk should be considered relative to the intended use of a product and in the case of | QUALITY RISK MANAGEMENT 1.5 Quality risk management is a systematic process for the assessment, control, communication and review of risks to the quality of the medicinal product. It can be applied both proactively and retrospectively. 1.6 The quality risk management system should ensure that: - the evaluation | **QUALITY RISK MANAGEMENT** **1.5** Quality risk management is a systematic process for the assessment, control, communication and review of risks to the quality of the medicinal product. It can be applied both proactively and retrospectively. **1.6** The quality risk management system should ensure that: |

| WHO [1] | Schedule M [2] | USFDA [3] | MHRA [4] | TGA[5]/PICS[6] |
|---|---|---|---|---|
| on scientific knowledge, experience with the process and ultimately links to the protection of the patient; and — the level of effort, formality, and documentation of the QRM process is commensurate with the level of risk. | | pharmaceuticals, patient safety and ensuring availability of medically necessary drug products. Management should assign priorities to activities or actions based on an assessment of the risk including both the probability of occurrence of harm and of the severity of that harm. It is important to engage appropriate parties in assessing the risk. Such parties include customers, appropriate manufacturing personnel, and other stakeholders. Implementation of quality risk management includes assessing the risks, selecting and implementing risk management controls commensurate with the level of risk, and evaluating the | of the risk to quality is based on scientific knowledge, experience with the process and ultimately links to the protection of the patient; - the level of effort, formality, and documentation of the quality risk management process is commensurate with the level of risk. | - the evaluation of the risk to quality is based on scientific knowledge, experience with the process and ultimately links to the protection of the patient; - the level of effort, formality, and documentation of the quality risk management process is commensurate with the level of risk. |

| WHO [1] | Schedule M [2] | USFDA [3] | MHRA [4] | TGA[5]/PICS[6] |
|---|---|---|---|---|
| | | results of the risk management efforts. Since risk management is an iterative process, it should be repeated if new information is developed that changes the need for, or nature of, risk management.<br>In a manufacturing quality systems environment, risk management is used as a tool in the development of product specifications and critical process parameters.<br>Used in conjunction with process understanding, quality risk management helps manage and control change. | | |

## QUALITY RISK ASSESSMENT IN PHARMACEUTICAL AND BIOTECH INDUSTRY

## DISCUSSION

Based on the above comparative study of Quality risk assessment in the pharmaceutical industry, we infer that as per WHO, Schedule M of D and C act, and USFDA, MHRA, and TGA/PICS guidelines. Discussion is carried out under different heading for better understanding purpose.

### Guidelines Chapters

**WHO** describes the Risk assessment in Annexure 3 good manufacturing practices for pharmaceutical products in sec 1.4 to 1.5. With the least information**.**

Schedule M doesn't specify the Quality Risk assessment in part I good manufacturing practices.

USFDA describes the Risk assessment in PART 211— Current Good Manufacturing Practice for Finished Pharmaceuticals.

Guidance for Industry Quality Systems Approach to Pharmaceutical CGMP Regulations — under Quality systems model evaluation activities of point 3 as Quality risk management.

MHRA describes the Risk assessment in Section II – 2EU Guidance on Good Manufacturing Practice (GMP) covered under 1.5 to 1.6.

TGA/PICS describes the risk Assessment in Chapter I of Quality management of section 1.5 to 1.6.

Based on limited information about Quality risk Management in WHO, USFDA, EU and TGA guide as an additional information cross-verified in ICH Q9 are briefed in detail about the Risk identification followed by Risk Mitigation based on Risk priority number.

## SUMMARY AND CONCLUSION

Based on the above comparative analysis and discussion on Quality Risk Management in the pharmaceutical industry as per the different regulatory guidelines below is the theory developed which is common for all the regulatory requirements. Following the below

common theory of all the regulatory guidelines concerning Quality Risk management. Quality risk management is a systematic process for the assessment, control, communication and review of risks to the quality of the medicinal product. It can be applied both proactively and retrospectively.

The quality risk management system should ensure that the evaluation of the risk to quality is based on scientific knowledge, experience with the process and ultimately links to the protection of the patient; and the level of effort, formality, and documentation of the quality risk management process is commensurate with the level of risk.

Effective decision-making in a quality systems environment is based on an informed understanding of quality issues. Elements of risk should be considered relative to the intended use of a product and in the case of pharmaceuticals, patient safety and ensuring availability of medically necessary drug products. Management should assign priorities to activities or actions based on an assessment of the risk including both the probability of occurrence of harm and of the severity of that harm. It is important to engage appropriate parties in assessing the risk. Such parties include customers, appropriate manufacturing personnel, and other stakeholders. Implementation of quality risk management includes assessing the risks, selecting and implementing risk management controls commensurate with the level of risk, and evaluating the results of the risk management efforts. Since risk management is an iterative process, it should be repeated if new information is developed that changes the need for, or nature of, risk management.

In a manufacturing quality systems environment, risk management is used as a tool in the development of product specifications and critical process parameters. Used in conjunction with process understanding, quality risk management helps manage and control change.

It is found that Quality Risk Management is not covered in all the selected guidelines, WHO GMP guide is having the limited information on QRM procedure and other selected guidelines is not having the information on QRM procedure, however it is cross-referenced to ICH Q9 is briefed about QRM as referred by USFDA and EU guideline of different section. However, implementing the QRM procedure as per ICH Q9 in the pharmaceutical industry will suffice the requirement of all the guidelines.

## REFERENCES

1. WHO describes the Risk assessment in Annexure 3-WHO Good Manufacturing Practices for Pharmaceutical Products.
2. Schedule M describes the Risk assessment in PART 1 Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products.
3. USFDA describes the Risk assessment in PART 211— Current Good Manufacturing Practice for Finished Pharmaceuticals Guidance for Industry Quality Systems Approach to Pharmaceutical CGMP Regulations — Risk assessment.
4. MHRA describes the Risk assessment in Section II – 2EU Guidance on Good Manufacturing Practice (GMP) -Risk assessment.
5. TGA/PICS describes the Risk assessment in CHAPTER 1 Quality Management Risk assessment.