

Quality Risk Management for Pharmaceuticals

Table of Contents

About the Author

- Introduction..... 5**
 - Implementation of QRM 6
 - Training..... 7
 - Organizational Maturity and Efficiency of QRM 8
 - Relationship Between the QRM Principles 9
 - Effort, Rigor and Formality of QRM..... 10
- Potential Applications and Uses of Quality Risk Management 13**
 - Integrated Application of QRM..... 14
 - Application of QRM in Pharmaceutical Development 15
 - Application of QRM During Technology Transfer..... 15
 - Application of QRM During Commercial Manufacturing and Marketing..... 16
 - Application of QRM During Discontinuation of Commercial Manufacturing and Marketing 17
 - Embedding of QRM in the Pharmaceutical Quality Management System..... 17
 - Benefits and Advantages of Integrated Quality Risk Management..... 19
- The Quality Risk Management Process 21**
 - Initiation of a QRM Process..... 23
 - Risk Assessment..... 24
 - Risk Identification 24
 - Risk Analysis 25
 - Risk Evaluation 25
 - Risk Control 26
 - Risk Reduction 27
 - Risk Acceptance 27
 - Risk Communication 28
 - Risk Review 30

Methods and Tools of Quality Risk Management	33
Basic Procedures for the Facilitation of QRM	35
Informal Methods and Tools	37
Stepwise Use of QRM Methods and Tools	38
Mind Map	40
Fault Tree Analysis	42
Cause and Effect Diagram	45
Failure Mode Effects Analysis	47
Probability of Occurrence	48
Detectability	49
Severity of Harm	50
Calculation of the Risk Priority Number	51
Hazard Analysis and Critical Control Points	55
Hazard Operability Analysis	60
Risk Ranking and Filtering	61
Supporting Statistical Methods	62
Control Charts	62
Weighted Moving Average	65
Design of Experiments	65
Histograms	65
Pareto Charts	66
Process Capability Analysis/Studies	66
Quality Risk Management Definitions	69
References	73