



Technical Report No. 54-6

Formalized Risk Assessment for Excipients



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Table of Contents

FOREWORD	v		
About Parenteral Drug Association (PDA)	v		
About IPEC Federation	v		
Joint Initiative between IPEC Federation and PDA	v		
1.0 INTRODUCTION.....	1		
1.1 Purpose	1		
1.2 Scope	2		
2.0 GLOSSARY AND ABBREVIATIONS	3		
2.1 Abbreviations	4		
3.0 OVERALL STRATEGY – A HOLISTIC VIEW	4		
3.1 Risk Areas Beyond Quality	5		
4.0 SUPPLY CHAIN — END TO END.....	6		
4.1 Types of Supply Chains and Risks Presented	6		
4.1.1 Direct Supply from Manufacturer	6		
4.1.2 Supply via a Distributor	7		
4.1.3 Supply Via Repackager	7		
4.1.4 Supply Via Broker	7		
4.1.5 Manufacturer Exporting Excipient Directly to End User	8		
4.1.6 Manufacturer and Contract Manufacturing Organizations	8		
5.0 DIFFERENT ROLES IN THE SUPPLY CHAIN AND INFORMATION-GATHERING	9		
6.0 A MODEL FOR QUALITY RISK MANAGEMENT FOR EXCIPIENTS.....	11		
6.1 Initiate Risk Management Activities and Identify Assessment Team	12		
6.2 Identify Intrinsic Risk Factors	12		
6.3 Excipient Risk Analysis	13		
		6.3.1 Impact of Excipient on Each Type of Drug Product	14
		6.3.2 Excipient Risk Profile based on Use and Intrinsic Factors	15
		6.4 Supply Chain Risk Analysis	17
		6.5 Risk Evaluation.....	19
		6.5.1 Risk Matrix—Option 1: Calculating Combined Risk Score (Overall _{RPN})	19
		6.5.2 Risk Matrix—Option 2: Calculating Final Risk Score	20
		6.6 Implementation of Controls—Risk Mitigation ..	21
		6.6.1 General Considerations on the Appropriate GMP Required to Meet Risk Mitigation Level Determined by Risk Assessment	23
		6.6.2 Applicability of GMP Standards	23
		7.0 ONGOING REVIEW—FORMALIZED RISK ASSESSMENT LIFECYCLE	25
		7.1 Triggers for Risk Assessment Review	25
		8.0 BENEFITS AND VALUE / QRM / KNOWLEDGE MANAGEMENT	26
		9.0 REFERENCES	26
		10.0 ANNEX I: REAL WORLD EXAMPLES OF RISK ASSESSMENTS	28
		10.1 Example 1: Company U.....	28
		10.2 Example 2: Company V.....	30
		10.3 Example 3: Company W.....	32
		10.4 Example 4: Company X.....	33
		10.5 Example 5: Company Y	34
		10.6 Example 6: Company Z	35
		11.0 REFERENCES (FOR ANNEX 1).....	36

FIGURES AND TABLES INDEX

Figure 1.0-1	Identifying Whether an Excipient is Fit for Use	Table 6.5.1-2	Decision Table to Determine Risk
	2	Table 6.5.2-1	Calculated Final Risk Score Examples
Figure 4.1.1-1	Supply Chain: Direct Supply from Manufacturer	Figure 6.6-1	Identify Further Mitigation Actions to Reach Acceptable Risk Control, and Communicate
	6		21
Figure 4.1.2-1	Supply Chain: Supply via Distributors	Table 6.6-1	Factors to Consider in Determining if Additional Actions are Needed
	7		22
Figure 4.1.3-1	Supply Chain: Supply via Repackager	Figure 6.6.1-1	Degree of Risk Mitigation Required Based on the Nature of the Manufacturing Controls Required for the Excipient
	7		23
Figure 4.1.4-1	Supply Chain: Supply via Broker	Table 6.6.2-1	GMP Standards by Standard Organization
	7		24
Figure 4.1.5-1	Supply Chain: Manufacturer Exporting Excipient Directly to End User	Figure 7.0-1	Simplified Overview of the Generic Lifecycle Model
	8		25
Table 5.0-1	Roles in the Supply Chain and Examples of Their Responsibilities	Figure 10.1-1	Risk Assessment Model for Company U
	9		29
Table 5.0-2	Common Scenarios in Information-Gathering	Table 10.1-1	Gap Analysis Matrix Used to Determine Severity of Risk
	10		30
Figure 6.0-1	The Complete Generic Risk Model for Excipients	Figure 10.2-1	Risk Assessment Model for Company V
	11		31
Figure 6.3-1	Steps in Excipient Risk Identification and Analysis	Figure 10.3-1	Risk Assessment Model for Company W
	13		32
Figure 6.3.1-1	Illustration of an Excipient Impact Assessment to Provide Specification Input	Figure 10.4-1	Risk Assessment Model for Company X
	14		33
Table 6.3.2-1	Excipient Risk Calculation Tool	Figure 10.5-1	Risk Assessment Model for Company Y
	16		34
Figure 6.4-1	Steps in the Supply Chain Risk Analysis ...	Figure 10.6-1	Risk Assessment Model for Company Z
	17		35
Table 6.4-1	Supply Chain Risk Calculation Tool		
	18		
Figure 6.5-1	Developing the Matrix of Combined Excipient + Supply Chain Risk Evaluation		
	19		
Figure 6.5.2-1	Calculating a Final Risk Score		
	20		
Table 6.5.1-1	Risk Matrix to Evaluate Combined Risk Score for Excipient and Supply Chain		
	20		

Foreword

Joint Initiative between IPEC Federation and PDA

In March 2018, the IPEC Federation and PDA announced their first joint initiative. Both associations signed a memorandum of understanding to collaborate on the development of a joint technical report on excipient good manufacturing practices risk assessment in response to input from their respective memberships. Prior to the collaboration announcement, however, both parties were active on the topic of quality risk management. PDA published the *PDA Technical Report No. 54* series. In March 2016, IPEC Europe published the *How-To Document – A Guide to Support Manufacturing Authorization Holders (MAH) in their Compliance with the European Commission Guidelines on Risk Assessment for Excipients (2015/C 95/02)*. Subsequently, in May 2017, IPEC-Americas and IPEC Europe jointly published the *Risk Assessment Guide for Excipient Makers, Users, and Distributors*.

Both PDA and IPEC Federation believe that presenting a common approach to the legal, regulatory, and related issues concerning excipients is best done as “one voice.” Both collaborators see significant potential benefit in leveraging the two organizations’ expertise on excipients and drug product manufacture. This technical report will serve as a practical guidance intended for use with existing regulatory and industry standards. The authors expect that the document will enable Manufacturing Authorization Holders of drug product to either set up or benchmark their quality systems, and further establish or continue to collaborate with parties in their excipient supply chain.

This joint PDA-IPEC technical report extends the *PDA Technical Report No. 54* series and provides guidance on risk assessments for excipients by presenting a model risk assessment, guidance on key elements, and a collection of actual examples from excipient users in the pharmaceutical industry.

About Parenteral Drug Association (PDA)

The Parenteral Drug Association (PDA) is the leading global provider of science, technology, and regulatory information and education for the pharmaceutical and biopharmaceutical community. Founded in 1946 as a nonprofit organization, PDA is committed to developing scientifically sound, practical technical information and resources to advance manufacturing science and regulation. Through the expertise of more than 10,000 members worldwide, PDA promotes the exchange of rapidly evolving information on science, technology, and regulations concerning high-quality pharmaceutical production to better serve patients.

About IPEC Federation

The IPEC Federation (IPEC) is a global organization that promotes quality in pharmaceutical excipients. The IPEC Federation represents five regional International Pharmaceutical Excipient Councils (IPECs) — IPEC-Americas, IPEC Europe, IPEC Japan, IPEC China, and IPEC India — and provides a unified voice to promote the best use of excipients in medicines as a means of improving patient treatment and safety. IPEC’s objectives are to contribute to the development and harmonization of international excipient standards, the introduction of useful new excipients to the marketplace, and the development of good manufacturing and good distribution practices for excipients.



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