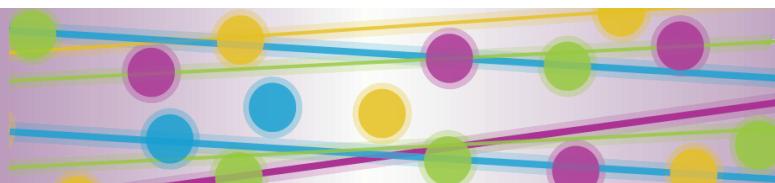


Pharmaceutical and Biopharmaceutical Manufacturing: Understanding Your Process Series

Risk Management Library, Volume 1

Lifecycle Risk Management



Edited by
Edwin Bills and Stan Mastrangelo

Risk Management Library, Volume 1

Lifecycle Risk Management

Edited by
Edwin Bills and Stan Mastrangelo

PDA
Bethesda, MD, USA

DHI Publishing, LLC
River Grove, IL, USA

www.pda.org/bookstore

10 9 8 7 6 5 4 3 2 1

ISBN: 978-1-942911-18-0

Copyright © 2018 Edwin Bills and Stan Mastrangelo
All rights reserved.

All rights reserved. This book is protected by copyright. No part of it may be reproduced, stored in a retrieval system or transmitted in any means, electronic, mechanical, photocopying, recording, or otherwise, without written permission from the publisher. Printed in the United States of America.

Where a product trademark, registration mark, or other protected mark is made in the text, ownership of the mark remains with the lawful owner of the mark. No claim, intentional or otherwise, is made by reference to any such marks in the book. Websites cited are current at the time of publication. The authors have made every effort to provide accurate citations. If there are any omissions, please contact the publisher.

While every effort has been made by the publisher and the authors to ensure the accuracy of the information expressed in this book, the organization accepts no responsibility for errors or omissions. The views expressed in this book are those of the authors and may not represent those of either Davis Healthcare International or the PDA, its officers, or directors.



Connecting People, Science and Regulation®



This book is printed on sustainable resource paper approved by the Forest Stewardship Council. The printer, Gasch Printing, is a member of the Green Press Initiative and all paper used is from SFI (Sustainable Forest Initiative) certified mills.

PDA Global Headquarters
Bethesda Towers, Suite 600
4350 East-West Highway
Bethesda, MD 20814
United States
www.pda.org/bookstore
001-301-986-0293

Davis Healthcare International Publishing, LLC
2636 West Street
River Grove
IL 60171
United States
www.DHIBooks.com

CONTENTS

1 RISK MANAGEMENT PROCESSES	1
<i>Edwin Bills</i>	
Introduction	1
Risk Terminology	3
What Process should we use?	8
Health Product Risk Management	10
Risk Assessment	11
Risk Control	11
Monitoring and Feedback	14
Composite Health Products Risk Management Process	14
Conclusion	16
References	16
About the Author	18
2 RISK MANAGEMENT CONSIDERATIONS AND STRATEGIES IN PRODUCT DEVELOPMENT	19
<i>Susan W. Neadle</i>	
Overview of Product Development Process	20
Voice of Customer/Unmet Needs/User Needs and Intended Uses	21
Research: Concept Exploration and Selection	22
Requirements Definition and Target Product Profile	25

Requirements Management: Implementing Mitigation and Controls Strategies	54
Verification and Validation	58
Conclusion	67
References	68
About the Author	71
3 WHY IMPLEMENT RISK MANAGEMENT FOR NON-PRODUCT SOFTWARE? 73	
<i>Tina Adamowski Krenc</i>	
A Process for Managing Risk Associated with NPSW	79
Determination of Risk Acceptance	81
Performing the Risk Assessment	84
Risk Reduction and Verification of Effectiveness of Control Measures	92
Risk Arising from Control Measures	95
Monitoring the Risk Management Program	96
Summary	97
References	98
About the Author	99
4 THE FUTURE OF RISK MANAGEMENT 101	
<i>Stan Mastrangelo</i>	
Enterprise Risk Management	101
The Future of Data	103
Health and Safety Risk Management	104
Combining Health and Safety Risk Management with Enterprise Risk Management	104
Every Idea does not Succeed	105
The Great Experiment	105
Elements on Risk-Based Thinking	107
Artificial Intelligence	110
Anticipated Developments	111
Conclusion	114
References	115
About the Author	115
CURRENT REGULATIONS, GUIDANCES, TECHNICAL REPORTS AND TEXTS USEFUL FOR FURTHER REFERENCE 117	