



Medical Device Vigilance

A hands-on international compliance guide

M G de Jong



Medical device vigilance
A hands-on international compliance guide

© M G de Jong
© Medidas

Published by
Medidas Medical Technologies
Wijk bij Duurstede, the Netherlands

July 2007

All rights reserved.

No part of this document may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, photocopying, recording, or otherwise without the express written permission of the publisher. This publication is sold subject to the condition that it shall not, by way of trade or otherwise, be lent, re-sold, hired out or otherwise circulated without the publisher's prior consent in any form other than that in which it is published and without a similar condition including this condition being imposed on the subsequent purchaser.

Koninklijke Bibliotheek Den Haag
ISBN 978-90-78027-03-4

Every effort has been made to ensure that the information reflected in this document is accurate at the time of writing. Neither the author nor the publisher accepts any liability for injury, damages, or losses arising from materials published in this report.



Medical Device Vigilance

A hands-on international compliance guide

Post-market surveillance includes complaint /adverse event handling and needs to be a pro-active activity to ensure preventive actions are taken in a timely manner to improve risk management process and overall safety of devices. To meet the international requirements, this how to guide helps in conducting and complying with the international medical device vigilance requirements

Table of Contents

Preface	5
Complaints	6
Adverse events	7
Expected versus Unexpected Adverse Events	7
Process	9
Documenting the process.....	9
Initial reporting	15
Screening.....	17
Initial reporting to the authorities.....	18
Investigating	20
Retrieving the product	21
Data analysis and root cause determination.....	22
Corrective and preventive actions.....	23
Follow-up of CAPA	24
Notification of CAPA	24
Closure, Final Notification and Archiving	26
Trending.....	27
Periodic reporting.....	27
Clinical trial related adverse events	28
Conclusions	31
Appendices	33
Appendix 1: Manufacturer's vigilance report form.....	34
Appendix II: Field safety corrective action report form.....	39
Appendix III: Field safety notices report format.....	42
Appendix IV: List of contact points for Medical Device Vigilance Reporting	43

Tables and Figures

Table 1 Applicable post-market related SOPS.....	9
Table 2 Minimum dataset.....	16
Table 3 Basic reporting criteria to determine reportability of an adverse event	17
Table 4 Information to be initially reported to the competent authorities.....	18
Figure 1 Flowchart for Complaint/ Medical Device Vigilance Process.....	14
Figure 2 Flowchart for clinical trial related adverse events.....	30