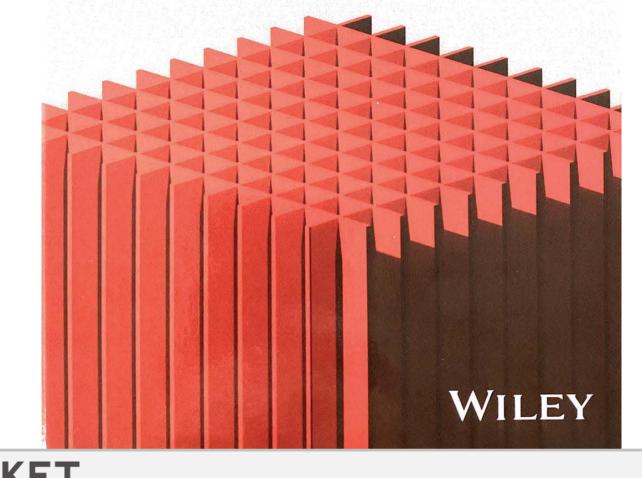
ICH Quality

An Implementation Guide

Edited by Andrew Teasdale, David Elder, Raymond W. Nims



Find authenticated court documents without watermarks at docketalarm.com.

Δ

ICH Quality Guidelines

An Implementation Guide

Edited by

Andrew Teasdale AstraZeneca, London, UK

David Elder Consultant (Former GSK), Hertford, Hertfordshire, UK

Raymond W. Nims RMC Pharmaceutical Solutions, Inc., Longmont, CO, USA

WILEY

DOCKE.

Δ

Find authenticated court documents without watermarks at docketalarm.com.

This edition first published 2018 © 2018 John Wiley & Sons, Inc.

© 2018 john whey & only and this publication may be reproduced, stored in a retrieval system, or transmitted, All rights reserved. No part of this publication may be reproduced, stored in a retrieval system, or transmitted, All rights reserved. No part of this publication, and photocopying, recording or otherwise, except as in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, except as in any form or by any means, electronics means are except a permitted by law. Advice on how to obtain permission to reuse material from this title is available at http://www.wiley.com/go/permissions.

The right of Andrew Teasdale, David Elder, and Raymond W. Nims to be identified as the editors of this work has been asserted in accordance with law.

Registered Office

John Wiley & Sons, Inc., 111 River Street, Hoboken, NJ 07030, USA

Editorial Office

111 River Street, Hoboken, NJ 07030, USA

For details of our global editorial offices, customer services, and more information about Wiley products visit us at www.wiley.com.

Wiley also publishes its books in a variety of electronic formats and by print-on-demand. Some content that appears in standard print versions of this book may not be available in other formats.

Limit of Liability/Disclaimer of Warranty

Limit of Liability/Disclaimer of warrance In view of ongoing research, equipment, incomparison and evices, the reader is urged flow of information relating to the use of experimental reagents, equipment, and devices, the reader is urged to review and evaluate the information provided in the package insert or instructions for each chemical. piece of equipment, reagent, or device for, among other things, any changes in the instructions or indication of usage and for added warnings and precautions. While the publisher and authors have used their best efforts in preparing this work, they make no representations or warranties with respect to the accuracy or completeness of the contents of this work and specifically disclaim all warranties, including without limitation any implied warranties of merchantability or fitness for a particular purpose. No warranty may be created or extended by sales representatives, written sales materials or promotional statements for this work. The fact that an organization, website, or product is referred to in this work as a citation and/or potential source of further information does not mean that the publisher and authors endorse the information or services the organization, website, or product may provide or recommendations it may make. This work is sold with the understanding that the publisher is not engaged in rendering professional services. The advice and strategies contained herein may not be suitable for your situation. You should consult with a specialist where appropriate. Further, readers should be aware that websites listed in this work may have changed or disappeared between when this work was written and when it is read. Neither the publisher nor authors shall be liable for any loss of profit or any other commercial damages, including but not limited to special, incidental, consequential, or other damages.

Library of Congress Cataloging-in-Publication Data

Names: Teasdale, Andrew, editor. | Elder, David (David P.), editor. | Nims, Raymond W. Title: ICH quality guidelines : an implementation guide / edited by Andrew Teasdale,

AstraZeneca, London, United Kingdom, David Elder, Consultant (fGSK), Hertford, Hertfordshire, SG14 2DE, United Kingdom, Raymond W. Nims, RMC Pharmaceutical

Solutions, Inc., Longmont, CO, USA.

Other titles: International Conference on Harmonization quality guidelines

Description: First edition. | Hoboken, NJ : Wiley, 2018. | Includes bibliographical references and index. |

Identifiers: LCCN 2017013162 (print) | LCCN 2017014318 (ebook) | ISBN 9781118971123 (pdf) | ISBN 9781118971130 (epub) | ISBN 9781118971116 (hardback)

Subjects: LCSH: Drug development. | Drugs-Testing. | Drugs-Quality control. |

BISAC: MEDICAL / Pharmacology. | TECHNOLOGY & ENGINEERING / Quality Control. | SCIENCE / Chemistry / Industrial & Technical.

Classification: LCC RM301.25 (ebook) | LCC RM301.25 .124 2018 (print) | DDC 615.1/9-dc23 LC record available at https://lccn.loc.gov/2017013162

Cover image: © Yagi Studio/Gettyimages Cover design by Wiley

Set in 10/12pt Warnock by SPi Global, Pondicherry, India

Printed in the United States of America

10 9 8 7 6 5 4 3 2 1

DOCKET

Contents

DOCK

List of Contributors *ix*

An Introduction to ICH Quality Guidelines: Opportunities and Challenges 1

- 1 ICHQ1A(R2) Stability Testing of New Drug Substance and Product and ICHQ1C Stability Testing of New Dosage Forms 3 Andy Rignall
- 2 Stability Testing: Photostability Testing of New Drug Substances and Products ICH Q1B 45 David Clapham
- 3 ICH Q1D: Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products 73 Raymond Peter Munden
- 4 ICH Q1E Evaluation for Stability Data 89 Garry Scrivens
- 5 Q2(R1) Validation of Analytical Procedures: Text and Methodology 127 Phillip Borman and David Elder
- 6 Impurities in New Drug Substances and New Drug Products: ICH Q3A/B: Key Guidelines in the General Impurity Management Process 167 Andrew Teasdale, David Elder, James Harvey, and Steven Spanhaak
- 7 ICH Q3C Impurities: Guideline for Residual Solvents 199 John Connelly

vi Contents

- 8 ICH Q3D Elemental Impurities 233 Andrew Teasdale and Sarah Thompson
- 9 ICH Q4: Pharmacopeial Harmonization and Evaluation and Recommendation of Pharmacopeial Texts for Use in the ICH Regions 281 David Elder
- 10 ICH Q5A: Viral Safety of Biotechnology Products 311 Daniel Galbraith
- 11 ICH Q5B Analysis of the Expression Construct in Cell Lines Used for Production of Recombinant DNA-Derived Protein Products 337 Jianxin Ye, Zhong Liu, and David Pollard
- **12** ICH Q5C Stability Testing of Biotechnological/Biological Products John G. Davies, Di Gao, Yoen Joo Kim, Richard Harris, Patricia W. Cash, Timothy L. Schofield, Roujian Zhang, and Qiang Qin
- 13 Q5D Derivation and Characterization of Cell Substrates Used for Production of Biotechnological/Biological Products 375 Mark Plavsic
- 14 Conduct of Risk Assessments: An Integral Part of Compliance with ICH Q5A and ICH Q5D 395 Raymond W. Nims
- 15 ICH Q5E Comparability of Biotechnological/Biological Products Subject to Changes in Their Manufacturing Processes: Summary and Analysis of ICH Q5E Guideline 409 Ramani R. Raghavan and Robert McCombie
- 16 ICH Q6A Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances 433 David Elder
- 17 ICH Q6B Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products 467 Scott R. Rudge and Raymond W. Nims
- 18 Process-Related Impurities in Biopharmaceuticals: A Deeper Dive into ICH Q6B 487 Anil Raghani, Kim Li, Jeanine L. Bussiere, Joel P. Bercu, and Jinshu Qiu

DOCKE

DOCKET A L A R M



Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.