Contents

Commentary

RE-EMERGENCE OF CHIKUNGUNYA AND OTHER SCOURGES:
THE ROLE OF GLOBALIZATION AND CLIMATE CHANGE
Giovanni Rezza 315

Section I

Development, implementation and compliance monitoring
of the principles of good laboratory practice
Edited by Sergio Caroli and Dian Turnheim 319

Preface
Sergio Caroli and Dian Turnheim 321

OECD Working Group on Good Laboratory Practice 322

THE POINT OF VIEW OF MONITORING AND REGULATORY AUTHORITIES
Current state of the implementation of the OECD GLP principles in the
OECD member countries and non-member economies in light of the outcome
of the 1998-2002 pilot project of mutual joint visits
Dian Turnheim 327

Quest for harmonisation: differences and similarities in national programmes
for GLP monitoring. A senior inspector’s viewpoint
Theo Helder 331

Future issues including broadening the scope of the GLP principles
Francisca E. Liem and Mark J. Lehr 335

OECD principles of GLP: what is working and what needs work
Chidambaram T. Viswanathan 341

Implementation of the OECD principles of good laboratory practice in test facilities
complying with a quality system accredited to the ISO/IEC 17025 standard
Etty Feller 344
Critical aspects in implementing the OECD monograph No. 14 “The application of the principles of GLP to *in vitro* studies”

*Hedwig Beernaert, Anne-Marie Vanherle and Sophie Bertrand* 348

Relationship between receiving authorities and monitoring authorities. The EMEA experience

*Brendan James Cuddy* 357

Collaboration between monitoring authorities, regulatory authorities and test facilities on GLP principles provides confidence in data quality with an emphasis on sound science.

GLP: an example of a focused effort that paid off

*Betsy Grim and Thomas Steeger* 359

National GLP programmes and implication of regulatory authorities for pharmaceuticals, pesticides and other chemicals

*Nobumasa Nakashima* 363

**THE POINT OF VIEW OF TEST FACILITIES AND PRIVATE ASSOCIATIONS**

Good laboratory practice 30 years on: challenges for industry

*Mark Goodwin* 369

Implementation of the OECD GLP principles at test facilities in Japan

*Shinoi Sakata* 374

Risk-based assessment applied to QA GLP audits. How to fulfill regulatory requirements while making the best use of our common sense, knowledge, talents and resources?

*Alain Piton* 379

Critical aspects regarding the application of the GLP principles to new compounds such as biotechnology products

*Maria Mercede Brunetti* 385

International GLP: a critical reflection on the harmonized global GLP standard from a test facility viewpoint

*Kathrin Ertz and Martina Preu* 390

Differences in the interpretation of the GLP requirements by OECD monitoring authorities: the point of view from the pharmaceutical industry

*Raymond K. Lowing* 395

OECD and USA GLP applications

*Del W. Huntsinger* 403

Responsibilities of test facility management and sponsor in a GLP environment

*Rik Hendriks, Hilde Van Eynde and Werner Coussement* 407

Developments in consultancy and training in the GLP arena: 1980 to 2020. A personal view

*David Long* 409

**Section II**

**BOOK REVIEWS, NOTES AND COMMENTS**

Edited by *Federica Napolitani Cheyne* 419

**WHO PUBLICATIONS**

Edited by *Anna Maria Rossi* 428

**INDEXES OF THE VOLUME**

Author index 431

Tables of contents of the volume 433