

TECHNICAL REPORT

ASQ TR1 – 2012

BEST QUALITY PRACTICES FOR BIOMEDICAL RESEARCH IN DRUG DEVELOPMENT

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ASQ TR

Best Quality Practices for Biomedical Research in Drug Development

Foreword

This Technical Report was created by a working group from the Food, Drug and Cosmetic Division of the American Society for Quality.

Introduction

In the U.S. alone, about \$100 billion per year is spent on biomedical research. However, poor repeatability of biomedical research findings has become an increasing and serious issue.¹ There are often fundamental doubts about the credibility of research data leading to costly and often futile repetition of biomedical research studies. This is a waste of limited valuable resources that were better spent on finding answers for the many unmet medical needs that still exist today. Overall, there has been a significant decline of productivity in biomedical research over the last 15 years when comparing the number of new medicines to the amount of money spent in R&D.²

One of the root causes for the repeatability problem is the lack of a common quality standard for non-regulated biomedical research. Routine medical laboratories involved in patient care are covered by well-defined international quality standards (ISO 15189) and national laws (42 CFR 493). In pharmaceutical research and development, only the nonclinical (not involving humans) laboratory safety studies are governed by the Good Laboratory Practices (GLP) regulations (21 CFR 58). No other well-defined quality standards exist in the United States for so-called non-GLP laboratory research. Because of the rapid progress of biological sciences, non-GLP laboratory research (e.g., biomarker development, exploratory, mechanistic studies, etc.) has become increasingly critical for modern drug development.

Traditionally, non-regulated biomedical research has been considered off-limits for formal quality standards. Scientists in general regard their work as a highly intellectual activity where quality is knowledge and experience is an integral part of the scientific rigor that they apply. A longstanding tradition of quality control in science has been peer review of the results, but modern pharmaceutical research has become so complex that peer review has a limited value today.

¹ G. Naik. Scientists' elusive goal: Reproducing study results. The Wall Street Journal, December 2, 2011

² J. W. Scannell, A. Blanckley, H. Boldon, B. Warrington: Diagnosing the decline in pharmaceutical R&D efficiency, Nature Reviews – Drug Discovery, Vol 11, March 2012, page 191-200

The scope and sheer dimension of modern research is moving science out of the individual scientist's domain and into a globalized team space where standards, transparency, and repeatability have become key requirements. Scientific work that cannot be reproduced or independently verified by others is a waste of valuable, limited resources. Also, biomedical research generates intellectual property, which has become increasingly subject to internal and external scrutiny and is often challenged in litigations. The authenticity and integrity of scientific data underlying an intellectual property claim are therefore of utmost importance. To prove the authenticity and integrity of scientific data, studies and experiments should be conducted under controlled and verifiable conditions.

A common quality management system guidance for biomedical research in drug development will help ensure the validity and credibility of scientific data from different research institutions and facilitate the mutual acceptance of research results. It will help to cut back on unnecessary duplication of research work, make published research data more reliable and thereby increase the overall productivity of biomedical research benefitting patients worldwide who are desperately waiting for new effective and safe drugs to treat their diseases.³

1. Scope

This Technical Report identifies important quality management system elements for non-regulated biomedical research in drug development in order to ensure credibility of biomedical research results. This includes both large and small molecule discovery and non-clinical development that is not covered by GxP.

The target audience for this report is the scientific staff at institutions and companies involved in drug development. Compliance with applicable regulatory and safety requirements is not covered by this report.

2. Normative references

- A. World Health Organization Handbook: Quality Practices in basic Biomedical Research, 2006
- B. ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories
- C. BARQA Guidelines for Quality in Non-Regulated Scientific Research, 2006
- D. ICH Q2 Validation of Analytical Procedures: Text and Methodology
- E. US FDA 21 CFR Part 58 (2011) Good laboratory practices for non-clinical studies
- F. ICH Q9 Quality Risk Management
- G. ISO 9000:2005 Quality management fundamentals and vocabulary
- H. ISO/IEC Guide 99:2007 International vocabulary of metrology – basic and general concepts and associated terms (VIM)
- I. ISO 3534-2 (2006) Statistics – vocabulary and symbols – Part 2 applied statistics

³ Proposal for a National Quality Standard for Biomedical Research, R. Calabrese, U. Palm, Quality Digest 2008.