

# ANALYTICAL METHOD VALIDATION AND QUALITY ASSURANCE

ISABEL TAVERNIERS, ERIK VAN BOCKSTAELE, AND MARC DE LOOSE

*Institute for Agricultural and Fisheries Research (ILVO), Scientific Institute of the Flemish Community, Melle, Belgium*

## Contents

- 1 Introduction
- 2 Traceability and Measurement Uncertainty
  - 2.1 Introduction: Quality of Analytical Results
  - 2.2 Role of Method Validation in Traceability and MU
  - 2.3 Guidelines on Traceability and Uncertainty of Results
  - 2.4 Concept of Traceability
  - 2.5 Concept of MU
  - 2.6 Different Operational Definitions of MU
  - 2.7 Approaches to Establish MU
  - 2.8 Importance of Traceability and MU
  - 2.9 Summary
- 3 Method Validation and Quality Assurance
  - 3.1 Role of Method Validation in AQA
  - 3.2 Guidelines and Guidance on AQA
  - 3.3 Approaches for Evaluating Acceptable Methods of Analysis
  - 3.4 Method Performance Characteristics and Criteria Approach
  - 3.5 Analytical Quality Assurance
- 4 Summary
- References

## 1 INTRODUCTION

Credibility of analytical data has never caught the public's eye more than today. Rather than on the used techniques and methodologies themselves, attention is nowadays paid to the quality and reliability of the final results. This is influenced by

---

*Pharmaceutical Sciences Encyclopedia: Drug Discovery, Development, and Manufacturing*  
Edited by Shayne C. Gad  
Copyright © 2010 John Wiley & Sons, Inc.