The Drug Manufacturer's Guide to Site Master Files

Table of Contents

Introduction

History	5
Focus of Recent Update (PE 008-4)	7
Regulatory Requirements	9
Appendices	21

- A. Explanatory Notes on the Preparation of a Site Master File
- B. Explanatory Notes for Pharmaceutical Manufacturers on the Preparation of a Site Master File
- C. Sample Document: SMF Appendix 8 Equipment and Devices for Production and Quality Control
- D. Sample Site Master File

About the Author

Cornelia Wawretschek is a pharmaceutical technical assistant with GxP Services in Germany and a freelance consultant for quality assurance. Prior to her consulting work, she worked for Schering AG Berlin in its department of pharmaceuticals as an analyst, chemical development and quality assurance, responsible for GMP optimization, SOP systems, manufacturing documentation, preparation and execution of audits and inspections by authorities, training programs, qualification and validation.