Table of Contents

Introduction			
Taylor, J.	Qualified Person within the European Legislative Framework	11	
Duties and Responsibilities of the Qualified Person			
Burgess, C.	Legal and Professional Duties of the Qualified Person	16	
Janssen, I.	Certification by a Qualified Person and Batch Release with a Special Focus on Batch Release of Biological Products	26	
Podpetschnig-Fopp, E.	Handling of Out-of-Specification Test Results / Discretion of the Qualified Person in batch certification when a batch does not fully meet the requirements	36	
Janssen, I.	Delegating and Differentiating the Responsibility of a Qualified Person	47	
Van Schuerbeek, J.	Duties and Responsibilities of the Qualified Person in the Certification of Investigational Medicinal Products for Clinical Trials	55	
The Qualified Person and the FDA			
Renger, B.	"Qualified Person" according to § 49 Directive 2001/83/EC and the FDA	64	
Personal Skills of the Qualified Person			
Hosseiny, A.	Profiles and Skills of a Qualified Person in the Pharmaceutical Manufacturing	76	

Annexes

Renger, B.	Annex 1: European Compliance Academy (ECA) Advisory Board Establishes European Qualified Person Association	82
	Annex 2: Requirements in the EU Member States – Draft Document with the permission of the European Qualified Person Association	86
List of Authors (with postal addresses)		104
List of Manufacturers and Co	onsultants	105
Available issues of the German-language publication series pharma technologie journal'		125