

Contents

1	Introduction.....	1
	Terrence P. Tougas, Jolyon P. Mitchell, Beth Morgan, and Helen Strickland	
2	Current Approaches to APSD Measurements of OIPs Based on Inertial Impaction.....	15
	Jolyon P. Mitchell and Daryl L. Roberts	
3	Physical Causes of APSD Changes in Aerosols from OIPs and Their Impact on CI Measurements.....	57
	Helen Strickland, Beth Morgan, and Jolyon P. Mitchell	
4	Good Cascade Impactor Practices	83
	Jolyon P. Mitchell	
5	The AIM and EDA Concepts: Why They Are Needed and How They Fit Together.....	119
	Jolyon P. Mitchell and Terrence P. Tougas	
6	Product Life Cycle Approach to Cascade Impaction Measurements	135
	Richard Bauer, J. David Christopher, Volker Glaab, Svetlana A. Lyapustina, Jolyon P. Mitchell, and Terrence P. Tougas	
7	Theoretical Basis for the EDA Concept	151
	Terrence P. Tougas and Jolyon P. Mitchell	
8	Performance Characterization of EDA and Its Potential to Improve Decision Making in Product Batch Release.....	173
	J. David Christopher, Helen Strickland, Beth Morgan, Monisha Dey, Alan Silcock, Terrence P. Tougas, Jolyon P. Mitchell, and Svetlana A. Lyapustina	

9	Verification of the EDA Concept Through an Assessment of Theoretical Failure Modes, Failure Mode Analysis, and Case Studies with Real Data	251
	Helen Strickland, Beth Morgan, J. David Christopher, Volker Glaab, Adrian Goodey, Keyur Joshi, Lei Mao, and Jolyon P. Mitchell	
10	Validating AIM-Based Instrumentation and Associated Measurement Techniques	283
	Mark Copley, Jolyon P. Mitchell, Mårten Svensson, J. David Christopher, Jorge Quiroz, Geoffrey Daniels, Melanie Hamilton, and Dave Russell-Graham	
11	The Regulatory and Compendial Pathways to Acceptance for AIM and EDA Concepts	359
	Steven C. Nichols, Jolyon P. Mitchell, Terrence P. Tougas, J. David Christopher, and Susan Holmes	
12	Applying the AIM Concept in Support of Developing Improved In Vitro–In Vivo Relationships for OIPs.....	375
	Jolyon P. Mitchell, Mark Copley, and Derek Solomon	
13	Future Directions for the AIM and EDA Concepts	401
	Terrence P. Tougas and Jolyon P. Mitchell	
14	Conclusions	411
	Terrence P. Tougas, Svetlana A. Lyapustina, and Jolyon P. Mitchell	
	Abbreviations.....	419
	About the Editors	425
	Symbols Used in Mathematical Expressions.....	427
	Index.....	433