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QUALITY BY DESIGN AND THE DESIGN SPACE; 9 APPLICATION OF QUALITY BY DESIGN AND RISK ASSESSMENT PRINCIPLES FOR THE DEVELOPMENT OF FORMULATION DESIGN SPACE; 10 APPLICATION OF QbD PRINCIPLES TO BIOLOGICS PRODUCT: FORMULATION AND PROCESS DEVELOPMENT; 11 QbD FOR RAW MATERIALS; 12 PAT TOOLS FOR BIOLOGICS: CONSIDERATIONS AND CHALLENGES; 13 EVOLUTION AND INTEGRATION OF QUALITY BY DESIGN AND PROCESS ANALYTICAL TECHNOLOGY; Index

Sommario/riassunto

The concepts, applications, and practical issues of Quality by Design Quality by Design (QbD) is a new framework currently being implemented by the FDA, as well as EU and Japanese regulatory agencies, to ensure better understanding of the process so as to yield a consistent and high-quality pharmaceutical product. QbD breaks from past approaches in assuming that drug quality cannot be tested into products; rather, it must be built into every step of the product creation process. Quality by Design: Perspectives and Case Studies presents the first systematic approach to QbD