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process design, process control, model development, process identification, and real-time optimization The chapter provides an overall description of optimization problem classes with a focus on problems with continuous variables It then describes where these problems arise in chemical engineering, along with illustrative examples This

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about the process and enhance the accessibility of such information later in the product lifecycle An integrated team approach to process validation that includes expertise from a variety of disciplines (eg, process engineering, industrial pharmacy, analytical chemistry, manufacturing, and quality assurance)

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second stage of pharmaceutical manufacturing and not the entire process Firms either sell APIs on the open market (merchant market ó) or use them to do their own final formulations manufacturing Firms that manufacture both APIs and final formulations will usually still buy and sell APIs on the merchant market

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Diagram developed from an original concept published by ISPE Source: ISPE Baseline® Pharmaceutical Engineering Guide, Volume 7 – Risk-Based Manufacture of Pharmaceutical Products, International Society for Pharmaceutical Engineering (ISPE), Second Edition, July 2017

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