

Process Understanding

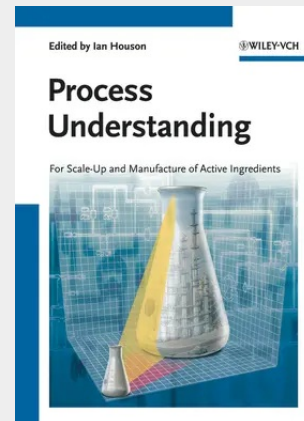
For Scale-Up and Manufacture of Active Ingredients

Process Understanding is the underpinning knowledge that allows the manufacture of chemical entities to be carried out routinely, robustly and to the required standard of quality. This area has gained in importance over the last few years, particularly due to the recent impetus from the USA's Food and Drug Administration. This book covers the multidisciplinary aspects required for successful process design, safety, modeling, scale-up, PAT, pilot plant implementation, plant design as well the rapidly expanding area of outsourcing.

In discussing what process understanding means to different disciplines and sectors throughout a product's life cycle, this handbook and ready reference reveals the factors important to the development and manufacture of chemicals. The book focuses on the fundamental scientific understanding necessary for a smoother technical transfer between the disciplines, leading to more effective and efficient process development and manufacturing. A range of case studies are used to exemplify and illustrate the main issues raised.

As a result, readers will appreciate that process understanding can deliver a real competitive advantage within the pharmaceuticals and fine chemicals industry. This book serves as an aid to meeting the stringent regulations required by the relevant authorities through demonstrable understanding of the underlying science.

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