

Preface

In the quest to develop new and better therapies to improve the quality of patients' lives, the pharmaceutical industry has relied on a combination of internal innovation and adaptation of external technologies to progress molecules to medicines. Today, melt extrusion stands as one of the several significant adaptations that have enabled therapies and produced novel drug products. The technology currently supports over a dozen commercial products and a range of novel compounds are currently in development using extrusion.

Having a lineage dating back to Archimedes, the concept of extrusion has progressed significantly over the centuries. The first modern designs for the twin screw extruder date back to the 1930s and with the development of the Erdmenger designs to achieve intermeshing and self-wiping in the 1950s, the technology has demonstrated utility and versatility. As an industrial process, the technology has supported a range of products, covering everything from space shuttle components to trash bags and wine corks. Serving as a low-cost production platform, the technology has penetrated a number of fields. Most recently, the technology has gained significant traction in the pharmaceutical space. Surprisingly to many, the technology traces its history back more than 30 years to the approval of Lacrisert, the first melt-extruded pharmaceutical product launched by Merck in 1981. Other major milestone products in the pharmaceutical space manufactured with hot-melt extrusion have included Rezulin, Kaletra, Nuvaring, and Ozerdex. Today, the technology is poised for an explosion as pharmaceutical applications extend into continuous processing, controlled release, and advance drug delivery devices.

It is also not surprising that interest in melt extrusion and the continued interest in solid dispersion technology has been supplemented by a wealth of publications. Within this space, *Melt Extrusion: Materials, Technology and Drug Product Design* has been developed to provide a definitive source on melt extrusion technology in the pharmaceutical arena. This text covers the history of and current technology for hot-melt extrusion. It also provides unique insight from excipient developers whose materials provide the basis for the production of solid dispersion products prepared using hot-melt extrusion. Fundamental overviews of formulation design and characterization are also presented and supplemented with unique industrial perspectives on modern applications of pharmaceutical hot-melt extrusion. The different viewpoints

expressed by the authors and their respective organizations highlights the versatility of extrusion technology and points to the future path of the technology within the industry. As editors we wish to acknowledge and thank the authors, for without their contributions and valuable insight this text could not have been possible. It is through their collective efforts that such a comprehensive and valuable text was created and it is hoped that this text will aid in the continued growth of pharmaceutical hot-melt extrusion.

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