

# Preface

The provision of effective healthcare to society is a global mandate for all healthcare professionals around the world. Discovering, developing, and manufacturing drug products are the traditional roles of the pharmaceutical industry that continue to deliver on its promises through innovative medicines every year. Based on the evidence for the efficacy of these pharmaceutical drug products, physicians are rationally prescribing the medicines to patients as part of their overall treatment expertise. As the medical and pharmaceutical sciences evolve, society and patient populations are evolving too. Since the majority of acute and chronic diseases can be treated or managed very effectively today, life expectancy increases by an average of three months every year. Even though this demographic development did not come as a surprise, we were not well-prepared for the very rapid growth of old, very old, multimorbid and frail patients that have substantially changed the characteristics of the patients appearing in the daily practice of primary and secondary health care providers. Along with the evolution of the new patient populations, the provider's related treatment plans have also changed. Effective drug therapy for most of the chronic diseases today is achieved through interventions at more than just one clinical target, which leads to the prescription of two or three different drug products simultaneously. The results are treatment plans for more than one chronic disease that often imply the prescription of more than five drugs. This situation of polypharmacy complicates the preparation of the treatment plan for the prescriber as well as for the patient who has to manage these various therapeutic schedules.

With these changes in patient populations and therapeutic complexity, new challenges in healthcare and healthcare provision occur that require collaborative efforts throughout the entire community of healthcare professionals. Leveraging the knowledge and expertise of each discipline and stakeholder, starting from the drug development through to the medicine in the hand of the patients executing the therapy successfully are crucial elements that provide important insight into the disciplinary aspects of healthcare provision. Since patient drug utilization trajectories span across several decades, they shift from acquiring a single disease and

appropriate medicine to managing a multiple disease and polypharmacy treatment concept in later life. These trajectories develop into very demanding medication management tasks for this patient population. The problem is compounded by the symptoms inherent in these patients: their capabilities and reserves might fade with multimorbidity and higher age. Successful healthcare delivery will have to address this issue and transition from the treatment of single diseases to the personalized treatment of the patient with her or his individual risk-benefit profile and achievable health outcomes. Yet, even with this realization, the clinical development of a new drug and the relevant regulatory guidance and requirements remain focused on a single disease intervention concept to establish drug product safety and efficacy. The major aspects of product quality still refer to the product itself, its manufacturability and stability within the targeted quality specifications.

Considering that each healthcare professional and stakeholder has one's own disciplinary challenge, other challenges are common between the disciplines and will most likely be solved by concerted and synergistic procedures. This multidisciplinary approach is stimulated by the different perspectives and solving approaches generated by the disciplinary view. The advances in technology, such as genome sequencing, information technology, digitalization, and others, are holding significant promises for applications in and across future healthcare delivery. This book intends to provide an opportunistic view on the challenge of developing and providing better drug products to the evolving patient populations being multimorbid and much older than previous ones. The distinguished multidisciplinary author panel covers the majority of disciplines involved in the development, manufacturing, prescribing, and monitoring of drug products to the respective patient populations. Their individual chapters discuss the disciplinary challenges, provide expertise and knowledge, as well as describe initiatives towards solutions and improvements. The diversity of expertise shared throughout the chapters should stimulate and encourage the reader to go beyond one's own area of expertise and enter interdisciplinary discussions. Especially as the challenge and the research in the area of drug therapy to older and multimorbid patients continue evolving, multidisciplinary collaborations and discussions will be necessary to find practical as well as efficient solutions.

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From Concept to Prescribing

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