unit doses undergoing the real conditions of the medication use process in hospitals and other healthcare settings. By now, reduction of dispensing errors and improvement of the compliance aid put a different perspective on the problem of repackaged drugs. To date, the pharmacist is advised to carry out its analysis of the risks.

Narayan, P. (2011). "Overview of drug product development." *Curr Protoc Pharmacol* Chapter 7: Unit 7.3.1–29.

The process for developing drug delivery systems has evolved over the past two decades with more scientific rigor, involving a collaboration of various fields, i.e., biology, chemistry, engineering, and pharmaceutics. Drug products, also commonly known in the pharmaceutical industry as formulations or "dosage forms," are used for administering the active pharmaceutical ingredient (API) for purposes of assessing safety in preclinical models, early- to late-phase human clinical trials, and for routine clinical/commercial use. This overview discusses approaches for creating small-molecule API dosage forms, from preformulation to commercial manufacturing.

Paudel, A. et al. (2015). "Raman spectroscopy in pharmaceutical product design." *Adv Drug Deliv Rev* 89:3–20.

Almost 100 years after the discovery of the Raman scattering phenomenon, related analytical techniques have emerged as important tools in biomedical sciences. Raman spectroscopy and microscopy are frontier, non-invasive analytical techniques amenable for diverse biomedical areas, ranging from molecular-based drug discovery, design of innovative drug delivery systems and quality control of finished products. This review presents concise accounts of various conventional and emerging Raman instrumentations including associated hyphenated tools of pharmaceutical interest. Moreover, relevant application cases of Raman spectroscopy in early and late phase pharmaceutical development, process analysis and micro-structural analysis of drug delivery systems are introduced. Finally, potential areas of future advancement and application of Raman spectroscopic techniques are discussed.

Razinkov, V. I. et al. (2015). "Accelerated formulation development of monoclonal antibodies (mAbs) and mAb-based modalities: Review of methods and tools." *J Biomol Screen* 20(4):468–483.

More therapeutic monoclonal antibodies and antibody-based modalities are in development today than ever before, and a faster and more accurate drug discovery process will ensure that the number of candidates coming to the biopharmaceutical pipeline will increase in the future. The process of drug product development and, specifically, formulation development is a critical bottleneck on the way from candidate selection to fully commercialized medicines. This article reviews the latest advances in methods of formulation screening, which allow not only the high-throughput selection of the most suitable formulation but also the prediction of stability properties under manufacturing and long-term storage conditions. We describe how the combination of automation technologies and high-throughput assays creates the opportunity to streamline the formulation development process starting from early preformulation screening through to commercial formulation development. The application of quality by design (QbD) concepts and modern statistical tools are also shown here to be very effective in accelerated formulation development of both typical antibodies and complex modalities derived from them.