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## New drug development and problem-solving in the pharmaceutical industry

**Satinder Ahuja**

Ahuja Consulting, USA

New drug development may take as many as nine years and requires input from medicinal chemistry, analytical chemistry, chemical development, pharmaceuticals, pharmacology, toxicology, manufacturing, marketing, and regulatory departments. The inputs from Analytical R&D are important for all of these operations because they can make the difference between slow and fast development. Drug discovery is generally initiated with the synthesis of a new chemical entity (NCE) based on combinatorial chemistry, or drugs are based on recombinant products. The molecular structure, including chirality, has to be confirmed. It is necessary to demonstrate the absence of any undesirable impurities, including enantiomers that may exhibit unusual pharmacologic or toxicologic activities (1–6). Finally, it is necessary to select an optimum dosage form, based on therapeutic and marketing needs. The selected dosage form has to meet GMP/GLP requirements. Discussion will focus on how various advances in chromatography and spectroscopy can help new drugs development and provide green chemistry-based solutions to a variety of problems encountered in the pharmaceutical industry. 1. S. Ahuja and S. Scypinski, *Handbook of Modern Pharmaceutical Analysis*, Elsevier, 2011. 2. S. Ahuja, *Chiral Separation Methods for Pharmaceuticals and Biotechnological Products*, Wiley, 2011. 3. S. Ahuja and M. Dong, *Handbook of Pharmaceutical Analysis by HPLC*, Elsevier, 2005. 4. S. Ahuja and K. Alsante, *Handbook of Isolation & Characterization of Impurities in Pharmaceuticals*, Elsevier, 2003. 5. S. Ahuja, *Handbook of Bioseparations*, Academic, 2000. 6. A. Staby, A. Rathore, and S. Ahuja, *Preparative Chromatography Separations of Proteins*, Wiley, 2017.

sandrine.ongeri@u-psud.fr