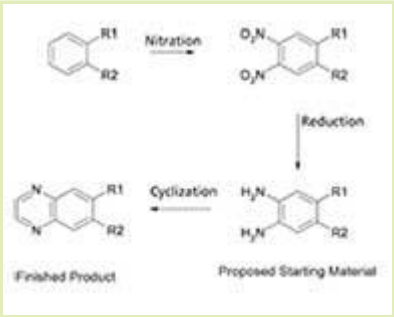
Designation of Regulatory Starting Materials in the Manufacturing of Drug Substances: Impact on ANDA Review Time

By **Barbara Scott Jun 21, 2016 7:00 am EDT**



The generic drug market has become increasingly competitive. The need for cheaper drugs in the American marketplace has driven the abbreviated new drug application (ANDA) submissions to staggering numbers, which in turn has lead to increasingly longer US Food and Drug Administration review and approval times. Section 3.2.S.2 of the Common Technical Document (CTD) is reviewed as part of the ANDA application and is intended to convey to the reviewer and field investigators all manufacturing process information, critical controls, and risk management related to the active pharmaceutical ingredient...