Strategic funding priorities in the pharmaceutical sciences allied to Quality by Design (QbD) and Process Analytical Technology (PAT); B. Aksu, T. de Beer, S. Folestad, J. Ketolainen, H.H. Lindén, J. Almeida Lopes, M. de Matas, W. Oostra, J. Rantanen, M. Weimer; European Journal of Pharmaceutical Sciences, 2012, 47, 402–405; DOI: 10.1016/j.ejps.2012.06.009

Abstract

Substantial changes in Pharmaceutical R&D strategy are required to address existing issues of low productivity, imminent patent expirations and pressures on pricing.

Moves towards personalized healthcare and increasing diversity in the nature of portfolios including the rise of biopharmaceuticals however have the potential to provide considerable challenges to the establishment of cost effective and robust supply chains.

To guarantee product quality and surety of supply for essential medicines it is necessary that manufacturing science keeps pace with advances in pharmaceutical R&D. In this position paper, the EUFEPS QbD and PAT Sciences network make recommendations that European industry, academia and health agencies focus attention on delivering step changes in science and technology in a number of key themes. These subject areas, all underpinned by the sciences allied to QbD and PAT, include product design and development for personalized healthcare, continuous-processing in pharmaceutical product manufacture, quantitative quality risk assessment for pharmaceutical development including life cycle management and the downstream processing of biopharmaceutical products. Plans are being established to gain commitment for inclusion of these themes into future funding priorities for the Innovative Medicines Initiative (IMI).