

Nigel Langley Abstract

Novel Excipient Innovation in Drug Development

Excipient innovation is becoming increasingly important as the current available pharmaceutical excipients will not be able to adequately address formulation and manufacturing challenges in drug development in the future. Formulation challenges include the anticipated increase in poorly water soluble, poorly permeable and bitter tasting active pharmaceutical ingredients (APIs) as well as the inherent instability of biologics drug products. Excipient innovation will also be critical in order to improve drug product manufacturing processes such as continuous manufacturing and new technologies such as 3 D printing.

This presentation will define the types of novel excipients and will describe some examples. The current regulatory landscape for the adoption of novel excipients in drug development will be reviewed and challenged. The presentation will conclude by providing an update on how the pharmaceutical Industry is aiming to accelerate excipient innovation by engaging with the FDA to define a more appropriate regulatory pathway in the future; a joint initiative by the IQ Pharmaceutical Consortium and IPEC Americas.