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Nigel Langley

BASF, USA

The need for excipient innovation in drug formulation development

Formulation challenges have increased over the last 10 years as more complex drug candidate molecules have been discovered. It is estimated that between 70-90% of new active pharmaceutical ingredients (APIs) are poorly water soluble with a significant portion also being poorly permeable. Another trend has seen an increase in bitter APIs where taste- masking is needed for patient compliance, especially in the case of pediatric and geriatric patients. This presentation will explore the ability of novel excipients in helping to meet the formulation challenges presented by APIs with poor solubility and bitter taste. Examples of novel excipients will be given and the utility of Soluplus® and Kollicoat Smartseal® highlighted. 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.

Biography

Nigel Langley, Director Technical Service and Scientific Affairs–BASF Pharma Solutions, provides technical support to the pharmaceutical industry and helps solve drug development challenges with BASF's platform solutions. Prior to joining BASF, he worked for Croda Inc. as Technical Director of Health Care, responsible for product and application development for both dietary supplements and Pharmaceutical Excipients. He has also worked in Japan and England with Croda. He gained his Chemistry (Hons) degree and PhD (Liquid Crystals) from the University of Hull, (UK) and an MBA from Leeds University (UK). He has been a member of the Executive Committee at IPEC Americas since 2010 and is currently VC Makers and Users. He is also helping to lead the Novel excipient initiative in collaboration with the IQ Pharma Consortium. He is also active in the BioPhorum Operations Group (BPOG) and has 30 years' experience within the Pharmaceutical excipient industry.

nigel.langley@basf.com

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