FOR IMMEDIATE RELEASE

The Medicine Maker Hosts Revealing Discussion with Experts from IPEC-Americas on the Importance of Novel Excipients for Pharmaceuticals

New York, USA, March 23, 2022 – The Medicine Maker brought together a panel of leading experts from IPEC-Americas to discuss the need for novel excipients in the pharmaceutical industry and how the FDA CDER's Novel Excipient Review Pilot Program could help influence the design of more optimized medicines for patients.

"Setting the Course for Novel Excipients" saw the panel discuss the unmet needs and challenges in drug formulation and how novel excipients can help – from improving solubility and bioavailability to preventing agglomeration, masking taste, and improving manufacturability. In the discussion, Nigel Langley, Chair of IPEC-Americas, explains, "It's important to consider that many of the excipients that formulators currently use were developed more than 50 years ago – and often weren't developed specifically for the pharmaceutical industry, so formulators don't necessarily have excipients designed specifically for the challenges they face. At the same time, drug modalities have been accelerating, with advances in different therapies. At IPEC-Americas, we feel that excipient use lags behind need."

Announced in 2021, the FDA CDER's Novel Excipient Review Pilot Program is a step in the right direction, helping to encourage pharma manufacturers to use novel excipients. Currently, there is no independent review pathway anywhere in the world for a novel excipient. The pilot program is the first of its kind and will allow excipient manufacturers to obtain FDA review of certain novel excipients prior to their use in drug formulations. IPEC has spent years advocating for ways to break down the hurdles associated with novel excipients.

Priscilla Zawislak, Past Chair of IPEC-Americas, says in the discussion, "If this pilot is successful – and we have every expectation that it will be – I hope that future expansion will incentivize companies to develop more novel excipients and encourage pharma companies to consider using them."

The expert panel from IPEC-Americas included:

- Kathy Ulman, President and owner of KLU Consulting, and Vice Chair of the Regulatory Affairs Committee at IPEC-Americas
- Nigel Langley, Global Technology Director for BASF and current Chair of IPEC-Americas
- Meera Raghuram, Director for Regulatory and Sustainability at Lubrizol, and Chair of IPEC-Americas Regulatory Affairs Committee
- Dave Schoneker, President and owner of Black Diamond Regulatory Consulting, and one of the original founders of IPEC-Americas.
- Priscilla Zawislak, Global Regulatory Affairs Advocacy Manager at International Flavours and Fragrances (IFF), and da Past Chair of IPEC-Americas

Stephanie Sutton, Editor of The Medicine Maker and moderator of the roundtable, says, "It's fantastic to see progress finally being made on the issue of novel excipients. Novel excipients could lead to more optimized drug formulations for patients. I'm proud and honored to have had the opportunity to discuss the importance of this topic with experts from IPEC-Americas."

Langley commented, “IPEC-Americas is really happy to be involved in interviews like this so that it can help enhance people’s understanding of how essential novel excipients are to drug development and why the FDA Novel Excipient Pilot Program is so important to spur innovation across the industry!”

The video of the full panel discussion can be viewed here.

You can also read an article based on the discussion in The Medicine Maker here.

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About IPEC-Americas

IPEC-Americas is a U.S. trade association whose members include excipient producers, distributors, and finished drug manufacturers, as well as companies and individuals that supply other specialized services to industry segments. Over 80 U.S. companies are IPEC-Americas members. IPEC-Americas brings together diverse stakeholders that share a common objective: Safe and effective production and use of excipients.

https://ipecamericas.org

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