



## USP International Excipient Workshop

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### PRESENTATION ABSTRACT

Title: Excipient Innovation, Classification, and Regulatory Acceptance

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Abstract: Excipient innovation for functionality and better drug delivery is one of the drivers of recent advances in medicine. Innovation of synthetic polymer excipients has been the hall mark of early drug development. Polymerization of vinylpyrrolidone to polyvinylpyrrolidone was patented in 1939. The mechanism of terminating polymerization of polyvinylpyrrolidone followed by spray drying and roller-drying led to Povidone NF grades of diverse molecular weights, properties and functional characteristics to enable their use in a variety of dosage forms, i.e., solid oral, injectable, topical etc. Popcorn or proliferative polymerization of polyvinylpyrrolidone resulted in cross-linked Povidone e.g., Crospovidone NF, a super tablet disintegrant.

Historically, innovation has resulted in various types of excipients, i.e., established chemical and natural excipients; mixed and co-processed excipients; and novel excipients. General regulatory review process and requirements for excipients use in drugs is presented. Novel excipient safety evaluation requirements are elaborated. Regulatory considerations for use of new and novel excipients are discussed. Discussion on how various pharmacopeia make a decision on inclusion (or exclusion) of an excipient in the monograph and the relevance of monograph status to the user industry will be discussed. Novel excipient use in drug products and regulatory acceptance is especially challenging despite their superior and unique functionality, primarily from safety perspective. The IPEC-Americas Safety Evaluation procedure for novel excipient review by FDA is described briefly focusing on the collaborative process and the outcome of the first novel excipient review under this program.