

USP Excipients Stakeholder Forum
Wednesday, November 13, 2019

General Chapter <1059> *Excipient Performance Updates*

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<1059> Excipient Performance –Update



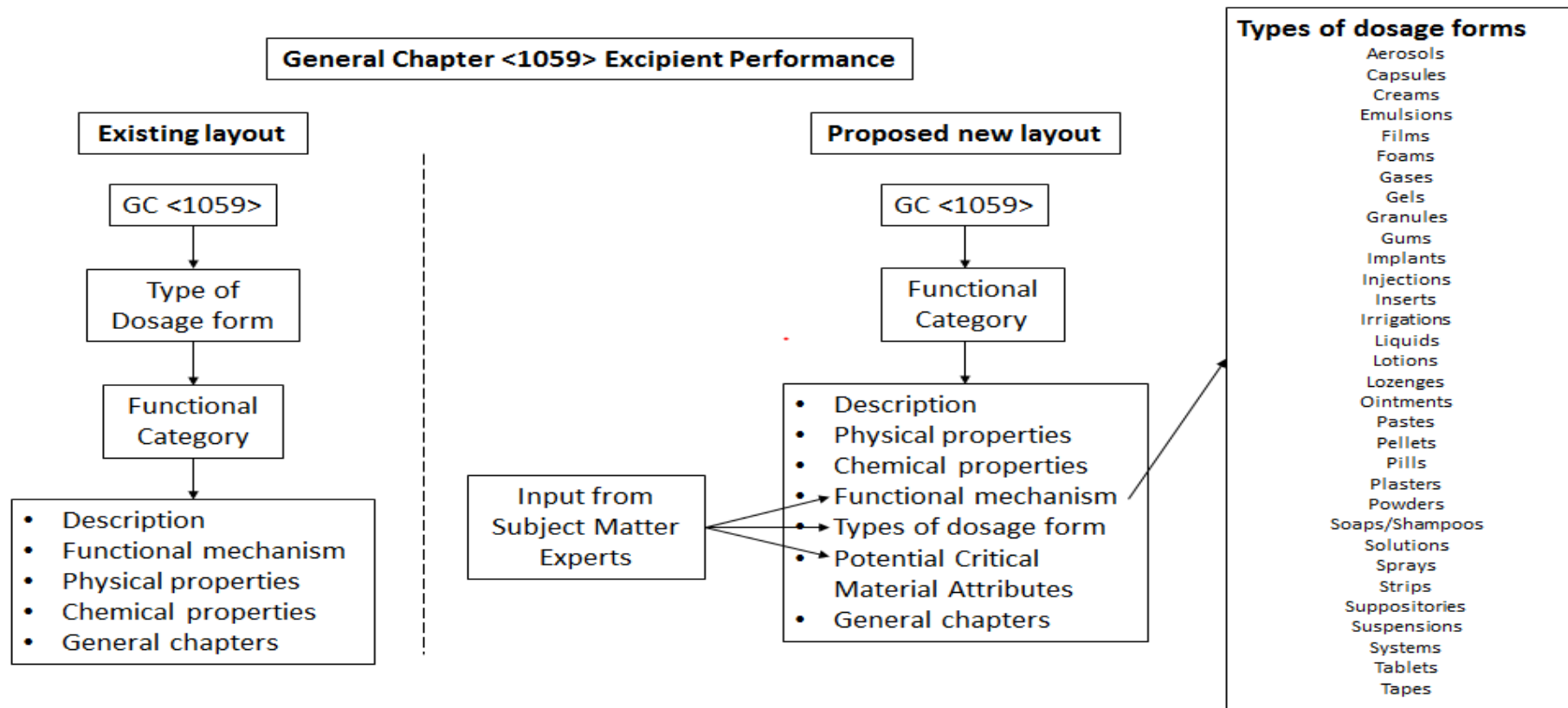
Updating <1059> was identified as a key tactic of the Excipients Strategy. The area of focus for the revision included:

- ▶ Addition of missing NF functional categories to <1059> and to the USP reference table “*USP and NF Excipients, Listed by Functional Category*” to include excipients used in specialized dosage forms according to <1151> Pharmaceutical Dosage Forms (for example biologics)
 - Currently, 48 functional categories in the USP reference table vs. 35 functional categories in <1059>
 - Total number of functional categories after revision to <1059> = 63
 - Examples of functional categories to be added:
 - Biodegradable polymer
 - Liposome forming agent
 - Viscosity lowering agent

<1059> Excipient Performance –Update (Cont'd)



- ▶ <1059> has a new structure



- ▶ The revision to <1059> and to corresponding section in “*USP and NF Excipients, Listed by Functional Category*” and *Description and Relative Solubility* will be published in PF46(1).

Thank You



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