

**MCC Overview**  
**for discussion of**  
**NIPTE Excipient Database**

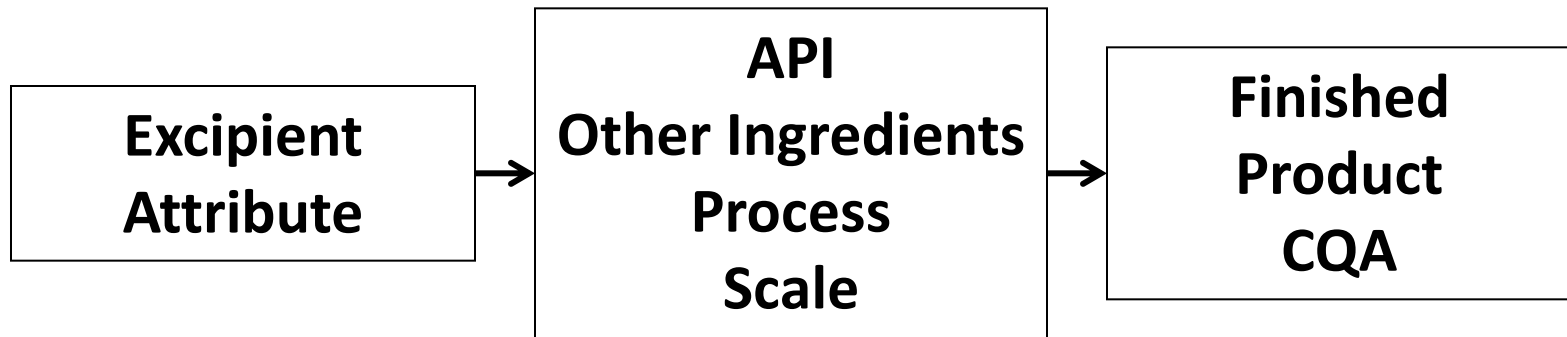
Brian Carlin

Director Open Innovation

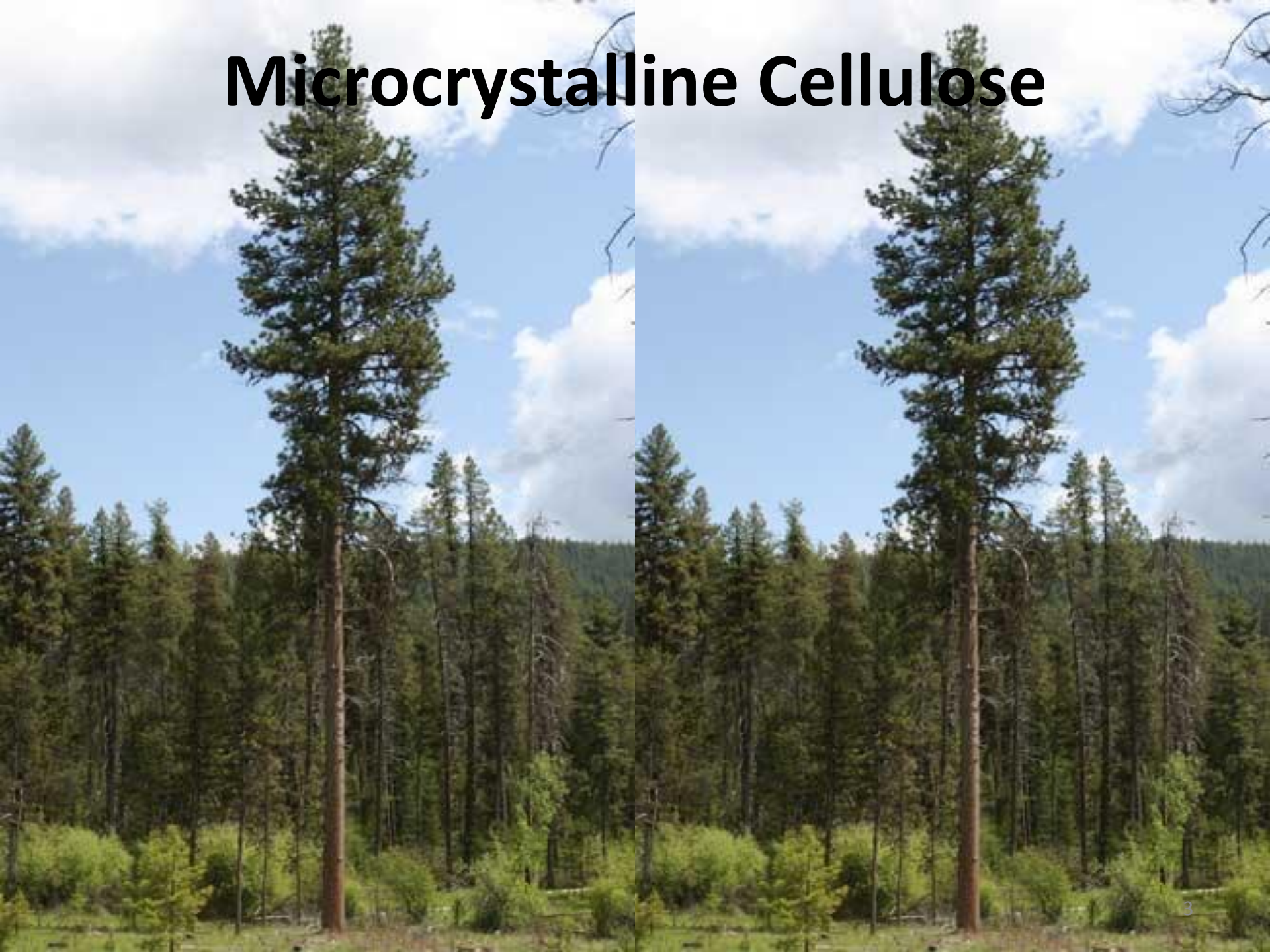
FMC BioPolymer

Chair IPEC QbD Committee

# Correlating Excipient Attributes to Finished Product Performance will be Application Specific!

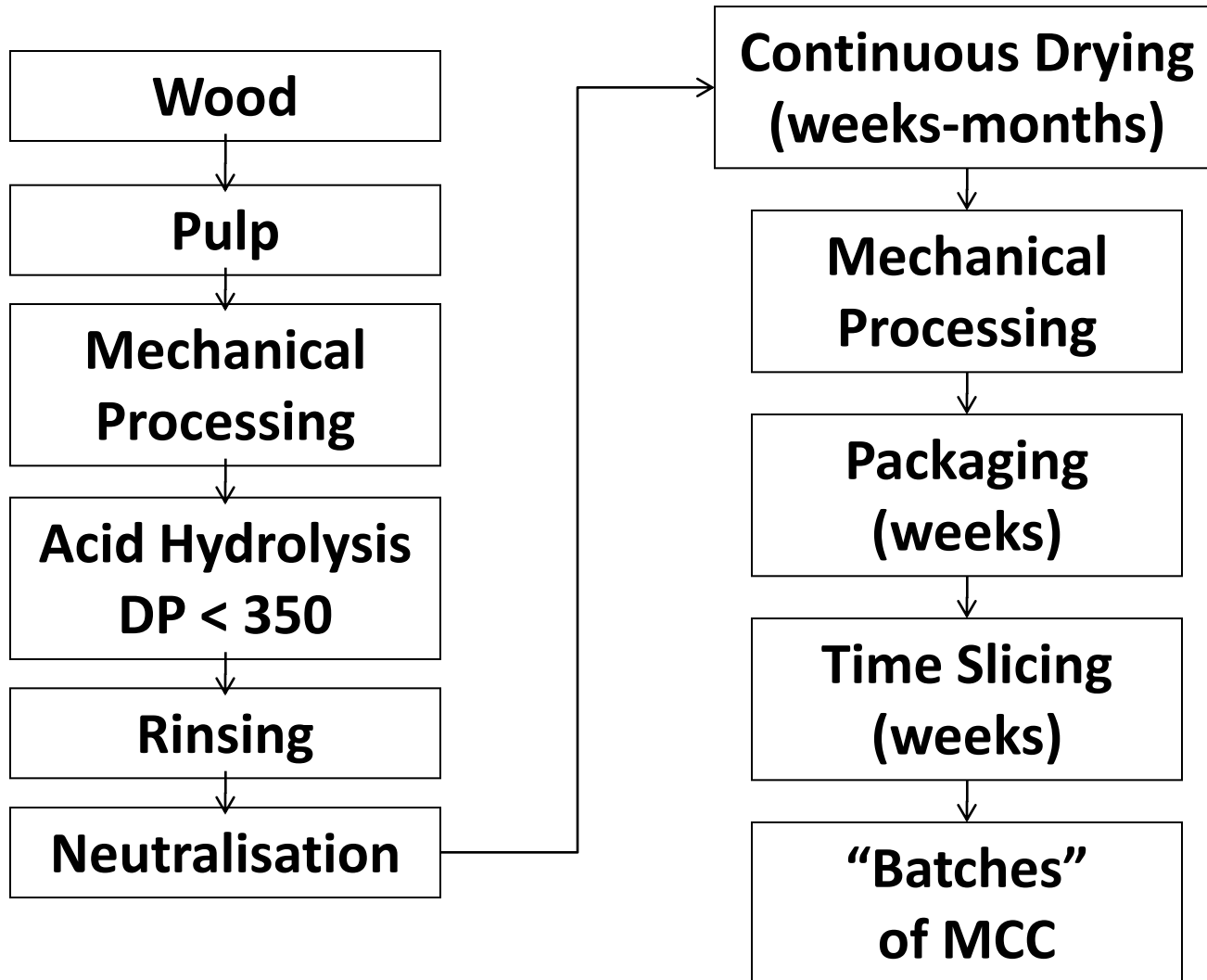


# Microcrystalline Cellulose

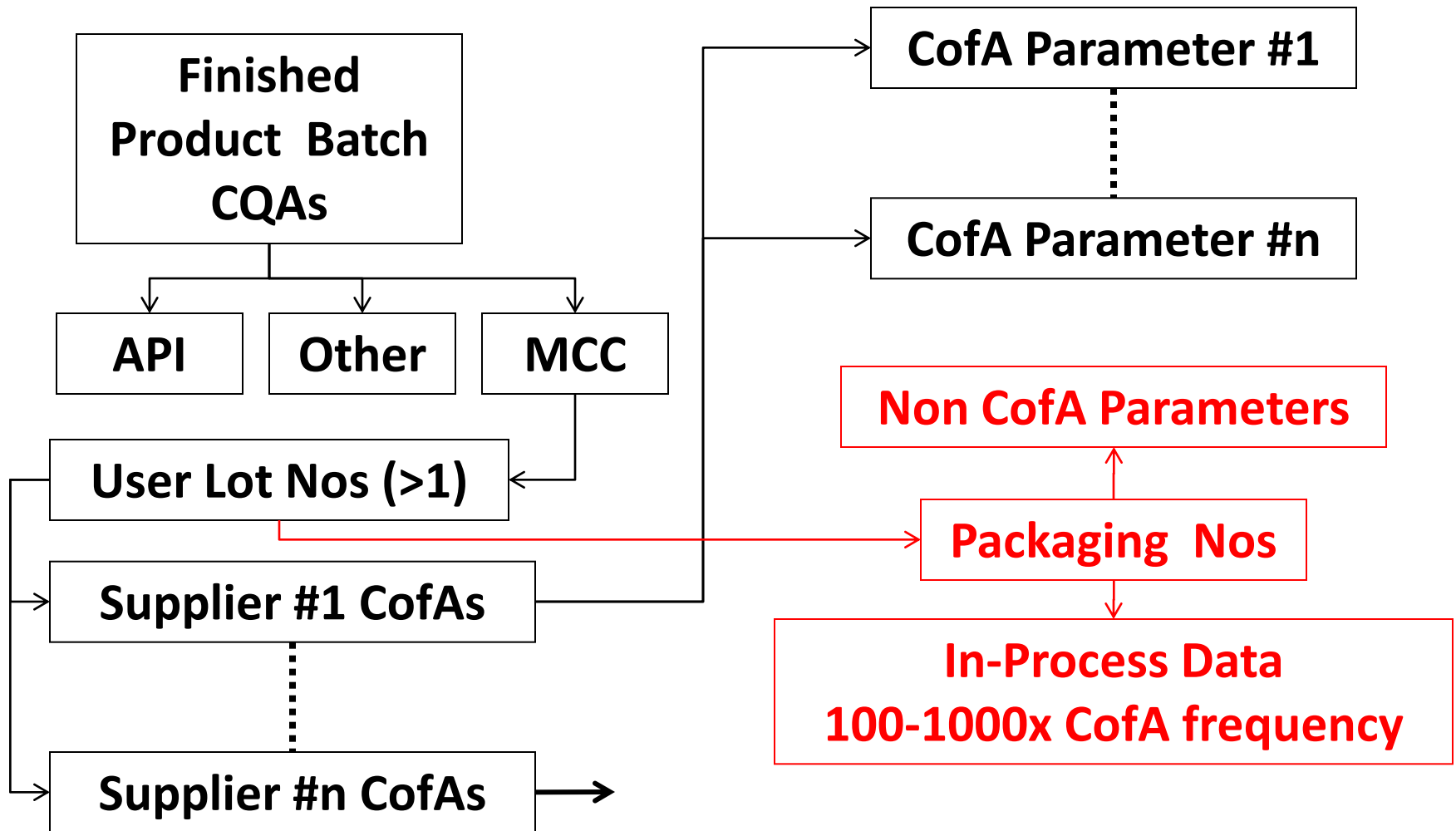


# Microcrystalline Cellulose Manufacture

## >100kT pa Continuous Production

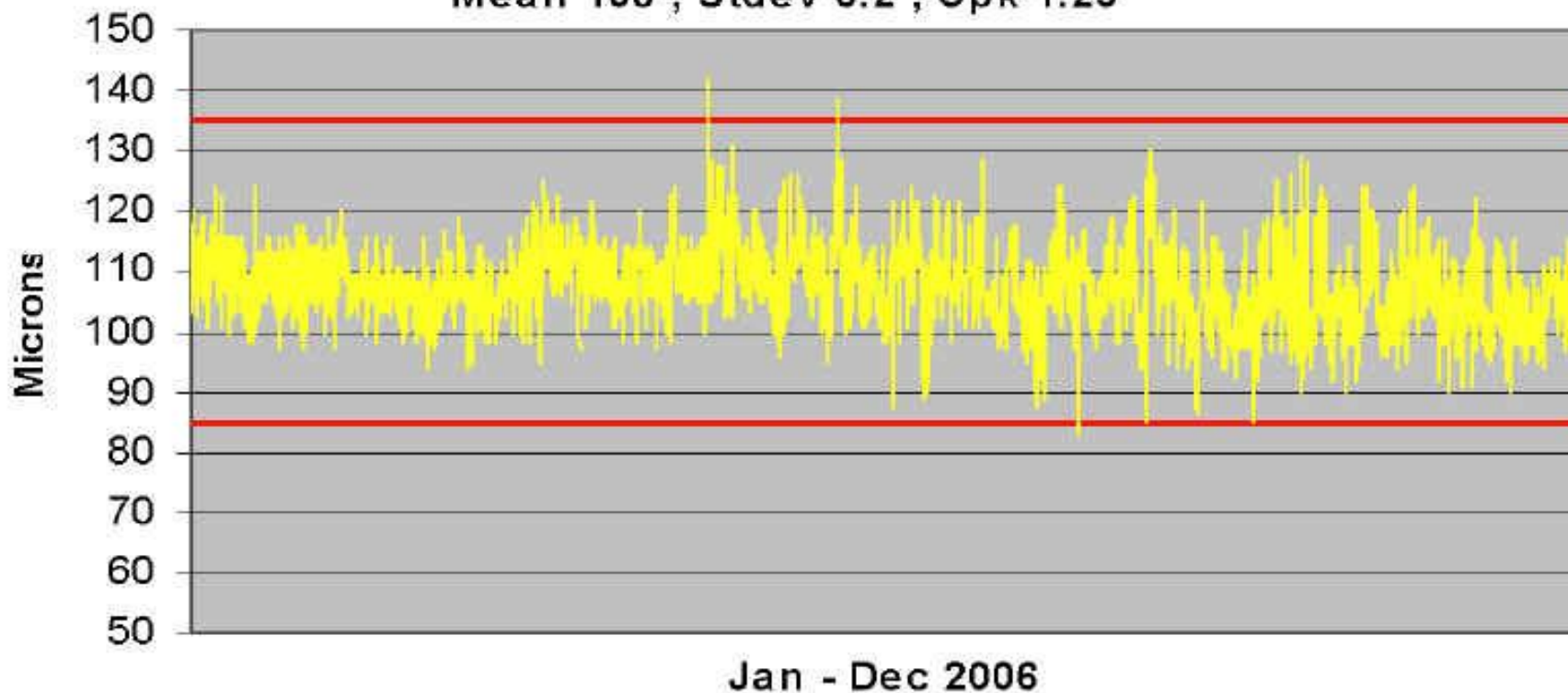


# Linking Finished Product CQAs to MCC Attributes



# Process capability

**PH102NF Average Particle Size**  
Mean 108 ; Stdev 6.2 ; Cpk 1.23



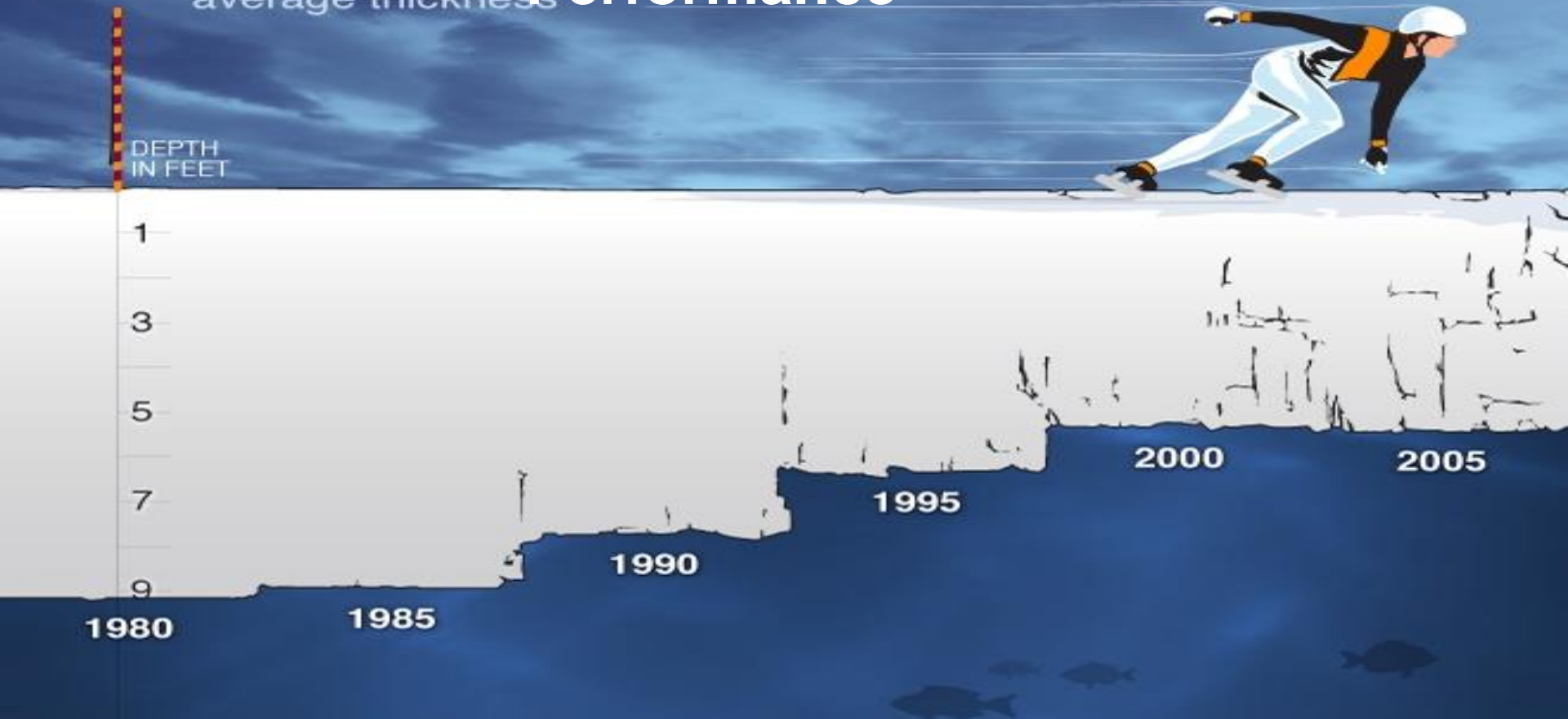
**Cpk value indicates PH102 manufacturing process is well-controlled**

**Courtesy of FMC BioPolymer**

[http://mediaserver.aapspharmaceutica.com/meetings/09AM/Slides/11.12.09\\_Thu/408%20B/0830/Bruno%20Hancock.pdf](http://mediaserver.aapspharmaceutica.com/meetings/09AM/Slides/11.12.09_Thu/408%20B/0830/Bruno%20Hancock.pdf)

# Thin Ice : Understanding Excipient Performance

Changes in fall Arctic sea ice average thickness



**Pharmaceutical Manufacturers Using Coefficient of Friction to Measure Thickness of Ice?**