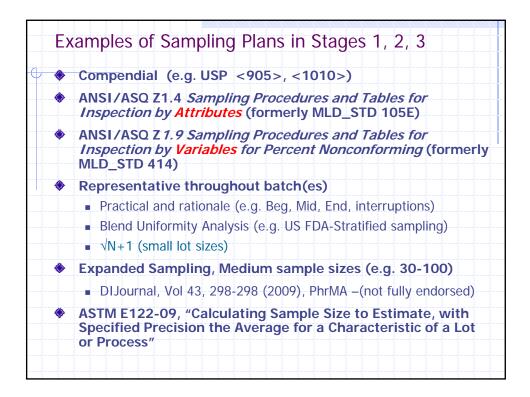
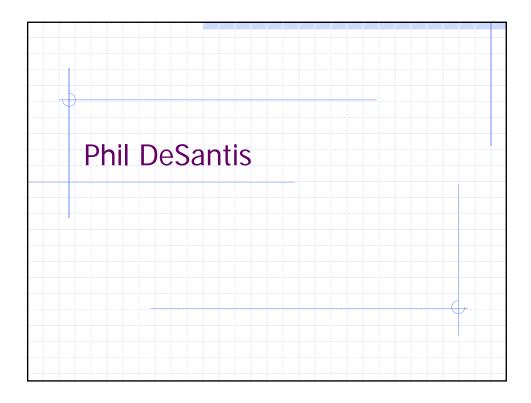


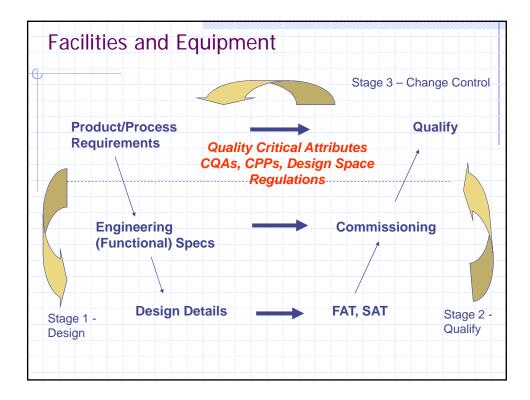
	Product Potency	Average	Range for evaluated lots	Standard deviation	Capability Index	Specification
Blend	25 mg/g	25.0	24.4- 25.5	0.04	1.24	95-105% (23.8- 26.3)
	2.5 mg	2.46	2.41-2.55	0.03	2.01	90-110%(2.25- 2.75)
Tablet	5.0 mg	4.92	4.83- 5.08	0.05	2.68	90-110% (4.5- 5.5)
	10.0 mg	10.0	9.7- 10.5	0.10	1.69	90-110% (9.0-11.0)
he Pro	ocess Ca 1.67 whi	apability i ch are typ		s of Tablets ong capat	s (all three	strengths) are s. Blends of

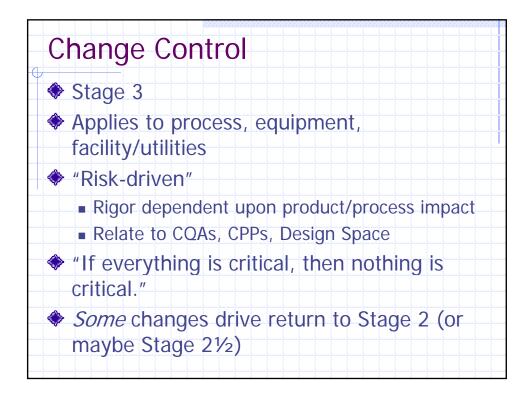


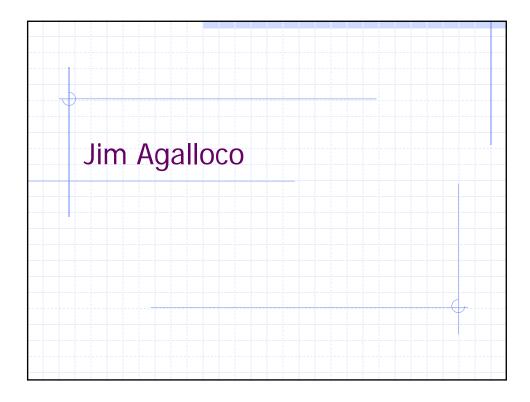
) Dth	ner References
	ASTM E2281-08(a) Standard Practice for Process and Measurement Capability Indices (Stage 3)- Describes CpK and PpK
	ASTM E2709-09 "Demonstrating Capability to Comply with a Lot Acceptance Procedure" - Using statistics for setting multi- stage specifications
	ASTM E2334- Sample size and confidence; Sample size and fraction non-conforming.
	ASTM E2587- Statistical Process Control Charts (stage 3 and 2)
~ -	NIST Engineering Statistics Handbook
	http://www.itl.nist.gov/div898/handbook/



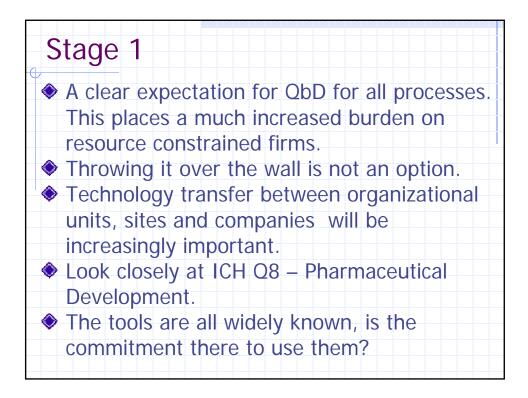








In	or out	of Scop	e?	
Activity	Stage I	Stage I	I Stage I	Π
Utilities				
Environments				
Computerized	с эст			
Clean / Prep				
Inspection				
Manual				
Sterilization				
Aseptic Processing	uru X A			
	ood	Poor	Not Applicable	



Current vs. QbD Approach to Pharmaceutical Development C. Chen & C. Moore, FDA - 20					
Current Approach	QbD Approach				
Quality assured by testing and inspection	Quality built into product & process by design, based on scientific understanding				
Data intensive submission – disjointed information without "big picture"	Knowledge rich submission – showing product knowledge & process understanding				
Specifications based on batch history	Specifications based on product performance requirements				
"Frozen process," discouraging changes	Flexible process within design space, allowing continuous improvement				
Focus on reproducibility – often avoiding or ignoring variation	Focus on robustness – understanding and controlling variation				

