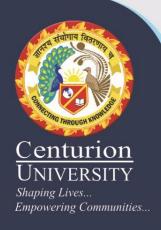
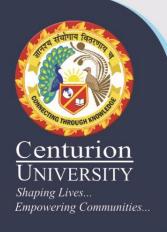


SESSION 5 CH-Q

HARAGOURI MISHRA
ASSITANT PROFESSOR
PHARMACEUTICAL ANALYSIS AND QUALITY ASSURANCE



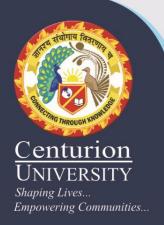
Q1A - Q1F Stability > Q1A(R2) Stability Testing of New Drug Substances and Products Stability Testing: Photostability Testing of New Drug Substances and Products > Q1B Stability Testing for New Dosage Forms > Q1C Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products > Q1D > Q1E **Evaluation of Stability Data** Stability Data Package for Registration Applications in Climatic Zones III and IV > Q1F Q2 Analytical Validation > Q2(R1) Validation of Analytical Procedures: Text and Methodology > Q2(R2)/Q14 EWG Analytical Procedure Development and Revision of Q2 (R1) Analytical Validation



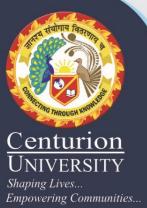
Q3E EWG

Q3A - Q3E Impurities Impurities in New Drug Substances Q3A(R2) Impurities in New Drug Products Q3B(R2) Maintenance of the Guideline for Residual Solvents Q3C(R6) Q3C(R8) Maintenance EWG Maintenance of the Guideline for Residual Solvents Q3D(R1) Guideline for Elemental Impurities Q3D(R2) Maintenance EWG Revision of Q3D(R1) for cutaneous and transdermal products Q3D training Implementation of Guideline for Elemental Impurities

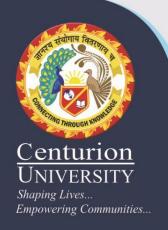
Impurity: Assessment and Control of Extractables and Leachables for Pharmaceuticals and Biologics



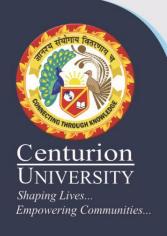
Q4A - Q4B Pharmacopoeias					
>	Q4A	Pharmacopoeial Harmonisation			
>	Q4B	Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions			
>	Q4B Annex 1	(R1) Residue on Ignition/Sulphated Ash General Chapter			
>	Q4B Annex 2	(R1) Test for Extractable Volume of Parenteral Preparations General Chapter			
>	Q4B Annex 3	(R1) Test for Particulate Contamination: Sub-Visible Particles General Chapter			
>	Q4B Annex 4	A(R1) Microbiological Examination of Non-Sterile Products: Microbial Enumeration Tests General Chapter			
>	Q4B Annex 4B(R1)	Microbiological Examination of Non-Sterile Products: Tests for Specified Micro-Organisms General Chapter			
>		Microbiological Examination of Non-Sterile Products: Acceptance Criteria for Pharmaceutical Preparation and Substances for Pharmaceutical Use General Chapter			
>	Q4B Annex 5	(R1) Disintegration Test General Chapter			
>	Q4B Annex 6	Uniformity of Dosage Units General Chapter			
>	Q4B Annex 7	(R2) Dissolution Test General Chapter			
>	Q4B Annex 8	(R1) Sterility Test General Chapter			
>	Q4B Annex 9	(R1) Tablet Friability General Chapter			
>	Q4B Annex 10	0(R1) Polyacrylamide Gel Electrophoresis General Chapter			
>	Q4B Annex 1	Capillary Electrophoresis General Chapter			
>	Q4B Annex 12	2 Analytical Sieving General Chapter			
>	Q4B Annex 13	3 Bulk Density and Tapped Density of Powders General Chapter			
>	Q4B Annex 1	4 Bacterial Endotoxins Test General Chapter			
>	Q4B FAQs	Frequently Asked Question			



Q5A - Q5E Qu	ality of Biotechnological Products					
> Q5A(R1)	Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin					
> Q5A(R2) E	EWG Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin					
> Q5B	Analysis of the Expression Construct in Cells Used for Production of r-DNA Derived Protein Products					
> Q5C	Quality of Biotechnological Products: Stability Testing of Biotechnological/Biological Products					
> Q5D	Derivation and Characterisation of Cell Substrates Used for Production of Biotechnological/Biological Products					
> Q5E	Comparability of Biotechnological/Biological Products Subject to Changes in their Manufacturing Proces					
Q6A- Q6B Specifications						
> Q6A	Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances					
> Q6B	Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products					
Q7 Good Manufacturing Practice						
> Q7	Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients					
> Q7 Q&As	Questions and Answers: Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients					
Q8 Pharmaceutical Development						
> Q8(R2)	Pharmaceutical Development					
> Q8/9/10	Q&As (R4) Q8/Q9/Q10 - Implementation					
Q9 Quality Risk Management						
> Q9	Quality Risk Management					
> Q9(R1) E	WG Quality Risk Management					
> Q8/9/10	Q&As (R4) Q8/Q9/Q10 - Implementation					



Q10 Pharmaceutical Quality System					
>	Q10	Pharmaceutical Quality System			
>	> Q8/9/10 Q&As (R4) Q8/Q9/Q10 - Implementation				
Q11 Development and Manufacture of Drug Substances					
>	Q11	Development and Manufacture of Drug Substances (Chemical Entities and Biotechnological/Biological Entities)			
>	Q11 Q&As	Questions & Answers: Selection and Justification of Starting Materials for the Manufacture of Drug Substances			
Q12 Lifecycle Management					
>	Q12	Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management			
>	Q12 IWG	Training on Regulatory and Technical Considerations for Pharmaceutical Product Lifecycle Management	t		
Q13	3 Continuous	s Manufacturing of Drug Substances and Drug Products	,		
>	Q13 EWG	Continuous Manufacturing of Drug Substances and Drug Products			
Q14	4 Analytical	Procedure Development	/		
>	> Q2(R2)/Q14 EWG Analytical Procedure Development and Revision of Q2 (R1) Analytical Validation				



THANK YOU