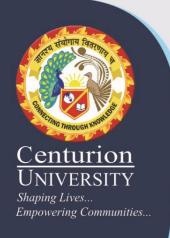


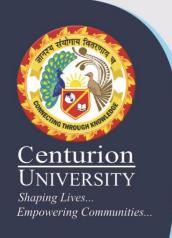
SESSION 3

HARAGOURI MISHRA
ASSITANT PROFESSOR
PHARMACEUTICAL ANALYSIS AND QUALITY ASSURANCE



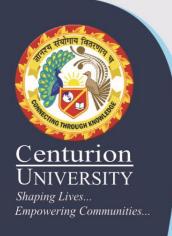
INTRODUCTION

- ICH stands for "International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use".
- ICH is a joint initiative involving both regulators and research based industry representatives of the EU, JAPAN and the US in scientific and technical discussions of the testing procedures require to assess and ensure the safety, quality and efficacy of medicines.



OBJECTIVES

- To increase international harmonisation of technical requirements to ensure that safe, effective and high quality medicines are developed and registered in the most efficient and cost effective manner.
- To eliminate unnecessary delay in the global development and availability of new medicines by maintaining quality, safety and efficacy to protect public health.

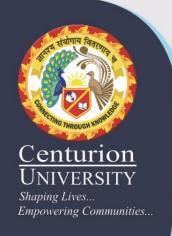


STRUCTURE OF ICH

- It's a joint initiative of regulators and industry as equal partners in scientific and technical discussion for the testing procedures which are required to ensure the safety, quality and efficacy of the medicine.
- The founder members of ICH are Europe, Japan and USA.
- ICH composed of six parties, three observers and IFPMA.

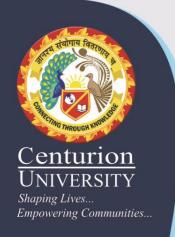
The six parties are:-

- 1. EU (European Union)
- 2. EFPIA (European Federation of Pharmaceutical Industry Association)
- 3. MHLW (Ministry of Health Labour Welfare, Japan)
- 4. JPMA (Japan Pharmaceutical Manufactures Association)
- 5. PhRMA (Pharmaceutical Research Manufactures of America)
- 6. FDA (Food and Drug Administration, USA)



The three observers are:-

- 1. WHO (World Health Organization)
- 2. EFTA (European Free Trade Association)
- 3. Health Canada Organization



ICH guidelines (Quality Guidelines)

Q1A - Q1F Stability

Q2 Analytical Validation

Q3A - Q3E Impurities

Q4A - Q4B Pharmacopoeias

Q5A - Q5E Quality of Biotechnological Products

Q6A-Q6B Specifications

Q7 Good Manufacturing Practice

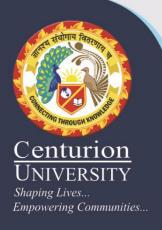
Q8 Pharmaceutical Development

Q9 Quality Risk Management

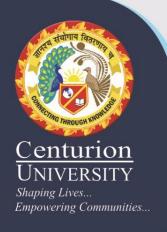
Q10 Pharmaceutical Quality System

Q11 Development and Manufacture of Drug Substances

Q12 Lifecycle



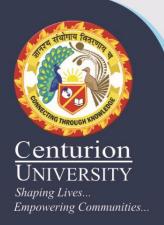
Q1A - Q1F Stability > Q1A(R2) Stability Testing of New Drug Substances and Products Stability Testing: Photostability Testing of New Drug Substances and Products > Q1B Stability Testing for New Dosage Forms > Q1C Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products > 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 Quality of Biotechnological Products



> Q5D	Products

> Q5E Comparability of Biotechnological/Biological Products Subject to Changes in their Manufacturing Process

Derivation and Characterisation of Cell Substrates Used for Production of Biotechnological/Biological

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

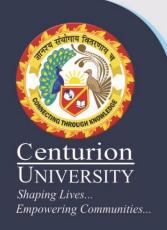
Q7 Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients
 Q7 Q&As Questions and Answers: Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients

Q8 Pharmaceutical Development

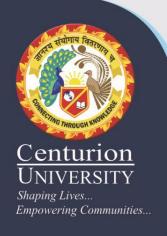
- > Q8(R2) Pharmaceutical Development
- > Q8/9/10 Q&As (R4) Q8/Q9/Q10 Implementation

Q9 Quality Risk Management

- > Q9 Quality Risk Management
- > Q9(R1) EWG Quality Risk Management
- > Q8/9/10 Q&As (R4) Q8/Q9/Q10 Implementation



Q10 Pharmaceutical Quality System					
> Q10	Pharmaceutical Quality System				
> Q8/9/10 Q8	> 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)	ıI			
> 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 Manageme	nt			
Q13 Continuou	s Manufacturing of Drug Substances and Drug Products	/			
> Q13 EWG	Continuous Manufacturing of Drug Substances and Drug Products				
Q14 Analytical Procedure Development					
> Q2(R2)/Q14 EWG Analytical Procedure Development and Revision of Q2 (R1) Analytical Validation					



THANK YOU