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# SESSION 3

# ICH

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# 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.



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# 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.



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# 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)



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The three observers are:-

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



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# **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**



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#### Q1A - Q1F Stability

- > Q1A(R2) Stability Testing of New Drug Substances and Products
- > Q1B Stability Testing : Photostability Testing of New Drug Substances and Products
- > Q1C Stability Testing for New Dosage Forms
- > Q1D Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products
- > Q1E Evaluation of Stability Data
- > Q1F Stability Data Package for Registration Applications in Climatic Zones III and IV

#### 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



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## Q3A - Q3E Impurities

- > Q3A(R2) Impurities in New Drug Substances
- > Q3B(R2) Impurities in New Drug Products
- > Q3C(R6) Maintenance of the Guideline for Residual Solvents
- > 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
- > Q3E EWG Impurity: Assessment and Control of Extractables and Leachables for Pharmaceuticals and Biologics





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## 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 4A\(R1\) 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](#)
- > [Q4B Annex 4C\(R1\) 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\(R1\) Polyacrylamide Gel Electrophoresis General Chapter](#)
- > [Q4B Annex 11 Capillary Electrophoresis General Chapter](#)
- > [Q4B Annex 12 Analytical Sieving General Chapter](#)
- > [Q4B Annex 13 Bulk Density and Tapped Density of Powders General Chapter](#)
- > [Q4B Annex 14 Bacterial Endotoxins Test General Chapter](#)
- > [Q4B FAQs Frequently Asked Question](#)



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## Q5A - Q5E Quality of Biotechnological Products ^

- > [Q5A\(R1\) Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin](#)
- > [Q5A\(R2\) 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 Process](#)

## 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](#)



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#### 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

#### Q13 Continuous 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



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**THANK YOU**