**ICH-International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use**

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| EFFICACY |
| E1 |  | The Extent of Population Exposure to Assess Clinical Safety for Drugs Intended for Long-term Treatment of Non-Life-Threatening Conditions |
| E2 | A | **Clinical Safety Data Management:** Definitions and Standards for Expedited Reporting |
|  | C | Periodic Benefit-Risk Evaluation Report (PBRER), Questions& Answers |
|  | D | Post-Approval Safety Data Management: Definitions and Standards for Expedited Reporting |
|  | E | Pharmacovigilance Planning |
|  | F | Development Safety Update Report, EXAMPLE COMMERCIAL DSUR, EXAMPLE NON - COMMERCIAL DSUR |
| E3 |  | Structure and Content of Clinical Study Reports and Questions & Answers  |
| E4 |  | Dose-Response Information to Support Drug Registration |
| E5 |  | Ethnic Factors in the Acceptability of foreign Clinical Data and Questions & Answers |
| E6 |  | **Guideline for Good Clinical Practice** |
| E7 |  | Studies in Support of Special Populations: Geriatrics and Questions & Answers |
| E8 |  | General Considerations for Clinical Trials |
| E9 |  | Statistical Principles for Clinical TrialsEstimands and Sensitivity Analysis in Clinical Trials |
| E10 |  | Choice of Control Group and Related Issues in Clinical Trials |
| E11 |  | Clinical Investigation of Medicinal Products in the Pediatric Population |
| E12 |  | Principles for Clinical Evaluation of New Antihypertensive Drugs |
| E14 |  | The Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs |
| E15 |  | Definitions for Genomic Biomarkers, Pharmacogenomics, Pharmacogenetics, Genomic Data and Sample Coding Categories |
| E16 |  | Biomarkers Related to Drug or Biotechnology Product Development: Context, Structure and Format of Qualification Submissions  |
| E17 |  | GENERAL PRINCIPLES FOR PLANNING AND DESIGN OFMULTI-REGIONAL CLINICAL TRIALS |
| E18 |  | GUIDELINE ON GENOMIC SAMPLING AND MANAGEMENT OF GENOMIC DATA |
| MULTIDISCIPLINARY |
| M3 |  | Guidance on Nonclinical Safety Studies for the Conduct of Human Clinical Trials and marketing authorization for Pharmaceuticals |
| M4 |  | Organisation of the Common Technical Document for the Registration of Pharmaceuticals for Human Use |
|  | E | The Common Technical Document for the Registration of Pharmaceuticals for Human Use EFFICACY – M4E(R1)Clinical Overview and Clinical Summary of Module 2Module 5 : Clinical Study Reports |
|  | E | Revision of M4E Guideline on Enhancing the Format and Structure of Benefit-Risk Information in ICH  |
|  | Q | The Common Technical Document for the Registration of Pharmaceuticals for Human Use:Quality – M4Q(R1)Quality Overall Summary of Module 2Module 3 : Quality |
|  | S | The Common Technical Document for the Registration of Pharmaceuticals for Human Use:Safety – M4S(R2)Nonclinical Overview and Nonclinical Summaries of Module 2 Organisation of Module 4 |
| M7  |  | Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk  |
| QUALITY  |
| Q1 | A | Stability Testing of New Drug Substances and Products |
|  | B | Stability Testing: Photostability Testing of New Drug Substances and Products |
|  | C | Stability Testing for New Dosage Forms Annex to the ICH Harmonised Tripartite Guideline on Stability Testing for New Drugs and Products |
|  | D | Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products |
|  | E | Evaluation for Stability Data |
| Q2 |  | Validation of Analytical Procedures: Text and Methodology |
| Q3 | A | Impurities In New Drug Substances |
|  | B | Impurities in New Drug Products |
|  | C | Impurities: Guideline for Residual Solvents |
|  | D | Guideline for Elemental Impurities |
| Q4 | B | Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions onResidue on Ignition/Sulphated Ash General Chapter Q4B  |
| Q5 | A | Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin |
|  | B | Quality of Biotechnological Products: Analysis of the Expression Construct in Cells used for Production of r-DNA Derived Protein Products |
|  | C | Quality of Biotechnological Products: Stability Testing of Biotechnological/Biological Products |
|  | D | Derivation and Characterisation of Cell Substrates Used for Production of Biotechnological/Biological Products |
|  | E | Comparability of Biotechnological/Biological Products Subject to Changes in their Manufacturing Process |
| Q6 | A | Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances |
|  | B | Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products |
| Q7 |  | Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients |
| Q8 |  | Pharmaceutical Development |
| Q9 |  | Quality Risk Management |
| Q10 |  | Pharmaceutical Quality System |
| Q11 |  | Development and Manufacture of Drug Substances (Chemical Entities and Biotechnological/Biological Entities) |
| SAFETY |
| S1 | A | Guideline on the Need for Carcinogenicity Studies of Pharmaceuticals |
|  | B | Testing for Carcinogenicity of Pharmaceuticals |
|  | C | Dose Selection for Carcinogenicity Studies of Pharmaceuticals |
| S2 |  | Guidance on Genotoxicity Testing and Data Interpretation for Pharmaceuticals Intended for Human Use |
| S3 | A | Note for Guidance on Toxicokinetics: The Assessment of Systemic Exposure in Toxicity Studies |
|  | B | Pharmacokinetics: Guidance for Repeated Dose Tissue Distribution Studies |
| S4 |  | Duration of Chronic Toxicity Testing in Animals(Rodent and Non Rodent Toxicity Testing) |
| S5 |  | Detection of Toxicity to Reproduction for Medicinal Products & Toxicity to Male Fertility |
| S6 |  | Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals |
| S7 | A | Safety Pharmacology Studies For Human Pharmaceuticals |
|  | B | The Non-Clinical Evaluation of the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) By Human Pharmaceuticals |
| S8 |  | Immunotoxicity Studies for Human Pharmaceuticals |
| S9 |  | Nonclinical Evaluation for Anticancer Pharmaceuticals |
| S10 |  | Photosafety Evaluation of Pharmaceuticals |