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Compressive Review on Role of ICH Guidelines in Registration of Pharmaceutical Products

Paramlal Ahirwar, Basant Khare*, Prateek Kumar Jain, Anushree Jain, Rubeena Khan, Bhupendra Thakur

Adina College of Pharmacy, ADINA Campus Rd, Lahdara, Sagar, MP, 470001

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*Address for Correspondence:
Mr. Basant Khare, Adina College Of Pharmacy, ADINA Campus Rd, Lahdara, Sagar, MP, 470001

E-Mail: Basant.Khare08@Gmail.Com

Abstract

The International Conference On Harmonization (ICH) Of Technical Requirements Is A Unique Project For Registration Of Pharmaceutical Products Which Are Intended For Human Use. This Brings Together The Regulatory Authorities Of Europe, Japan And United States And Experts From The Pharmaceutical Industry In The Three Regions To Discuss Scientific And Technical Aspects Of Product Registration.The Purpose Is To Make Recommendations On Ways To Achieve Greater Harmonization In The Interpretation And Application Of Technical Guidelines And Requirements For Product Registration In Order To Reduce Or Obviate The Need To Duplicate The Testing Carried Out During The Research And Development Of New Medicines.The Objective Of Such Harmonization Is A More Economical Use Of Human, Animal And Material Resources And The Elimination Of Unnecessary Delay In The Global Development And Availability Of New Medicines Whilst Maintaining Safe Guards On Quality, Safety And Efficacy And Regulatory Obligations To Protect Public Health. It Creates A Venue That Allows All Key Pharmaceutical Regulatory Authorities And Industry Stakeholders The Opportunity To Be More Actively Involved In Pharmaceutical Harmonization Work. It Aimed At The Standardization Of Requirements And Format Along With The Content Of Regulatory Documentation And Brings Down The Pressure On The Price Of Medicines By Enabling Greater Economies Of Scale And A Labelled Regulatory Playing Field. This Paper Is An Effort To Provide The Detailed Information About ICH Guidelines.

Keywords: International Conference On Harmonization, Product Registration, Medicines, Pharmaceutical

Introduction

The International Council For Harmonisation Of Technical Requirements For Pharmaceuticals For Human Use (ICH) [1] Is A Unique Project In Bringing Together The Regulatory Authorities And Pharmaceutical Industry To Discuss Scientific And Technical Aspects Of Drug Registration. Since Its Inception In 1990, ICH Has Gradually Evolved, To Respond To The Increasingly Global Face Of Drug Development. Harmonisation Leads To A More Sensible Use Of Human, Animal And Other Resources, The Elimination Of Unnecessary Delay In The Global Development, And Availability Of New Medicines While Maintaining Safeguards On Calibre, Welfare, Efficacy, And Regulatory Obligations To Protect Public Health. Harmonisation Can Be Achieved Through The Development Of ICH Guidelines Via A Process Of Scientific Consensus With Regulatory And Industry Experts Working Side-By-Side. The Basic Key To The Success Of This Process Is The Commitment Of The ICH Regulators To Implement The Final Guidelines. The Mission Of ICH Is To Make Recommendations Towards Achieving Greater Harmonisation In The Interpretation And Application Of Technical Guidelines And Requirements For Pharmaceutical Product Registration And The Maintenance Of Such Registrations. It Also Monitors And Update Harmonised Technical Requirements Leading To A Greater Mutual Acceptance Of Research And Development Data. ICH Helps To Facilitate The Adoption Of New Or Improved Technical Research And Development Approaches Which Update Or Replace Current Practices. It Helps To Develop Policy For The ICH Medical Dictionary For Regulatory Activities Terminology (Meddra) [2] Whilst Ensuring The Scientific And Technical Maintenance, Development And Dissemination Of Meddra As A Standardised Dictionary Which Facilitates The Sharing Of Regulatory Information Internationally For Medicinal Products Used By Humans. Its Objectives Are, Thus, As Follows:

- More Efficient And Effective Use Of Human, Animal And Material Resources
- Reduce The Development Times And Unwanted Delays Of Drugs
- End Duplicate Clinical Trials
- Facilitate The Concurrent Launch Of New Drug In Different Countries, Across All Three ICH Members
- Create Guidelines To Ensure That The Highest Level Of Safety, Quality And Efficacy Is Applied To Drug Development, With An Eye Towards Globalization.

Structure of ICH [3]

- ICH Assembly
- ICH Management Committee
- Meddra Management Committee
- ICH Secretariat

The ICH Assembly Works In Bringing Together All Members And Observers Of The ICH Association As The Overarching Governing Body Of ICH. It Takes Decisions On Particular Matters Such As On The Adoption Of ICH Guidelines,

Admission Of New Members And Observers, And The ICH Association's Work Plans And Budget. Member Representatives Appointed By The Assembly Are Supported By ICH Coordinators Who Represent Each Member To The ICH Secretariat On A Daily Basis. The ICH Management Committee (MC) Is That Body Which Supervises The Operational Aspects Of ICH On Behalf Of All Members, Including Administrative And Financial Matters And Oversight Of The Working Groups (Wgs).The Meddra Management Committee (MC) Has Responsibility For Providing Direction Of Meddra, ICH's Standardised Medical Terminology. The Meddra MC Is Responsible For Managing, Supporting, And Facilitating The Maintenance, Development, And Dissemination Of Meddra. The ICH Secretariat Is Responsible For Day-To-Day Management Of ICH, Coordinating ICH Activities As Well As Providing Support To The Assembly, The MC And Working Groups. The ICH Secretariat Also Provides Support To The Meddra MC. The ICH Secretariat Is Located In Geneva, The Development Of A New Harmonised Guideline And Its Implementation (The Formal ICH Procedure) Involves 5 Steps [4] (Figure1).

ICH Guidelines

Objective Of ICH Is To Increase International Harmonization Of Technical Requirements To Ensure That Safe, Effective, And Higher Quality Medicines Are Developed And Registered In The Most Efficient And Cost Effective Manner. ICH Has Developed Over 45 Harmonized Guidelines.There Are Four Major Categories Into Which The ICH Guidelines Are Divided. **Quality** Those Relating To Chemical And Pharmaceutical Quality Assurance. **Safety** Those Relating To In Vitro And In Vivo Preclinical Studies. **Efficacy** Those Relating To Clinical Studies In Human Subject [5].

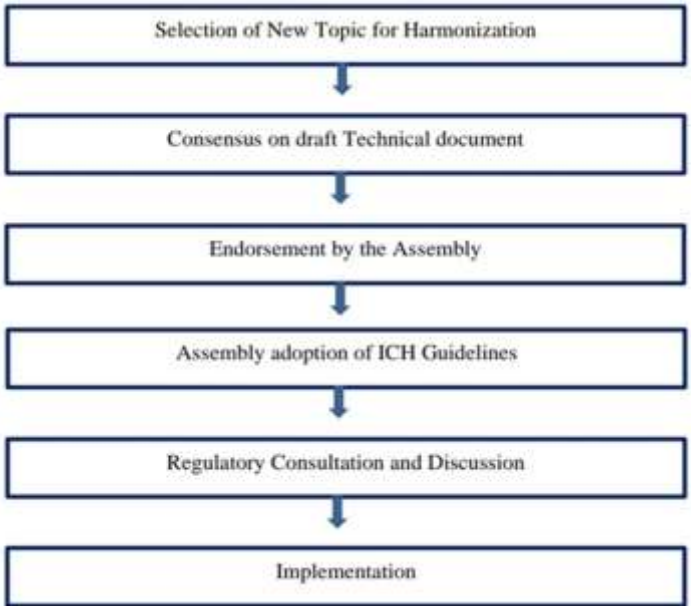

Figure 1: Flow Chart Showing ICH Harmonization Process

QUALITY	
Stability	Good manufacturing practice
Analytical validation	Pharmacopoeias
Pharmaceutical development	Specifications
Quality risk management	Impurities
Development and manufacture of drug substances	Pharmaceutical quality system

SAFETY	
Carcinogenicity studies	Biotechnology products
Pharmacology studies	Reproductive toxicology
Immunotoxicology studies	Photosafety evaluation
Nonclinical evaluation for anticancer pharmaceuticals	Toxicity testing
Genotoxicity studies	Toxicokinetics and Pharmacokinetics

EFFICACY	
Clinical safety	Clinical trials
Clinical study reports	Clinical evaluation by therapeutic category
Dose-response studies	Clinical evaluation
Ethnic factors	Pharmacogenomics
Good clinical practice	

MULTIDISCIPLINARY	
MedDRA terminology	Data elements and standards for drug
Electronic standards	Dictionaries
Nonclinical safety studies	Gene therapy
CTD and eCTD	Genotoxic impurities

Guidelines

The Present Study Is An Attempt To Provide Detailed Information About ICH On The Basis Of Literature.

Quality

Stability Testing

The Objective Of Stability Study [6] Is To Provide Proof On How The Quality Of Drug Substance Or Drug Product Changes With Time Under The Effect Of A Variety Of Environmental Factors Such As Temperature, Humidity And Light And Recommended Storage Conditions, Re-Test Periods And Shelf-Life To Be Established. The Choice Of Test Conditions Depends On Climatic Conditions In The Areas Of EU, JAPAN And USA.

Drug Substance

Information On The Stability Of The Drug Substance Is An Integral Part Of The Systematic Approach To Stability Evaluation. Stress Study Of The Drug Substance Can Help Identify The Degradation Products Which Can In Turn Help Establish The Degradation Pathways And Validate The Stability Indicating Power Of The Analytical Procedures Used [7]. The Nature Of The Stress Study Will Depend On The Individual Drug Substance And The Type Of Drug Product Used. Stress Study Is To Be Carried Out On A Single Batch Of The Substance. It Should Include The Effect Of Temperature, Humidity. The Study Should Also Evaluate The Susceptibility Of The Drug Substance To Hydrolysis Across A Wide Range Of Ph Values When In Solution Or Suspension. Photostability Study Should Be An Integral Part Of Stress Testing [8]. The Standard Conditions For Photo Stability Studies Are Described In ICH Q1B [9]. Data From Formal Stability Studies Should Be Provided On At Least Three Batches. The Batches Should Be Manufactured To A Pilot Scale By The Same Route As Used Earlier And Using A Method Of Manufacture And Procedure That Simulates The Final Process For Production Batches. The Stability Studies Should Be Conducted On The Drug Substance Packed In Final Packing. Specification Is A List Of Tests, Reference To Analytical Procedures And Proposed Acceptance Criteria, Which Are Addressed In ICH Guideline Q6A And Q6B. Additionally, Specification For Degradation Of Products In A Drug Substance Is Discussed In Q3A. Stability Studies Include Study Of Those Of Attributes Of The Drug Substance That Are Susceptible To Change During Storage And Are Likely To Affect Quality, Safety And Efficacy. The Study Should Cover, As Appropriate, The Physical, Chemical, Biological And Microbiological Attributes. Validated Stability-Indicating Analytical Procedures Should Be Applied Whether And To What Extent Replication Should Be Performed Will Depend On The Results From Validation Studies [10].

Study Frequency

For Long-Term Studies, Frequency Of Testing Should Be Sufficient To Establish The Stability Profile Of The Active Pharmaceutical Product (API). For Apis With A Proposed Re-Test Period Or Shelf-Life Of At Least 12 Months, The Frequency Of Testing At The Long-Term Storage Condition Should Normally Be In Every Three Months Over The First Year, In Every Six Months Over The Second Year, And Annually Thereafter Throughout The Proposed Re-Test Period Or Shelf-Life.At The Accelerated Storage Condition, A Minimum Of At Least Three Time Points, Including The Initial And Final Time Points (E.G. 0, 3 And 6 Months), From A Six Months Study Is Recommended. When A Testing At The Intermediate Storage Condition Is Required As A Result Of Significant Change At The Accelerated Storage Condition, A Minimum Of Four Time Points, Including The Initial And Final Time Points (E.G. 0, 6, 9 And 12 Months), From A 12-Month Study Is Recommended.

Storage Conditions

In General, An API Should Be Evaluated Under Storage Conditions (With Appropriate Tolerances) That Test Its Thermal Stability And, If Applicable, Its 91 Sensitivity To Moisture. The Storage Conditions And The Lengths Of Studies Chosen Should Be Sufficient To Cover Storage And Shipment. Storage Condition Tolerances Are Defined As The Acceptable Variations In Temperature And Relative Humidity Of Storage Facilities For Stability Studies. In The Rare Case Of Any API Of Non-Biological Origin Being Intended For Storage In A Freezer, The Re-Test Period Or Shelf-Life Should Be Based On The Long-Term Data Obtained At The Long-Term Storage Condition. In The Absence Of An Accelerated Storage Condition For Apis Intended To Be Stored In A Freezer, Testing On A Single Batch At An Elevated Temperature (E.G. 5°C± 3°C Or 25°C ±2°C Or 30°C ± 2°C) For An Appropriate Time Period Should Be Conducted To Address The Effect Of Short-Term Excursions Outside The Proposed Label Storage Condition, E.G. During Shipping Or Handling. Apis Intended For Storage Below -20 °C Should Be Treated On A Case-By-Case Basis.

Evaluation

The Purpose Of The Stability Study Is To Establish And Evaluating The Stability Information Including, As Appropriate, Results Of The Physical, Chemical, Biological And Microbiological Tests, A Re-Test Period Applicable To The Other Batches Of The API Manufactured Under Similar Circumstances. The Degree Of Discrepancy Of An Individual Batch Affects The Conviction That A Future Production Batch Will Remain Within Specification Throughout The Assigned Re-Test Period.

On-going Stability Studies

The Stability Of The API Should Be Monitored On The Basis Of Continuous And Appropriate Programme That Will Permit The Detection Of Any Stability Issue (E.G. Changes In Levels Of Degradation Products). The On-going Stability Programme Is Required To Monitor The API And To Determine That The API Remains, And Can Be Expected To Remain, Within Specifications Under The Storage Conditions Indicated On The Label, Within The Re-Test Period In All Future Batches. The Ongoing Stability Programme Should Be Described In A Written Protocol And The Results Are Presented In A Formal Report.

Table 1 General case

STUDY	STORAGE CONDITION	MINIMUM TIME PERIOD
Long-term	25 °C ± 2 °C/60% RH ± 5% RH or 30 °C ± 2 °C/65% RH ± 5% RH or 30 °C ± 2 °C/75% RH ± 5% RH	12 months
Intermediate	30 °C ± 2 °C/65% RH ± 5% RH	6 months
Accelerated	40 °C ± 2 °C/75% RH ± 5% RH	6 months

Table 2 Active pharmaceutical ingredients intended for storage in a refrigerator

STUDY	STORAGE CONDITION	MINIMUM TIME PERIOD
Long-term	5 °C ± 3 °C	12 months
Accelerated	25 °C ± 2 °C/60% RH ± 5% RH or 30 °C ± 2 °C/65% RH ± 5% RH or 30 °C ± 2 °C/75% RH ± 5% RH	6 months

Table 3 Active pharmaceutical ingredients intended for storage in a freezer

STUDY	STORAGE CONDITION	MINIMUM TIME PERIOD
Long-term	-20 °C ± 5 °C	12 months

The Protocol For An On-going Stability Programme Should Extend To The End Of The Re-Test Period And Shelf-Life And Should Include The Following Parameters:

- Number Of Batches And Batch Sizes, If Applicable;
- Relevant Physical, Chemical, Microbiological And Biological Test Methods;
- Acceptance Criteria;
- Reference To Test Methods;
- Description Of The Container Closure System(S);
- Testing Frequency;

Description Of The Storage Conditions (Standardized Conditions For Long-Term Testing As Described In These Guidelines, And Consistent With The API Labelling, Should Be Used); Other Applicable Parameters Specific To The API.

Validation

Validation Of An Analytical Procedure Is The Process By Which It Is Established, By Laboratory Studies So That The Performance Characteristics Of The Procedure Meet The Requirements For The Intended Analytical Applications. Method Validation Provides An Assurance Of Reliability During Normal Use, And Is Sometime Referred To As The Process For Providing Documented Evidence That The Method Does What It Is Intended To Do [11].

Repeatability

Repeatability Is Termed As The Use Of The Analytical Procedure Within A Laboratory Over A Hort Period Of Time Using The Same Analyst With The Same Equipment. It Should Be Evaluated Using A Minimum Of Nine Determinations Covering The Specified Range For The Procedure (I.E., Three Concentrations And Three Replicates Of Each Concentration Or Using A Minimum Of Six Determinations At 100% Of The Test Concentration)

Reproducibility

Reproducibility Indicates The Precision Between Laboratories (Collaborative Studies, Usually Applied To Standardisation Of Methodology). It Is Usually Demonstrated By Means Of An Inter-Laboratory Trial [12, 13].

• Specificity: Specificity Is The Ability To Measure Accurately And Specifically The Analyte Of Interest In The Presence Of Other Components That May Be Expected To Be Present In The.

• Linearity: It Is A Mathematical Relationship Or Function Which Means That It Can Be Graphically Represented As A Straight Line. It Can Be Established Initially By Visual Examination Of A Plot Of Signals As A Function Of Analyte Concentration Of Content. It Is Suggested To Have A Minimum Of Five Concentration Levels, Along With Certain Minimum Specified Ranges. For Performing The Assay, The Minimum Specified Range Is From 80% -120% Of The Target Concentration.

• Detection Limit And Quantitation Limit: The Detection Limit Refers To The Lowest Concentration Of An Analyte In A Sample That Can Be Detected But Cannot Quantify. The Quantitation Limit Refers To The Lowest Concentration Of An Analyte In A Sample That Can Be Determined With Acceptable Precision And Accuracy Under The Stated Operational Conditions Of The Analytical Procedures.

Good Manufacturing Practices

Good Manufacturing Practices (GMP) Is A Part Of Quality Assurance (QA) Which Ensures That Products Are Consistently Produced And Controlled In Accordance With The Quality Standards That Are Appropriate For Their Intended Use And As Required By The Marketing Authorization [14]. GMP Guidelines Provide Minimum Requirements For Pharmaceutical Or A Food Product Manufacturer To Assure That The Products Are Of High Quality And Do Not Pose Any Risk To The Consumer. Additionally, GMP Has Issued Guidelines For The Achievement Of Consistent Product Quality, With Interpretation And Individual Variations Being Accepted. GMP Implemented In The United States By The US FDA, Under Section 501(B) Of The 1938 Food, Drug, And Cosmetic Act (21 USCS § 351). The Regulations Use The Phrase "Current Good Manufacturing Practices" (Cgmp) And It Describes The Guidelines [15].

Pharmacopoeia

A Pharmacopoeia Is A Legally Binding Collection Of Standards And Quality Specifications For Medicines Used In A Country Or Region [16]. Within The Pharmacopoeia, A Quality Specification Is A Set Of Appropriate Tests That Will Confirm The Identity And Purity Of The Product, Ascertain The Strength (Or Amount) Of The Active Substance And, When Needed, The Performance Characteristics. Reference Substances That Are Used In Testing Help To Ensure The Quality, Strength And Purity Of The Drugs. A Pharmacopoeia Covers The Information Regarding The Pharmaceutical Starting Materials, Excipients, Intermediates And Finished Pharmaceutical Products (Fpps). Details Of General Requirements May Also Be Provided On Important Subjects Related To Drugs Quality, Such As Analytical Methods, Microbiological Purity, Dissolution Testing, Or Stability. The Modern Pharmacopoeia Points Out Certain Quality Specifications For Active Pharmaceutical Ingredients (Apis), Fpps And General Requirements. The Existence Of Such Specifications And Requirements Is Necessary For The Proper Functioning Or Regulatory Control Of Medicines Production [17].

Quality Guidelines

Table 2: Quality Guidelines

S.No.	Guidelines
1	**Q1A-Q1F Stability:** Q1A: 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
2	**Q2 Analytical validation:** Validation of analytical procedures
3	**Q3A-Q3D Impurities:** Q3A Impurities in new drug substances Q3B Impurities in new drug products Q3C Impurities: Guidelines for residual solvents Q3D Impurities: Guidelines for elemental impunities
4	**Q4A-Q4B Pharmacopeias:** Q4A: Pharmacopeial Harmonization Q4B Evaluation and recommendation of pharmacopeial texts for use In the ICH regions
5	**Q5A-Q5E Quality of biotechnological products:** Q5A Viral safety evaluation of biotechnology products derived from cell lines of human or animal origin Q5B Analysis of expression construct in cells used for production of r-DNA derived protein products Q5C Stability testing of biotechnological/ biological products Q5D Derivation and characterization of cell substrates used for production of biotechnological/ biological products Q5E comparability of biotechnlogical / biological products subject to changes in their manufacturing process
6	**Q6A-Q6B Specifications:** Q6A Test procedures and acceptance criteria for new drug substances and new drug products: Chemical substances Q6B Test procedures and acceptance criteria for biotechnological/ biological products
7	Q7 Good manufacturing practices for Active pharmaceutical ingredients
8	Q8 Pharmaceutical development
9	Q9 Quality risk management
10	Q10 Pharmaceutical quality system
11	Q11 Development and manufacture of drug substances (Chemical entities and biological entities)

2. Safety guidelines:

ICH has prepared a comprehensive set of safety guidelines to reveal potential risks like carcinogenicity, reprotoxicity and genotoxicity.

A recent finding has been a non-clinical testin schema for determining the QT interv prolongation liability.

Table 3: Safety Guidelines

S.No.	Guidelines
1	**S1A-S1C Carcinogenicity studies:** S1: Rodent carcinogenicity studies for human Pharmaceuticals S1A: Need for carcinogenicity studies of Pharmaceuticals S1B: Testing for carcinogenicity of Pharmaceuticals
2	**S2 Genotoxicity studies** S2 (R1) Guidance on genotoxicity testing and data interpretation for Pharmaceuticals intended for human use

3	**S3A-S3B Toxicokinetics and pharmacokinetics:** S3A note for guidance on toxicokinetics: The assessment of systemic exposure in toxicity studies S3B Pharmacokinetics: Guidance for repeated dose tissue distribution studies
4	**S4 Toxicity testing:** S4 Duration of chronic testing in animals (Rodent and non rodent toxicity testing)
5	**S5 Reproductive toxicology:** S5 Detection of toxicity to reproduction for medicinal products and toxicity to male fertility
6	**S6 Biotechnological products:** S6 Preclinical safety Evaluation of biotechnology derived Pharmaceuticals
7	**S7-S7B Pharmacology studies:** S7A Safety pharmacology studies for human Pharmaceuticals S7B The non clinical evaluation of the potential for delayed ventricular repolarization by human Pharmaceuticals
8	**S8 Immunological Studies:** S8 Immunotoxicity studies for human Pharmaceuticals.
9	**S9 Nonclinical evaluation for anti cancer Pharmaceuticals**
10	**S10 Photosafety evaluation of Pharmaceuticals**

3. Efficacy guidelines:

The Efficacy guidelines are concerned with the design, carrying, and safety and reporting of clinical trials. It also gives information related to novel types of medicines derived from biotechnological methods and the use of pharmacogenomics techniques to produce better targeted drug.

Table 4: Efficacy Guidelines

S.No	Guidelines
1	E1 Clinical safety for drugs used in long term treatment
2	E2A-E2F Pharmacovigilance
3	E3 Clinical study reports
4	E4 Dose response studies
5	E5 Ethnic factors
6	E6 Good clinical practice
7	E7 Clinical trials in geriatric population
8	E8 General Consideration for clinical trials
9	E9 Statistical principles for clinical trials
10	E10 choice of control group in clinical trials
11	E11 Clinical trials in paediatric population
12	E12 Clinical evaluation by therapeutic category
13	E14 Clinical evaluation
14	E15 Definitions in pharmacogenetics/ Pharmacogenomics
15	E16 Qualification of genomic biomarkers
16	E17 Multi regional clinical trails
17	E18 Genomic sampling methodologies

4. Multidisciplinary Guidelines:

These guidelines contains topics which are unique, and do not fit into one of the Quality, Safety and Efficacy guidelines category. *Multidisciplinary Guidelines* describes about Common Technical Document (CTD), medical terminology (MedDRA), and the development of Electronic Standards for the Transfer of Regulatory Information (ESTRI).

Table 5: Multidisciplinary Guidelines

S.No.	Guidelines
1	M1-MedDRA terminology :(Medical dictionery for regulatory activities)
2	M2 Electronic standerds
3	M3 Non clinical safety studies
4	M4 Common technical document
5	M5 Data elements and standers for drug dictionaries
6	M6 Gene therapy
7	M7 Genotoxic impurities
8	M8 Electronic common technical document (eCTD)

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8	M8 Electronic common technical document (eCTD)

Conclusion

The ICH Is A Major Global Undertaking To Affect The Harmonization Of Regulatory Requirements In The 3 Major Regions Involved. The Creation Of The ICH – The International Conference Of Harmonization, Was Fuelled By Trade Reasons, To Even Out The Competition Between Markets And End The Aforementioned Stagnation. ICH Was Created To Deliver Health Care Technology Providers A Common, Almost Global Regulatory Framework For Them To Develop Their Products. The ICH's Work Is Far From Over, As More And More Regulatory Scrutiny Is Demanded From Manufacturers And Investigators And More Pressure Is Applied To Pharmaceutical Companies To Increase Data Transparency, Who Look Up For ICH's Guidance.

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