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An Overview on ICH Guidelines: New Inclusions

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Abstract: *The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) plays a pivotal role in unifying global standards for pharmaceutical development, regulatory approval, and manufacturing. Among its extensive guidelines, the recent inclusions of ICH Q13 and Q14 mark significant advancements in the realm of continuous manufacturing and analytical procedure development. ICH Q13 addresses the increasing adoption of continuous manufacturing (CM) processes in the pharmaceutical industry. Unlike traditional batch manufacturing, CM allows for the ongoing production of pharmaceuticals, which can enhance efficiency, consistency, and scalability. This guideline provides a framework for the implementation of CM, focusing on the technical and regulatory considerations necessary for it adoption. ICH Q14 focuses on modernizing the development and validation of analytical procedures. Analytical methods are critical for ensuring the quality, safety, and efficacy of pharmaceutical products. Q14 aims to streamline the development process, enhance method robustness, and facilitate regulatory approval. The inclusion of ICH Q13 and Q14 represents a significant stride towards enhancing pharmaceutical manufacturing and analytical practices. ICH Q13 facilitates the transition to continuous manufacturing, promising greater efficiency and product consistency, while ICH Q14 modernizes analytical method development, ensuring robust and reliable procedures. Together, these guidelines reflect the ICH's commitment to fostering innovation, regulatory flexibility, and global harmonization in the pharmaceutical industry.*

Keywords: Analytical methods

I. INTRODUCTION

This guideline describes science and risk-based approaches for developing and maintaining analytical procedures suitable for the assessment of the quality of drug substances and drug products. The systematic approach suggested in ICH Q8 Pharmaceutical Development together with principles of ICH Q9 Quality Risk Management can also be applied to the development and lifecycle management of analytical procedures. When developing an analytical procedure, a minimal (also known as traditional) approach or elements of an enhanced approach can be applied. Furthermore, the guideline describes considerations for the development of multivariate analytical procedures and for real time release testing (RTRT). This guideline is intended to complement ICH Q2 Validation of Analytical Procedures.

Submitting knowledge and information related to development of analytical procedures to regulatory agencies may provide additional evidence to demonstrate that the analytical procedure is appropriate for its intended purpose. Using the tools described in ICH Q12 Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management, the guideline describes principles to support change management of analytical procedures based on risk management, comprehensive understanding of the analytical procedure and adherence to predefined criteria for performance characteristics. Knowledge gained from application of an enhanced approach to analytical procedure development can provide better assurance of the performance of the procedure, can serve as a basis for the analytical procedure control strategy and can provide an opportunity for more efficient regulatory approaches to related post approval changes. The guideline also describes submission of analytical procedure development and related lifecycle information in the Common Technical Document (CTD) format (ICH M4Q, The Common Technical Document for the Registration of Pharmaceuticals for Human Use: Quality –M4Q)

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Figure 1 Different ICH Guidelines

QUALITY GUIDELINES:

1. QIA - QIF Stability
2. Q2 Analytical Validation
3. Q3A - Q3E Impurities
4. Q4A - Q4B Pharmacopoeias
5. Q5A-Q5E Quality of Biotechnological Products
6. Q6A-Q6B Specifications
7. Q7 Good Manufacturing Practice
8. Q8 Pharmaceutical Development
9. Q9 Quality Risk Management
10. Q10 Pharmaceutical Quality System
11. Q11 Development and Manufacture of Drug Substances
12. Q12 Lifecycle Management
13. Q13 Continuous Manufacturing of Drug Substances and Drug Products
14. Q14 Analytical Procedure

ANALYTICAL PROCEDURE DEVELOPMENT Q14

Objective:

- This guideline describes science and risk-based approaches for developing and maintaining analytical 4procedures suitable for the assessment of the quality of drug substances and drug products.
- The systematic approach suggested in ICH Q8 Pharmaceutical Development together with principles of ICH Q9 Quality Risk Management can also be applied to the development and lifecycle management of analytical procedures.
- When developing an analytical procedure, a minimal (also known as 8 traditional) approach or elements of an

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enhanced approach can be applied.

- Furthermore, the guideline describes considerations for the development of multivariate analytical procedures and for real time release testing (RTRT).
- This guideline is intended to complement ICH Q2 Validation of Analytical Procedures. Submitting knowledge and information related to development of analytical procedures to regulatory agencies may provide additional evidence to demonstrate that the analytical procedure is appropriate for its intended purpose.
- Using the tools described in ICH Q12 Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management, the guideline describes principles to support change management of analytical procedures based on risk management, comprehensive understanding of the analytical procedure and adherence to predefined criteria for performance characteristics.
- Knowledge gained from application of an enhanced approach to analytical procedure development can provide better assurance of the performance of the procedure, canserve as a basis for the analytical procedure control strategy and can provide an opportunity for more efficient regulatory approaches to related post approval changes.
- The guideline also describes submission of analytical procedure development and related lifecycle information in the Common Technical Document (CTD) format (ICH M4Q, The Common Technical Document for the Registration of Pharmaceuticals for Human Use: Quality – M4Q).

SCOPE :

This guideline applies to new or revised analytical procedures used for release and stability testing of commercial drug substances and products (chemical and biological/biotechnological). The guideline can also be applied to other analytical procedures used as part of the control strategy (ICH Q10, Pharmaceutical Quality System) following a risk-based approach. The scientific principles described in this guideline can be applied in a phase-appropriate manner during clinical development. This guideline may also be applicable to other types of products, with appropriate regulatory authority consultation as needed. Development of pharmacopoeial analytical procedures is out of scope.

The Analytical Procedure Lifecycle:

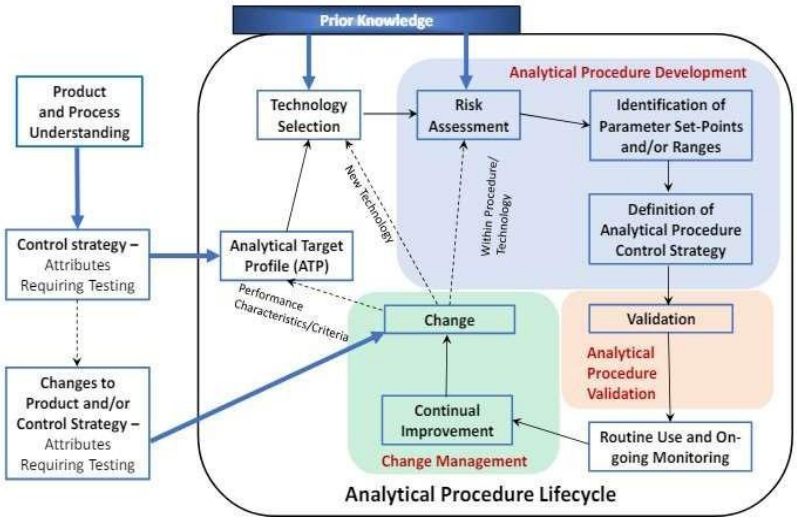

Figure 2 Analytical Procedure Lifecycle

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ANALYTICA TARGET PROFILE (ATP):

Product and process understanding (ICH Q8 and ICH Q11 Development and Manufacture of Drug 113 Substances) leads to the identification of quality attributes requiring analytical measurement for 114 control which are described (for example) in a quality target product profile (QTPP)Measurement 115 needs can be captured in an ATP which forms the basis for development of the analytical procedure.

CONTINUOUS MANUFACTURING OF DRUG SUBSTANCES AND DRUG PRODUCTS Q13

Objective:

This guideline describes scientific and regulatory considerations for the development, implementation, operation, and lifecycle management of continuous manufacturing (CM). Building on existing ICH Quality guidelines, this guideline provides clarification on CM concepts and describes scientific approaches and regulatory considerations specific to CM of drug substances and drug products.

Scope:

This guideline applies to CM of drug substances and drug products for chemical entities and therapeutic proteins. It is applicable to CM for new products (e.g., new drugs, generic drugs, biosimilars) and the conversion of batch manufacturing to CM for existing products. The principles described in this guideline may also apply to other biological/biotechnological entities.

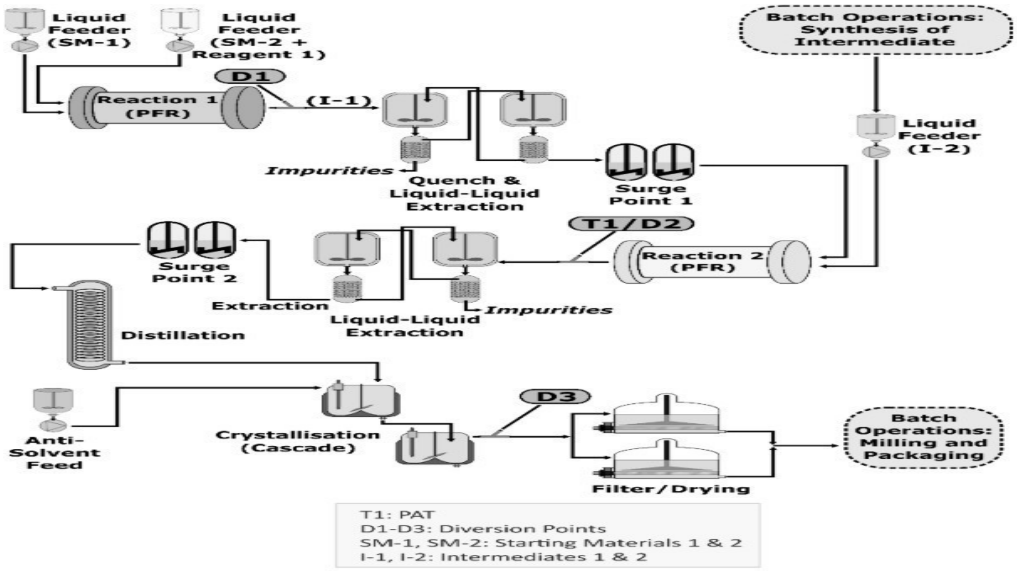

Figure 3 annex ii: continuous manufacturing of drug products (chemical entities

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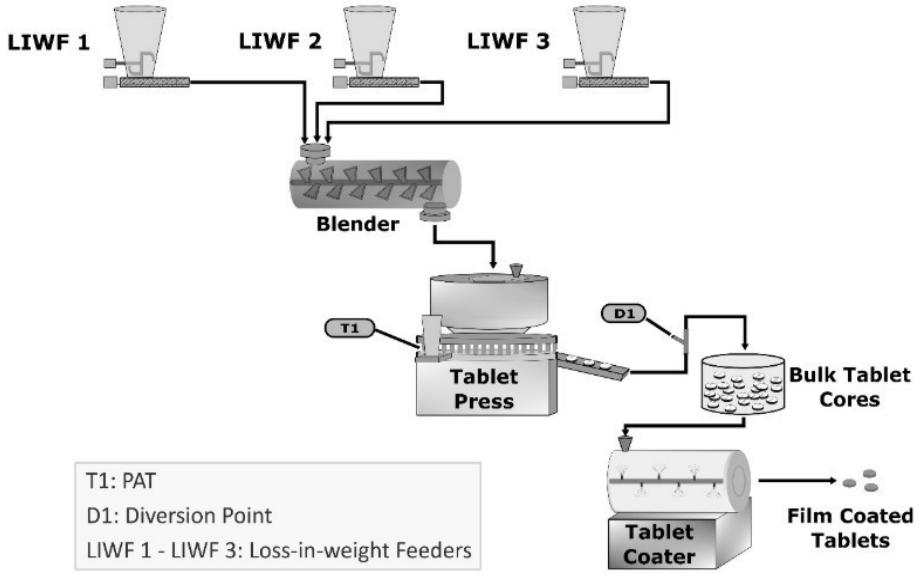

Figure 4

Annex ii: continuous manufacturing of drug products (chemical entities)

II. CONCLUSION

The inclusion of ICH Q13 represents a significant advancement in the pharmaceutical manufacturing paradigm. By providing a detailed framework for CM, it encourages the adoption of innovative technologies that enhance efficiency, product quality, and flexibility. This can lead to faster production times and more robust manufacturing processes, ultimately benefiting patients through more reliable access to medications ICH Q14 provides a robust framework for the development and management of analytical procedures, which is essential for ensuring the quality and consistency of pharmaceutical products.

By standardizing the approach to analytical method development and validation, it helps to mitigate risks and improve the reliability of test results. This leads to better quality control and assurance throughout the drug development and manufacturing processes, ultimately ensuring that safe and effective products reach the market.

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