# Training Seminar on ICH-Q2(R2), ICH-Q8(R2), and ICH-Q14
# EDA, Cairo, Egypt
**Location: Egypt**

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## Learning Objectives:

**ICH-Q2(R2)**

- *Understand Key Validation Parameters*: Participants will gain a thorough understanding of the essential validation parameters outlined in ICH-Q2(R2), including accuracy, precision, specificity, detection limit, quantitation limit, linearity, and range, and how to apply these parameters in the validation of analytical procedures.
- *Develop and Document Analytical Procedures*: Participants will learn how to effectively develop and optimize analytical methods in line with ICH-Q2(R2) guidelines and will be equipped with best practices for documenting validation studies and reporting results in a compliant manner.
- *Troubleshoot Validation Challenges*: Participants will acquire the skills to identify and address common challenges and pitfalls in the validation of analytical methods, ensuring robust and reliable results in compliance with regulatory standards.

**ICH-Q8(R2)**

- *Understand the Principles and Scope of ICH-Q8(R2):* Participants will gain a comprehensive understanding of the ICH-Q8(R2) guidelines, including the principles of Quality by Design (QbD), Critical Quality Attributes (CQAs), and Critical Process Parameters (CPPs), and their application in pharmaceutical development.
- *Develop and Implement Robust Control Strategies:* Participants will learn how to develop and implement effective control strategies by linking CQAs, CPPs, and Process Analytical Technology (PAT) tools, ensuring that pharmaceutical products meet the required quality standards throughout their lifecycle.
- *Navigate Regulatory Expectations and Submission Requirements:* Participants will be equipped with the knowledge to meet regulatory expectations related to ICH-Q8(R2) and understand how to document and communicate QbD approaches effectively in regulatory submissions, facilitating successful product approvals.

**ICH-Q14 Training**

- *Understand the Principles of Analytical Procedure Development*: Participants will gain a clear understanding of the key principles and scope of ICH-Q14, including the Analytical Target Profile (ATP) and how to apply these concepts in the development and lifecycle management of analytical procedures.
- *Apply Quality by Design (QbD) in Analytical Method Development*: Participants will learn how to integrate Quality by Design (QbD) principles into the development and validation of analytical procedures, including the use of Design of Experiments (DoE) and risk management strategies to ensure robust and reliable methods.
- *Navigate Regulatory Requirements and Lifecycle Management:* Participants will be equipped with the knowledge to meet regulatory expectations related to analytical procedures under ICH-Q14, including validation, verification, and documentation for regulatory submissions, ensuring compliance throughout the procedure's lifecycle.

| *Day 1: Sunday, October 20th* | | | |
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| **Introduction to ICH-Q2(R2): Analytical Procedure Development and Validation** | | | |
| 09:00 - 09:30 | 30′ | Registration (light refreshments) | |
| 09:30 – 10:15 | 45′ | Overview of ICH-Q2(R2)<br>• Introduction to the International Conference on Harmonisation (ICH).<br>• Detailed overview of ICH-Q2(R2) Pharmaceutical Development guidelines.<br>• Understanding the objectives and scope of ICH-Q2(R2). | Jared Auclair |
| 10:00-11:00 | 60′ | Principles of Analytical Procedure Development<br>• Key concepts in analytical procedure development<br>• Considerations for method selection and optimization | Jared Auclair |
| 11:00-11:15 | 15′ | Coffee Break | |
| 11:15-12:30 | 45′ | Validation Characteristics for Analytical Procedures<br>• Understanding the validation parameters: accuracy, precision, specificity, detection limit, quantitation limit, linearity, and range<br>• Practical examples of method validation | Jared Auclair |
| 12:30-13:00 | 30′ | Case Study: Method Validation in Practice<br>• Review of a real-world case study demonstrating the application of ICH-Q2(R2) principles | Jared Auclair |
| 13:00 – 14:00 | 60′ | Lunch | |
| 14:00 – 15:00 | 60′ | Documentation and Reporting of Validation Results<br>• Best practices for documenting validation studies<br>• Requirements for validation reports in accordance with ICH-Q2(R2) | Jared Auclair |
| 15:00-16:00 | 60′ | Troubleshooting and Common Pitfalls in Method Validation<br>• Identifying common issues in analytical method validation<br>• Strategies for troubleshooting and ensuring robust validation results | Jared Auclair |

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| 16:00-16:15 | 15′ | Coffee Break | |
| 16:15 - 16:45 | 30′ | Case Study 2: Addressing Validation Challenges<br>• An in-depth look at challenges encountered during validation and how they were resolved | Jared Auclair |
| 16:45 – 17:00 | 60′ | Q&A and Wrap-Up | Jared Auclair |
| 17:00 – 17:10 | 10′ | Close of Day 1 | |

| ***Day 2: Monday, October 21st*** | | | |
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| **Introduction to ICH-Q8(R2): Pharmaceutical Development** | | | |
| 09:00 - 09:30 | 30′ | Registration (light refreshments) | |
| 09:30 – 10:15 | 45′ | Overview of ICH-Q8(R2)<br>• Introduction to the International Conference on Harmonisation (ICH).<br>• Detailed overview of ICH-Q8(R2) Pharmaceutical Development guidelines.<br>• Understanding the objectives and scope of ICH-Q8(R2).<br>• Discussion on the importance of Quality by Design (QbD) principles. | Jared Auclair |
| 10:15-10:45 | 30′ | Pharmaceutical Development<br>• Understanding the concepts of pharmaceutical development.<br>• Key elements: Critical Quality Attributes (CQAs), Critical Process Parameters (CPPs), and Critical Material Attributes (CMAs).<br>• Case studies and examples. | Jared Auclair |
| 10:45-11:00 | 15′ | Coffee Break | |
| 11:00 – 12:00 | 60′ | Quality by Design (QbD) Principles<br>• Detailed exploration of QbD principles as applied to ICH-Q8(R2).<br>• Design of Experiments (DoE) and risk management.<br>• Integration of QbD into pharmaceutical development.<br>• Practical examples and case studies. | Jared Auclair |

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| 12:00 –12:45 | 45′ | Regulatory Considerations<br>• Regulatory expectations and submission requirements.<br>• The role of ICH-Q8(R2) in the regulatory approval process.<br>• How to document and communicate QbD approaches to regulatory agencies. | Jared Auclair |
| 12:45-13:45 | 60′ | Lunch | |
| 13:45-14:30 | 45′ | Process Analytical Technology (PAT)<br>• Overview of PAT tools and their role in ICH-Q8(R2).<br>• Real-time monitoring and control strategies.<br>• Implementation of PAT in pharmaceutical processes | Jared Auclair |
| 14:30-15:15 | 45′ | Control Strategy Development<br>• How to develop a robust control strategy under ICH-Q8(R2).<br>• Linking CQAs, CPPs, and PAT tools.<br>• Case studies and real-world examples. | Jared Auclair |
| 15:15-15:30 | 15′ | Coffee Break | |
| 15:30-16:15 | 60′ | Design Space and Continuous Improvement<br>• Understanding the concept of design space in the context of ICH-Q8(R2).<br>• Developing and implementing design space for pharmaceutical products.<br>• Continuous improvement and its role in maintaining compliance. | Jared Auclair |
| 16:15-16:45 | 30′ | Interactive Workshop: Application of ICH-Q8(R2)<br>• Group activities focusing on applying the ICH-Q8(R2) guidelines to a hypothetical pharmaceutical product.<br>• Discussion on challenges and solutions in implementation. | Jared Auclair |
| 16:45-17:00 | 15′ | Q&A and Closing Remarks<br>• Open floor for questions and discussions.<br>• Summary of key takeaways. | Jared Auclair |

| *Day 3: Tuesday, October 22nd* | | | |
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| **Introduction to ICH-Q14: Analytical Procedure Development** | | | |
| 09:00 - 09:30 | 30′ | Coffee and Breakfast | *Networking* |
| 09:30 - 10:15 | 45′ | Overview of ICH-Q14<br>• Introduction to ICH-Q14 guidelines for analytical procedure development.<br>• Key principles and scope of ICH-Q14.<br>• Relationship between ICH-Q14 and other ICH guidelines (e.g., Q8, Q9, Q10). | Jared Auclair |
| 10:15-10:45 | 30′ | Analytical Procedure Development and Lifecycle Management<br>• Fundamental concepts of analytical procedure development.<br>• Lifecycle management of analytical procedures.<br>• The role of Analytical Target Profile (ATP) in ICH-Q14.<br>• Case studies and practical examples. | Jared Auclair |
| 10:45-11:00 | 15′ | Coffee Break | |
| 11:00-12:00 | 60′ | Quality by Design (QbD) in Analytical Procedure Development<br>• Application of Quality by Design (QbD) principles in analytical procedures.<br>• Design of Experiments (DoE) for method development.<br>• Risk management and control strategies for analytical procedures.<br>• Examples and case studies. | Jared Auclair |
| 12:00-12:45 | 45′ | Validation and Verification of Analytical Procedures<br>• Overview of validation requirements under ICH-Q14.<br>• Key differences between validation and verification.<br>• Continuous verification and lifecycle management.<br>• Practical insights and examples. | Jared Auclair |

| *Day 3: Tuesday, October 22nd* | | | |
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| 12:45-13:45 | 60′ | **Lunch** | |
| 13:45-14:30 | 45′ | Analytical Procedure Transfer and Knowledge Management<br>• Principles and best practices for analytical procedure transfer.<br>• Knowledge management throughout the analytical procedure lifecycle.<br>• Documentation and communication of analytical knowledge. | Jared Auclair |
| 14:30-15:15 | 45′ | Regulatory Considerations and Submission<br>• Regulatory expectations for analytical procedures under ICH-Q14.<br>• Documentation requirements for regulatory submissions.<br>• Case studies on successful submissions.<br>• Discussion on common challenges and solutions. | Jared Auclair |
| 15:15-15:30 | 15′ | Coffee Break | |
| 15:30-16:15 | 45′ | Case Studies and Practical Application<br>• Group discussion on real-world case studies.<br>• Application of ICH-Q14 principles to hypothetical scenarios.<br>• Interactive exercises on analytical procedure development and validation. | Jared Auclair |
| 16:15-16:45 | 30′ | Interactive Workshop: Developing an Analytical Procedure<br>• Hands-on group activity focused on developing an analytical procedure using ICH-Q14 guidelines.<br>• Discussion of challenges and strategies for effective implementation. | Jared Auclair |
| 16:45-17:00 | 15′ | Q&A and Closing Remarks<br>• Open floor for questions and discussions.<br>• Summary of key takeaways. | Jared Auclair |