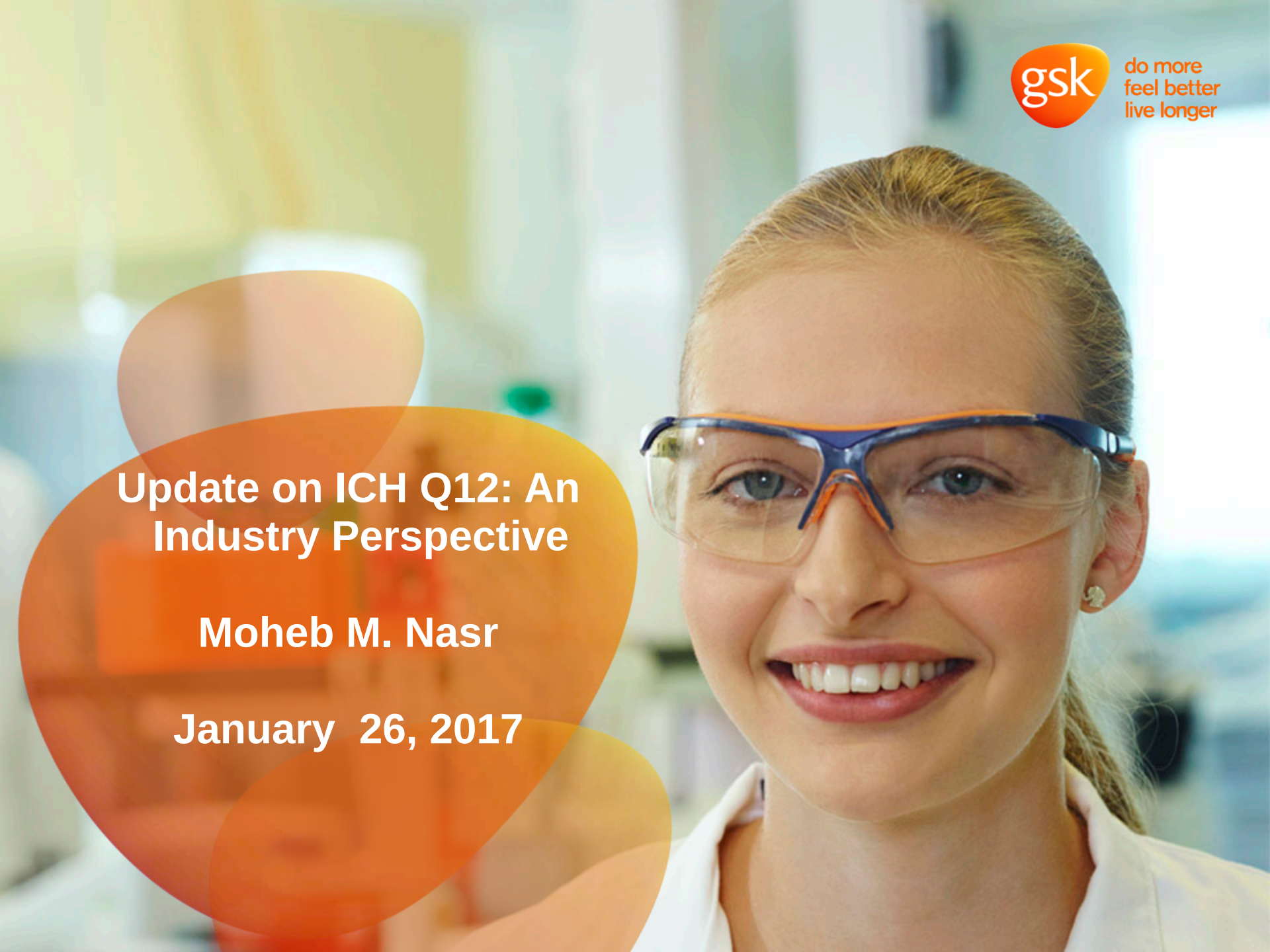

Update on ICH Q12: An Industry Perspective

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January 26, 2017

Disclosures

- The speaker is solely responsible for the content of this presentation
- The views presented here do not necessarily represent the views of GSK or ICH

Presentation Contents

- Background
- Established Conditions - Historical Perspective
- Marketed Products – Opportunities and Challenges
- Progress and Next Steps
- Acknowledgments

ICH Quality Strategy Workshop (1)

- June, 2014, Minneapolis, USA
- Purpose: To reflect on progress made since 2003 and develop a future vision and strategy
- Assessment of ICH Quality Vision and Needs
  - Implementation of ICH Q8, Q9, Q10 and Q11 provides opportunities for a more science and risk based approaches to assessing changes across the lifecycle
  - Main emphasis of these guidelines was on development stage of lifecycle
  - Opportunities and benefits have not been fully realized/enabled, and the envisioned “operational flexibility” has not been achieved
  - Need for more focus on the Commercial Manufacturing phase of the lifecycle

ICH Quality Strategy Workshop (2)

- Agreement on vision and needs
- Developed 5 years workplan
- Priorities Identified:
  - **ICH Q12: “Technical and Regulatory Considerations of Pharmaceutical Product Lifecycle Management”**
  - API Starting Materials (ICH Q11 IWG)
  - Quality Overall Summary
  - Enhanced Approaches for Development and Utilization of Analytical Procedures (AQbD)
  - Continuous Manufacturing of Pharmaceuticals

Q12 Scope and Objectives

- Scope
  - The proposed guideline will apply to pharmaceutical products, including currently marketed chemical, biotechnological and biological products
- Objectives include:
  - Provide a framework to facilitate the management of post-approval Chemistry, Manufacturing and Controls (CMC) changes in a more predictable and efficient manner across the product lifecycle
  - Optimization of industry and regulatory resources
  - Support innovation and continual improvement and assure drug product supply

Established Conditions

- Clarity of “Regulatory Commitment” a major objective of Q12
- Concept exists and/or evolving in some regions (defined details for compliance and regulatory notification of changes)
  - Japan: ‘Approved Matters’
  - USA: Draft Guidance on ‘Established Conditions: Reportable CMC Changes for Approved Drug and Biologic Products’
- Gaps include:
  - Defining Established Conditions (EC) to simplify regulatory process
  - Consideration of different approaches, e.g. performance/outcome based ECs
  - Regulatory implementation (within and outside ICH regions) and need to revise regional guidelines
  - Implementation for marketed products

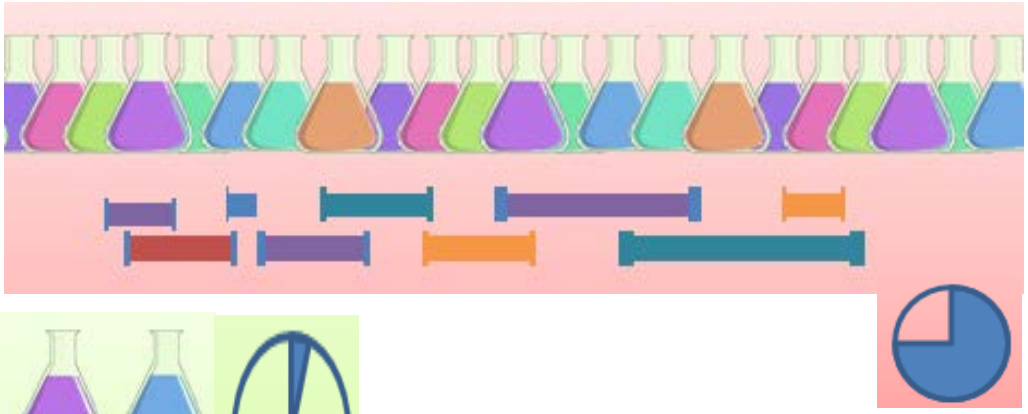
Marketed Products

- All Q12 regulatory tools are applicable to marketed products
- In addition, Q12 can provide specific guidance to implement post-approval manufacturing changes (Do and Tell)
  - Critical to implementation of Q12
- Focus on frequent manufacturing changes, e.g. changes to analytical methods
  - Currently, it is difficult to switch to modern analytics due to regulatory cost, resources (Illustrative example next)

Magnitude of the Challenge : An Analytical Example

- GSK central stability testing laboratory tests a wide range of different products which contain 20 different active and would benefit tremendously from being able to run these using a single “always on” method

From: 22 mobile phases / 9 columns / Average Run Time : 45 minutes



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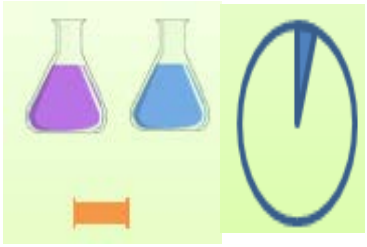

- These products are sold in 174 different countries
- Implementation require changing 6364 licenses!

Progress and Next Steps

- Q12 is a priority for industry and regulators
- Considerable progress to date
- Q12 version 7 under review
  - Q12 EWG interim meeting, April 4-7, 2017 to review comments and address remaining challenges
- Q12 EWG to reach step 1/2A in June 2017

Acknowledgements – Q12 EWG

Questions?