A Scoping Review of Regulatory Guidelines for the Assurance of Medicinal Product Quality throughout their Lifecycle

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INTRODUCTION

- Pharmaceutical industry is often considered as the most regulated one [Woodcock J, 2004; Reham M. et al, 2015].
- **Quality:**
  - defined as the degree to which a set of inherent characteristics fulfills requirements [ICH Q9; ICH Q10],
  - remains a crucial part of regulatory framework,
  - many requirements and guidelines, not always fully binding, aiming the safe use of medicinal products by assuring highly qualitative products.

- **The aim** of this paper was analyzing the existing guidelines for pharmaceutical quality, thus providing encompassing information.

METHODS

- This scoping review provides insights on the current state of the art within the quality requirements, guidelines, practices, standards and steps taken toward continual improvement.
- Databases and guidelines of International Conference of Harmonization (ICH) (Table 1), European Union (EU), World Health Organization (WHO) and International Standards of Harmonization (ISO) were analyzed.
- Additional published data were included from PubMed search engine.

Tabe 1. ICH guidelines particularly analyzed

ICH Q10	application in continual improvement, through **quality monitoring systems**, **corrective actions and preventive actions**
ICH Q9	application and importance of **quality risk management** in all the lifecycle of medicinal product
ICH Q12	the harmonization with other quality guidelines, and the need for this guideline toward the filling the gaps such as **post- approval changes, continual improvement**
ICH Q8 & ICH Q11	**integration** with the above guidelines

RESULTS

- Amongst many components that enable the system to function in service of the main purpose of the system itself, quality undeniably reaches the top of the list.

- **Qualitative medicinal products** throughout the lifecycle is achieved by risk- and science-based approaches, through creation of Quality Management System (QMS) based on:
  - ICH Guidelines,
  - Good Manufacturing Practice (GMP) certification and
  - ISO standards.

- 2003 → ICH developed the **Quality Vision** "Develop a harmonized pharmaceutical quality system applicable across the life cycle of the product emphasizing an integrated approach to quality risk management and science" [Brussels July 2003]
  - afterwards several Guidelines (Q8-Q11) have been generated.

- STILL - gaps exist in complete benefits realization – aimed to be met by the new guideline:
  - ICH Q12 guideline aiming continual assurance of high-quality products, promoting innovation and continual improvement, a transparent and efficient management of post-approval Chemistry [ICH Q12].

- Using these guidelines – a very complex system of quality must be in place, to help for:
  - ➢industry → to ensure high quality medicinal products:
    → through set of assessments
    → science and risk-based approach *[Kelley B et al., 2016].*
  - ➢regulators → to offer greater assurance;

Top 5 quality attributes related to management responsibility and continual improvement:
(i) management communication that quality is everyone's responsibility,
(ii) site has formal quality improvement objectives and targets,
(iii) clear performance criteria for feedback and coaching,
(iv) quality topics included in at least half of all-hands meetings, and
(v) collecting error prevention metric [Patel et al., 2015].

DISCUSSION & CONCLUSION

- *"If it`s not written down, it didn`t happen"* [Patel et al, 2011].
- Global emphasis in post- approval product lifecycle management and changes supported by risk and science-based approaches will help industry reach goals and objectives.
- The concept on ICH Q12 Guideline will make possible the quality assurance of products during their full lifecycle, including stages after regulatory approval.
- Pharmaceutical quality management and product lifecycle management remains crucial for harmonizing the industry, assessors and inspectors.

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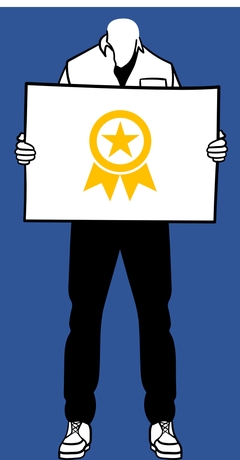

7 Congress of PHARMACY in North Macedonia with international participation