Assessing the impact of the new ICH Q10 standard on the pharmaceutical industry

I. Baldacchino, F. Wirth, M.C. Zammit, M. Zarb Adami, L.M. Azzopardi, A. Serracino-Inglott, Adrian Zahra
University of Malta, Department of Pharmacy, Msida MSD 2080, Malta
email: ianb310@gmail.com

Introduction

The ICH Q10[1] describes a model for a good and effective pharmaceutical quality system which is based on International Standards quality concepts and Good Manufacturing Practice (GMP). The aim of this study was to assess the impact of the ICH Q10 guideline in a live pharmaceutical quality system achieved by the compilation and distribution of a questionnaire. A gap analysis of the system was also performed.

Method

Documents pertaining to ICH Q8, Q9, Q10 and supporting documentation on the published guidelines[2] were reviewed. A questionnaire was compiled and validated by an expert panel, consisting of experts in the pharmaceutical industry. The questionnaire was amended accordingly. The final version of the questionnaire was distributed to 50 key persons working within and alongside the local pharmaceutical industry targeting mainly Heads of Departments, Quality Assurance Managers, Qualified Persons in industry, Quality Assurance Supervisors, Coordinators, Pharmacists, Chemists and Officers.

Results and Discussion

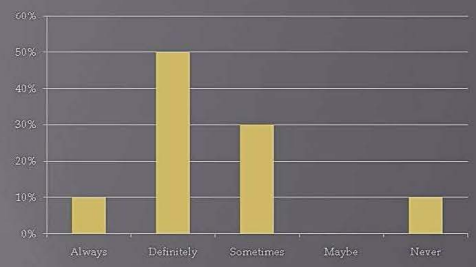
Out of the 50 questionnaires distributed, 40% (n=20) were returned. Data from each questionnaire was inputted into Microsoft® Excel 2007 and descriptive statistics were obtained.

Figure 1: Role in the Pharmaceutical Industry

The majority of the participants held top managerial positions: Thirty four percent (n=17) were Heads of Departments and 27% (n=13) were Qualified Persons (Figure 1).

Fifty percent (n=25) of the participants commented that during their work experience they encountered scenarios in pharmaceutical companies where ISO and GMP standards were considered to be a useful combination on which to base a pharmaceutical quality system. The other fifty percent of the participants stated that such a combination would always (10%; n=5), sometimes (30%; n=15) and never (10%; n=5) be beneficial (Figure 2).

Figure 2: Scenarios were both ISO & GMP can be applied



The participants considered the incorporation of the ICH Q10 guidelines into a live system based on cGMP guidelines as not difficult (60%; n=30), fairly easy (30%; n=15) and fairly difficult (10%; n=5).

The incorporation of ISO and GMP standards into a live quality system based on ISO guidelines was tackled separately. The response obtained showed that 80% (n=40) of the participants stated that this would be fairly difficult whereas 20% (n=10) stated that this incorporation could be relatively easy.

More than half of the participants (60%; n=12) expressed the wish that the regulatory bodies should recognize the ICH Q10 standard in 1-2 years time, and 40% (n=8) expected this to take longer, namely, in 2-10 years time. The majority of the participants (70%; n=14) agreed that realistically 2-10 years, was the right time for the regulatory infrastructure to identify and support the ICH Q10 guideline to utilise the maximum benefits.

The highest ranked benefits were to provide and/or improve:

1. Preventive action culture
2. Consistency across the regions in the global pharmaceutical environment
3. Scientific and risk-based approach to quality decisions
4. Quality monitoring and review
5. Transparency of systems, processes, organisational and management responsibility

Conclusion

Key persons in the Maltese pharmaceutical industry have sufficient knowledge and experience to guide a pharmaceutical company towards the adoption of the ICH Q10 Quality Standard license. This supports the view that "there are elements of other quality systems mirrored in the ICH Q10"[3].

The overall positive feedback given shows the interest of the qualified personnel in the pharmaceutical industry in embracing new and evolving quality standards.

References

1. EMEA. ICH Q10: Pharmaceutical quality system. ICH harmonized tripartite guideline. EMEA/CHMP/ICH/214732/2007
2. EMEA. ICHQ-IWG. ICH draft supporting documentation Q-IWG on ICH Q8/Q9/Q10
3. Kirk A. ICH seeks harmony on quality. Pharm. Tech. Eur. 20(1): 13-14 (2008)