Guidance for Industry

Q8(R2) Pharmaceutical Development

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

November 2009
ICH

Revision 2

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Contains Nonbinding Recommendations

Guidance for Industry[1]

Q8(R2) Pharmaceutical Development

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

This guidance is a revision of the ICH guidance *Q8 Pharmaceutical Development* (Q8 parent guidance) that published in May 2006. In June 2009, the Q8 parent guidance was revised to add an annex, which provides further clarification of the key concepts outlined in the May 2006 guidance and describes the principles of quality by design (QbD). The Q8(R1) document issued in June 2009 includes the Q8 parent guidance and the annex. This second revision, Q8(R2), provides corrected captions for figures 2a and 2b in Appendix 2, section C.

I. INTRODUCTION (1, 1.1)[2]

The Q8 parent guidance describes the suggested contents for the 3.2.P.2 (Pharmaceutical Development) section of a regulatory submission in the ICH M4 Common Technical Document (CTD) format.

The Pharmaceutical Development section provides an opportunity to present the knowledge gained through the application of scientific approaches and quality risk management (for

[1] This guidance was developed within the Expert Working Group (Quality) of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and has been subject to consultation by the regulatory parties, in accordance with the ICH process. This guidance includes an annex to *Q8 Pharmaceutical Development* (the Q8 parent guidance). The annex has been endorsed by the ICH Steering Committee at *Step 4* of the ICH process, November 2008. At *Step 4* of the process, the final draft is recommended for adoption to the regulatory bodies of the European Union, Japan, and the United States. Following the addition of the annex to the Q8 parent guidance, ICH recoded the guidance Q8(R1). In August 2009, ICH issued Q8(R2) with corrected captions for figures 2a and 2b in Appendix 2, section C.

[2] Arabic numbers reflect the organizational breakdown of the Q8 parent guidance endorsed by the ICH Steering Committee at Step 4 of the ICH process, November 2005.

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