Preface

Drugs are those with useful pharmacological effects for humans selected among the many substances with pharmacological actions and it is impossible to completely eliminate harmful effects on humans. It is up to the wisdom of human beings to minimize risk and bring out the benefits of drugs.

To achieve the optimum therapeutic effects of drugs, it is very important to provide drugs with assured efficacy, safety and quality in the medical practices hand in hand with sufficient and necessary information so that proper use can be achieved. Appropriate risk management continuing from the development stage is indispensable for feedback of information from medical practices and establishment of a cycle for more effective and safer use, i.e., “drugs are developed through use.”

With international activities such as the establishment of the E2E Guideline by ICH and the strengthening of post-marketing risk management in the United States, major steps have been taken to expand drug risk management to a consistent approach covering the development and review stages and also post-marketing stage from the one stressed in the past on former.

Japan has established a pharmaceutical regulatory system for comprehensive risk management from development to post-marketing of the highest level in the world based on knowledge obtained from health damage incidents by drugs, etc. that occurred repeatedly in the past. I hope that this book helps people overseas understand the history and structure of risk management in Japan.

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