

平成 30 年度「日本薬局方の試験法等に関する研究」研究報告  
バイオ医薬品の品質確保の基本的考え方に関する検討\*<sup>2</sup>

柴田 寛子\*<sup>1, #</sup>, 石井 明子\*<sup>1</sup>

Study on the Basic Concepts for Ensuring Quality of Biopharmaceuticals

Hiroko SHIBATA \*<sup>1, #</sup> and Akiko ISHII-WATABE\*<sup>1</sup>

**Summary**

Basic concepts and elements for quality risk management to ensure the quality of biopharmaceuticals are summarized with reference to the ICH guidelines (ICH Q5A-E, Q6B, and Q8-Q11) in accordance with the QbD approach. The biopharmaceutical-specific concepts will be used for the drafting of a general information chapter about the basic concepts for the quality assurance of biopharmaceuticals.

**Key words**

Biopharmaceuticals, Quality Risk Management, Control Strategy