JAPANESE
INDUSTRIAL
STANDARD

Translated and Published by
Japanese Standards Association

JIS Q 2101 : 2025

(FIRM/JSA)

Biotechnology — Cell manufacturing Process Management System (CPMS)

ICS 07.080;03.120.10
Reference number: JIS Q 2101 : 2025 (E)

Date of Establishment: 2025-02-20

Date of Public Notice in Official Gazette: 2025-02-20

Investigated by: Japanese Industrial Standards Committee
Standards Board for ISO area
Technical Committee on Medical Equipment

JIS Q 2101 : 2025, First English edition published in 2026-01

Translated and published by: Japanese Standards Association
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In the event of any doubts arising as to the contents,
the original JIS is to be the final authority.

Printed in Japan HN

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Foreword

This Japanese Industrial Standard has been established by the Minister of Economy, Trade and Industry through deliberations at the Japanese Industrial Standards Committee according to the proposal for establishment of Japanese Industrial Standard submitted by Forum for Innovative Regenerative Medicine (FIRM)/Japanese Standards Association (JSA) with a draft being attached, based on the provision of Article 12, paragraph (1) of the Industrial Standardization Act.

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Biotechnology — Cell manufacturing Process Management System (CPMS)

Introduction

Cell processing product is a “product containing cells as active ingredients” produced by processing living cells, and its characteristic and function have a great potential to develop a new industry as a next-generation product with a new value that could not have been realized until now.

However, because cells are highly diverse and changing object, they have complex and difficult quality attribute to control compared with products experienced by many industries, and their use of advanced science has not led to a complete understanding. Furthermore, since the basic technology for processing living cells is still at the forefront of innovation, much risk comprehension and control in the manufacturing process is time-consuming and experienced.

In this situation, it is crucial that cell processing product are assured on quality to be stably provided to customer by early acquisition of the ability of cell manufacturing organization to realize consistency of quality through product lifecycle and sustain this through continual efforts. Since cell manufacturing is a new technical challenge even in the past manufacturing industry history, it is necessary to establish a new quality control of concept for manufacturing process development and realization, which were difficult to manage by conventional concept alone.

Quality control’s basic concept in the production of product is known as “Quality Management System (QMS)” in **ISO 9001** issued by International Organization for Standardization (**ISO**), which already supports various manufacturing industries worldwide. QMS is a mechanism for the continual improvement of quality of products and services provided to customers as an organization. Specifically, QMS provides “how to conduct activity (How to do)”, e.g. the concept to establish a mechanism to implement organizational management and direction to efficiently address “the contents to be implemented (What to do)” (e.g. customer requirements, regulations, etc.) required of the organization. Particular characteristic is a system for efficiently managing and directing continual improvement as an organization through activities as Plan (planning) Do (implementation), Check (evaluation), and Act (improvement), i.e. PDCA cycle of activity which is called management system.

In Japan, Japanese Industrial Standard (**JIS**) has also standardized as **JIS Q 9001** with **ISO 9001** equivalence, and has been introduced in many industries.

In the manufacturing of medicinal products, concept of QMS of **ISO 9001** has been introduced as “pharmaceutical quality management system” in **ICH Q10** (pharmaceutical quality system) issued by The International Council for Harmonisation of Tech-