

Comparative examination of GxPs in computerized system-related guidance

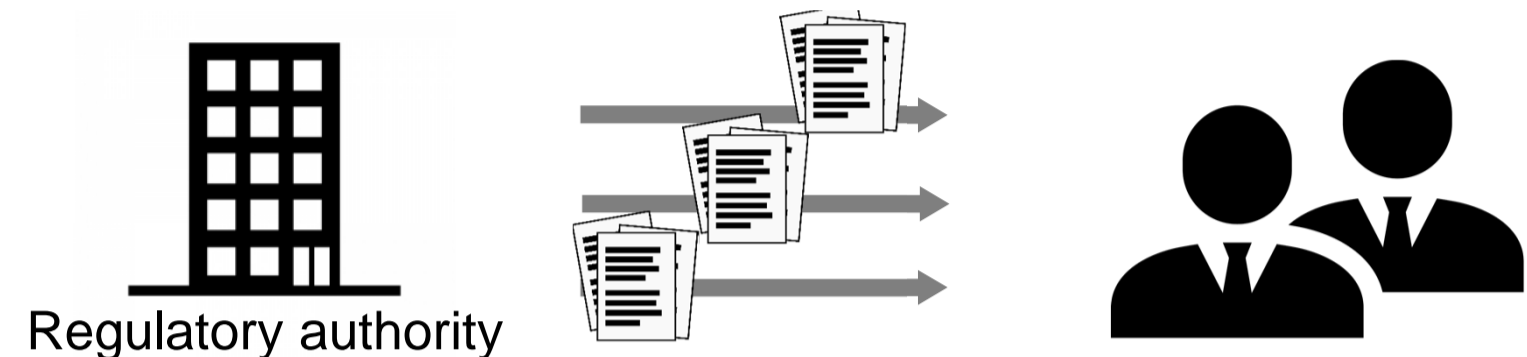
- Extraction of Focused Guidance and View to the Future for GLP in Japan -

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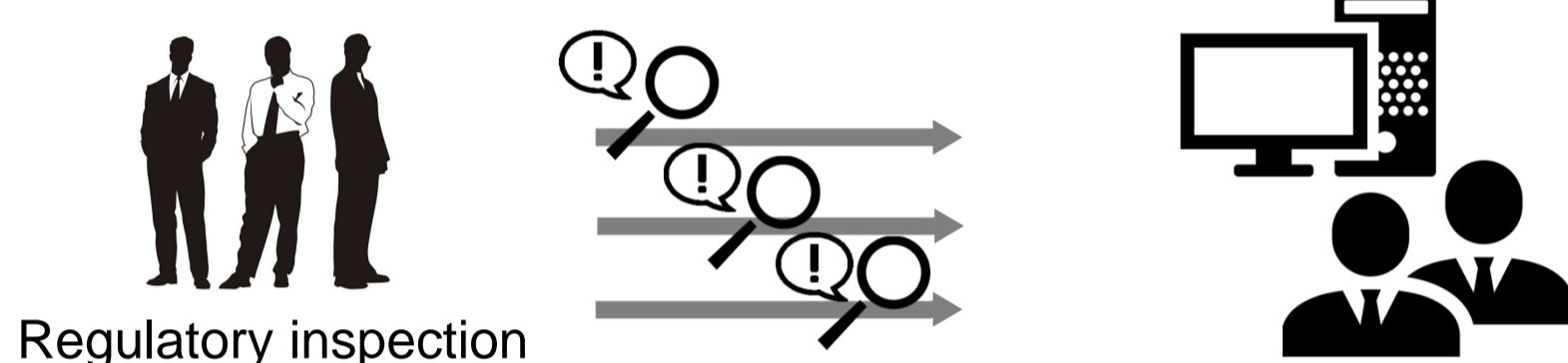


Introduction

Globally, many computerized system-related guidance have been issued



Recently regulatory authorities inspections are focusing more on computerized systems



Which guidance should be focused on at the GLP facility in Japan ?

There are few guidance on computerized systems in Japan, so many Japanese GLP facilities have a strong interest in how to best establish domestic GLP computerized system management which meets global standards. Therefore, we took the following approach to consider appropriate management of the GLP computerized system in Japan.

Purpose

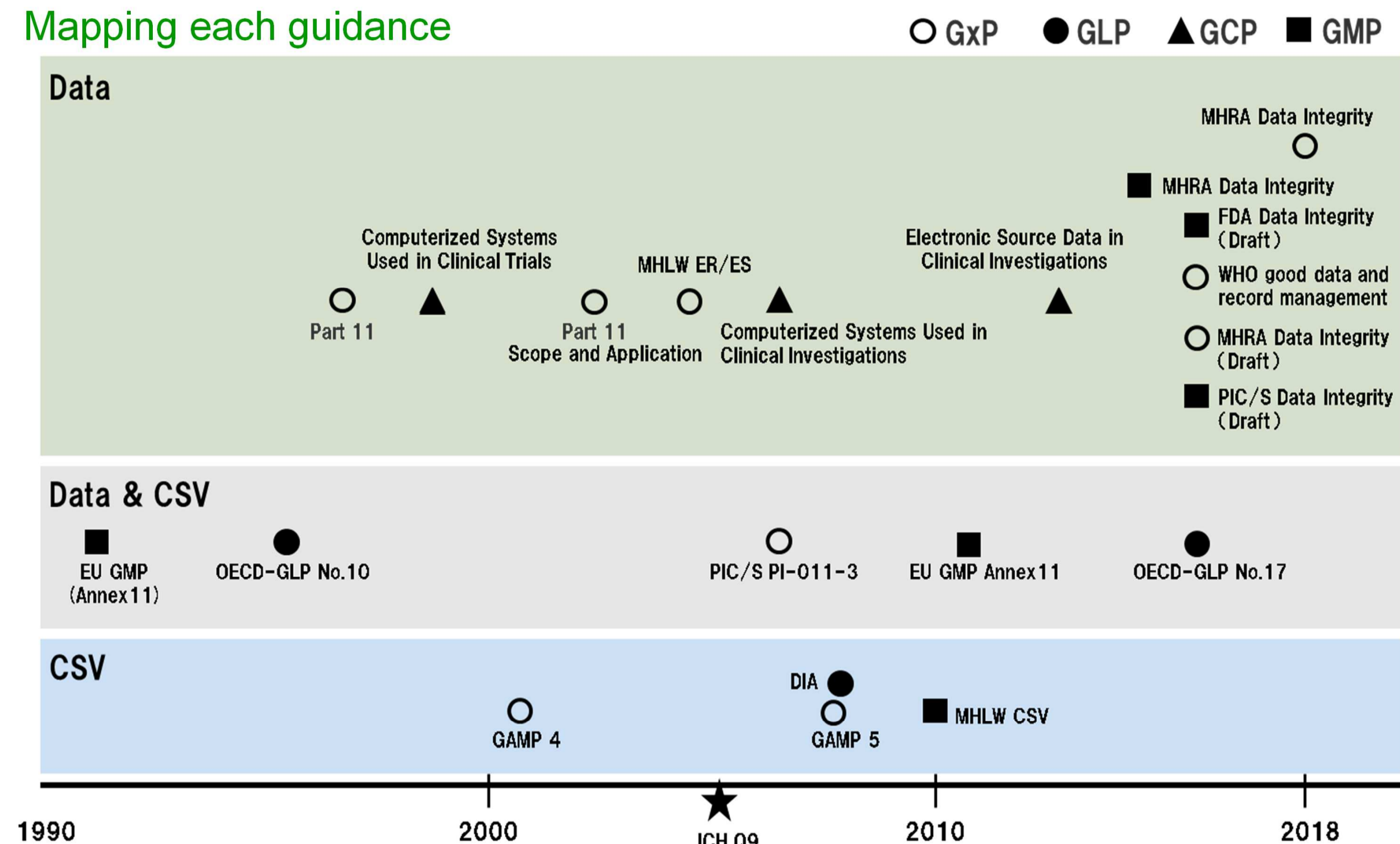
Extraction of Focused Guidance

Method

- Collated** Computerized system-related guidance issued in Japan, the United States, or Europe
- Categorized** GXP category (GLP / GCP / GMP)
Subject material (CSV / Data)
- Mapping** Mapping each guidance chronologically and by category and subject

Result 1

Mapping each guidance



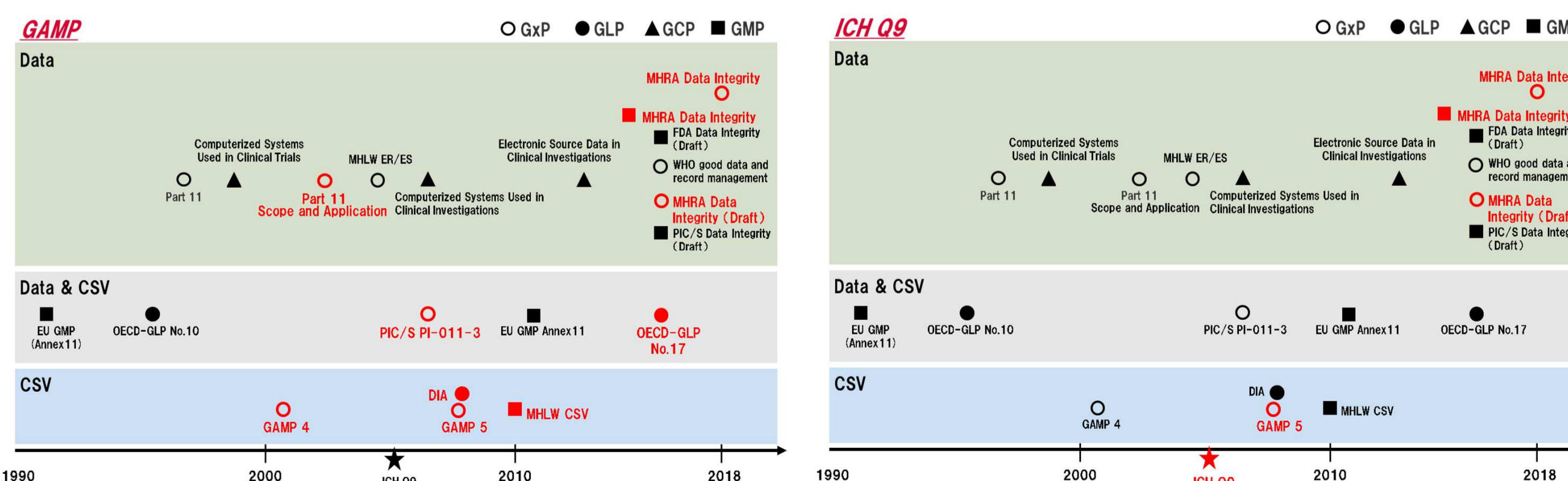
Discussion

By mapping each guidance chronologically and by category and subject, we could arrange by relevance according to past or current trends. We then extracted and focused further by conducting a keyword search (ALCOA / GAMP / ICH Q9). By using these extraction methods we could focus on what we considered as the appropriate management of the GLP computerized system in Japan. OECD-GLP No.17 was mentioned as a global standard for computerized system-related guidance in GLP. Focusing on CSV, it was found that "GAMP" has led the industry. Focusing on Data, in recent years many guidance on data integrity have been issued, and it was found that they were founded from "ALCOA". Furthermore, since "ICH Q9" was issued, "quality risk management" has become an important way of thinking and it is an important basis when introducing guidance in Japan. Based on these results, it is important to incorporate quality risk management for implementation of CSV and data integrity.

Result 2

Extracted and focused further by conducting a keyword search

- ALCOA (Data integrity)
- GAMP (CSV)
- ICH Q9 (Quality risk management)



Conclusion

It is considered that an appropriate management of the GLP computerized system in Japan could be carried out by conducting management in accordance with OECD-GLP No. 17. However, it is considered that in Japan risk-based approaches are to be indispensable in advancing the establishment of a system for securing data integrity at a global level. Therefore, incorporating GAMP 5 for CSV implementation and to incorporate the essence of MHRA GXP Data Integrity guidance for data integrity would provide appropriate management of the GLP computerized system in Japan.

Focused Guidance for GLP in Japan

