Viedoc Technologies
Supplier Assessment Report (2023)

Bunzen Co., Ltd.

January 2024

About the Assessment Report

- Bunzen conducted an independent on-site supplier assessment of Viedoc Technologies AB (hereafter, Viedoc Technologies) in December 2023 without sponsorship of regulated entities.
- With Viedoc Technologies' consent, Bunzen sells the Assessment Report to regulated entities.
- The Assessment Report is available both in English and Japanese.
- The Assessment Report covers basic topics that are discussed in GAMP 5.
- Viedoc Technologies development/maintenance/operational process is reported accurately and thoroughly:
- It also provides additional information such as:
  - Electronic Records and Electronic Signatures controls
  - Use of a product developed by the Agile methodology
  - Validation hints in building Viedoc studies
- "Bunzen Assessment Report Acknowledgement Form" is available along with the Assessment Report as a record to have read the report.

Why is the Assessment Report necessary?

When an application package is used in a clinical trial, it is expected the regulated users audit the supplier, because the ultimate responsibility for the quality and integrity of the trial data always resides with the sponsor. The sponsor needs to ensure that service providers (including vendors of computerised systems) have the knowledge and the processes to ensure that they can perform their tasks in accordance with ICH E6 [1)].

Since the burden of time and cost could be significant, it is an accepted practice to use shared audits conducted by trusted third parties [2, 3)]. This assessment report is developed to assist regulated users in assessing the processes used in the construction and validation of Viedoc, an Electronic Data Capturing product of Viedoc Technologies. This report covers standard topics which would be asked in typical supplier audits.

The assessor is a subject matter expert on computerized system validation and information system audits. The assessor reviewed all Standard Operation Procedures (SOPs) and most of the relevant documents and interviewed key personnel through the remote access and on-site visit.

1) Annex 1, “Guideline on computerised systems and electronic data in clinical trials”, EMA, 2023
2) Q8 (pp. 9-11), Guidance for Industry (Draft Guidance), " Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations Questions and Answers ", US FDA, 2023
3) Sec. 10.6 (Appendix M2), GAMP 5 2nd Edition, "A Risk-Based Approach to Compliant GxP Computerized Systems", ISPE, 2022.

Summary of Assessment

Assessor	Kenichi Nakano Senior Consultant, Bunzen Co., Ltd. <Qualifications> • Information Systems Auditor (Japan IPA) • Certified Information System Auditor (ISACA) <Experience> Over 20 years of experience in providing consultation services to pharmaceutical companies, CROs and suppliers with computerized system validation
Assessment dates	17/Nov/2023 – 10/Dec/2023: Review of SOPs 11/Dec/2023 – 14/Dec/2023: Onsite visit at Uppsala, Sweden
Scope	The topics covered in this assessment include the following. • Quality Management System; • Viedoc development and maintenance process; • Control of Information Systems (including Information Security); • Support process.

Viedoc Technologies
Supplier Assessment Report (2023)

Table of Contents

To Purchase the Assessment Report

If you would like to purchase Viedoc Technologies Supplier Assessment Report (2023), please contact:

info1@bunzen.co.jp

For more information on Bunzen Co., Ltd., please go to: https://bunzen.co.jp/