Viedoc Technologies
Supplier Assessment Report (2025)

Bunzen Co., Ltd.

September 2025

About the Assessment Report

- Bunzen conducted an independent on-site supplier assessment of Viedoc Technologies AB (hereafter, Viedoc Technologies) in May 2025, without sponsorship of regulated companies, clinical institutions, or Viedoc Technologies.
- With Viedoc Technologies' consent, Bunzen provides the Assessment Report to interested 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.

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	30/Apr/2025 – 18/May/2025: Review of SOPs 19/May/2025 – 22/May/2025: 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.

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Why is the Assessment Report necessary?

When a sponsor decides to use a system developed by a supplier, the sponsor needs to ensure the supplier's validation (qualification) documentation is in place, as clearly stated in ICH E6 R3.

The responsible party should ensure that the computerised systems are validated as fit for purpose for use in the trial, including those developed by other parties. They should ensure that validation documentation is maintained and retained.

III Annex I, 4.3.4 Validation (g), ICH E6 R3, 2025

While Viedoc Technologies provides abundant information on its qualification activities including Viedoc eLearning, Viedoc Inspection Readiness Packet (VIRP), and EDC Management Sheet, a sponsor still should make sure what is presented is really the case.

Conditions to ensure supplier's validation/qualification documentation

To quote a guidance from European Medical Agency, the conditions for a sponsor to use the vendor's qualification documentation include, but are not limited to, the following:

- the sponsor has a thorough knowledge about the vendor's quality system and qualification activities, which will usually be obtained through an in-depth assessment/audit;
- an assessment/audit has been performed by qualified staff, with sufficient time spent on the activities and with cooperation from the vendor;
- an assessment/audit has gone sufficiently deep into the activities and that a suitable number of examples for relevant activities have been looked at (and documented);
- the assessment/audit report determined the vendor's qualification documentation to be satisfactory or that shortcomings can be mitigated by the sponsor- e.g. that the sponsor is performing part of the qualification;
- the sponsor, or when applicable the clinical research organization (CRO) performing these activities for the sponsor, has detailed knowledge about the qualification documentation and can navigate in it and explain the activities as if they had performed the activities themselves;
- when required during a GCP inspection, the qualification documentation is made available to the inspectors in a timely manner irrespective of whether it is provided by the sponsor, CRO or the vendor.

Bunzen's Assessment Report is a good fit

1. **Share Assessment Report is an accepted practice**
   Using shared audits conducted by trusted third parties indicated in several guidelines.
   - "Other independent third-party assessment reports may also be relevant and useful. "
     (6.2.5.3 Supplier Assessment and Education, GAMP 5 2nd Edition, 2022, ISPE)
   - "The responsible party, or where applicable, the service provider performing the examination activities on their behalf, should have a detailed understanding of the validation documentation."
     (A2.1, Guideline on computerised systems and electronic data in clinical trials, 2023, EMA)
2. **The assessor is independent**
   The assessor is free from bias. The assessor bore all the costs (including travel and time) to create the report. All the findings are included in the report.
3. **The assessor is qualified**
   The assessor has 20+ years of industrial experience, is a Certified Information System Auditor (CISA), and is an active member of eClinical Forum.
4. **Viedoc Technologies' documentation is thoroughly reviewed**
   The assessor reviewed all relevant SOPs, supporting documents, and actual records. The assessor interviewed key personnel.
   The assessor has a deep understanding of Viedoc and Viedoc Technologies through previous assessments which have been performed every other year since 2013.
5. **The assessment covers industry standard topics**
   The assessment report is organized by key operation areas covering the quality management systems and system development life cycle activities. Where applicable, relevant SOPs are quoted. The actual documents/records created according to the procedures are reviewed.

Why the Assessment Report helps you

- **Save time on auditing Viedoc Technologies**
  Auditing a supplier is a time-consuming effort. Qualified personnel who understand the computerized system validation needs to prepare, conduct the audit, and complete the audit report. Then, it may not be possible to dig sufficiently deep enough with a few hours of the remote audit.
  We recommend using our Assessment Report and spare precious time for the audit of other suppliers.
- **Use the attached Acknowledgement Form**
  The assessment report provides sufficient information, including observations, to assist the reader of the report to decide whether the management systems and practices of Viedoc Technologies are satisfactory. Just owning the report is not sufficient. It is recommended that the reader of the report read and complete the Acknowledgement Form, which will be provided separately from the Assessment Report.

To purchase the Assessment Report

If you would like to purchase the Viedoc Technologies Supplier Assessment Report (2025), please contact:

info1@bunzen.co.jp

For more information on Bunzen Co., Ltd., please go to:

https://bunzen.co.jp/en/