Viedoc Technologies
Supplier Assessment Report (2021)

Bunzen Co., Ltd.

June 2021

Introduction

The ultimate responsibility for the quality and integrity of the trial data always resides with the sponsor. The sponsor should ensure and document that the electronic data processing system(s) conforms to the sponsors established requirements for completeness, accuracy, reliability, and consistent intended performance (i.e. validation) [1].

When application packages are used in a clinical trial, it is expected the supplier is audited. 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].

This assessment report is developed to assist regulated users to assess the development methodologies used in the construction of Viedoc, an Electronic Data Capturing product of Viedoc Technologies, as well as their validation documentation. This report covers standard topics which would be asked in typical supplier audits.

This report does not certify or endorse the supplier or the supplier's system. Readers are expected to make decisions on their own using the information written in this report.

[1]ICH, "Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice E6(R2)", Step 4 version, 2016
[2]FDA, Guidance for Industry (Draft Guidance), "Use of Electronic Records and Electronic Signatures in Clinical Investigations Under 21 CFR Part 11 - Questions and Answers", 2017

Features of the Assessment Report

- Covers basic topics that are discussed in GAMP 5 and 21 CFR Part 11.
- Provides additional information such as:
  - Electronic Records and Electronic Signatures controls;
  - Evaluation as a SaaS solution;
  - Validation hints in setting up Viedoc.
- Assesses the supplier’s process more accurately and thoroughly:
  - Conducted by an experienced subject matter expert;
  - Full one-week audit gives the report depth and breadth.

Summary of Assessment

Assessor	Kenichi Nakano Senior Consultant, Bunzen Co., Ltd. <Qualifications> • Information Systems Auditor (Japan IPA) • Certified Information System Auditor (ISACA) • PDA-certified Assessor (PDA) <Experience> The assessor has provided consultation services to pharmaceutical companies, CROs and vendors with computerized system validation for over 20 years.
Assessment date	Web conferences & emails: March 8 - April 26, 2021
Assessment method	Remote interview with responsible personnel and review of procedures and records

Assessment Report

- Bunzen conducts an independent on-site supplier assessment to Viedoc Technologies AB (hereafter, Viedoc Technologies) without sponsorship of regulated entities.
- With Viedoc Technologies' consent, Bunzen sells the Assessment Report to regulated entities.

Viedoc Technologies
Supplier Assessment Report (2021)

- Approximately 70 pages
- Available both in English and Japanese

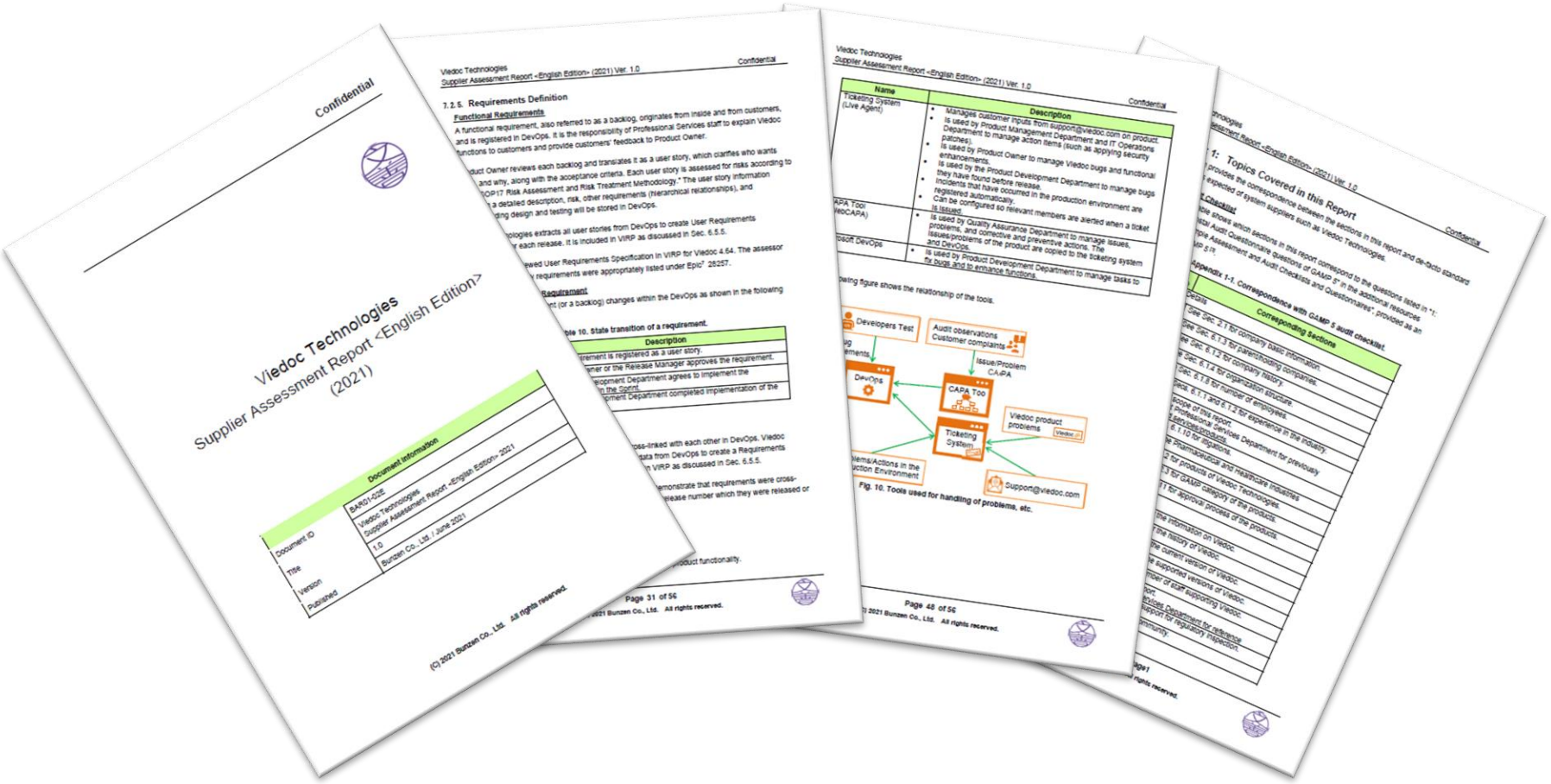


Table of Contents

Scope of the Assessment Report

In-Scope

- Quality control system
- Information system management (Includes information security)
- Viedoc 3 and Viedoc 4 (Includes Viedoc Clinical, ViedocMe, Viedoc PMS) development process
- Viedoc support process

Note:
The same assessor audited Viedoc Technologies and issued assessment reports in 2013, 2015, 2017, and 2019 as an employee of Azbil Corporation.
Bunzen Co., Ltd. has obtained permission from Azbil Corporation to use its past assessment reports, and valid findings are copied in this report.

Evaluation Criteria

Issues identified in the assessment that could impair patient rights / safety / health or data quality / integrity were listed as challenges and classified as follows:

Observations/ Recommendations		Description
Observations	Critical	Practices or processes that adversely affect the rights, safety or well-being of the subject and/or the quality and integrity of data. Critical observations are considered totally unacceptable and must be corrected immediately.
	Major	Practices or processes that might adversely affect the rights, safety, or well-being of the subject and/or the quality and integrity of data. Major observations should be addressed and corrected as soon as possible.
	Minor	Practices or processes that would not be expected to adversely affect the rights, safety or well-being of the subject and/or the quality and integrity of data. There is the need for improvement of conditions, practices, and processes.
Recommendations		Practices or processes that the assessor considered it desirable to be changed.

Shared Assessment Report (1)

The conditions to share assessment reports are enumerated in GAMP5 as the following:

- “If another regulated company has already assessed the supplier for the same reason, then subject to that company agreeing to share that information, **an additional assessment may not be necessary**. The justification for not assessing a specific supplier should formally documented.

  6.2.5.3 Supplier Assessment and Education - GAMP 5

- Shared Audit Reports

  If an audit report is to be shared the following topics should be documented:
  - that the scope of the audit is valid for the recipient of the audit report
  - that the auditor(s) qualifications meet the requirements of the recipient of the audit report
  - that the audit process, including the use of any checklists, is acceptable to the recipient of the audit report

  There may be liability and confidentiality issues where audit reports are shared. If reports are shared, then the agreement of all parties involved should be obtained and documented, including that of the supplier.

  Appendix M2 6. Shared Audit Reports

Shared Assessment Report (2)

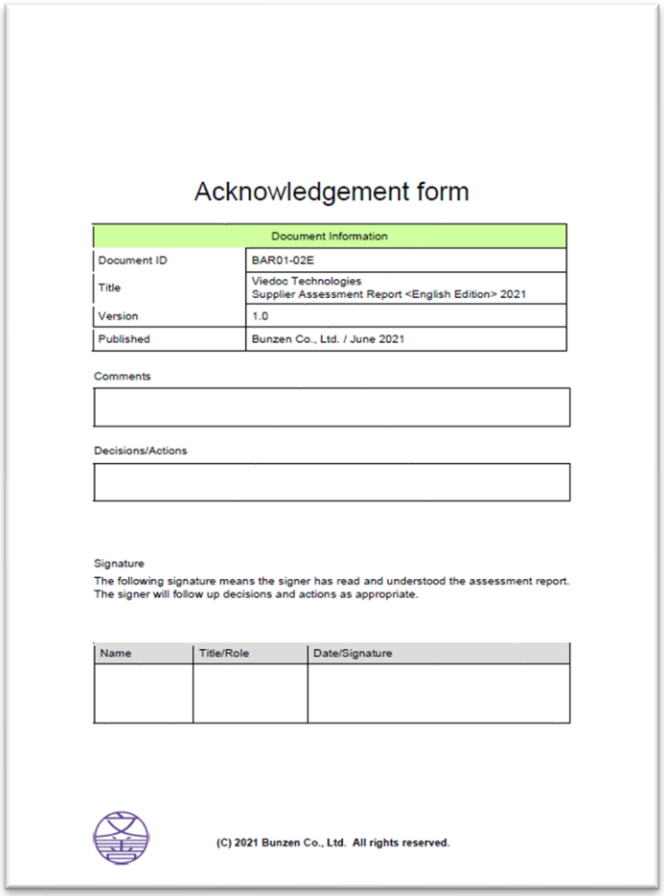
Sharing of assessment reports is also suggested by FDA in its draft guidance issued in 2017, “Use of Electronic Records and Electronic Signatures in Clinical Investigations Under 21 CFR Part 11 - Questions and Answers”

Q3　Should sponsors and other regulated entities perform audits of the vendor’s electronic systems and products?

Sponsors and other regulated entities often perform audits of the vendor’s electronic systems and products to assess the vendor’s design and development methodologies used in the construction of the electronic system or the product, as well as the vendor’s validation documentation. To reduce the time and cost burden, **sponsors and other regulated entities should consider periodic, but shared audits conducted by trusted third parties.** (The rest is omitted.)

Acknowledgement Form

- “Bunzen Assessment Report Acknowledgement Form” is provided along with the assessment report. Use this form to record that you have read the report.



Acknowledgement form

Document Information	
Document ID	BAR01-02E
Title	Viedoc Technologies Supplier Assessment Report <English Edition> 2021
Version	1.0
Published	Bunzen Co., Ltd. / June 2021

Comments

Decisions/Actions

Signature

The following signature means the signer has read and understood the assessment report.
The signer will follow up decisions and actions as appropriate.

Name	Title/Role	Date/Signature

(C) 2021 Bunzen Co., Ltd. All rights reserved.

To Purchase the Assessment Report

If you would like to purchase Viedoc Technologies Supplier Assessment Report (2021), please contact:

info1@bunzen.co.jp

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

https://bunzen.co.jp/