CRScube, Inc./cubeSolutions Compliance Assessment Report

Bunzen Co., Ltd.

July 2026

About Bunzen's Compliance Assessment Report

- The Compliance Assessment Report presents the results of an assessment of CRScube, Inc. (hereinafter referred to as CRScube) and its integrated clinical trial solutions, cubeSolutions, focusing on the processes and their implementation.

- Sponsors conducting clinical trials (including post-marketing clinical trials and post-marketing surveillances) that use critical application packages are expected to ensure that the supplier has the necessary knowledge and processes to perform its tasks in accordance with GCP.

- Bunzen’s Compliance Assessment Report aims to reduce the time, cost, and effort required for supplier qualification while providing sponsors with an independent expert assessment of supplier compliance and quality systems.

Assessment Overview

Assessor	Kenichi Nakano (Bunzen Co., Ltd.) [Qualifications] • Information Systems Auditor / Special Grade, Information Processing Engineer (Japan IPA) [Experience] Over 20 years of experience providing CSV consultation and supporting the development of ER/ES policies and procedures for pharmaceutical companies and CROs.
Timeline	2025-08-04 - 2025-12-18
Methodology	• Online review of Standard Operating Procedures (SOPs) and other relevant documentation. • On-site audit conducted at the CRScube headquarters in Seoul, Korea. • Remote interviews and document viewing via online collaboration tools.

Four Compliance Assessment Reports

- Compliance Assessment Report (Technical Report)
  CRScube, Inc. / cubeSolutions (2026) [English]

- Compliance Assessment Report (Executive Report)
  CRScube, Inc. / cubeSolutions (2026) [English]

- Compliance Assessment Report (Technical Report)
  CRScube, Inc. / cubeSolutions (2026) [Japanese]

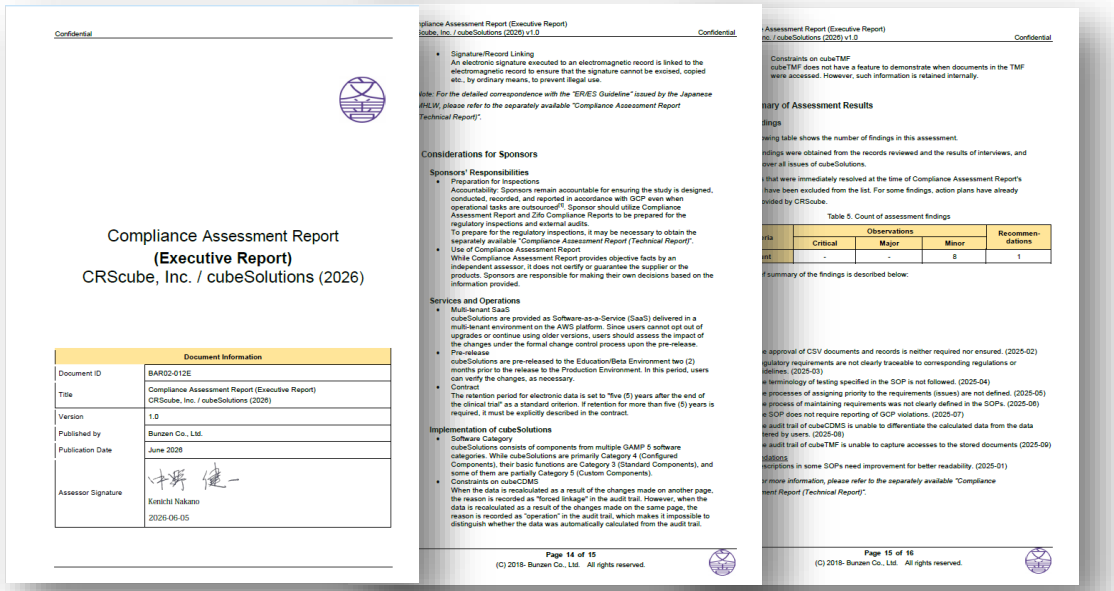
- Compliance Assessment Report (Executive Report)
  CRScube, Inc. / cubeSolutions (2026) [Japanese]

Positioning of the Compliance Assessment Reports

Item	Compliance Assessment Report (Technical Report)		Compliance Assessment Report (Executive Report)	
Language	Japanese	English	Japanese	English
Page Count	72 pages	77 pages	18 pages	18 pages
Intended Use	• Supplier evaluation and selection • Internal approval of the supplier selection • Supplier risk assessment • Validation planning • Regulatory inspection readiness		• Supplier evaluation and selection • Internal approval of the supplier selection • Supplier risk assessment	
Key Contents	• Detailed assessment of the development process • Descriptions of the contents of SOPs, with SOP IDs and versions, referenced in each process • Actual implementation status of each process • Detailed compliance status with ER/ES requirements • Detailed assessment findings • Considerations for sponsors • Summary of assessment results		• Summary of the key development processes • Summary of ER/ES compliance status • List of assessment findings • Considerations for sponsors • Summary of assessment results	
Price	5,500 USD		1,500 USD	

Compliance Assessment Report (Executive Report) CRScube, Inc. / cubeSolutions (2026)

Table of Contents



Confidential

Compliance Assessment Report
(Executive Report)
CRScube, Inc. / cubeSolutions (2026)

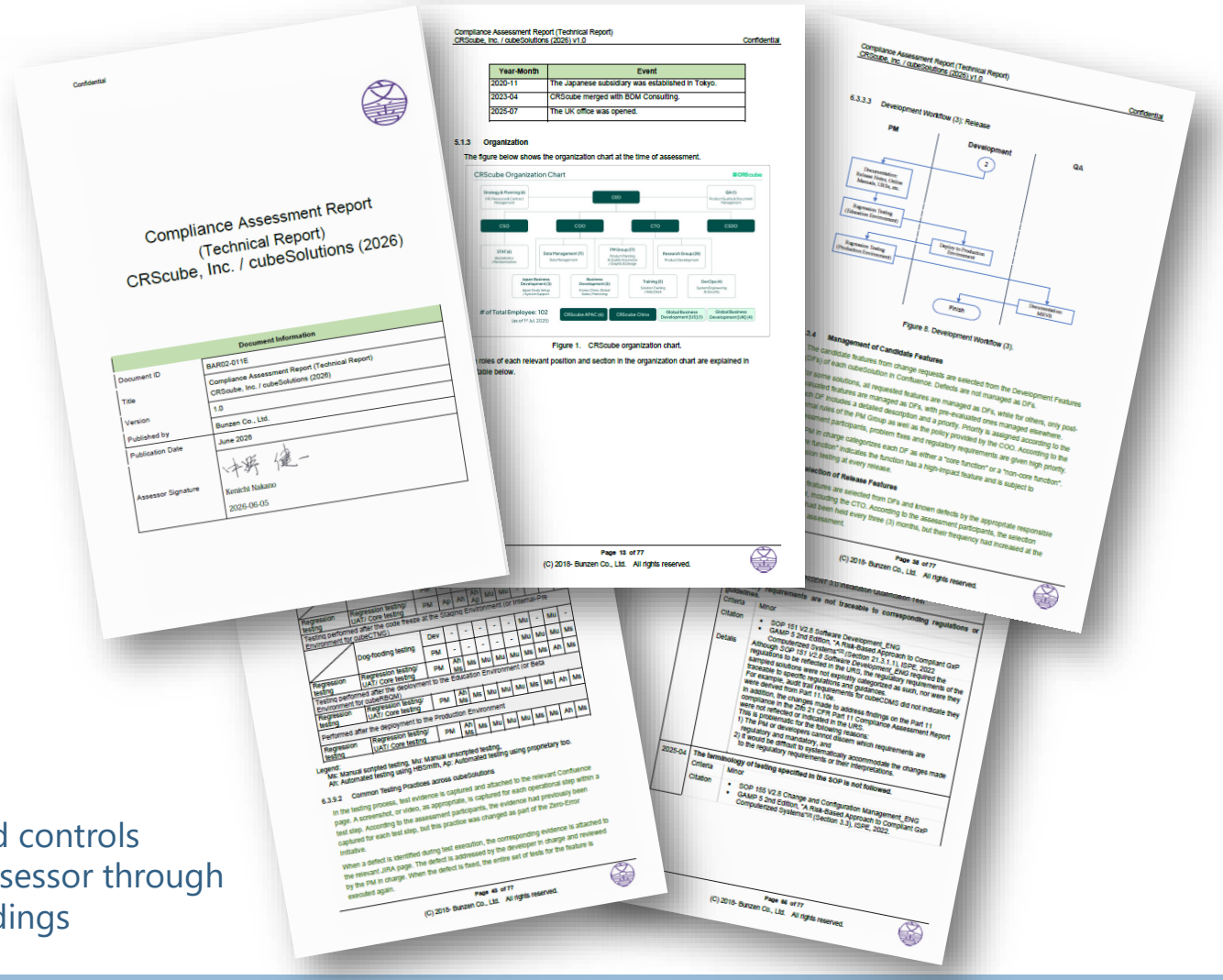
Document Information	
Document ID	BAR02-012E
Title	Compliance Assessment Report (Executive Report) CRScube, Inc. / cubeSolutions (2026)
Version	1.0
Published by	Bunzen Co., Ltd.
Publication Date	June 2026
Assessor Signature	Kenichi Nakano 2026-06-05

Page 14 of 15
(C) 2018- Bunzen Co., Ltd. All rights reserved.

Page 15 of 16
(C) 2018- Bunzen Co., Ltd. All rights reserved.

Compliance Assessment Report (Technical Report) CRScube, Inc. / cubeSolutions (2026)

Table of Contents



The Technical Report includes an overview of the processes and controls defined in the SOPs, along with information obtained by the assessor through document reviews and interviews, and detailed assessment findings (including specific descriptions and their regulatory citations).

cubeSolutions in Scope

Name	Description	Latest Ver.
cubeCDMS	An EDC solution with optimal eCRF configuration, convenient features, and automated validation.	V1.1 B20250914
cubeIWRS	A study drug management solution with convenient and diverse management functions related to randomization, study drug allocation, and transportation.	V1.1 B20250914
cubeCTMS	A comprehensive clinical trial management solution that improves overall trial efficiency through convenient central monitoring of each process.	V1.1 B20250907
cubeSAFETY	Web-based PV solution that can be linked with EDC.	V1.1 B20250907
cubePRO	Real-time EDC (cubeCDMS)-linked mobile subject reporting solution.	V1.0 B20250914
cubeCONSENT	An electronic consent form solution that can be used anywhere, anytime.	V1.0 B20240925
cubeDDC	Direct Data Capture Solution leads clinical trials to a paperless era.	V1.0 B20250914
cubeTMF	A paperless eTMF solution that manages all clinical trial documents in the cloud.	V1.1 B20250907
cubeRBQM	A comprehensive risk-based quality management solution for clinical trials.	V1.0 B20250918

Assessment Criteria and Applicable Regulations

[Global]

- ICH, Good Clinical Practice E6(R3), Step 4, 2025.
- ISPE, GAMP 5 2nd Edition

[Japan]

- “Guidance on the Use of Electronic Records and Electronic Signatures for Applications for Marketing Approval or Licensing of Pharmaceuticals, etc.” [6] (Notification No. 0401022), Japan Ministry of Health, Labour and Welfare, 2005.
- “Guideline on Management of Computerized Systems for Marketing Authorization Holders and Manufacturers of Drugs and Quasi-drugs.” (Notification No. 1021-11), Japan Ministry of Health, Labour and Welfare, 2010.
- “EDC Management Sheet (for Sponsor/Marketing Authorization Holder)”, Version. 2.00, Japan Pharmaceuticals and Medical Devices Agency, 2021.

[US]

- FDA, 21 CFR Part 11, 1997.
- FDA, Guidance for Industry, Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations Questions and Answers, 2024.

[EU]

- EMA, Guideline on computerised systems and electronic data in clinical trials, 2023.
- EMA, Guideline on the content, management and archiving of the clinical trial master file (paper and/or electronic), 2018.
- EMA, Q&A: Good clinical practice (GCP).

Why Sponsors Need Evidence of Supplier Oversight

When a sponsor decides to use a system developed by a supplier, the sponsor must ensure that the supplier's validation (qualification) documentation is appropriately maintained, as specified 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

Bunzen's Compliance Assessment Report provides independent and objective evidence to support supplier oversight activities.

Why Sponsors Purchase Bunzen's Compliance Assessment Report?

- **Save internal resources**
  Reduce supplier qualification activities from weeks to days.
- **Leverage independent expertise**
  Assessment performed by a senior CSV and IT audit specialist.
- **Support regulatory inspection readiness**
  Maintain documented evidence demonstrating supplier oversight activities.
- **Accelerate supplier selection**
  Enable faster qualification of critical GxP vendors.
- **Reduce validation effort**
  Use assessment outputs to support risk assessments and validation planning.

How to Use the Compliance Assessment Report

- After purchasing the Compliance Assessment Report, read and understand its contents
  - Is the supplier's product development process acceptable?
  - Are additional control measures (e.g., additional testing) required when implementing the products?
- Maintain a record of your review to demonstrate that you have read and understood the Compliance Assessment Report.

Frequently Asked Questions

1. **Can we use an assessment report conducted by a third party instead of conducting an audit ourselves?**
   Sharing assessment results provided by a trusted third party is a widely accepted practice. Both ICH E6 and GAMP 5 recognize the use of third-party assessments as part of supplier oversight. Sponsors are expected to read and understand the Compliance Assessment Report and perform their own evaluation.

2. **Isn't the report biased in favor of the supplier?**
   Bunzen bears all costs associated with the creation of this report. All assessment findings are recorded objectively in the report without any bias in favor of the supplier.

3. **Is the assessor qualified?**
   The assessor possesses the official qualifications, knowledge, and experience necessary to conduct audits. Details of the assessor's credentials are provided in *Assessment Overview*.

4. **Does the Compliance Assessment Report cover everything that is typically verified in a standard audit?**
   The report covers the key areas typically reviewed during supplier audits, including quality management, software development lifecycle processes, computerized system validation, data integrity controls, electronic records/electronic signatures compliance, and process implementation. The assessment includes a comprehensive review of relevant SOPs, supporting documentation, sample records, and interviews with key personnel.

5. **Does the report have an "expiration date"?**
   There is no formal expiration date. However, because organizations and processes evolve over time, Bunzen updates the assessment every two years to provide users with current and relevant information.

Example of Resource Savings

Conducting a Remote Audit	Duration	Effort/Cost
Audit Plan Formulation	1 week	5 hours 500 USD
Coordination with Supplier	1 week	5 hours 500 USD
Audit Preparation • Document review (approx. 20 docs) • Formulating questions • Checklist preparation • Pre-audit coordination (4 members)	2 weeks	50 hours 5,000 USD
Audit Execution • One 5-hour session with 4 participants	2 weeks	5 hours x 4 2,000 USD
Post-Audit Activities • Result confirmation & organizing findings • Report creation	2 weeks	20 hours 2,000 USD
Total Note: Labor cost is assumed at 100 USD/hour.	**8 weeks**	**100 hours 10,000 USD**

Utilizing the Compliance Assessment Report	Duration	Effort/Cost
Obtaining the Report (Contracting)	1 week	5 hours 500 USD
Compliance Assessment Report (Executive Report)	-	1,500 USD
Reading and Understanding the Report	1 week	5 hours 500 USD
Total	**2 weeks**	**10 hours 2,500 USD**

Key Takeaway
An illustrative example suggests that supplier qualification effort may be reduced by approximately **90%** compared with conducting a dedicated audit.

EMA GCP Q&A B9 Requirements

B9. What is the level of validation/qualification needed to be performed by a sponsor when using an electronic system previously qualified by a provider? What documentation is required to be available for inspections?

EMA GCP Q&A B9 Requirements (Excerpts)	Bunzen's Compliance Assessment Report
Having in-depth knowledge of the supplier's quality system and qualification activities, which can typically be obtained through a detailed assessment/audit.	The assessor is well-versed in the latest regulatory trends, industry standards, and best practices, and holds professional qualifications as an Information Systems Auditor
Qualified staff conduct the assessment/audit, dedicating sufficient time and receiving cooperation from the supplier.	The assessor conducted a one-month review of all relevant SOPs, followed by a one-week onsite visit to verify implementation records and interview managers responsible for quality assurance and development of each solution.
Thoroughly examining the details of each activity and reviewing (recording) an appropriate number of examples for those activities.	The assessor reviewed the development processes and relevant records for the solutions in scope.
Determining in the assessment/audit report whether the supplier's qualification documentation is satisfactory or if the sponsor can mitigate any identified issues.	Bunzen's Compliance Assessment Report presents objective facts and findings. Ultimately, sponsors are responsible for making their own decisions.
The sponsor (or CRO acting on their behalf) possesses detailed knowledge of the supplier's qualification documentation, understands its structure, and can explain the activities as if they had performed the activities themselves.	Please utilize the "Compliance Assessment Report (Technical Report)", which contains detailed assessment records, to prepare for regulatory inspections and other audits.
Qualification documentation can be provided to inspectors in a timely manner during a GCP inspection, regardless of whether it is supplied by the sponsor, CRO, or supplier.	Ensure that the latest version of the Compliance Assessment Report is appropriately maintained.

https://www.ema.europa.eu/en/human-regulatory-overview/research-development/compliance-research-development/good-clinical-practice/qa-good-clinical-practice-gcp

Key Benefits

- Independent assessment by expert auditor
- Supports supplier oversight
- Supports inspection readiness
- Up to 90% reduction in qualification effort
- Available in Executive and Technical versions

How to Obtain the Compliance Assessment Report

If you wish to purchase Bunzen's Compliance Assessment Report, please contact us at the following email address:

info1@bunzen.co.jp

For more information about Bunzen Co., Ltd., please visit our website:

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

Bunzen's Consultation Services

Establishment of a Company-wide and Departmental Regulatory Compliance Frameworks

- Establishment of regulatory compliance frameworks (development and revision of policies, standards, guidelines, and SOPs)

System-Specific Support

- Validation support for system implementation and system modification
- Supplier assessments and audits

Training

- Comprehensive training programs for all levels, from beginner to advanced, covering topics such as CSV, Data Integrity, and ER/ES

General Consultation

- Advisory and research services available on an hourly basis. No retainer fee is required.

Contact
info1@bunzen.co.jp