

Oryx DataStation

Equipment Data Management Software

Trusted records Confident decisions

From equipment data collection to reports and audit trails



Turn equipment records
into reviewable data

Collection · Process Review · Reports · Audit Trails

Auto Collection · Record Protection · Review & Storage

Six Core Record Functions

Why it matters

Collect and protect records, with reports and review history.



Collect & Protect Records

Automatic record collection
File protection

p. 3



Reports & Review

Generate reports
for each review purpose

p. 4



Originals & Versions

Verify issued originals
Identify later versions

p. 5



Audit · Roles · E-Signatures

Set role permissions
Assign review responsibility

p. 6



Backup & Retention

Scheduled backups
Long-term storage

p. 7



Remote Record Review

From the office
review site records

p. 8

Equipment control and record management serve different roles

Oryx System

Equipment Control

Controller · Operator Interface



Oryx DataStation

Record Management

Collection · Protection · Reports

DataStation manages records. Equipment controller/operator interface (PLC/HMI) programs are supplied separately.

Separate Solution | Oryx LockDown · Restrict Windows Operations

p. 9

Run approved apps · Restrict desktop access and configured Windows shortcuts

Record Collection & Protection

Why it matters

Auto-collect equipment records to find and review when needed.



CSV File

Original data
from equipment



DB File

Database file
for storage and retrieval



PDF File

Reports for
review and printing



Check Records on Site

Review values and trends over time, with setpoints and actual measurements.



Why Convert to DB Files?

To store collected records systematically and quickly find and retrieve needed data.



Why Password-Protect Files?

Encryption and file permissions restrict unauthorized viewing and editing.
Applies to new CSV, DB and PDF files.

Why Use CSV for Original Equipment Records?

Collect records as simple CSV files without macros to reduce tampering risk through macros.
After collection, encryption and access restrictions limit unauthorized changes.

Existing unencrypted CSV/DB files can also be processed. Works with electronic signatures, backup and restore.

Reports · Result-Based Details · Report Protection

Report Generation & Review

Why it matters

Create reports for the review purpose and find relevant information easily.



Generate Reports

Turn work records into reports



Conditional Printing

Set PASS and FAIL conditions

Review by Exception (RbE)

Review records with anomalies or exceptions first.

DataStation supports this by including Raw Data according to the final result.

PASS Result

Omit Raw Data when configured. For manual reissue, choose to include it.

FAIL Result

Raw Data is always included.

Preventive Check Advice

Supported reports show history-based check advice. Results stay unchanged.

Raw Data: raw measurements. This choice affects only this manual report; the original is kept.

Readable Reports

Choose Korean/English and date format; supplier sets templates for equipment/process.

Why Lock Reports?

Protect reviewed content by limiting edits under the app's permissions policy.

Automatic printing uses configured result conditions and the Windows default printer.

Digital Fingerprints · Original Comparison · Version Storage

Original Verification & Versioning

Why it matters

Check received reports against issued originals and identify later versions.

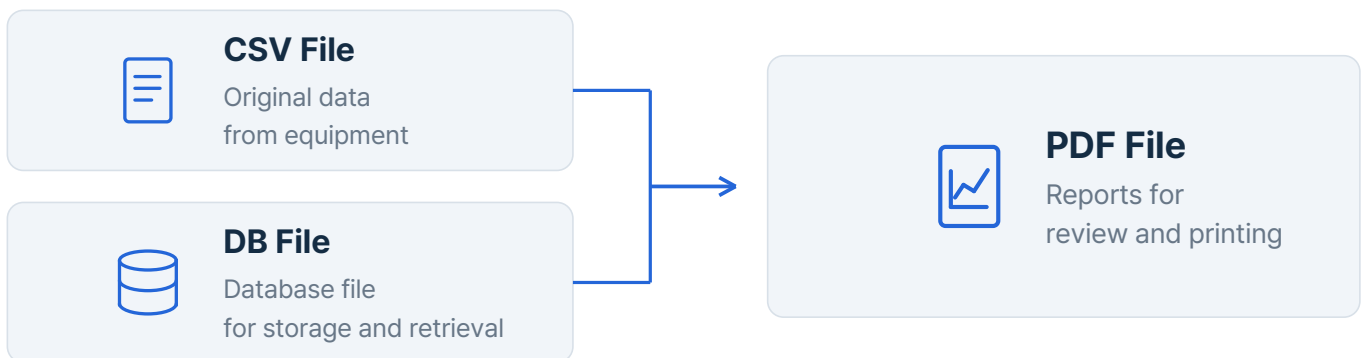


A hash is a file's digital fingerprint, like a person's fingerprint.

Even adding a single dot changes it.

Compare with the stored original's hash to check for file changes.

The PDF records stored CSV/DB filenames and their digital fingerprints.

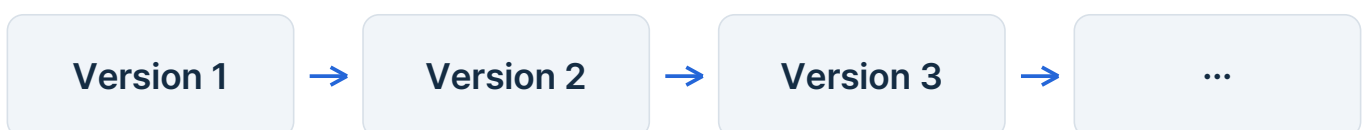


Compare Received Reports with Issued Originals



A different hash means the file differs from its issued version.

Keep the First Report and Later Versions



Keep the first report. Save regenerated reports as separate versions, using filenames and hashes.

Electronically signed PDF reports cannot be regenerated in DataStation.

[Audit Trails](#) · [Role Permissions](#) · [Sequential E-Signatures](#)

Audit Trails · Roles · E-Signatures

Why it matters

Record who did what; define each user's permissions and review responsibility.



Equipment Audit Trails

Import Audit Trails from connected equipment.
View operations and changes; export reports.



Application Audit Trail

Log app use and system activity.
Review selected entries and full history.

Electronic Signatures: Work · Review · Approval



Operator

Check work records
First signature



Reviewer

Review after Operator signs
Review signature



Approver

Final review after Reviewer signs
Approval signature

Auditor

View/export records and Audit Trails

Administrator

Manage accounts, permissions, settings, backups

Why Separate Permissions?

Assign access and review duties by role. Set password, inactivity and account-lock rules.
Auditor access alone does not permit signing; approval requires the Approver role.

E-Signatures: Professional / Enterprise. Assess regulatory compliance with product settings and customer procedures.

Scheduled Backup · Retention · PC Time Sync

Backup & Long-Term Retention

Why it matters

Archive records regularly for recovery and long-term operation.



Scheduled Backup and Restore

Scope, path & schedule → Save backup files → Restore selected data

Back up records and settings on a schedule, then select the scope to restore.



External Storage

Set retention period → Archive externally → Apply PC cleanup policy

Archive to networked NAS/server PC shares or external media such as USB. After confirming the archive, apply the PC cleanup policy.



Automatic PC Time Synchronization

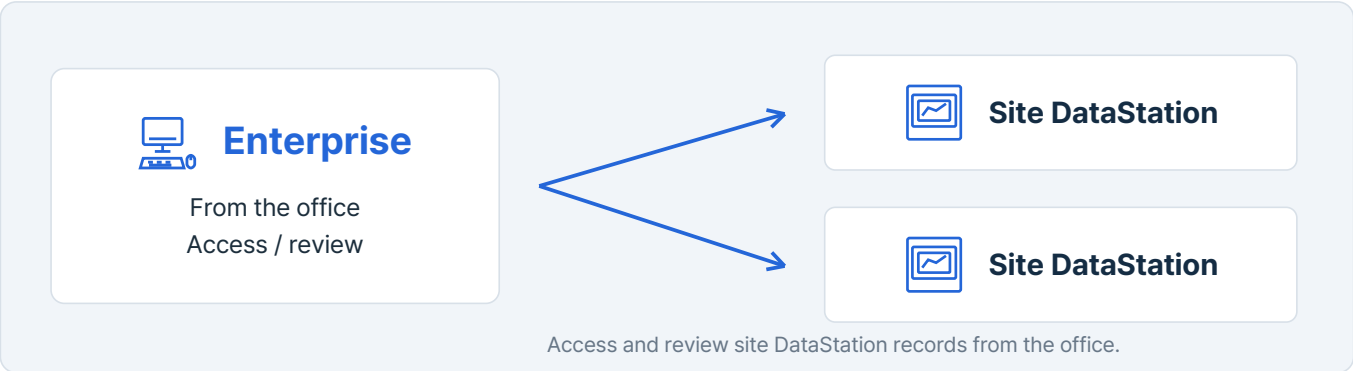
Time server & schedule → Check reference time → Synchronize PC time

Each DataStation PC synchronizes its clock with the designated time server (NTP).

Set backup scope, run times and retention to suit site operating requirements.

Remote Review of Site Records

Why it matters Access and review site records from the office for verification.



Feature	Standard	Professional	Enterprise
Primary role	Manage site records	Manage site records	Remote access / review
Account roles	Admin / auditor	Adds signing / management roles	Adds signing / management roles
Electronic signatures	Not available	Available	Available
Remote record access / review	Site PC integration	Site PC integration	Review from the office
Signed reports / history Dedicated archive	Not available	Not available	Available



Throughout the app:
Korean / English switching

Professional saves electronically signed reports.
Enterprise collects PDFs and signature history in a dedicated archive for review.

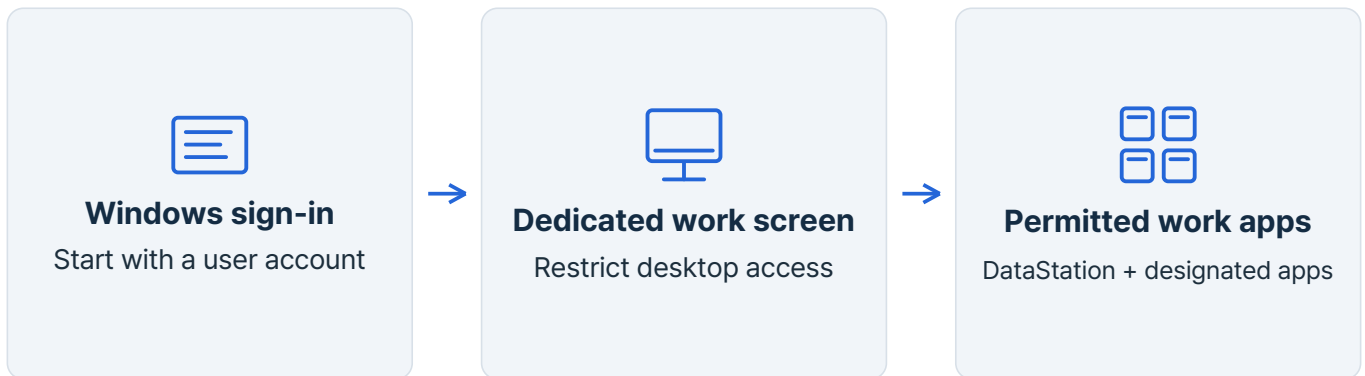
Oryx LockDown · Separate solution linked to DataStation

A Dedicated PC Work Environment

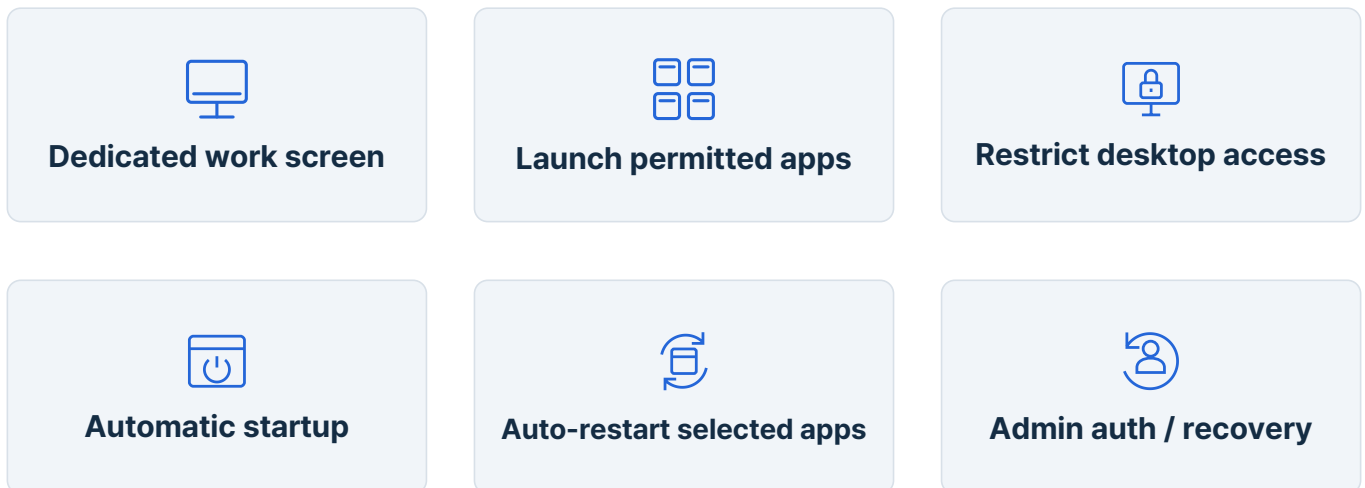
Why it matters

Restrict direct Windows access

Work through permitted apps in the user environment; desktop access and configured Windows shortcuts are blocked.



A dedicated operating environment applied after Windows sign-in.



Select and launch permitted work apps. Configure automatic startup and selected-app restart, then manage the environment through administrator authentication and recovery.

Report layouts shown in actual output

Sterilization & Test Reports

See the layout and presentation of reports delivered to reviewers.

High-pressure steam sterilization report

DataStation report (Korean) · p. 1



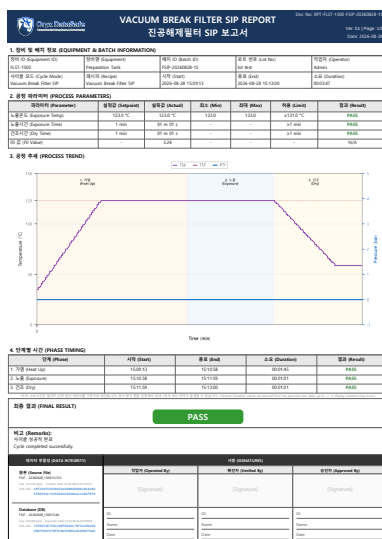
Chamber leak test

DataStation report (Korean) · p. 1



Vacuum-breaker filter SIP

DataStation report (Korean) · p. 1



Bowie-Dick test

DataStation report (Korean) · p. 1



Further report pages and detailed measurement records are available in the separate detailed documentation.

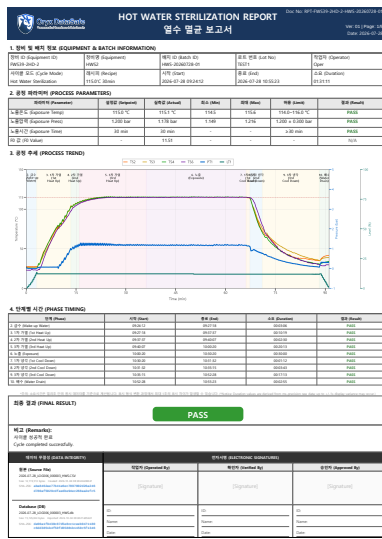
Report layouts shown in actual output

Sterilization & Manufacturing Reports

See the layout and presentation of reports delivered to reviewers.

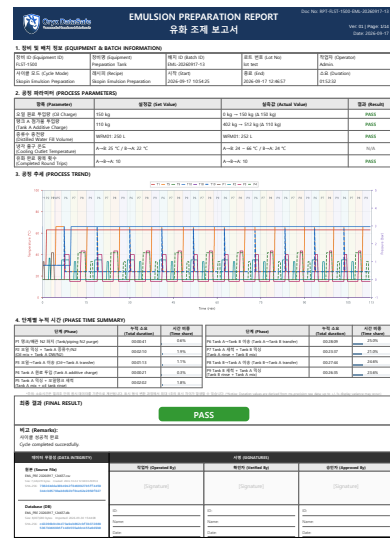
Hot-water sterilization report

DataStation report (Korean) · p. 1



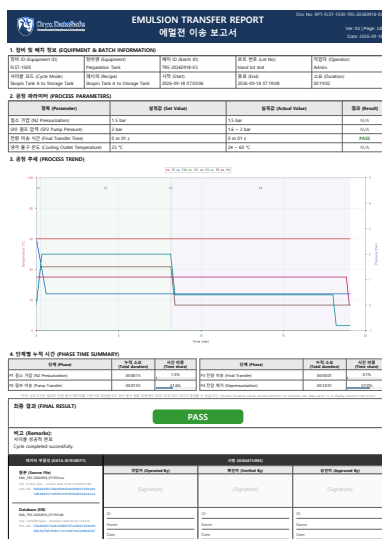
Formulation report

DataStation report (Korean) · p. 1



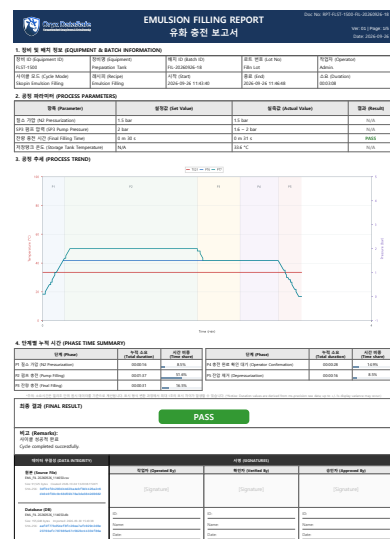
Transfer report

DataStation report (Korean) · p. 1



Filling report

DataStation report (Korean) · p. 1



Further report pages and detailed measurement records are available in the separate detailed documentation.

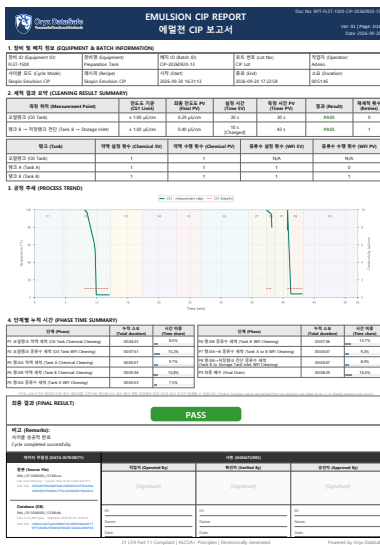
Cleaning / sterilization reports and filter test forms

Cleaning, Sterilization & Filter Forms

Review cleaning, sterilization and filter test report formats for implementation.

Equipment cleaning (CIP) report

DataStation report (Korean) · p. 1



EMULSION CIP REPORT
에멀션 CIP 보고서

1. 장비 및 배치 정보 (EQUIPMENT & BATCH INFORMATION)

장비 ID (Equipment ID)	장비 이름 (Equipment Name)	배치 번호 (Batch No.)	배치 이름 (Batch Name)	작업자 (Operator)
001-001	Preparation Tank	001-001	001-001	Admin
장비 제조사 (Equipment Manufacturer)	장비 모델 (Equipment Model)	배치 일자 (Batch Date)	배치 시간 (Batch Time)	배치 장소 (Batch Location)
Equip. Manufacturer: CIP	Equip. Model: CIP	2024-09-24 16:21:10	09:00	001-001

2. 세척 결과 요약 (CLEANING RESULT SUMMARY)

세척 단계 (Cleaning Step)	세척 온도 (°C) (Cleaning Temp. (°C))	세척 시간 (min) (Cleaning Time (min))	세척 압력 (bar) (Cleaning Pressure (bar))	세척 결과 (Cleaning Result)	비고 (Remarks)
1. 세척 (1. Wash)	4.0 (4.0)	10.0 (10.0)	0.5 (0.5)	PASS	
2. 세척 (2. Wash)	4.0 (4.0)	10.0 (10.0)	0.5 (0.5)	PASS	
3. 세척 (3. Wash)	4.0 (4.0)	10.0 (10.0)	0.5 (0.5)	PASS	

3. 세척 추세 (CLEANING TREND)



4. 단계별 시간 요약 (PHASE TIME SUMMARY)

단계 (Phase)	작업자 (Operator)	시간 (Time)	비고 (Remarks)
1. 세척 (1. Wash)	Admin	00:00:10	
2. 세척 (2. Wash)	Admin	00:00:10	
3. 세척 (3. Wash)	Admin	00:00:10	

5. 최종 결과 (FINAL RESULT)

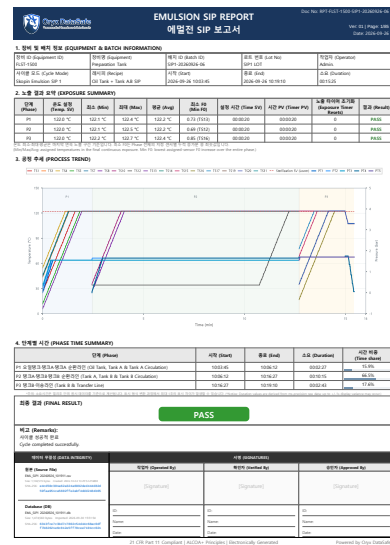
PASS

6. 서명 (SIGNATURE)

인원 (Person)	직책 (Position)	서명 (Signature)
Operator	Operator	
Inspector	Inspector	
Approver	Approver	

Equipment sterilization (SIP) report

DataStation report (Korean) · p. 1



EMULSION SIP REPORT
에멀션 SIP 보고서

1. 장비 및 배치 정보 (EQUIPMENT & BATCH INFORMATION)

장비 ID (Equipment ID)	장비 이름 (Equipment Name)	배치 번호 (Batch No.)	배치 이름 (Batch Name)	작업자 (Operator)
001-001	Preparation Tank	001-001	001-001	Admin
장비 제조사 (Equipment Manufacturer)	장비 모델 (Equipment Model)	배치 일자 (Batch Date)	배치 시간 (Batch Time)	배치 장소 (Batch Location)
Equip. Manufacturer: SIP	Equip. Model: SIP	2024-09-24 16:21:10	09:00	001-001

2. 살균 결과 요약 (STERILIZATION RESULT SUMMARY)

살균 단계 (Sterilization Step)	살균 온도 (°C) (Sterilization Temp. (°C))	살균 시간 (min) (Sterilization Time (min))	살균 압력 (bar) (Sterilization Pressure (bar))	살균 결과 (Sterilization Result)	비고 (Remarks)
1. 살균 (1. Sterilization)	121.0 (121.0)	10.0 (10.0)	0.5 (0.5)	PASS	
2. 살균 (2. Sterilization)	121.0 (121.0)	10.0 (10.0)	0.5 (0.5)	PASS	
3. 살균 (3. Sterilization)	121.0 (121.0)	10.0 (10.0)	0.5 (0.5)	PASS	

3. 살균 추세 (STERILIZATION TREND)



4. 단계별 시간 요약 (PHASE TIME SUMMARY)

단계 (Phase)	작업자 (Operator)	시간 (Time)	비고 (Remarks)
1. 살균 (1. Sterilization)	Admin	00:00:10	
2. 살균 (2. Sterilization)	Admin	00:00:10	
3. 살균 (3. Sterilization)	Admin	00:00:10	

5. 최종 결과 (FINAL RESULT)

PASS

6. 서명 (SIGNATURE)

인원 (Person)	직책 (Position)	서명 (Signature)
Operator	Operator	
Inspector	Inspector	
Approver	Approver	

Filter test form · p. 1

Synthetic form · not DataStation output



PUPSIT INTEGRITY TEST REPORT
필터 무결성 시험 보고서

1. 시험 및 장비 정보 (TEST & EQUIPMENT INFORMATION)

시험 단계 (Test Step)	시험 장비 (Equipment)
필터 ID (Filter ID)	필터 모델 (Filter Model)
시험 방법 (Test Method)	시험 일자 (Test Date)
시험 일시 (Test Time)	시험 장소 (Test Location)

2. 시험 결과 (TEST RESULT)

측정값 (Actual)	허용 기준 (Limit)	결과 (Result)
12.4 mL/min	≤ 18.0 mL/min	PASS

3. 시험기 데이터 연결 정보 (DATA LINKAGE)

Integrity Tester	데이터 연결 (Data Linkage)	보고서 (Report)
Integrity Tester	데이터 연결 (Data Linkage)	보고서 (Report)

4. 시험기 데이터 연결 정보 (DATA LINKAGE)

Integrity Tester	데이터 연결 (Data Linkage)	보고서 (Report)
Integrity Tester	데이터 연결 (Data Linkage)	보고서 (Report)

Filter test form · p. 2

Synthetic form · not DataStation output



PUPSIT INTEGRITY TEST REPORT
필터 무결성 시험 보고서

4. RAW DATA (원시 데이터)

Integrity Tester에서 받은 5 초당 시간별 시험 데이터의 형식 예시입니다.

시험 시간 (Test Time)	시험 압력 (Test Pressure)	시험 유량 (Test Flow)	시험 결과 (Test Result)
00:00	2.50 bar	12.1 mL/min	수집
00:30	2.50 bar	12.3 mL/min	수집
01:00	2.50 bar	12.4 mL/min	수집
01:30	2.50 bar	12.4 mL/min	수집
02:00	2.50 bar	12.4 mL/min	수집

데이터 항목 예시

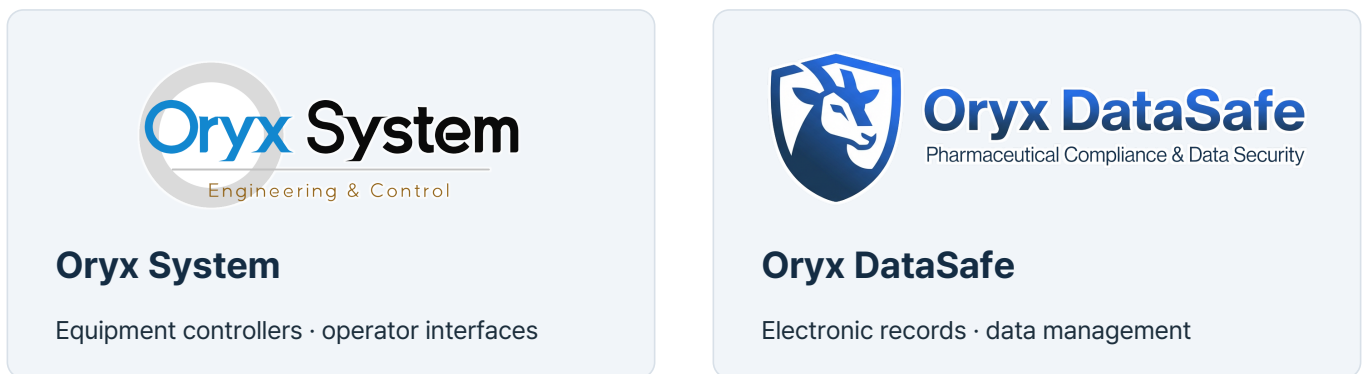
항목 (Item)	항목 설명 (Item Description)
시험기	시험기/필터 연결 정보와 시험 일자
시험 결과	시간별 시험 유량과 압력
결과 분석	기준값과 시험 결과 분석

PUPSIT: post-sterilization pre-use filter integrity test; synthetic forms, not DataStation output; validate each equipment integration.

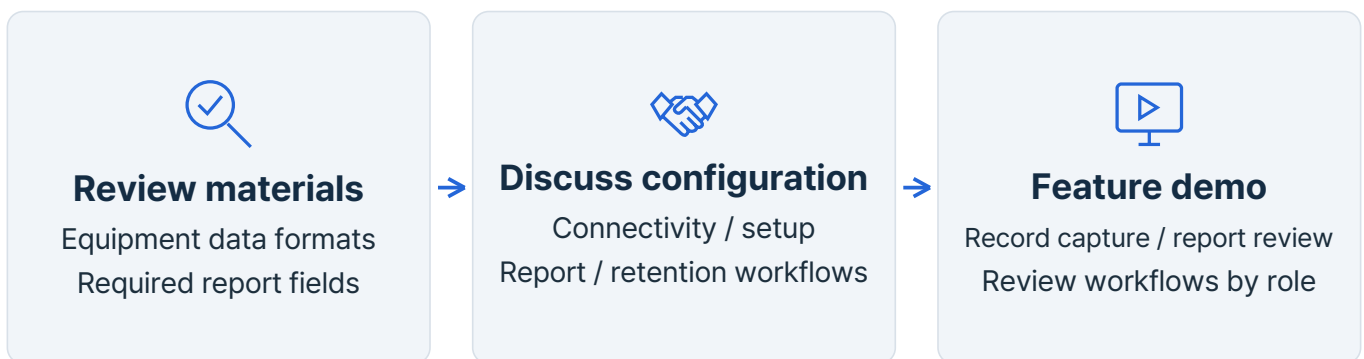
[Review Inputs](#) · [Discuss Configuration](#) · [Feature Demo](#)

Site Configuration & Consultation

Confirm a configuration suited to site data and operations before implementation.



Agree report formats and connectivity for site operations.
Configure equipment control and record management for their respective roles.



See actual app screens and detailed reports in consultations, demos or detailed material for specialists.

Consultation & Demos
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Oryx DataSafe | oryxdatasafe.com