

REGULATED INTEGRITY RECORDS

Prove your records never changed.

Your archive keeps the records.

DNA Shield keeps an independent check beside it: a written-once package of fingerprints, kept offline in DNA for centuries.

WHY THIS MATTERS

Regulators can ask about an approved record decades later. EU rules require the trial master file to be kept for at least 25 years after a trial ends. Validated archives, audit trails and replicated storage keep records safe and easy to find. But showing that a record never changed, after decades and several system moves, is a different problem.

GAPS CAN REMAIN

An independent check

The archive is asked to vouch for itself.

Many system moves

Every migration is a chance for a record to change.

Decades passing

Suppliers, formats and people change long before records expire.

WHAT DNA SHIELD DOES

When a record is approved, your system creates its fingerprint, a short code calculated from the file. DNA Shield writes these fingerprints, together with your most critical documents, into DNA and keeps them offline. Years, decades, even centuries later, you can compare them with your archive. If they match, the record is verified. If they do not, check your other archive copies.

Approved year 1	Copy 1 year 7	Copy 2 year 20	Copy 1 year 20
7F3A 9C2E	7F3A 9C2E	B41D 6E5A	7F3A 9C2E

Match: the record is verified. No match: check your other archive copies.

WHAT WE PROTECT

- Locked trial protocols
- Approved risk models
- Audit records
- Statistical analysis plans
- Engineering approvals
- The fingerprints of each record

50 to 500 KB
typical package size

Air-gapped
offline by design

Written once
no remote changes

0
energy used at rest

HOW IT WORKS FOR YOU

1

Lock

When a record is approved, your system creates its fingerprint.

2

Store

DNA Shield writes the fingerprints and key documents into DNA.

3

Keep

The package stays in a vault for decades. No power, no migration.

4

Check

When asked, we read it back and you compare it with your archive.

WHAT CHANGES

	Today	With DNA Shield
Where the proof is	Inside the archive it is meant to check	In a separate, offline copy
Across system moves	Each move is a chance for change	The fingerprints never change
When an inspector asks	The archive vouches for itself	An independent check
How long it lasts	3 to 30 years, then copy again	Decades, even centuries

NO NEW DEPENDENCY Your recovery still works without DNA Shield. Biomemory will hold the codec in escrow, so your data can be decoded even if Biomemory no longer exists, and will follow the SNIA DNA Data Storage Alliance standards.

WHO IT IS FOR

Pharmaceuticals and biotech

Contract research organizations

Medical devices

Banks, for model risk

Testing laboratories

Records operators

Usually led by the Head of Clinical Quality or Model Risk, with the Chief Quality or Risk Officer.

THE RULES THAT ALREADY ASK FOR THIS



21 CFR Part 11 trustworthy e-records



EU GMP Annex 11 accurate data



EU Clinical Trials 25-year retention



ICH E6(R3) protected trial records



SR 11-7 reviewable models



GDPR no personal data stored

DNA Shield supports these controls. It does not by itself make an organization compliant.

Let's protect the proof that matters most.

Start with an early access pilot: one closed trial or one approved model, sealed in DNA, and one check.

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AIR-GAPPED | BIOSECURE | IMMUTABLE | 150-YEAR MOLECULAR RETENTION