ONFAB

PRODUCT BROCHURE · ADC FLEXIBLE ISOLATOR

ONFAB ADC ISOLATOR

Flexible isolator for ADC manufacturing, custom fit for your high-potency workflow.



Potent payload. Open process. Fast changeovers.

Antibody-drug conjugate (ADC) payloads are among the most potent compounds you will handle. The risk sits at a few open steps, and those steps change with every programme.

> **"ADC work shouldn't mean rebuilding your facility. We build the isolator around the process you already run, so your team keeps its equipment, its SOPs and its momentum."**
>
> **Mike Brown**, General Manager, ONFAB

Programmes change. CDMOs and multi-product sites run many compounds in one facility. Your next customer won't look like your last.

Every open step is an exposure. Payload synthesis, weighing, compounding, conjugation, sampling and waste handling all open the process.

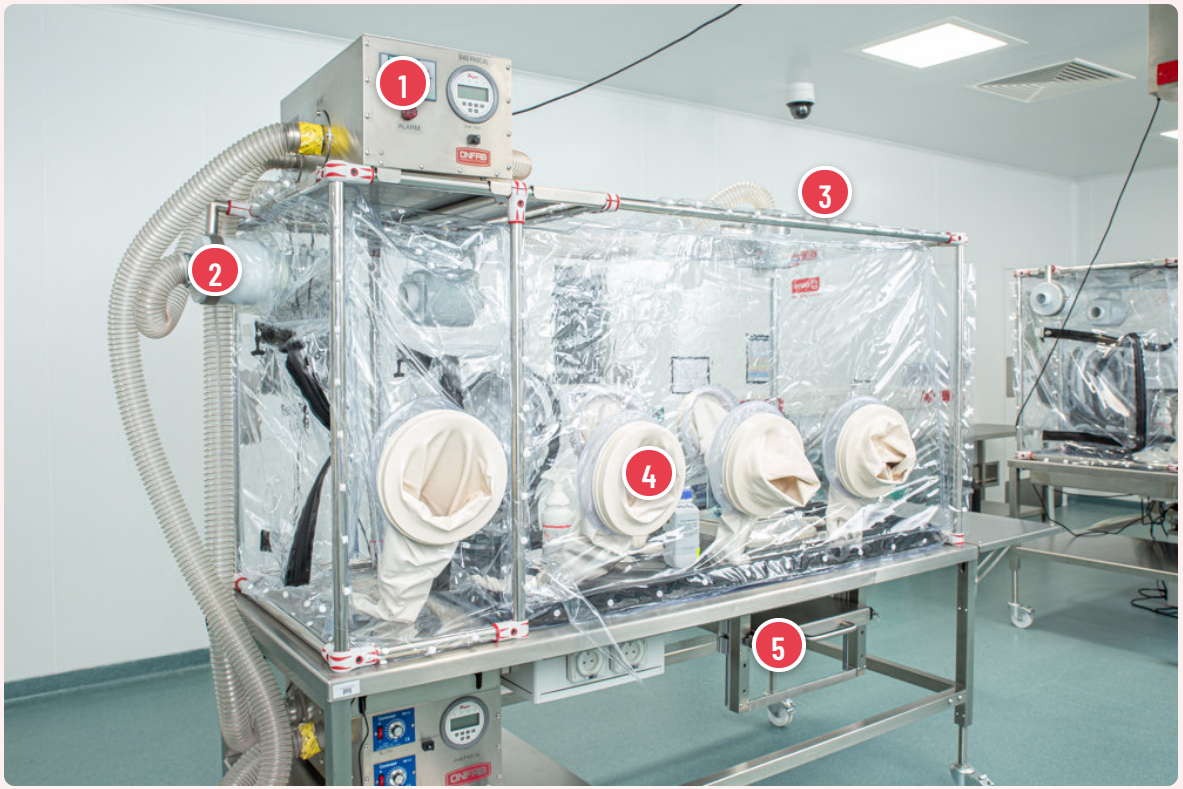
Rigid containment resists change. Most containment makes you change your process to fit the equipment, with rebuilds, revalidation and downtime.

Cleaning slows campaigns. Cleaning and validating a fixed isolator between payloads is time your line is not producing.

QA needs proof. Containment claims need measured data and documents your quality team can audit.

01

THE SOLUTION



Also built in: an integrated bag-in/bag-out (BIBO) continuous liner for safe offload of powder and waste from the isolator or process equipment.

Built around your workflow

1. **ONFAB automated pressure control**
   Negative pressure operation, with an automatic pre-start pressure decay test before every campaign.

2. **H14 HEPA filtration**
   H14 inlet and transfer filters, with 2-stage single-use exhaust.

3. **Anti-static polyurethane film**
   A gas-tight zipper for access. The whole assembly is single-use.

4. **Solvent-resistant glove sleeves**
   Glove sleeves and base resistant to solvents.

5. **Adjustable height table**
   Raise and lower the workstation for sitting or standing operators, with a solvent drip tray.

100% customised. Your SOPs unchanged.

Every ONFAB ADC Isolator is custom-built around your facility, equipment and workflow, so you keep your validated SOPs. Your process doesn't change to fit the isolator.

No change to your SOPs. Built around how your operators already work, with no rewriting of validated SOPs.

Keep your equipment. Around 98% of process equipment can be retrofitted.

Ready fast. Custom-built in as little as 8–10 weeks.

Tailored sizing. Tailored sizing options, with technical drawings on request.



NANOGRAM-LEVEL CONTAINMENT, CUSTOM FIT FOR YOUR HIGH-POTENCY ADC WORKFLOW

Containment without compromise: protect your product, process and people, all while moving faster between campaigns.

100%
customised to your workflow

<10 ng/m³
typical test data

~98%
of process equipment retrofitted

8–10 WKS
custom-built in as little as

01 –

NANOGRAM-LEVEL CONTAINMENT

Negative pressure, H14 HEPA filtration and a gas-tight zipper keep potent material contained.

Tested with a naproxen sodium surrogate

02 –

ADJUSTABLE HEIGHT

Raise and lower the workstation to suit sitting or standing operators, for better ergonomics.

Sit or stand at the same isolator

03 –

ONE SUITE, MANY PAYLOADS

Weighing, compounding and transfer from a single location, integrity-tested before every campaign.

Automatic pre-start pressure decay test

Specifications

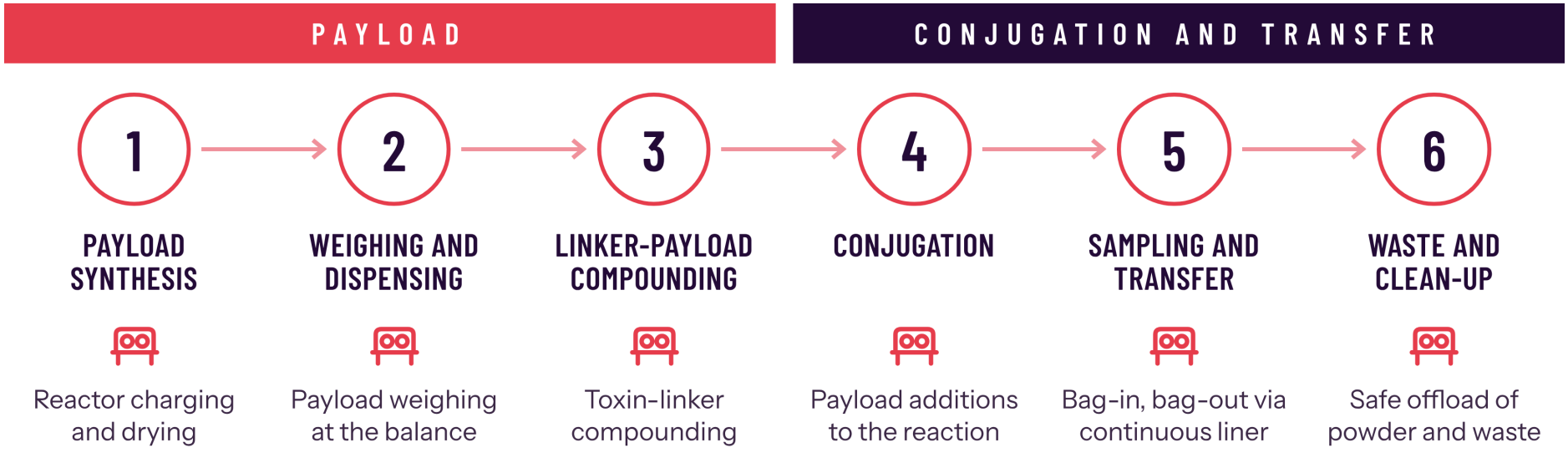
Typical configuration. Every isolator is custom-built around your process.

ATTRIBUTE	VALUE
Containment	Below 10 ng/m³ (typical test data)
Construction	Anti-static polyurethane film; glove sleeves and base resistant to solvents; gas-tight zipper access
Filtration	H14 air inlet and transfer filters; 2-stage H14 single-use exhaust filters
Pressure	ONFAB automated pressure control system; negative pressure operation; automatic pre-start pressure decay test
Transfer	Fully integrated bag-in/bag-out (BIBO) continuous liner system
Workstation	Adjustable height table; solvent drip tray; equipment shelf
Product contact	No API contamination of stainless steel parts
Sizing	Tailored sizing options; technical drawings on request
Quality	ISO 9001 QMS



Built for every open step

Every open step where potent payload is handled, contained in the ONFAB ADC Isolator, from payload synthesis to waste and clean-up.



Contained in the ONFAB ADC Isolator. Pair it with ONFAB accessories, from fan sets to continuous liners, to complete your system.

02

THE BENEFITS

Why the ONFAB ADC Isolator

CDMOs don't just buy an isolator. They buy a way to take on ADC work without rebuilding their facility.

For antibody-drug conjugate (ADC) manufacturers and CDMOs who need to add or scale ADC work without rebuilding their facility, ONFAB provides the ONFAB ADC Isolator, custom fit for your high-potency ADC workflow, so you can protect your product, process and people, all while moving faster between campaigns.

Protect your people

Negative pressure, H14 HEPA filtration and a gas-tight zipper keep potent payload away from operators: below 10 ng/m³ in typical test data.

Protect your product

A new, single-campaign isolator eliminates cross-contamination risk between payloads.

Protect your process

100% customised around your facility, equipment and validated SOPs.

Move faster between campaigns

No cleaning validation of the isolator itself, and custom-built in as little as 8–10 weeks.

Quality you can document

Confidence comes from measured data, not assumption. Containment is tested with a naproxen sodium surrogate, with the documents your QA team needs.

<10 ng/m³

containment performance in typical test data

PERFORMANCE SUMMARY

Airborne concentration of naproxen sodium over task (ng/m³). Three powder handling runs and one dismantling run.

LOCATION	RUN 1 (43 MIN)	RUN 2 (43 MIN)	RUN 3 (40 MIN)	DISMANTLING
Pre-trial background*	< 0.83	< 0.83	< 0.83	N/A
Personal 1	< 0.58	< 0.58	< 0.63	< 0.82
Personal 2	N/A	N/A	N/A	< 0.83
Position 1	< 0.58	< 0.58	< 0.63	< 0.83
Position 2	< 0.58	< 0.58	< 0.63	< 0.83
Position 3	< 0.58	< 0.58	< 0.63	< 0.83
Position 4	< 0.58	< 0.58	< 0.63	< 0.83
Position 5	< 0.58	< 0.58	< 0.69	N/A
Position 6	< 0.58	< 0.58	< 0.63	N/A
Position 7	< 0.58	< 0.58	< 0.63	N/A

*Pre-trial background run time was 30 minutes. These are sample results from a specific study using naproxen sodium as a surrogate. Similar results can be achieved under comparable conditions, but individual results may vary with your process and operating environment. We recommend verifying performance in your own application.

DOCUMENTATION

- ✓ **Every shipment:** Certificate of Conformance for each item
- ✓ **On request:** Material Safety Data Sheet (MSDS) and training manual
- ✓ **With installation:** operator training and support from first survey to replenishment
- ✓ **On request:** technical drawings
- ✓ **Quality:** ISO 9001 quality management system

Two workflows. One partner.

An ADC brings two workflows together: sterile biologics and highly potent active pharmaceutical ingredient (HPAPI) chemistry. Together, Savillex and ONFAB support every stage, from the antibody and the payload to the final drug product.

BIOLOGICS WORKFLOW — SAVILLEX

Sterile manufacture of the monoclonal antibody

- Cell culture
- Harvest and clarification
- Purification
- UF/DF
- Intermediate storage

FOCUS · sterility · yield · single-use integrity

HPAPI WORKFLOW — ONFAB

High-potency payload manufacture

- Payload synthesis
- Weighing and dispensing
- Linker-payload compounding
- Sampling and transfer
- Waste and clean-up

FOCUS · operator protection · containment · no cross-contamination

CONJUGATION: WHERE BIOLOGY BECOMES AN ADC

Payload additions contained in the ONFAB ADC Isolator, with Purillex® bags and bottles for sterile fluid transfer.

DOWNSTREAM AND FINISH

Purification, UF/DF, sterile filtration, formulation, fill/finish, storage and distribution.

ANALYTICAL CONFIDENCE

Ultra-pure acids and PFA labware for trace-metal testing before final release.

ONFAB ADC ISOLATOR

SAVILLEX + ONFAB ACROSS THE ADC WORKFLOW

More of your ADC workflow. One partner. Flexible containment from ONFAB and high-purity fluid handling from Savillex, from the antibody and the payload to the final drug product.

ONFAB ACCESSORIES



ONFAB FAN SET
Steady pressure and air flow, run after run



ONFAB PRESSURE ALARM
Know the moment pressure moves out of range



ONFAB VENTURI AIR EJECTOR
Safe negative pressure, no fan needed



ONFAB ISOLATOR HALF SUIT
More reach and heavier handling inside your isolator

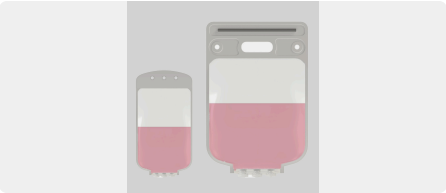


ONFAB CLASP LINER TIES
Secure continuous liner separation



ONFAB CONTINUOUS LINER
Safe offload of powder and waste

FROM SAVILLEX



PURILLEX® 2D BAG ASSEMBLIES
Single-use bags for media, buffer and intermediate storage



PURILLEX® PETG BOTTLES
Protect high-value materials in storage and transport



HARVESTMAX FILTER RESERVOIR SYSTEM
Maximise product recovery during filtration



DST ACID PURIFICATION SYSTEMS
High-purity acids for trace-metal analysis before release

Also from Savillex: SeptoVent sterile vented closures, Purillex® PFA/FEP bottles and ultra-pure PFA labware.

03

GETTING STARTED

How to get started

From the first conversation to your first campaign, one ONFAB team supports you at every step.

01
TALK TO AN ENGINEER
A short call about your process, your compounds and the containment level you need to reach.

02
SITE SURVEY
We visit your site and look at your equipment, your SOPs and how your operators actually work.

03
DESIGN AROUND YOUR WORKFLOW
We design the isolator around your equipment and process, with technical drawings for your review.

04
BUILD AND TEST
Custom-built in as little as 8–10 weeks, with an automatic pre-start pressure decay test before every campaign.

05
INSTALL AND TRAIN
Operator training and support with installation, from first survey to replenishment.

06
RUN AND REPLENISH
Single-use assemblies for every campaign, with a Certificate of Conformance with every shipment.

WHAT TO TELL US

- ✓ **Equipment:** Make, model and plant reference
- ✓ **Attachment point:** Shapes support, equipment and ergonomics
- ✓ **Air quality:** Nitrogen or conditioned air when the process needs it
- ✓ **Waste:** Everything generated inside has to come out safely
- ✓ **Containment target:** Ideally as a band; the OEL refers to the material
- ✓ **Pressure and vacuum:** At any point in the operation, seals included
- ✓ **Batch size and number:** Drives how material goes in and comes out
- ✓ **Photos and dimensions:** From a distance, on all sides, plus room and access

READY TO START?

Book 20 minutes with an ONFAB engineer to talk through your ADC workflow.

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CONTAINMENT THAT FITS YOUR WORKFLOW. NOT THE OTHER WAY AROUND.

See how the ONFAB ADC Isolator fits your ADC workflow.

TALK TO AN ENGINEER

DOWNLOAD DATA SHEET

Or connect with an ONFAB engineer at enquiries@onfab.co.uk.

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SAFETY. RELIABILITY. CONFIDENCE.