THE FUTURE OF PROCESSING - HIGHLY TOXIC MOLECULES

Mike Brown, ONFAB

Introducing ONFAB

Founded in 2004, ONFAB are specialists in the design, manufacture, and installation of flexible containment technology used in the pharmaceutical manufacturing process and drug discovery, especially involving high potent powders or improving GMP conditions.

Our cost-effective systems protect users from exposure to hazardous substances typically to a performance of < 30ng/m3 down to 1ng/m3. They also drive efficiency by reducing cleaning validation times and can be retrofitted to your existing equipment.

Introducing ONFAB

- Serving clients in Europe, Far East, US and rest of world
- Over 5,000 containment systems in use globally
- ISO 9001 accreditation
- Audited manufacturing premises
- Short lead times for new and replacement systems
- Reliable after-sale care and fast replenishment

Cert No. 12431


ONFAB HQ (Middlewich, UK)

ONFAB USA (Eden Prairie, Minnesota)

Proud to work with

ONFAB partners

coperion

SANOFI

BAYER

gsk

MERCK

MERCK

BASF
We create chemistry

AstraZeneca

abbvie

NOVARTIS

Bristol Myers Squibb

Roche

Pfizer

Johnson & Johnson

FERRING
PHARMACEUTICALS

Takeda

evotec

GILEAD

Abbott

Hovione

3M

Piramal

Lilly

Glatt

Dr.Reddy's

QuayPharma

amri

ADCBIO

Quotient

药明康德
WuXi AppTec

janssen

Boehringer Ingelheim

Catalent

teva

Now part of the Savillex family!

- Manufacturer of clean, innovative container solutions for life sciences, lab, and technology applications
- Custom fluoropolymer injection/stretch blow molding
- Industries served include pharma, biotech, geochemistry, semiconductor, and aerospace
- Founded in 1976
- Headquartered in Eden Prairie, MN
- Brand new IBM facility for manufacturing of newly launched PETG Square Media Bottles

Savillex featured products

Purillex® PETG Square Media Bottles

deal for storing liquid media, buffers, sera, and other sensitive materials

Purillex® PFA Bottles

Ideal for bulk drug storage, cell & gene therapy, tissue engineering, etc.

Purillex® PFA Vials

Ideal for stability testing, vaccine seed stock preparation, etc.

NEW additions from Optimum Processing, Inc

SeptaVent® Spin Tubes

50mL bioreactor spin tube ideal for automation applications

HarvestMax®

Filter reservoir system designed for one-step cell harvest clarification

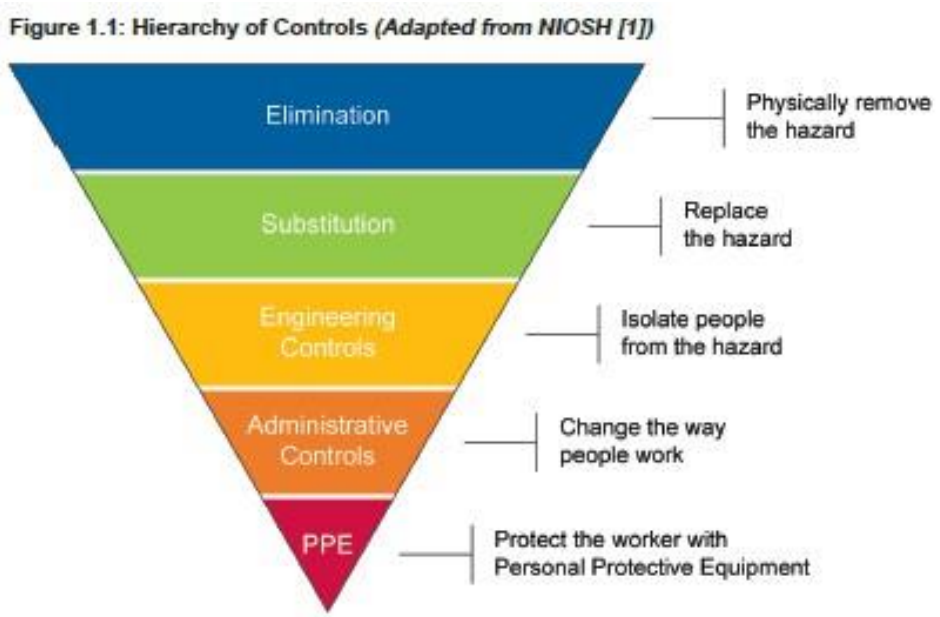
XpressVent

Disposable liquid handling system assemblies

Why is containment technology needed?

- Increase in the use of high potent active pharmaceutical ingredients
- Reclassification of compound potency
- Driven by better drug discovery
- The increase in targeted therapy (ADC and PDC growth)
- Need to improve safety

What is the hierarchy of control?



Elimination

Substitution

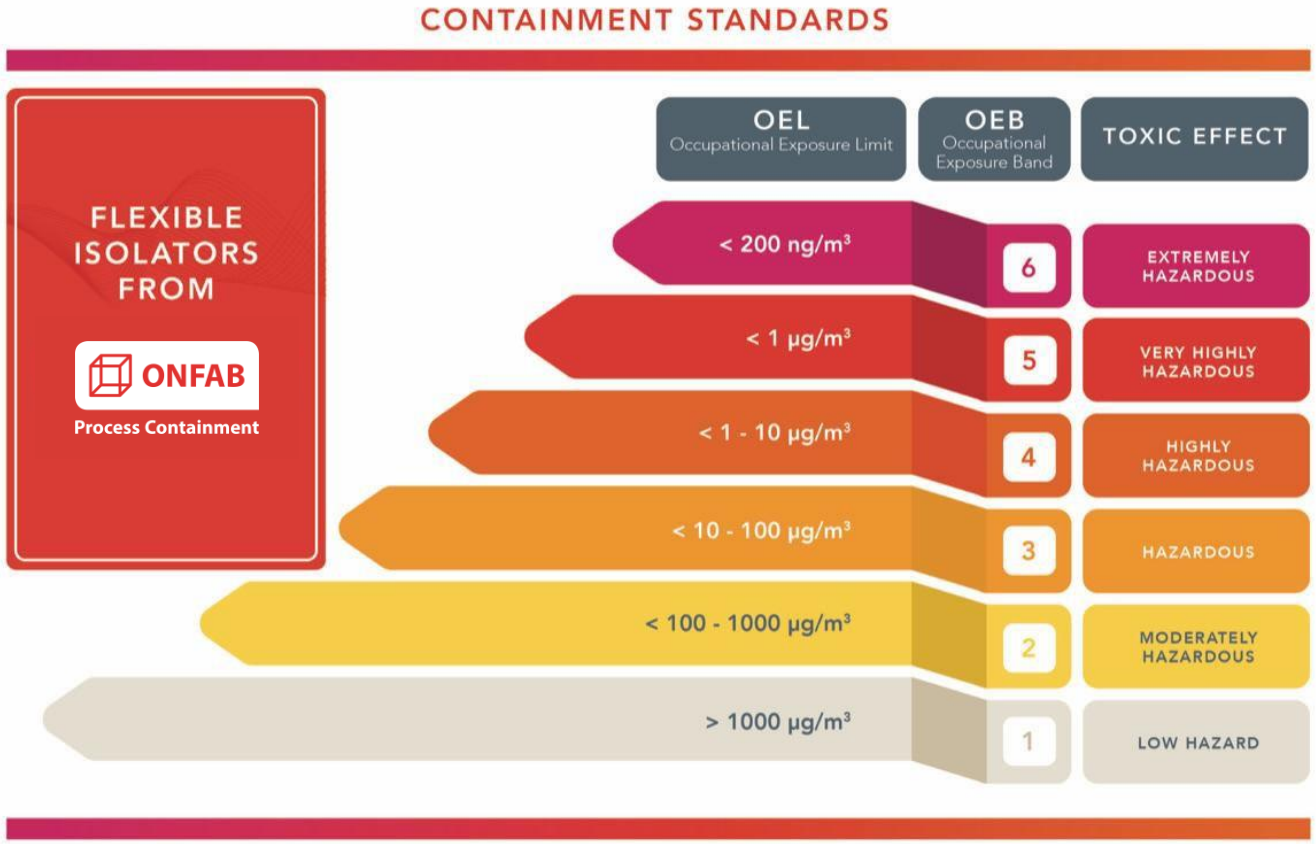
Implementation of Engineering control

Training of best practices

Respirators, Air hoods etc

What is a HPAPI?

- Drug compounds that are effective at low dosage
- Having a 10 microgram per m3 or below OEL sitting in Band 3 4 5 or 6



How to handle HPAPI's safely?

- Remove the reliance on PPE
- Move towards engineering control
- Focus upon CONTAINMENT at source
- Find the right partner with experience in providing safe solutions

Options available

- Valve Technology
- Rigid Isolation
- Vacuum systems
- Flexible Containment

FLEXIBLE CONTAINMENT IS THE **ONLY** TECHNOLOGY THAT CAN BE DEPLOYED IN ALL HPAPI HANDLING SCENARIOS

Why flexible containment?

COST EFFECTIVE

Achieve high containment without large up-front capital expenditure or ongoing equipment depreciation

EFFICIENT

Reduced cleaning and cleaning validation processes, improved sustainability

SAFE

Keep users protected and reduce risk of cross- contamination

COMPLIANT

Can provide product specific environmental conditioning and cover ATEX applications

IN CONTROL

Control lead times with just-in time-delivery, plus ensure production costs are defined

ERGONOMIC

Minimal impact to existing SOPs

FUTUREPROOF

Your existing process equipment can handle both non-potent and high potent compounds with minimal downtime for engineering changeout

Applications

- Proven success in all pharma applications
- Oral solid dose, hormone, bio pharma, and antibody drug conjugation
- Supporting low humidity product handling to increase GMP
- Air classification improvement

Flexible isolator's past

- Simple ambient enclosures
- Protection to 10 micrograms per meter cubed
- Simple Structures
- No Ergonomic assessments
- Poor films
- Limited filtration
- OSD development and manufacturing applications

Flexible isolator‘s future

- ADC market
- Picogram level of protection
- Fully disposable product contacting parts
- Multiple staged H14 HEPA filtration
- Pre Start pressure test

ONFAB ADC Isolator

- Demonstrated performance to less than 1 Nanogram levels of performance.

Typical Containment Test Data

The following results reflect the airborne concentration of naproxen sodium over task (ng/m³).

	Powder Handling Runs			Dismantling Run
Test Location	Run 1 (43 mins.)	Run 2 (43 mins.)	Run 3 (40 mins.)	Run 1
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.*

THANK YOU
FOR YOUR ATTENTION

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