



Alexander Wagner

MOTUS Engineering

After his studies of physics at the University of Marburg and mechanical engineering at German THM Giessen Alex started as a young engineer in 1992 with mechanical design and stress calculation for freeze dryers at a today well known German freeze dryer manufacturer. Later on he was the head of the mechanical engineering department and project and sales manager.

In the year 2000 he founded the MOTUS Engineering company at Marburg together with his long-term study fellow and college Ralf Battenberg. MOTUS focused on the development and manufacturing of loading and unloading systems for freeze dryers and on all nonstandard machines and devices in the fill finish area. Recently MOTUS offers new systems for monitoring in respect to the current annex 1.

Alex and Ralf had set up several patents as inventors in the technical field of lyos and loading systems for lyos.

Alex is also busy by seminars and consulting for retrofit projects.

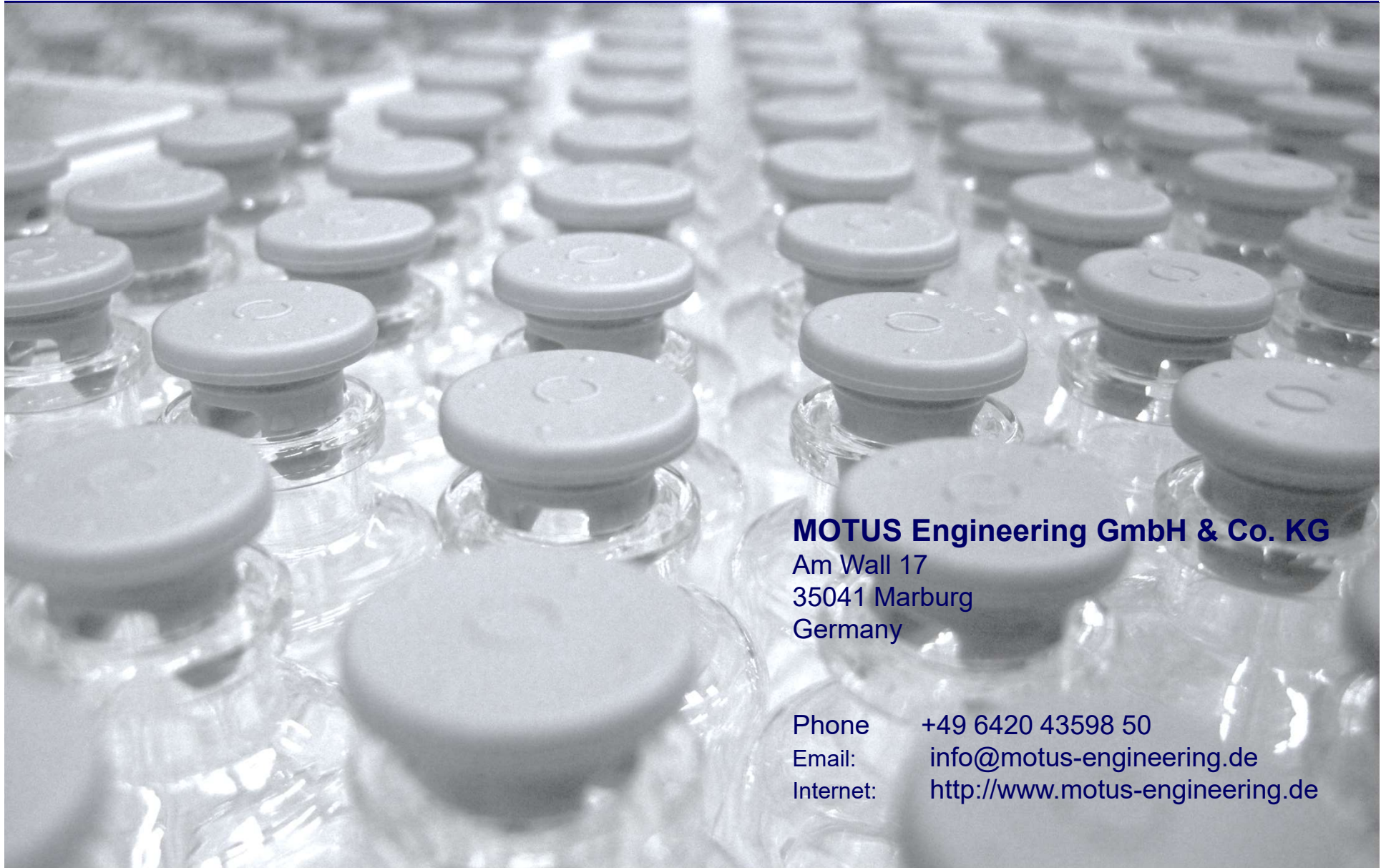
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Conceptual Planning of Lyoloading in Projects

Guest Presentation: Alexander Wagner, *Motus Engineering*



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Conceptual Planning of Lyoloading in Projects

Our Location



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 **Machines**



 **Equipment**



 **Engineering**

- **Lyoloader for Freeze Driers**
- **Retrofit loading and unloading systems**
- **Frameloader / Trayloader**
- **Environmental monitoring**
- **Tray filling**
- **Powdertransportsystems**
- **Sterilcontainer**
- **Consulting**
- **Projectmanagement**



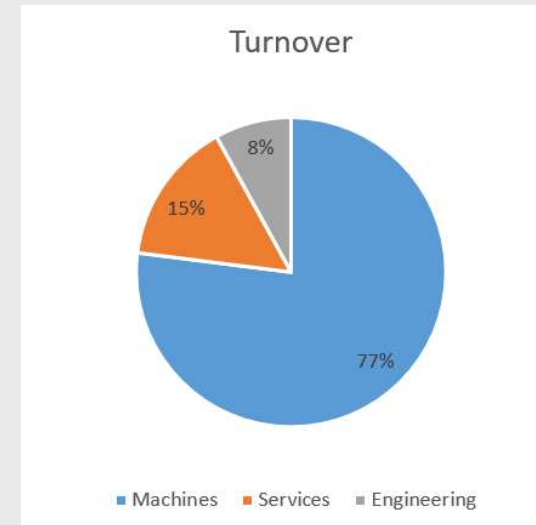
Company profile

Numbers and facts

- CFO/ company owner
Dipl.-Ing. Alexander Wagner



- CEO/ company owner
Dipl. Ing. Ralf Battenberg

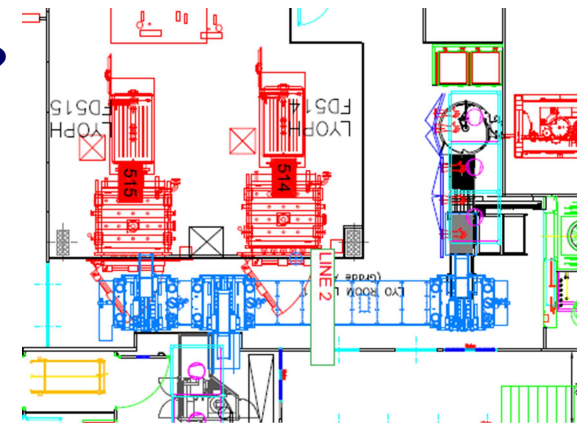


- Main business are the LYOLOADERS and mechanical devices
- Main market is the pharmaceutical industry



What to consider before starting planning ?

- Is it a retrofit project or a new project?
- Which constraints do you have ?
 - compliancy with „Annex 1“
 - space?
 - load on floor?
 - two level set up?
 - existing machines? E.g. filler, capper other lyos?
 - excape routes, emergency exits?
 - insertion, setup?
 - maintainance access?



What to consider before starting planning ?

- Is the product hazardous?
 - ATEX?
 - OEB Level?
 - special decontamination? (e.g. Hypochlorine, VHP,..)

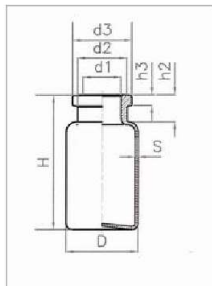
- Containment ?
 - production area classification (e.g. A, B, C)
 - oRABS?
 - cRABS?
 - Isolator?



What to consider before starting planning ?

- Primary packing materials?
 - Tubing glass DIN EN ISO 8362-1
2R, 4R, 6R, 10R, 15R, 20R, 25R, 30R, 50R
 - Blow molded glass DIN EN ISO 8362-4
5H, 7H, 8H, 15H, 20H, 25H, 30H, 50H, 100H, 250H

Nominal Volume	Nominal Size	Height x Diam. in mm acc. to ISO 8362								
			D	d1	d2	d3	H	h2	h3	s
2 ml	2 R	35x16	16	7	10,5	13	35	8	3,6	1
4 ml	4 R	45x16	16	7	10,5	13	45	8	3,6	1
6 ml	6 R	40x22	22	12,6	16	20	40	8,5	3,6	1
8 ml	8 R	45x22	22	12,6	16	20	45	8,5	3,6	1
10 ml	10 R	45x24	24	12,6	16,5	20	45	9	3,6	1
15 ml	15 R	60x24	24	12,6	16,5	20	60	9	3,6	1
20 ml	20 R	55x30	30	12,6	17,5	20	55	10	3,6	1,2
25 ml	25 R	65x30	30	12,6	17,5	20	65	10	3,6	1,2
30 ml	30 R	75x30	30	12,6	17,5	20	75	10	3,6	1,2



What to consider before starting planning ?

- **Performance?**
 - **Vials per minute [pce/min] filling / loading lyo?**
 - **Vials per minute [pce/min] capping/ unloading lyo?**
 - **Define performance for each vial size.**

	Loading (Filling)	Max. Performance 2ml/2R pce/min
Lab		60
Pilot		200
Production		400

	Unloading (Capping)	Max. Performance 2ml/2R pce/min
		60 to 120
		300
		600

What to consider before starting planning ?

- **Lyo capacity / batch size?**
 - sqm shelf area?
 - kg ice capacity?
 - vials per batch for each vial size?

- **Working shift situation?**
 - 1 shift?
 - 2 shift?
 - 3 shift? – 7/24h?



No.	type	dia [mm]	row [pce/m]	row shape plate [pce/m ²]	hex-shape plate [pce/m ²]
1	2R	16	62	3844	4428
2	4R	16	62	3844	4428
3	6R	22	45	2025	2314
4	8R	22	45	2025	2314
5	10R	24	41	1681	1904
6	15R	24	41	1681	1904
7	20R	30	33	1089	1235
8	25R	30	33	1089	1235
9	30R	30	33	1089	1235
10	5H	20,8	48	2304	2613
11	7H	22,1	45	2025	2314
12	8H	23	43	1849	2125
13	10H	25,4	39	1521	1733
14	15H	26,5	37	1369	1570
15	20H	32	31	961	1068
16	25H	36	27	729	822
17	30H	36	27	729	822
18	50H	42,5	23	529	608
19	100H	51,6	19	361	407
20	INF50	46	21	441	492
21	INF100	49	20	400	449
22	INF250	66	15	225	247
23	INF500	78	12	144	161
24	INF1000	95	10	100	114

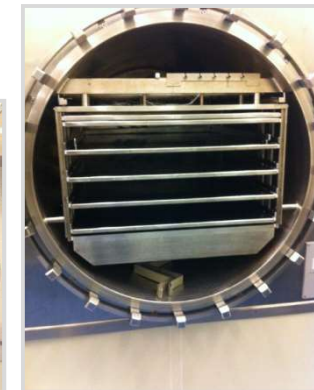
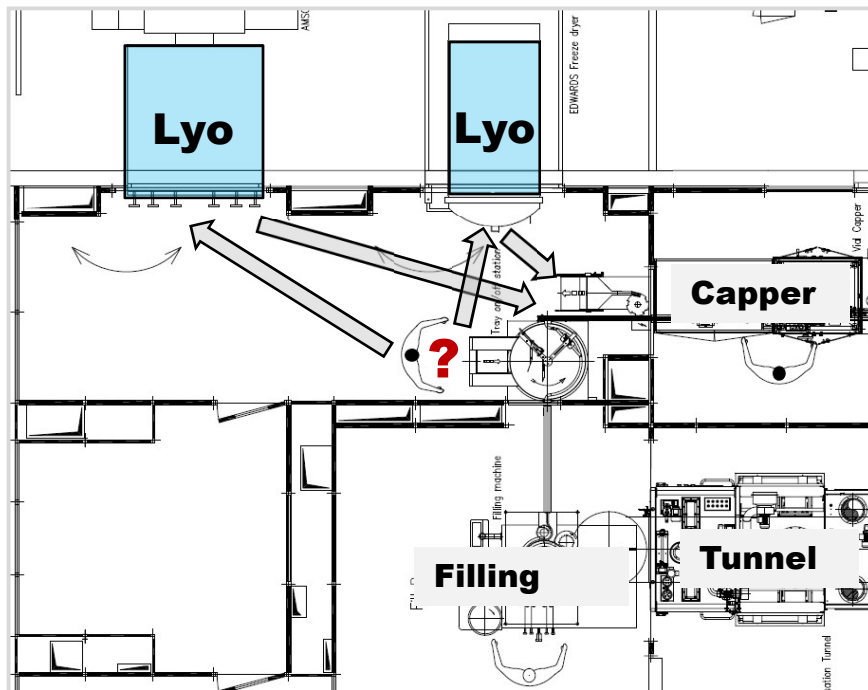
estimated hex-/row-shape factor : approx. 0,87

- all figures without warranty, calculation base without tolerances, related to 1 sqm -

Case Studies

Semi automatic loading, frames, trolley ACS001

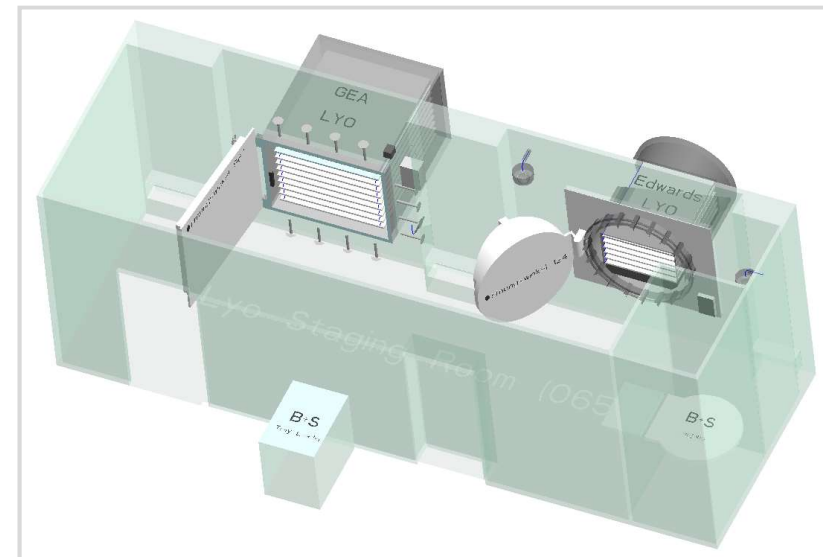
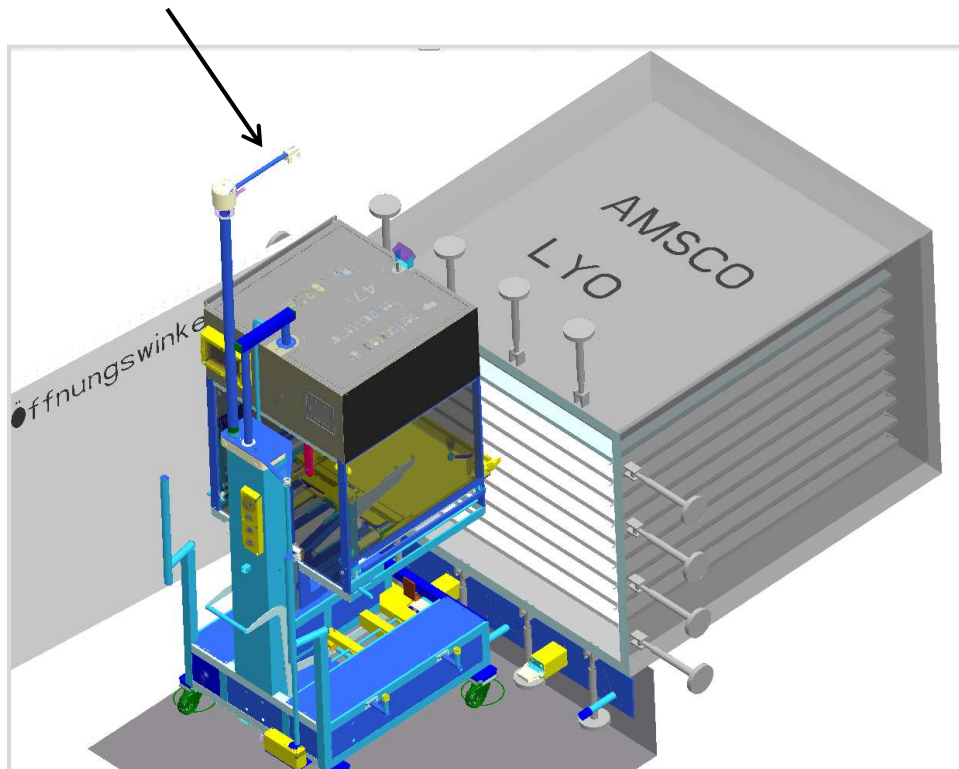
- Filling of Liquid- and Lyoproducts
- 2 x Freeze Dryer, 5m² and 16m² of different shape and no constant level possible
- No separation between operator and product during loading and unloading
- Manual transport of open vials between filling and freeze dryer



Case Studies

Semi automatic loading, frames, trolley ACS001

- Barrier system between operator and product
- Laminar air unit on top of loading/ unloading cart
- Vertical movement of loading height as no constant level is available at freeze dryers
- Flexible cable connection requested because of weight an reliability

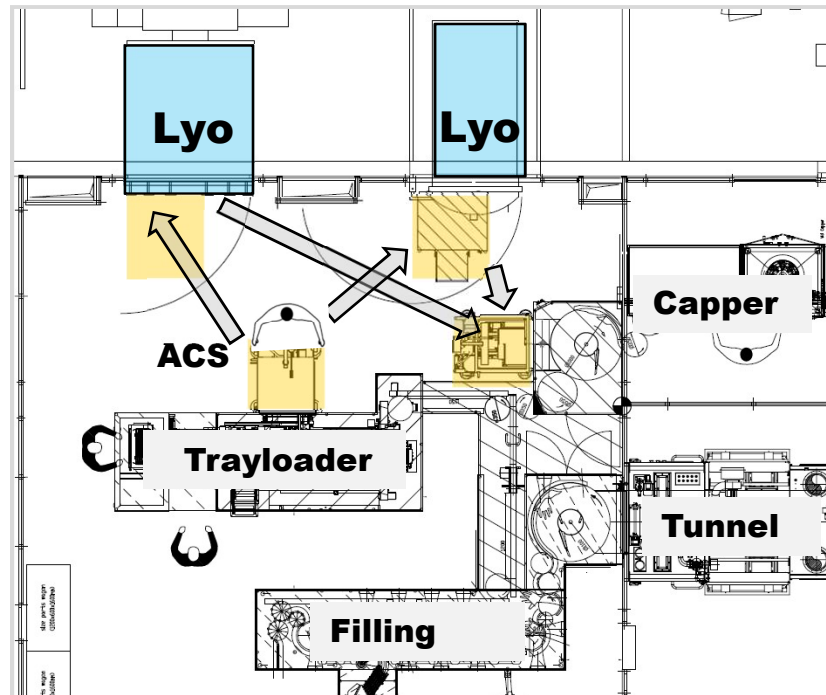


Case Studies

Semi automatic loading, frames, trolley ACS001

- Semi-automatisches loading system ACS001H-LF
- Flexible cable connection
- Loading frames out of PEEK for ergonomic and weight reasons
- Frames with coupling mechanism

ACS001H-LF



Case Studies

Semi automatic loading, frames, trolley ACS001



LOADING TROLLEY ACS001-H-212

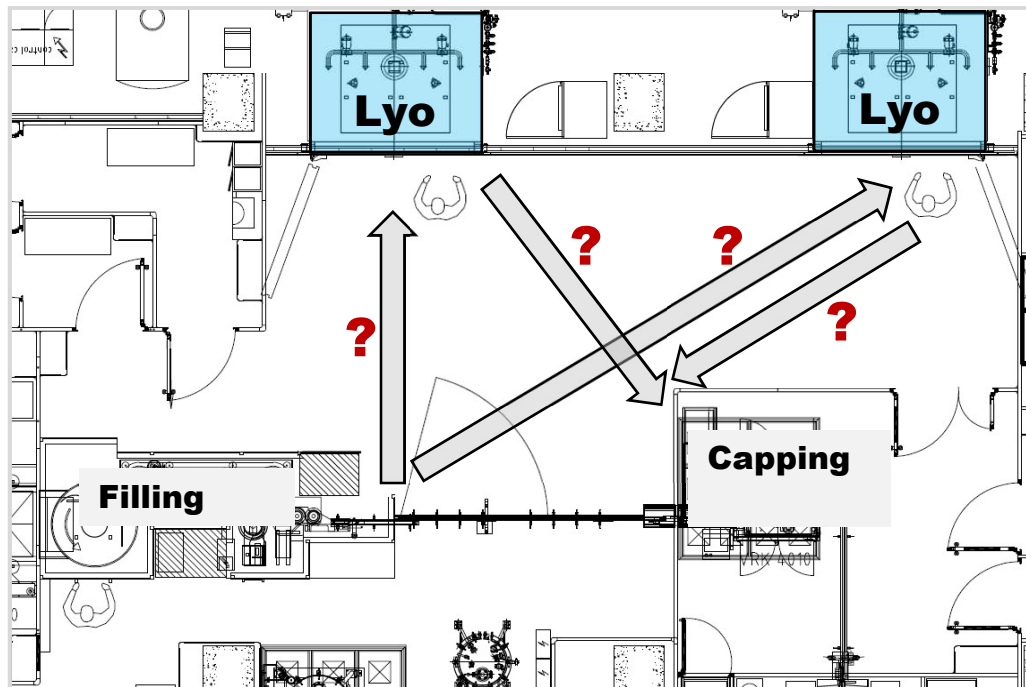
P1753



Case Studies

Semi automatic loading, frames, RABS unit ACS017

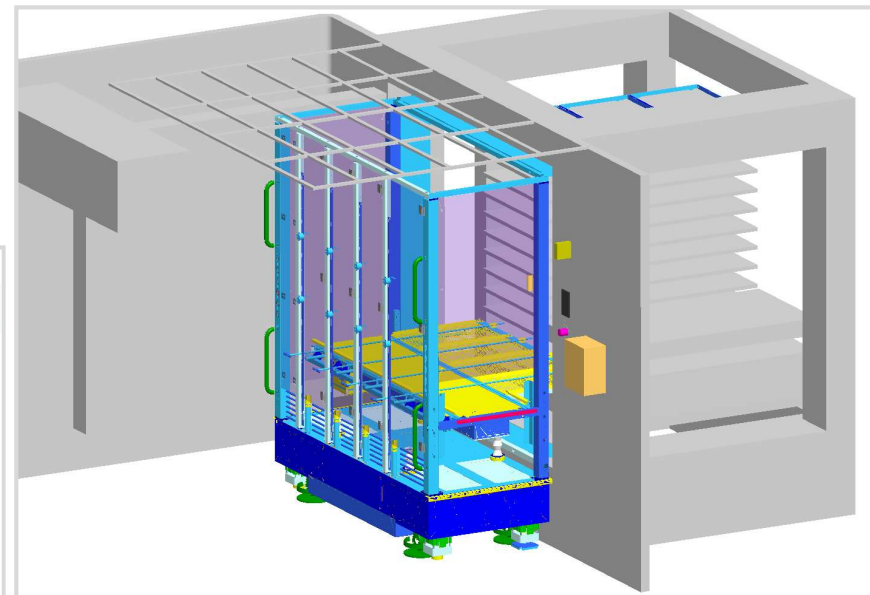
- Filling of Liquid and Lyoproducts
- 2 x freeze dryer with 24 m² shelv area each
- No separation between operator and product during loading and unloading
- Manual transport of open vials between filling and freeze dryer



Case Studies

Semi automatic loading, frames, RABS unit ACS017

- Barrier system between operator and product
- Semi-automatic loading / unloading
- Reliable product handling with frame system
- 4 vialformats (2ml – 400 pce/min)
- Connection to filler and capper
- Framesterilisation and storage within autoclave



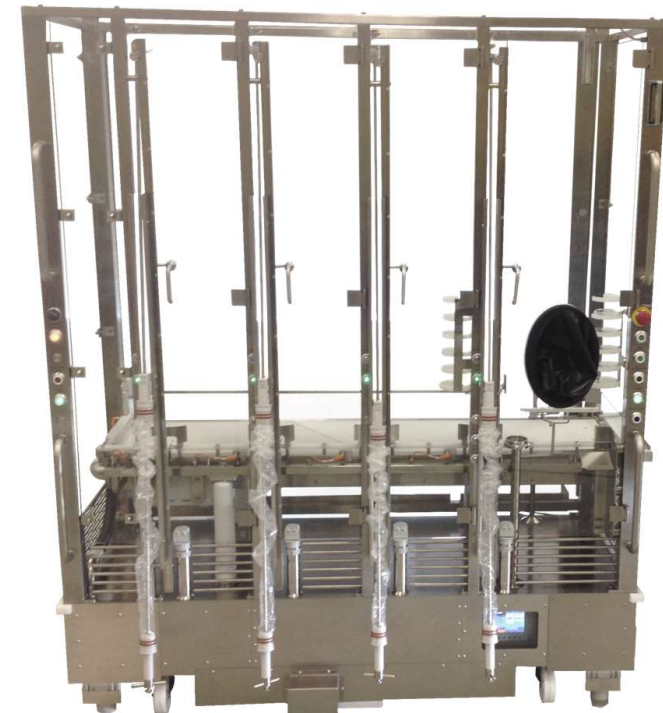
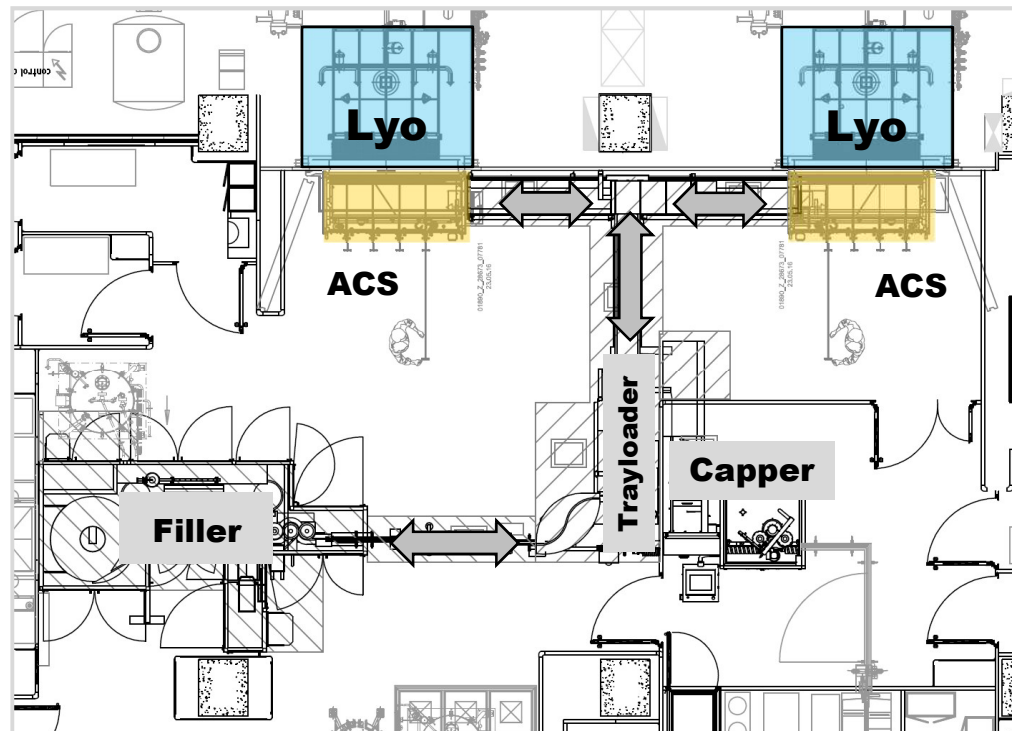
Case Studies

Semi automatic loading, frames, RABS unit ACS017

- Semi-automatic loading system ACS017s
- Loading system movable, undock the system for door opening at freeze dryer
- Laminar air protection for frames within cart for frame storage
- Frames with mechanical coupling mechanism

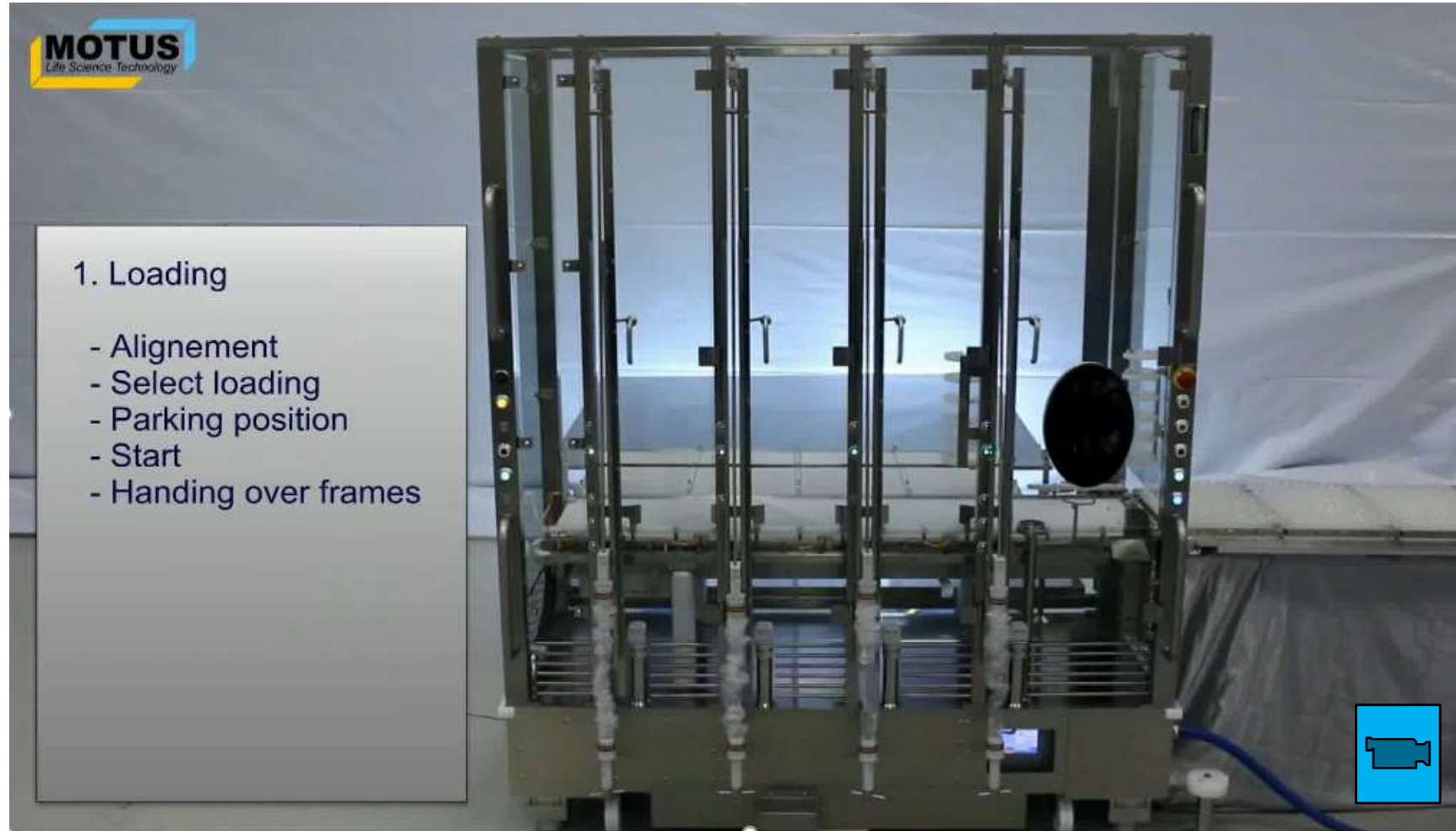


ACS017s



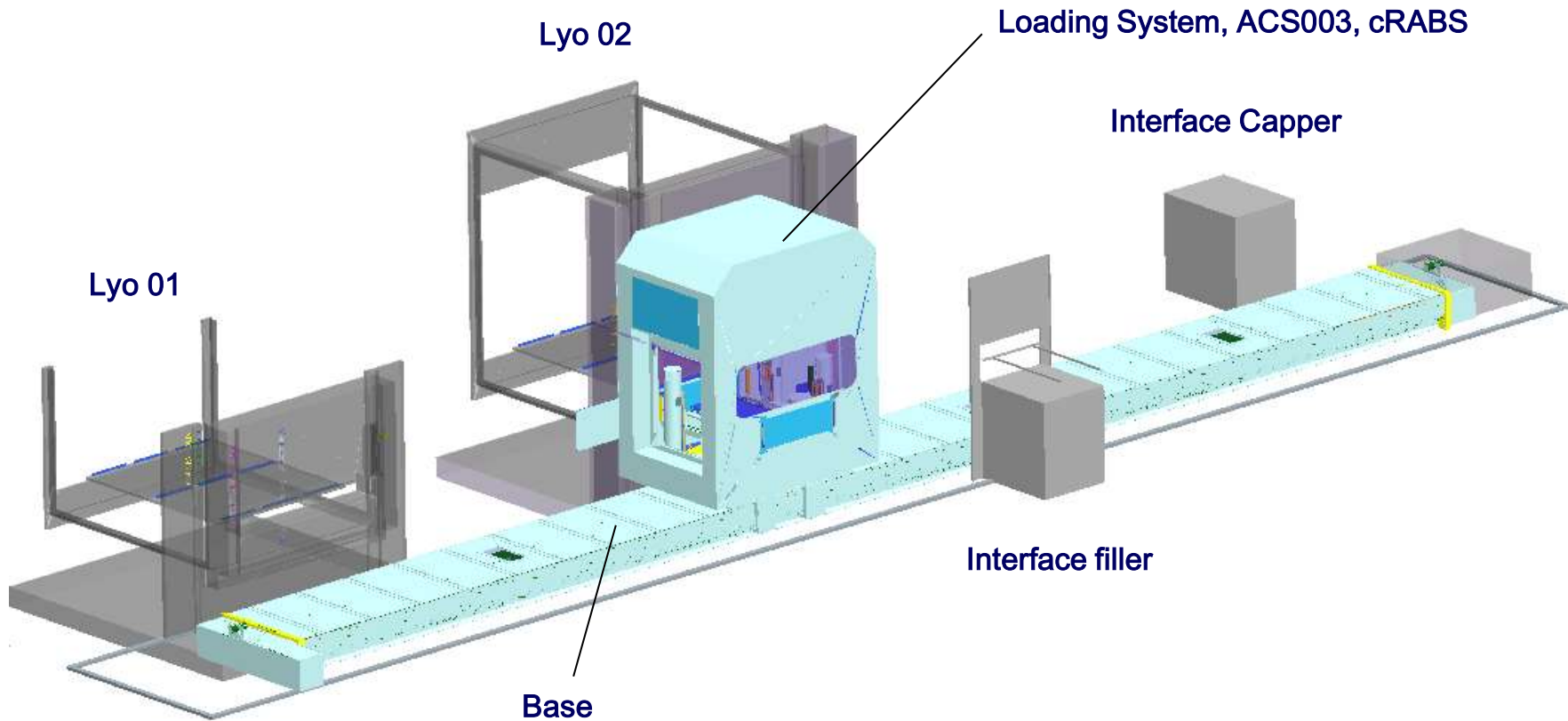
Case Studies

Semi automatic loading, frames, RABS unit ACS017



Case Studies

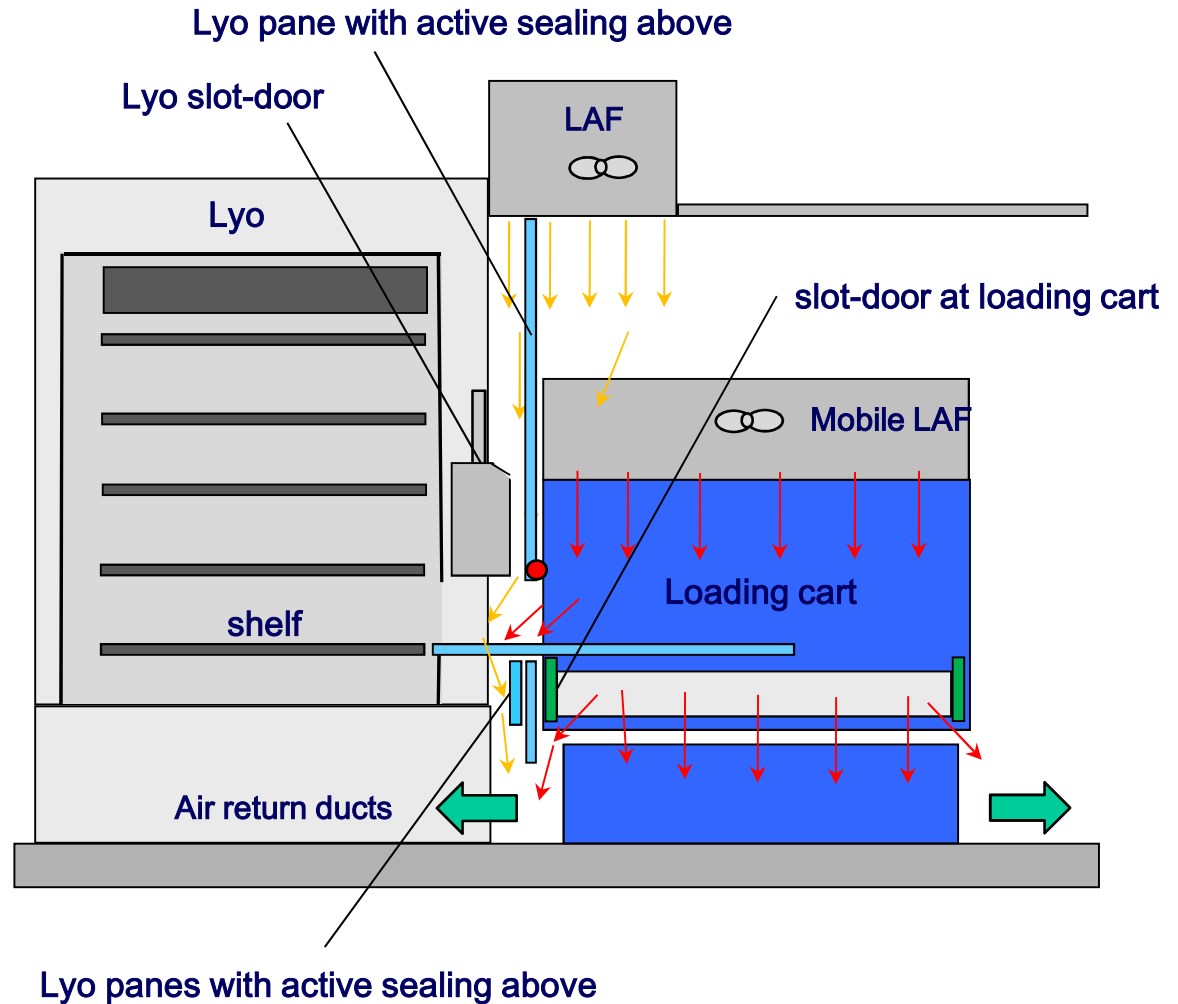
Automatic loading, frames, ACS003



Case Studies

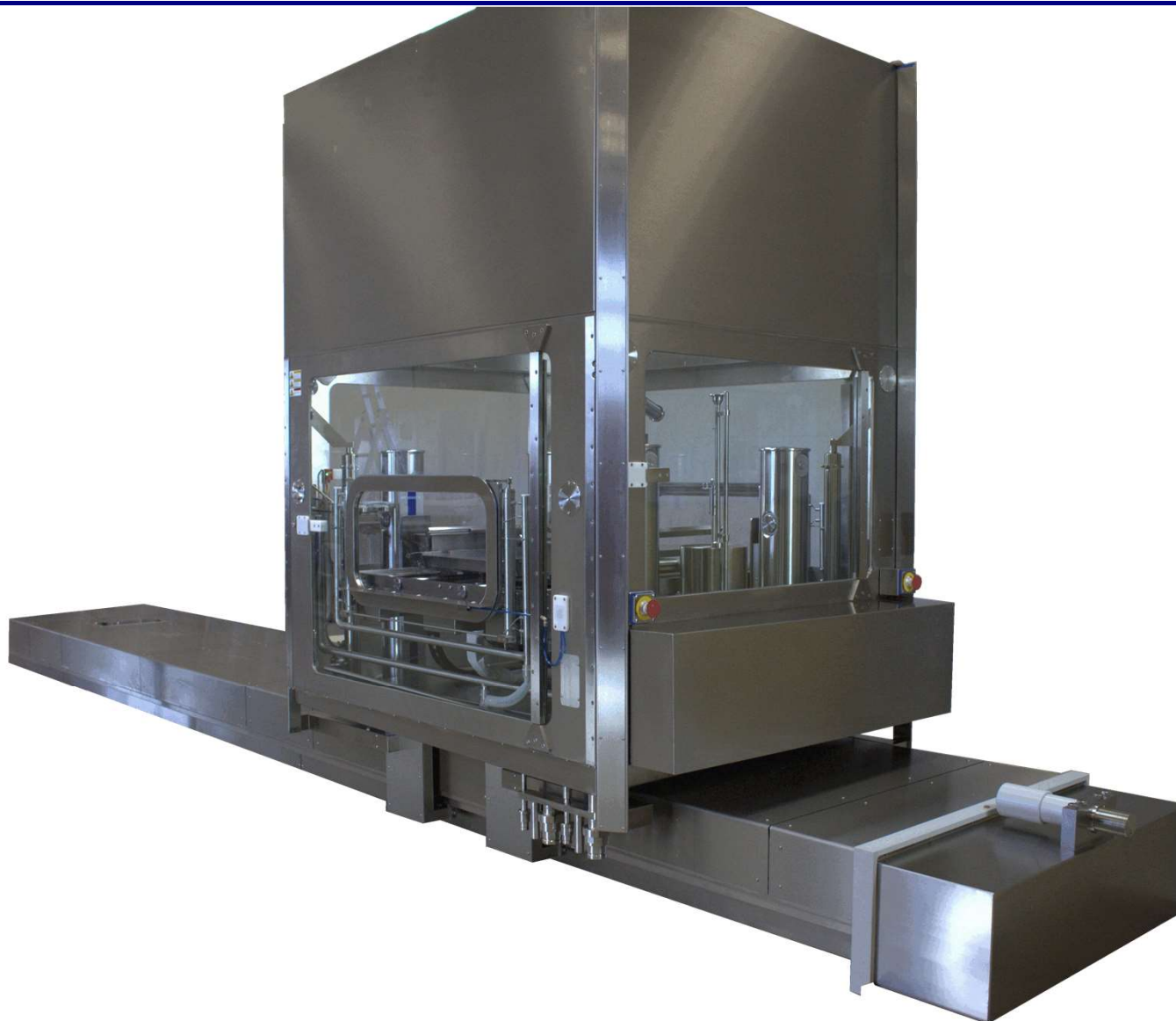
Automatic loading, frames, ACS003

- Air flow at Lyo slot door area improved
- Class B surfaces travel into Class A areas, sealing, dwell time, slot pane at cart, slot pane at lyo
- Air turbulences at lyo slot door area improved
- Air return ducts necessary below lyo slot door area
- Air return ducts necessary opposite to lyo slot door area
- less filters, lower air exchange rate, lower energy consumption, lower invest, lower service costs, less surfaces contaminated



Case Studies

Automatic loading, frames, ACS003



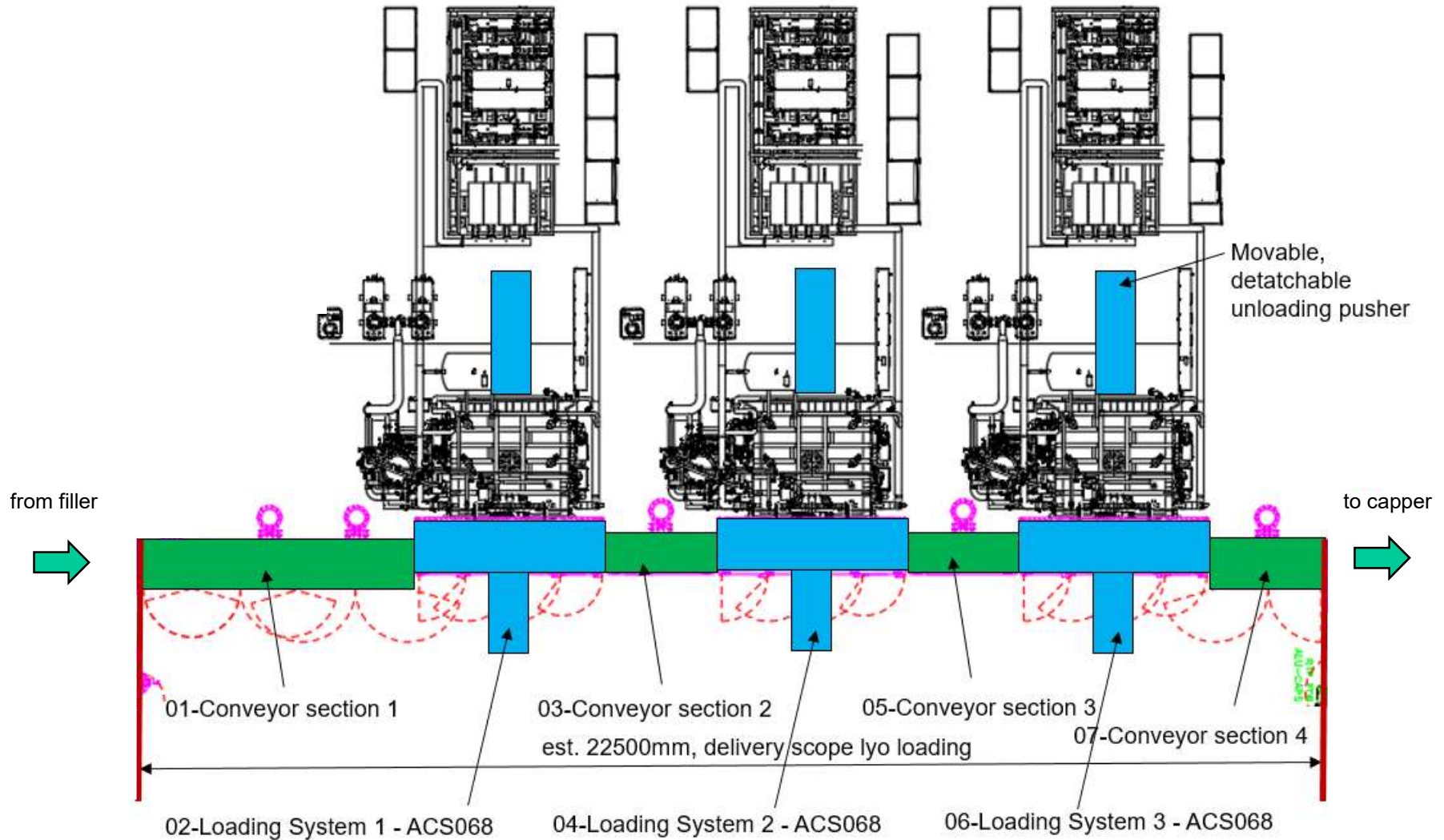
Case Studies

Automatic loading, frames, ACS003



Case Studies

Automatic loading, row by row, ACS068



Case Studies

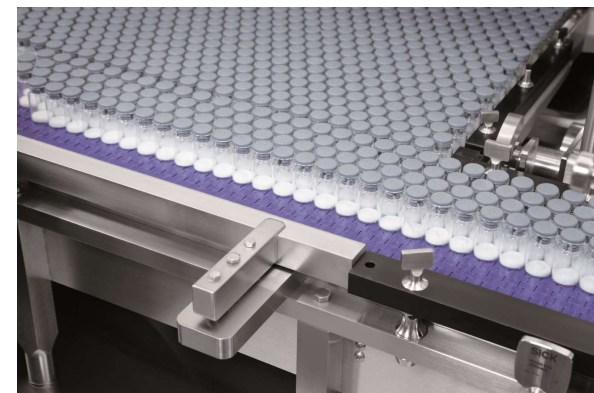
Automatic loading, row by row, ACS068

Performance ACS068:

- 2R – 400 pce/min – dia 16mm → 6400 mm/min
- 10R – 270 pce/min – dia 24mm → 6480 mm/min
- 20R – 210 pce/min – dia 30mm → 6400 mm/min
- 50H – 100 pce/min – dia 42,5mm → 4250 mm/min

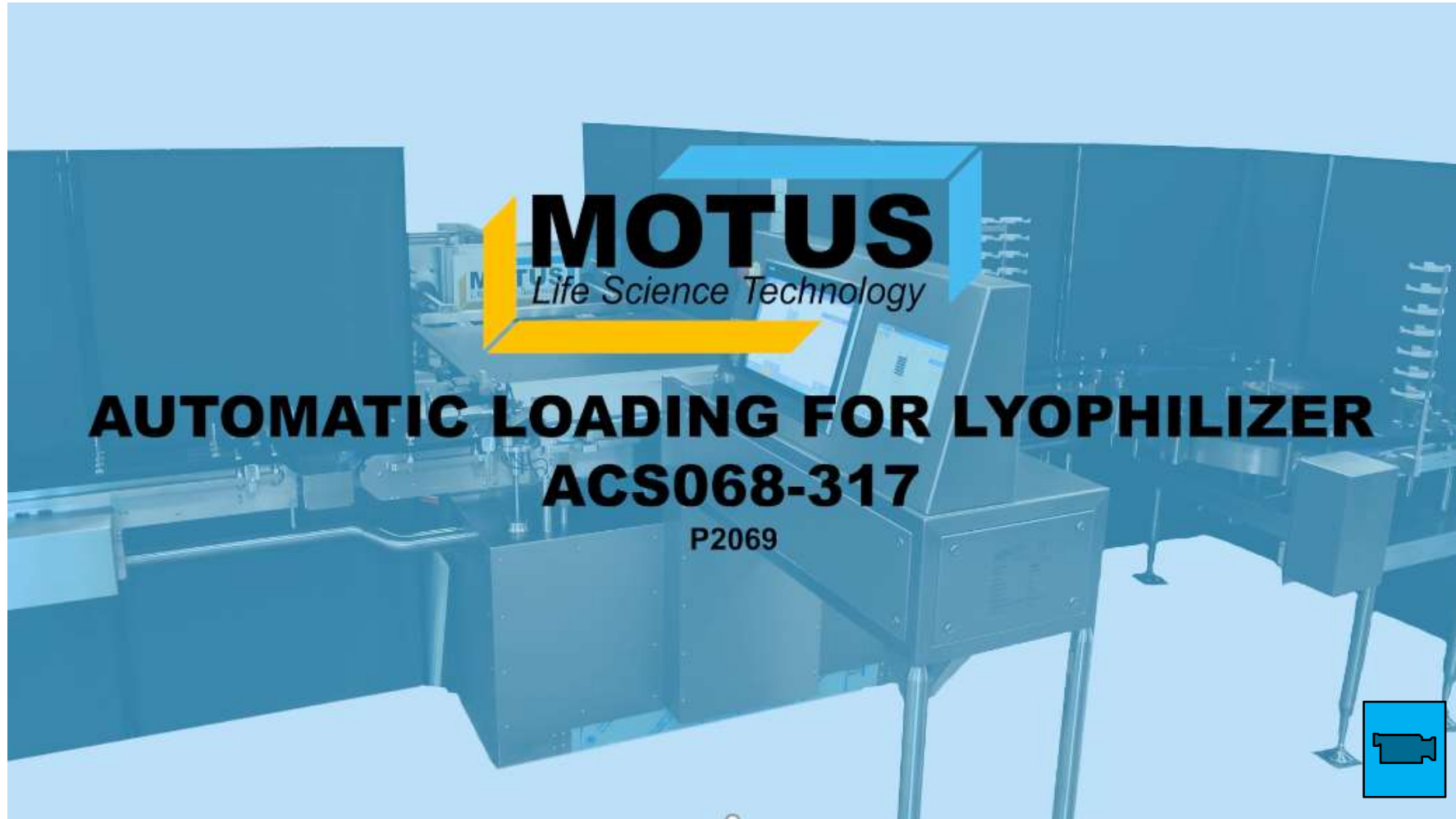
Total 4 format sets loading

Total 2 x format sets unloading (left, right)



Case Studies

Automatic loading, row by row, ACS068



Loading system ACS003

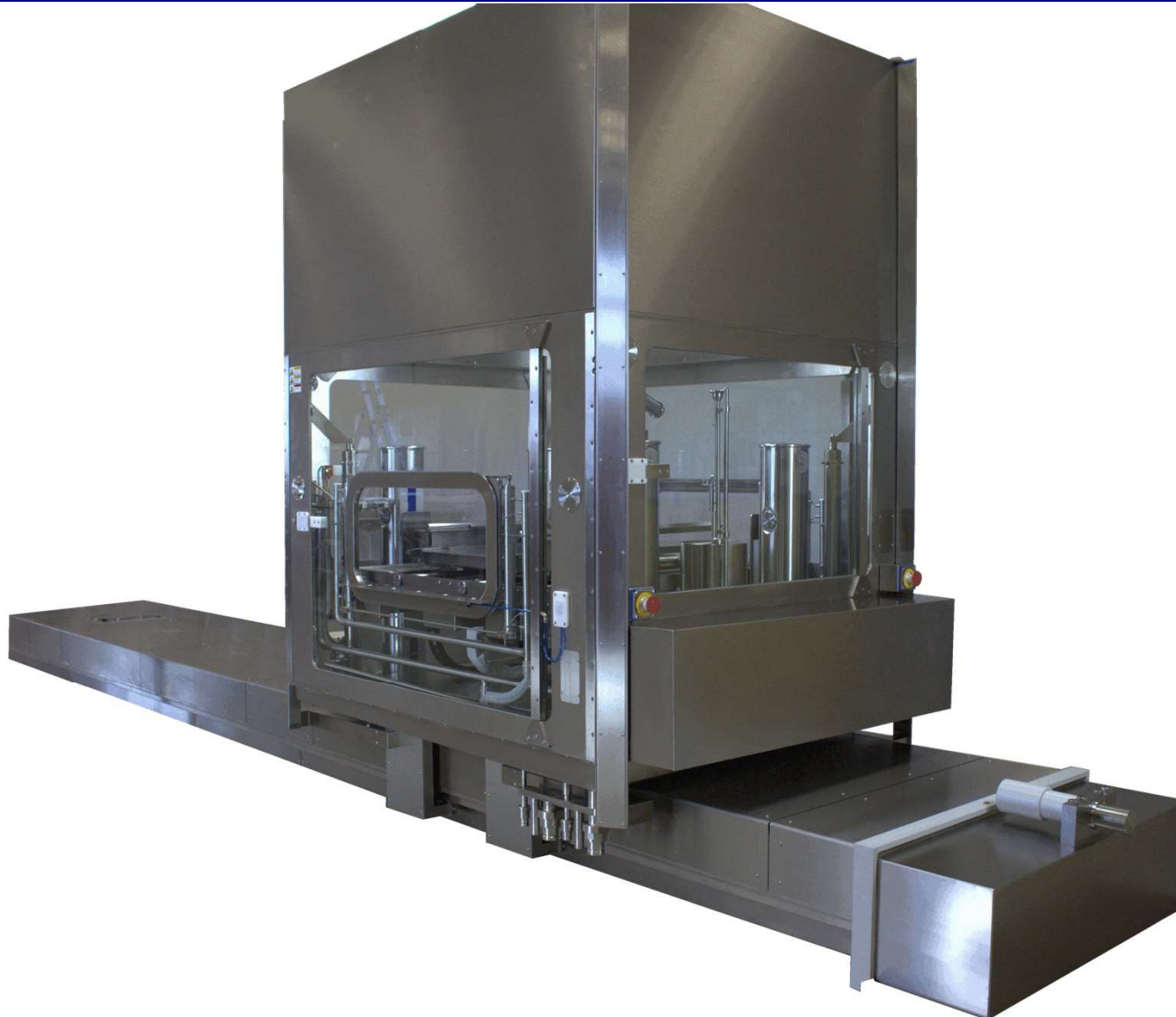
Automatic frames



Conceptual Planning of Lyoloading in Projects

Loading system ACS003, cRABS

Automatic frames



Loading system ACS022

Automatic vials row by row



Loading system ACS022

Automatic vials row by row



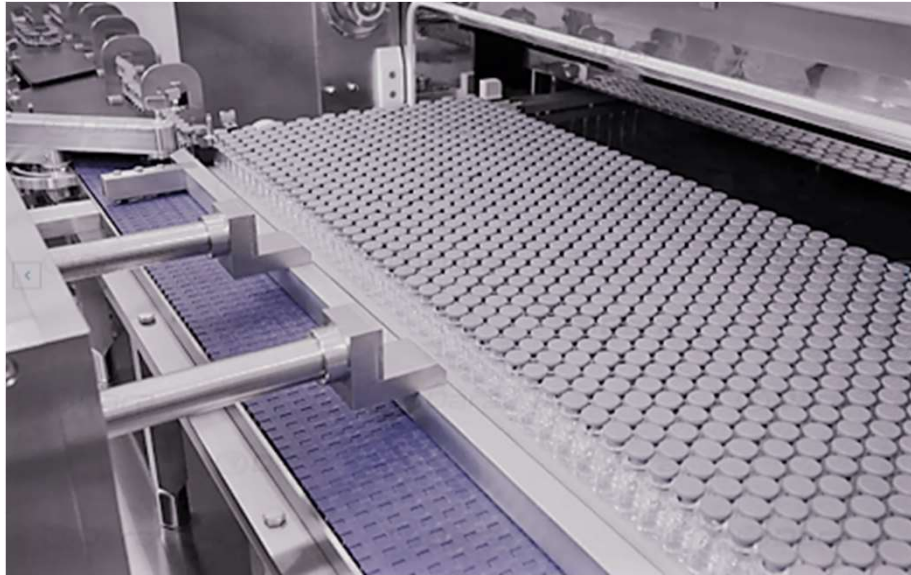
Loading system ACS068

Automatic vials row by row



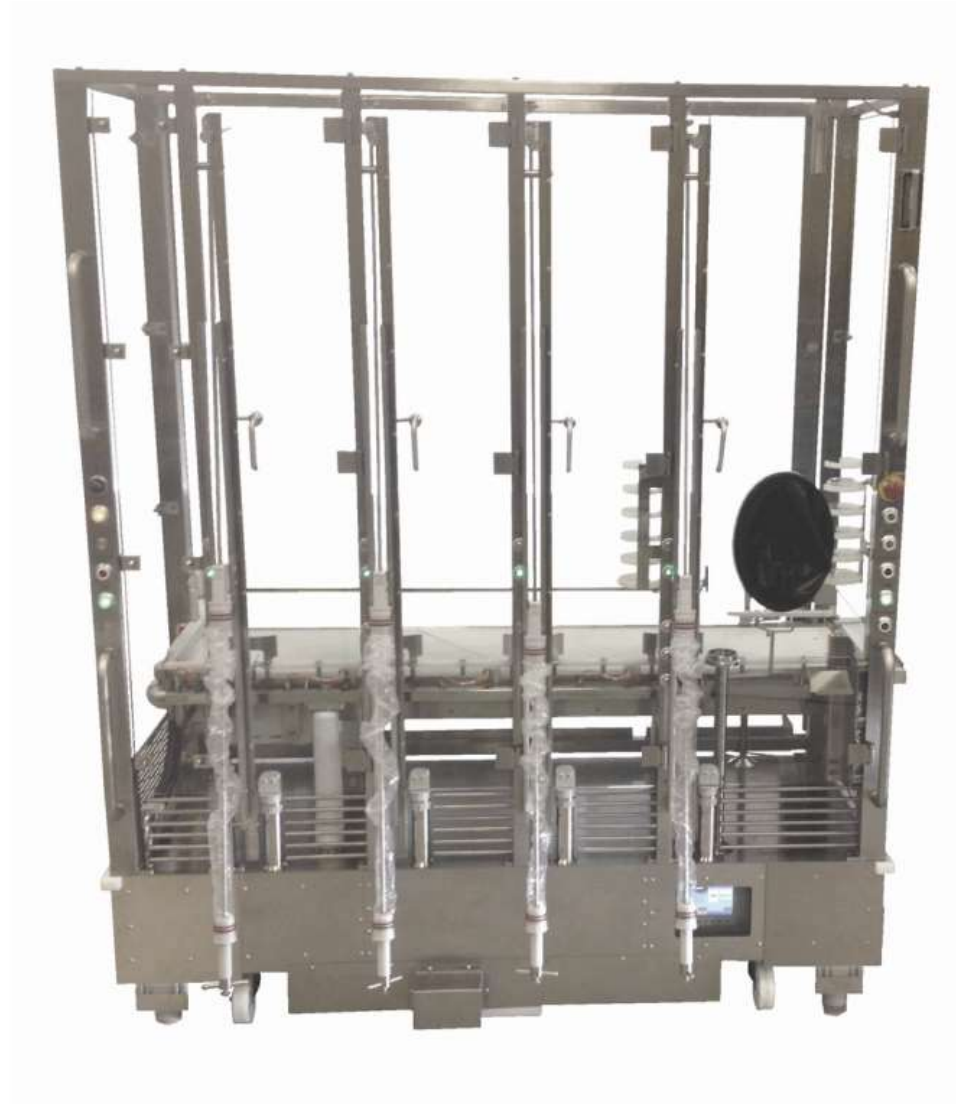
Loading system ACS068

Automatic vials row by row



Loading system ACS017

Semi automatic frames



Loading system with frameloader ACS001 - FL

Manuel frames – semiautomatic frameloading



Loading system ACS001

Semiautomatic frames



Conceptual Planning of Lyoloading in Projects
Loading system pilot lyophilizer ACS025
Semiautomatic frames



Loading system with frameloader ACSFL-286

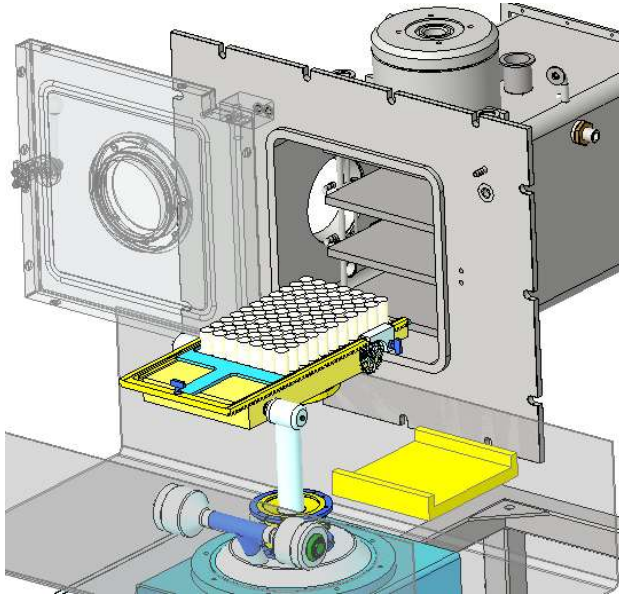
Semiautomatic frames



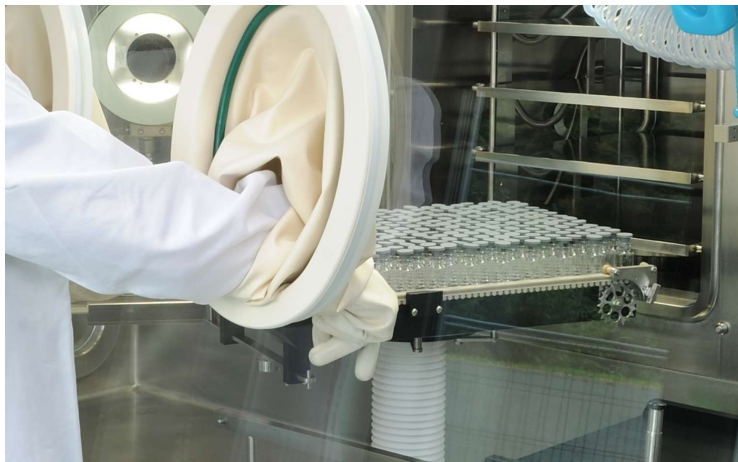
Conceptual Planning of Lyoloading in Projects

Loading system „LyoLift“ ACS072

Pilot Lyoloading



-patented-



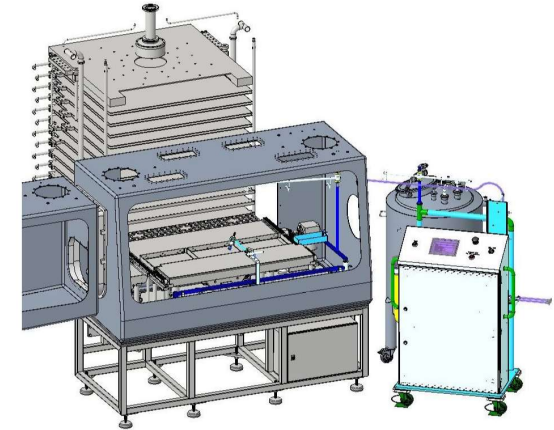
Frاملoader HPFL

Automatic, 4 stations



Tray filling, loading and powder handling

with Lyoshuttle



Tray filling, loading and powder handling

with Lyoshuttle



8.126 Points to consider for the design of loading (and unloading, where the lyophilised material is still unsealed and exposed), include but are not limited to:

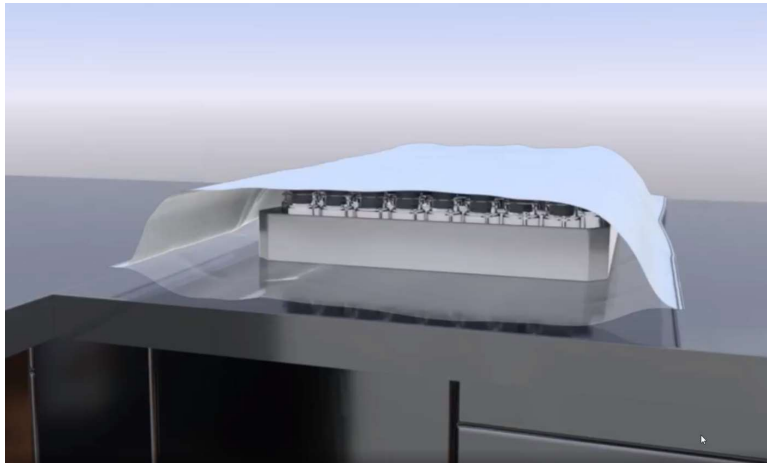
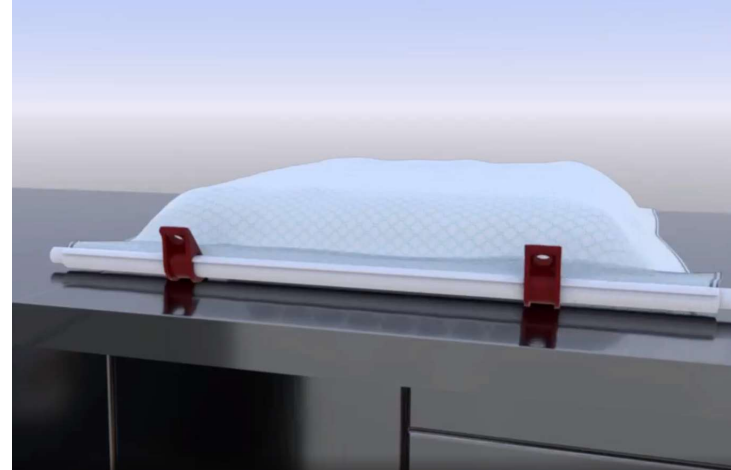
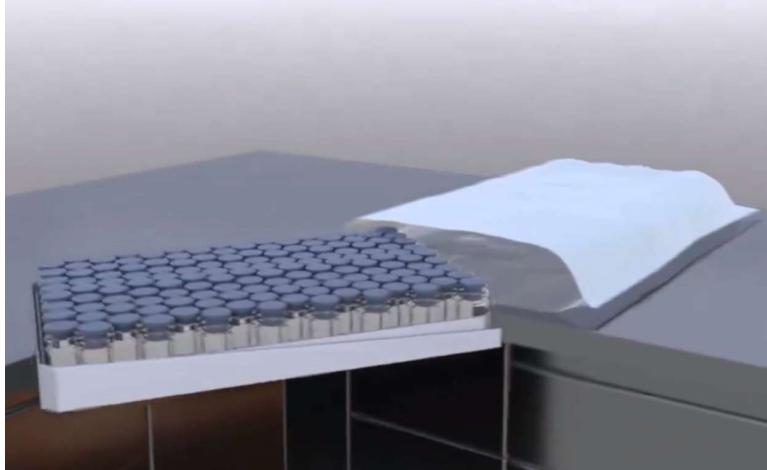
- i. The loading pattern within the lyophilizer should be specified and documented.
- ii. The transfer of partially closed containers to a lyophilizer should be undertaken under grade A conditions at all times and handled in a manner designed to minimize direct operator intervention. Technologies such as conveyor systems or portable transfer systems (e.g. clean air transfer carts, portable unidirectional airflow workstations) should be used to ensure that the cleanliness of the system used to transfer the partially closed containers is maintained. Alternatively, where supported by validation, trays closed in grade A and not reopened whilst in the grade B area may be used to protect partially stoppered vials (e.g. appropriately closed boxes).

Teclen

Lyoprotect® Lyophilization Bag

News, Annex 1

Teclen, lyo bag



News, Annex 1
Sealed box / Sealed bag

Sealed Box SB001



- Integrity test feasible
- Overpressure can be monitored
- Simple, light weight

Teclen bag



<https://teclen.com/en/>

The tray or frame containing the vials will then be placed in the lyophilization bag, which is already in place in the freeze-drier. For the frame, an auxiliary sheet will be used. It will be removed after positioning the frame. Then, the bag is closed and secured with the Closing Stick.
If aseptic criteria must be met, filling of vials, placement in the bag and closure of the bag can take place under a laminar flow. For the handling from the laminar flow to the freeze-drier another auxiliary sheet will be used (outside the bag), which is removed after the bag has been placed on the shelf in the freeze-drier.
When the drying process is finished, the vials can be securely closed with the lyo-plug. This is done within the freeze-drier by lowering the shelves. The flexible materials of the Lyoprotect® Bag easily follow the movements and mechanical loads when the plugs are pushed in.



- Integrity test?
- Monitoring?

Transfer tray with grid on top,
prevent bag touching stoppers



Frame or tray

Teclen bag



Thanks for your attention !

