



Welcome
to
Tofflon





**Tofflon has been working for Freeze Drying System
in the past 22 years**



Globally largest freeze drying system manufacturer



0.2 m² - 50m² Freeze Dryers

400+ production size Lyophilizers Annual Output

5,000+ Installations Since 1993 (Include FD >4,000)

400+ Installations in more than 30 countries

80+% market share for FD System in China

Nearly 1,500 customers base.



Maybe, the world's largest Freeze Dryer manufacturer is in here.
You know...?



- Four Manufacturing Plants :
 1. Freeze Dryer Facility – 35,000 sqm
 2. R&D Center – 9,100 sqm
 3. Freeze Drying System (Preparation,Loading,Barrier) – 45,000 sqm;
 4. Pressure Vessel Land (Chamber,Condenser,Shelf – 66,000 sqm;
 5. Tofflon-Dehui

The employees: 2,000 +

workers: 1,200+

engineers: 480+

QA: 100+

Sales: 68

Services: 150+



Tofflon developing partners

Freeze Dryer

Since 1993

Shanghai KYOWAC

Joint Venture with Japan Kyowac in China 2003

Tofflon USA

Technical support and service in USA 2008

Tofflon Dehui

Clean Room System and AHU 2011

Tofflon Airex

Barrier System, 2012

Tofflon TOP

Preparation System 2012

Tofflon Aqua-Nova

Manufacturing Water System in Tofflon 2012

Design House

Design equipment for FD system in Italy 2010



ZERTIFIKAT ■ CERTIFICATE ■ CERTIFICADO ■ CERTIFICAT ■ 認證證書 ■ ZERTIFIKAT ■ CERTIFICATE ■ CERTIFICADO ■ CERTIFICAT ■ 認證證書 ■ ZERTIFIKAT ■ CERTIFICATE ■ CERTIFICADO ■ CERTIFICAT ■ 認證證書



CERTIFICATE

The Certification Body
of TÜV SÜD Management Service GmbH
certifies that

Shanghai Tofflon Science & Technology Co., Ltd.
No. 1509, Duhui Road, Minhang District, Shanghai, P. R. China
Post Code: 201108
Organization code: 80760106 A

including the sites and scope of application
see enclosure

has established and applies
a Quality Management System.

Performance of audits (Report No. **70015074**)
has furnished proof that the requirements, under:

ISO 9001:2008

are fulfilled.

The certificate is valid from **2015-07-16** until **2018-07-15**.

Certificate Registration No.: **12 100 14649 TMS**.

Information about this certificate can be inquired at the official website
of Certification and Accreditation Administration of the People's Republic of China (www.cnca.gov.cn)

M. Weger

Product Compliance Management
Munich, 2015-07-13



Page 1 of 2



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has established and applies
a Quality Management System for

**Design, Assembly and Sales of Lyophilizer; Assembly and Sales of Automatic
Loading and Unloading Equipment.**

An audit was performed, Report No. **70015074**
Proof has been furnished that the requirements
according to

ISO 9001:2008

are fulfilled.

The certificate is valid in conjunction
with the main certificate from **2015-07-16** until **2018-07-15**

Certificate Registration No.: **12 100 14649/01 TMS**.

Information about this certificate can be inquired at the official website
of Certification and Accreditation Administration of the People's Republic of China (www.cnca.gov.cn)

M. Weger

Product Compliance Management
Munich, 2015-07-13





CE Certificate (MD / LVD/ PED)



APRAGAZ



Member of
CEOC

Chaussée de Vlieland, 159
Aldershotweg 159
B-1320 Brussels/Bruxelles
Tel.: 32 (0)2 264 01 60
Fax: 32 (0)2 268 89 34
http://www.apragaz.com
info@apragaz.com

APRAGAZ - UTS
(Representative Office)
Room B1240, Lianfang
International Mansion No.79,
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200131 Shanghai, China
Tel.: +86 21 51096699
Fax: +86 21 51096686
http://www.utscc.com
e-mail:utscc@utscc.com.cn

| | | |
|---|-------------------------------|---|
| CERTIFICATE OF COMPLIANCE | | Certificate N° 06/CN/1420-0-REV 4 |
| Review of Manufacturer's Technical File | | Page 1/2 |
| Manufacturer | Name | SHANGHAI TOFFLON SCIENCE AND TECHNOLOGY CO., LTD. |
| | Address | 219E, FANGHE RD., SHANGHAI, CHINA N°1509 DUHUI RD, SHANGHAI, CHINA |
| Concerned Equipment: LYOPHILIZER | | |
| MODEL: LYO-50(CIP,SIP) (its variants and modifications) | | |
| As described in the Technical Construction File ref.: TOFFLON-100111 - Issue date 11/01/2010 | | |
| This is to declare that the Technical File issued by SHANGHAI TOFFLON SCIENCE AND TECHNOLOGY CO., LTD. , concerning the above mentioned equipment has been prepared according to the essential safety requirements of the Machinery Directive 2006/42/EC and the Low Voltage Directive 2006/55/EC | | |
| The manufacturer is allowed to affix the "CE" mark, under its own responsibility, to the concerned equipment, in the conditions described in the Directive, providing all measures described in the Technical File ref.: TOFFLON-100111 - Issue date 11/01/2010 have been applied to the product put on the European Market. | | |
| All modifications to the Technical File should be first submitted to the Third Party Inspection Authority to ensure further validity of this compliance certificate. | | |
| Date: 05/05/2010 | Name: Ch. Lepiet | Position: General Manager |
| APRAGAZ Belgium Inspecting Authority | | Signature: CE |
| Third Party Authority stamp: | | |
| Third Party Authority reference: | 0604/P/0080/LVD/1/MD/1 | |



APRAGAZ



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CEOC


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e-mail:utscc@utscc.com.cn

| | | | | |
|--|-------------------------------|----------------------------------|-----------------|---|
| CERTIFICATE OF COMPLIANCE | | | | Certificate N° 06/CN/1420-0-REV 4 |
| Review of Manufacturer's Technical File | | | | Page 2/2 |
| Model No. | Model No. | Model No. | Model No. | |
| LYO-0.2(SIP,CIP) | LYO-0.4(SIP,CIP) | LYO-0.5(SIP,CIP) | LYO-1(SIP,CIP) | |
| LYO-2(SIP,CIP) | LYO-3(SIP,CIP) | LYO-5(SIP,CIP) | LYO-8(SIP,CIP) | |
| LYO-9(SIP,CIP) | LYO-10(SIP,CIP) | LYO-13(SIP,CIP) | LYO-14(SIP,CIP) | |
| LYO-16(SIP,CIP) | LYO-20(SIP,CIP) | LYO-22(SIP,CIP) | LYO-25(SIP,CIP) | |
| LYO-30(SIP,CIP) | LYO-35(SIP,CIP) | LYO-40(SIP,CIP) | LYO-45(SIP,CIP) | |
| LYO-50(SIP,CIP) | LYO-0.2(CIP) | LYO-0.4(CIP) | LYO-0.5(CIP) | |
| LYO-1(CIP) | LYO-2(CIP) | LYO-3(CIP) | LYO-5(CIP) | |
| LYO-8(CIP) | LYO-9(CIP) | LYO-10(CIP) | LYO-13(CIP) | |
| LYO-14(CIP) | LYO-16(CIP) | LYO-20(CIP) | LYO-22(CIP) | |
| LYO-25(CIP) | LYO-30(CIP) | LYO-35(CIP) | LYO-40(CIP) | |
| LYO-45(CIP) | LYO-50(CIP) | LYO-0.2 | LYO-0.4 | |
| LYO-0.1 | LYO-1 | LYO-2 | LYO-3 | |
| LYO-5 | LYO-8 | LYO-9 | LYO-10 | |
| LYO-13 | LYO-14 | LYO-16 | LYO-20 | |
| LYO-22 | LYO-25 | LYO-30 | LYO-35 | |
| LYO-40 | LYO-45 | LYO-50 | LYO-50(CIP,SIP) | |
| USER: UDWD019 | Name: Ch. Lepiet | Position: General Manager | | |
| APRAGAZ Belgium Inspecting Authority | | Signature: CE | | |
| Third Party Authority stamp: | | | | |
| Third Party Authority reference: | 0604/P/0080/LVD/1/MD/1 | | | |



The American Society of Mechanical Engineers



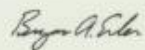
CERTIFICATE OF AUTHORIZATION

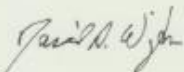
The named company is authorized by the American Society of Mechanical Engineers (ASME) for the scope of activity shown below in accordance with the applicable rules of the ASME Boiler and Pressure Vessel Code. The use of the certification mark and the authority granted by this Certificate of Authorization are subject to the provisions of the agreement set forth in the application. Any construction stamped with this certification mark shall have been built strictly in accordance with the provisions of the ASME Boiler and Pressure Vessel Code.


COMPANY:
 Shanghai Tofflon Science and Technology Co., Ltd.
 No. 399, Jinliu Road
 Jinshan District
 Shanghai 201506
 People's Republic of China

SCOPE:
 Manufacture of pressure vessels at the above location only

AUTHORIZED: June 16, 2014
EXPIRES: August 25, 2017
CERTIFICATE NUMBER: 37,798


 Vice President, Conformity Assessment


 Director, Conformity Assessment



ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT


 Management Service

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 an Occupational Health and Safety Management System for

**Design, Assembly and Sales of Lyophilizer;
 Assembly and Sales of Automatic Loading and Unloading Equipment**

An audit was performed, Report No. **70015074**
 Proof has been furnished that the requirements
 according to

BS OHSAS 18001:2007

are fulfilled. The certificate is valid from **2013-07-25** until **2016-07-24**.
 Certificate Registration No. **12 116 14649 TMS**


 Product Compliance Management
 Munich, 2013-07-29


Deutsche
 Akkreditierungsstelle
 D-20114-1413-01-05

TÜV SÜD Management Service GmbH • Zertifizierungsstelle • Ridlerstraße 65 • 80339 München • Germany **TUV®**

21 CFR PART 11 ASSESSMENT CERTIFICATE

for the

TOFFLON MASTER - 4000 CONTROL SYSTEM (v3.0)

The Tofflon Master-4000 Control System (v3.0) was assessed on 15 February 2006 for compliance with FDA regulation, 21 CFR Part 11; Electronic Records; Electronic Signatures. The result of the assessment concludes that the system conforms to the 21 CFR Part 11 regulation and provides sufficient technological and procedural controls to be implemented as part of an overall 21 CFR Part 11 compliant system.



MICHEL SOUCY

15 FEBRUARY 2006

Date

USFDA 21 CFR PART 11 COMPLIANCE



Steel certificate



February 12, 2009

CONTROL OF RADIOACTIVE CONTAMINATION AT OUTOKUMPU PRODUCTION SITES

Outokumpu has implemented strict control of radioactive contamination at all its steel making plants.

All incoming scrap and raw materials are being screened for radioactivity via a radiation detection system. Samples are also taken in the production process and tested for radioactivity. These procedures are detailed in the management systems we operate (ISO 9001 and ISO 14001) and ensure that the levels of radioactivity are below the IAEA recommended levels to protect human health.

The products that we sell are free from radioactive contamination

Outokumpu Group

Camilla Kaplin

Camilla Kaplin
Manager Product Stewardship

Outokumpu Oyj
Corporate Management

Riikitehtaantie 7 B, P.O. Box 140, FI-02201 Espoo, Finland
Tel: +358 9 4211, Fax: +358 9 421 3809, www.outokumpu.com
Domestic Espoo, Finland, Business ID 0251294-2, VAT FI0212252-2

ARCERORMITTAL

MILL CERTIFICATE RS EN 10242-1
CERTIFICAT DE QUALITE EN EN 10242-1
ABRANGÓMÉRLEKÉNYEK EN EN 10242-1

Approved by: RD 2008 Revizor: 4070 01/08 by TÜV SÜD Germany 20 000 2000
Certified by: 3003 P02002, Annex 1 43 for certificate No. 004 007 000
Approved by: 3003 P02002, Annex 1 43 for certificate No. 004 007 000
Approved by: 3003 P02002, Annex 1 43 for certificate No. 004 007 000

AMSE

| Item | Value | Unit | Standard |
|-------------------|-------|-------------------|------------|
| Yield strength | 275 | N/mm ² | EN 10242-1 |
| Tensile strength | 475 | N/mm ² | EN 10242-1 |
| Elongation | 22 | % | EN 10242-1 |
| Reduction of area | 50 | % | EN 10242-1 |
| Impact strength | 27 | J | EN 10242-1 |

CHEMICAL ANALYSIS - ANALYSE CHIMIQUE - CHEMISCHE ZUSAMMENSETZUNG

| Element | C | Si | Mn | P | S | Cr | Ni | Mo | Al | As | Se | Co | Cu | Nb | Bi | Te | Fe |
|----------|------|------|------|------|-------|------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| Analysis | 0.14 | 0.03 | 0.28 | 0.01 | 0.005 | 0.02 | 0.005 | 0.005 | 0.005 | 0.005 | 0.005 | 0.005 | 0.005 | 0.005 | 0.005 | 0.005 | 0.005 |

MECHANICAL PROPERTIES - PROPRIÉTÉS MÉCANIQUES - MECHANISCHE EIGENSCHAFTEN

| Property | Value | Unit | Standard |
|-------------------|-------|-------------------|------------|
| Yield strength | 275 | N/mm ² | EN 10242-1 |
| Tensile strength | 475 | N/mm ² | EN 10242-1 |
| Elongation | 22 | % | EN 10242-1 |
| Reduction of area | 50 | % | EN 10242-1 |
| Impact strength | 27 | J | EN 10242-1 |

APRAGAZ

Quality Department



**A Workshop with
Health, Safety and Environment Protection**



Harmony with Nature

Tofflon

冻干工艺研究室

Lyophilization Lab

Lyophilization Lab

“Fastest Sublimation, Without Risk”



**Freeze Drying Microscope (UK)
(Lyophilized Drug Thermal Property Detection)**



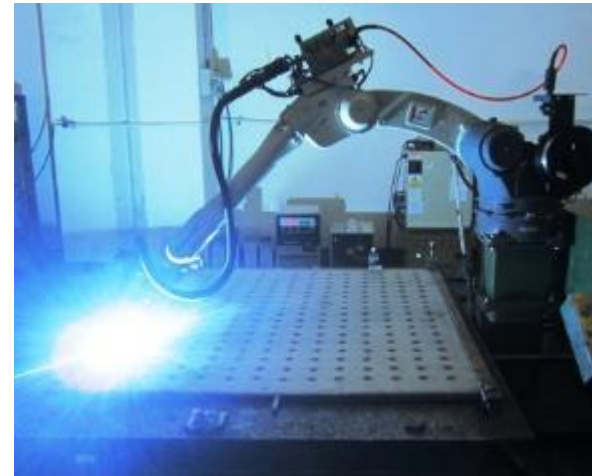


Assembling and FAT





Automatic machine to make Chamber; condenser; shelf



**Pressure Vessel Compliance:
Chinese GB150-1998/European PED/American ASME**



Chamber; condenser; shelf all are made by Tofflon





Modern manufacturing facilities and tools





**World-class, Reliable and High Quality Components
(USA, Europe and Japan)**



Use first class compressor and vacuum pump, storage for fast **delivery**

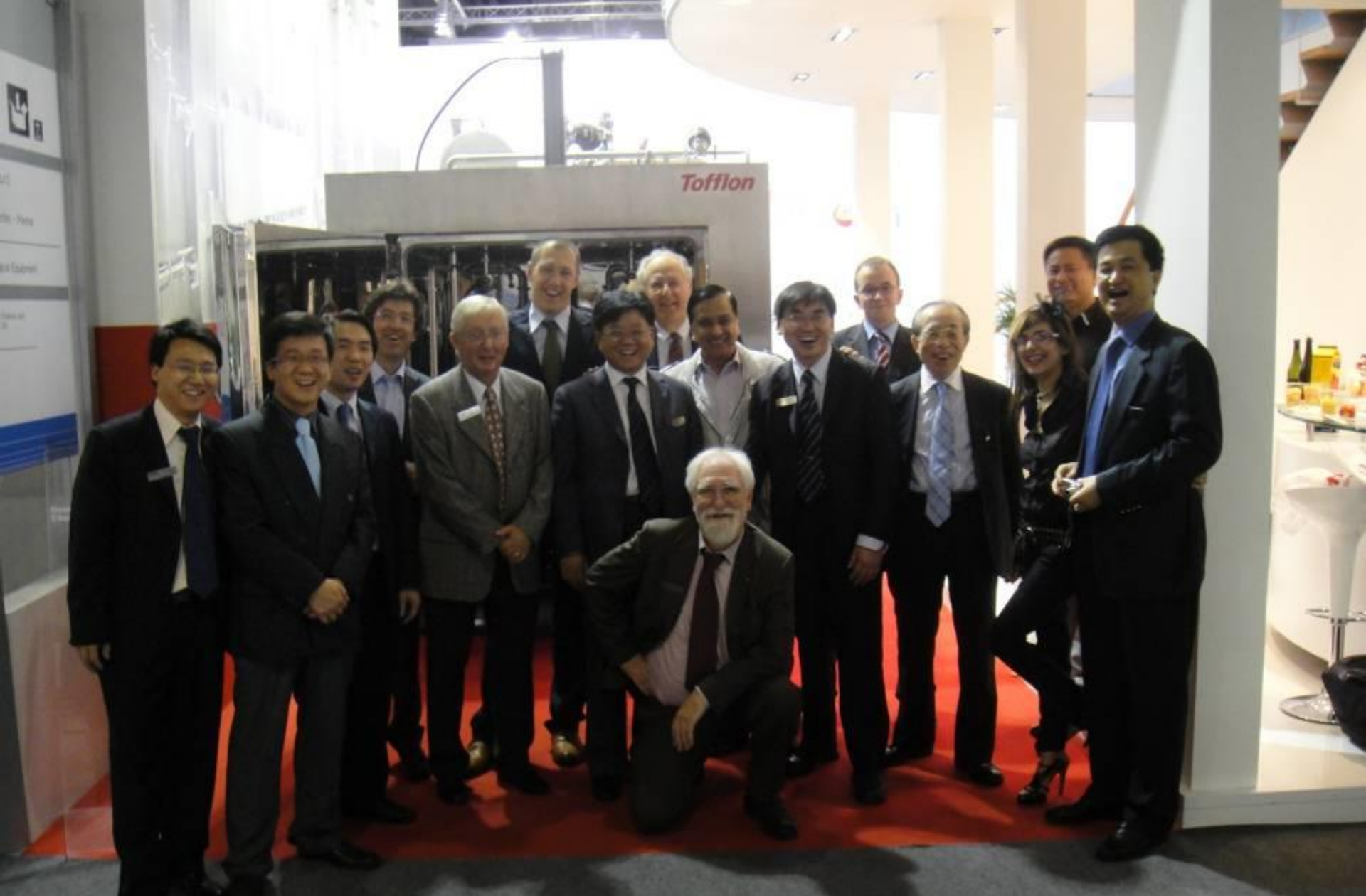




Freeze Dryer Assembly Line

A wide-angle photograph of a large industrial facility, likely a cryogenic storage or processing plant. The room is filled with several large, stainless steel cryogenic storage units (LYO-22) arranged in a row. Each unit has a large, heavy door with a viewing window. In the foreground, there is a complex system of pipes, valves, and electrical control panels, including a control cabinet with a red emergency stop button. A person is standing near a control console with a laptop. The floor is green with white dashed lines. In the background, more equipment and workers are visible, along with a large open door. The overall scene depicts a busy industrial environment.

5 x LYO-22 + 2 x LN2 Refrigeration System + 2 x Automatic Loading and Unloading System



Tofflon Global Team in Achema (Germany) in 2009



Achema 2009 in Frankfurt, Germany





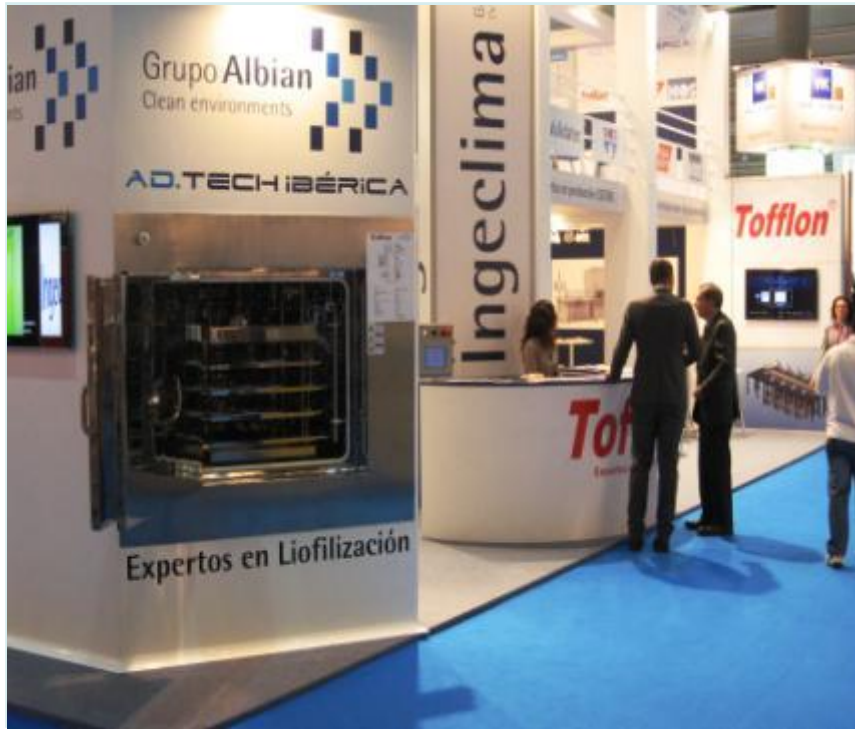
Tofflon Booth in Achema 2012



Tofflon Booth in Achema 2015

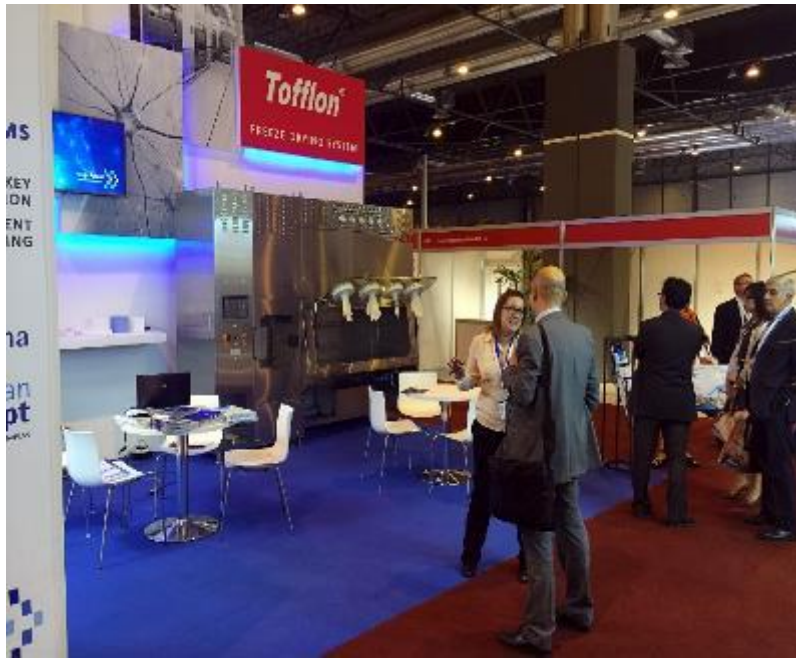


Expoquimia 2011 in Barcelona, Spain





CPhi Worldwide Madrid 2015





Tofflon Global Team





Tofflon Global Team



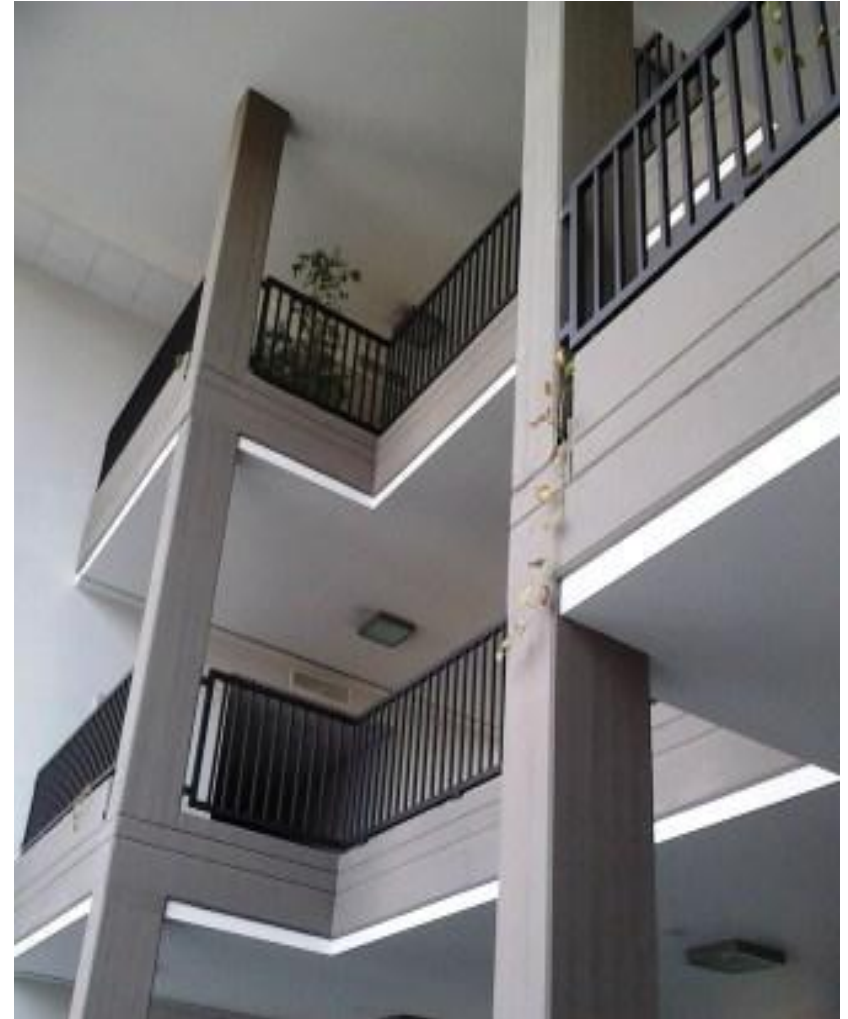


Lyophilizer specialist in Tofflon USA





Italian Design Centre



A wide-angle photograph of a large industrial facility, likely a cryogenic storage or processing plant. The room is filled with large, dark-colored metal units, which are cryogenic storage containers. In the foreground, there are several control panels and equipment racks. A person is visible in the middle ground, working at a control station. The floor is green with white dashed lines. The background shows more of the facility, including pipes and structural elements.

5 x LYO-22 + 2 x LN2 Refrigeration System + 2 x Automatic Loading and Unloading System





RABS/c-RABS/Isolatore System

Tofflon are developing new product in Isolator technology and RABS, which use in the core area of complete Freeze Drying Production Systems (from filling line + Automatic loading and Unloading system + Lyophilizer + Capping, etc...). Isolators and RABS can thus replace the expensive clean-room and offer both, product and operator protection.

The advantage to use Isolator and RABS in the core area of Freeze Drying System

- To assure a superior degree of product protection because of high-value and expensive products, or operator protection because of toxic products
- Reduce high class control area (class A or 100)
- Reduce operation cost
- Whole area in same condition, no contamination.
- Compliance to cGMP requirement, and subject to FDA or EMEA regulatory guidelines



RABS/c-RABS and Isolator in freeze drying core production area

- No crack in cabinet, round corner inside.
- Finishing level: Ra ≤ 0.4µm inside; Ra ≤ 0.8µm outside.
- Big Gloves flanges can reach all place inside cabinet and easy operation
- Materials: S.S. 316L inside; S.S. 304 outside. All sealing materials compliance to GMP and FDA requirement.
- VHP (H₂O₂) gas sterilization available.
- To transfer and process materials or devices through small openings (called "mouse holes") designed to enter and exit such equipments Transfer in different area through "mouse holes"



AGV with RABS



Features of the isolator in difference processing

- Good ergonomic design and effective transfer systems
- Increase production efficiency and product quality
- Reduce the risk of cross contamination,
- Design for CIP/WIP and VHP gas sterilization (Option)
- Using "Bag-in/ Bag-out" for filter change in air return for Toxic products
- RTP and waste liquid discharge (Option)





Preparation System





Project Management

The Objectives

Good Communications

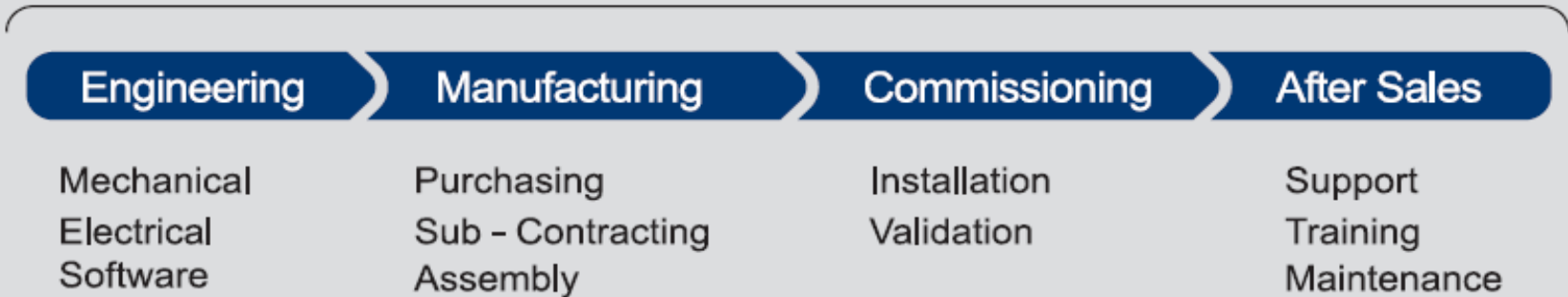
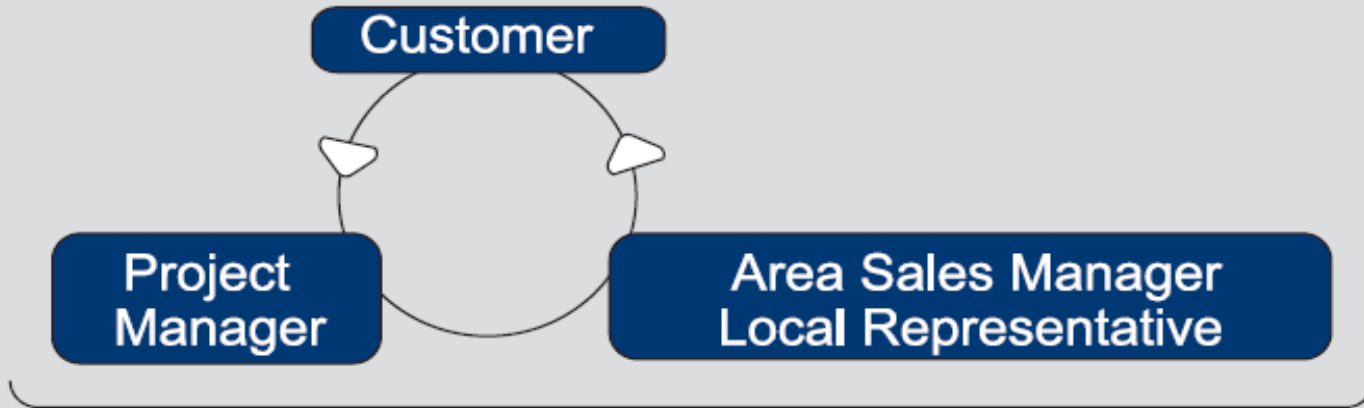
On-Time Delivery

Quality Maintained



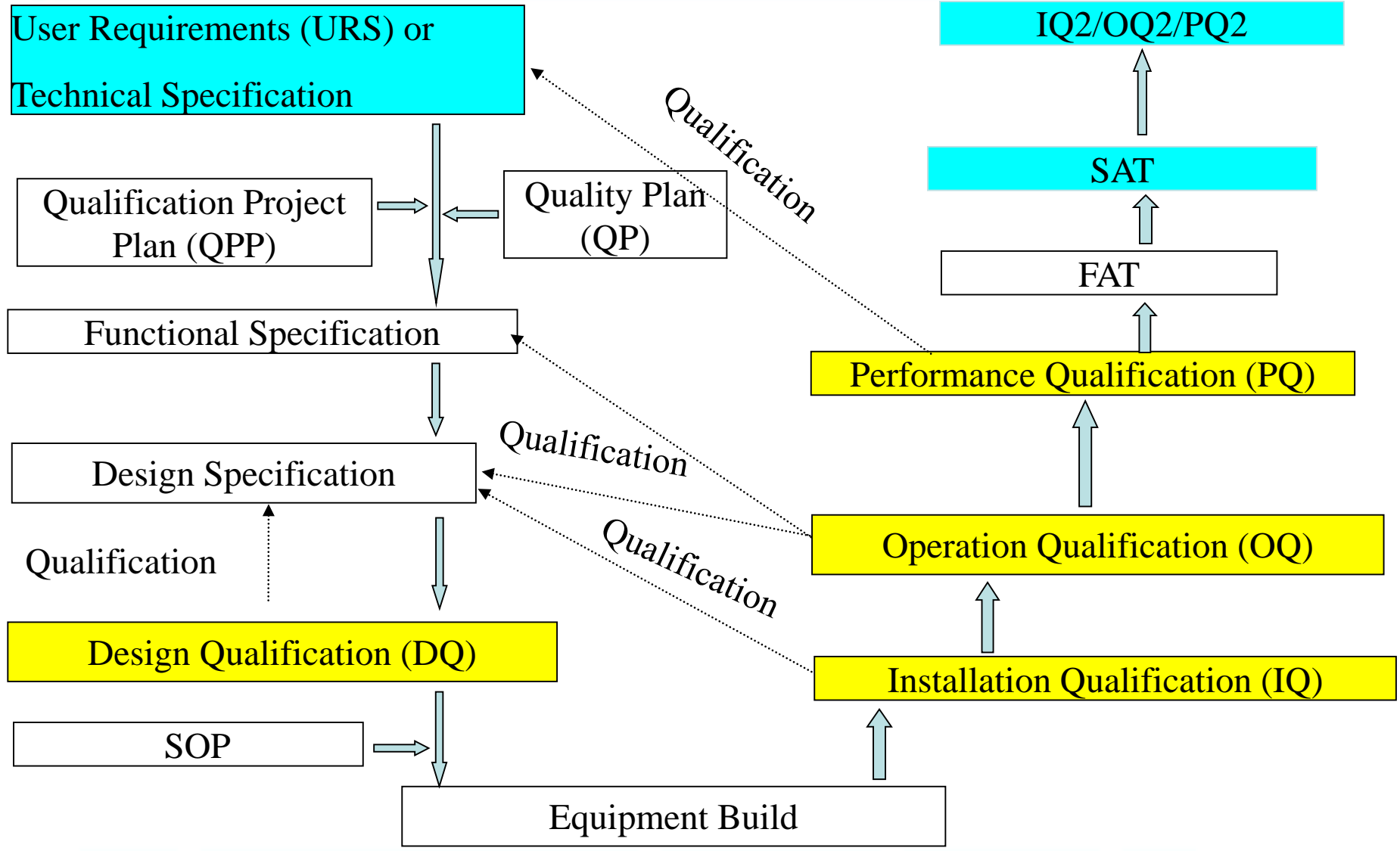


A Team of a Project





Equipment Qualification





Inspection and Validation tools



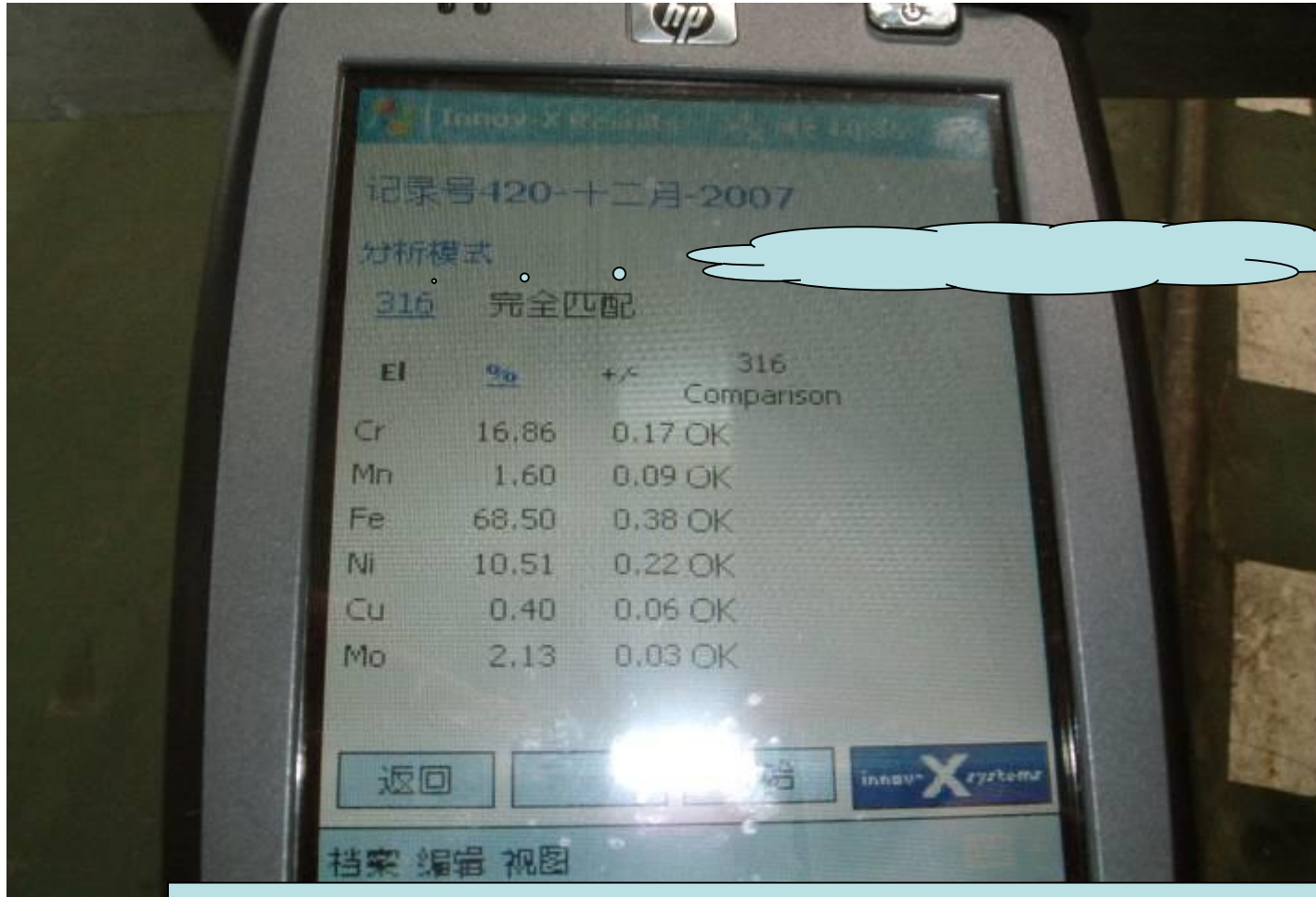


QA

Indicator showing test result



**Alloy Analyzer
to test chamber materials**

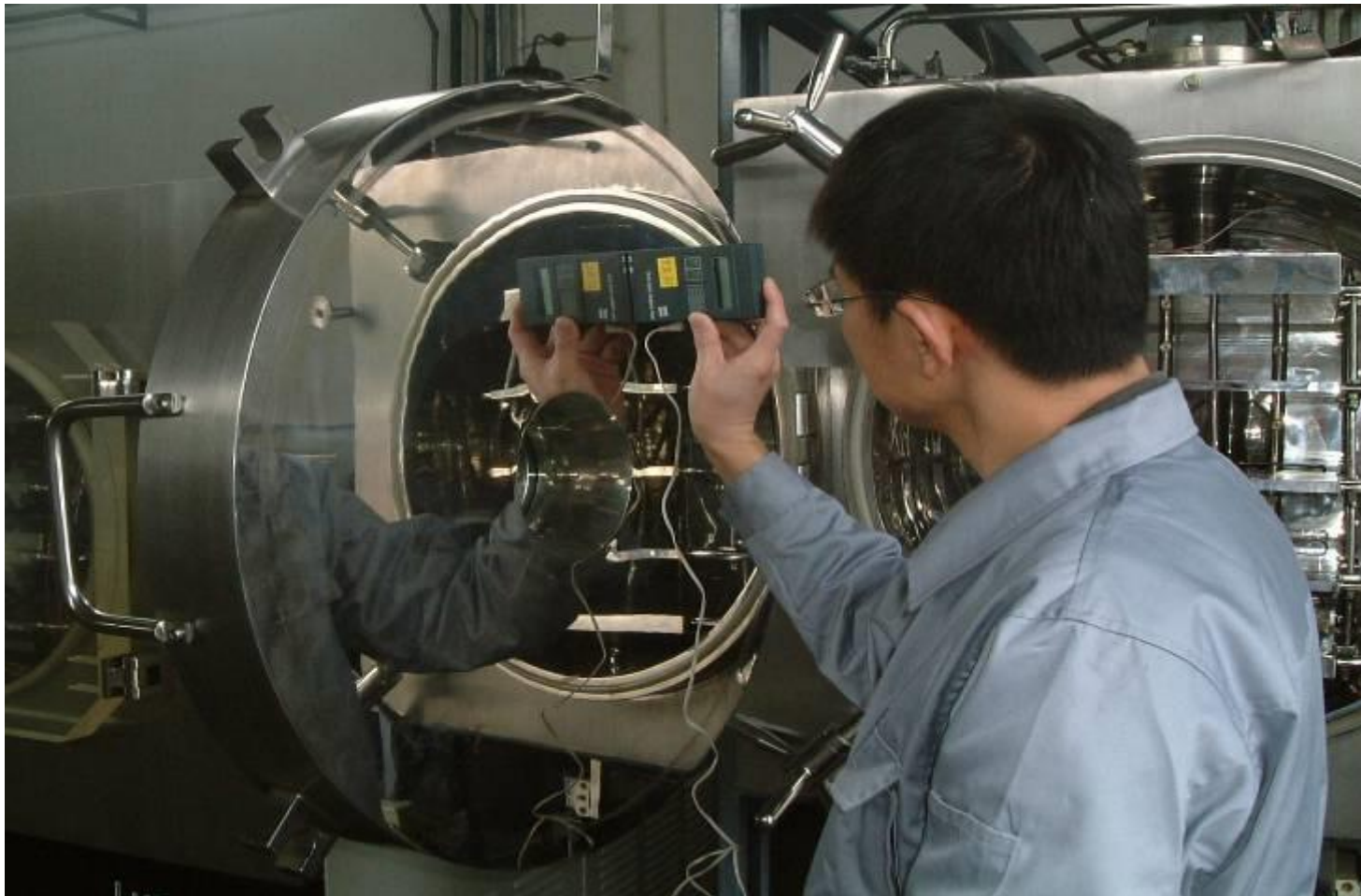


316

**Materials test result
can be stored and printed out with Excel Format**



**Ultrasonic Thickness Inspector
to test shelves thickness**



**Roughness Inspector
to test chamber door roughness**



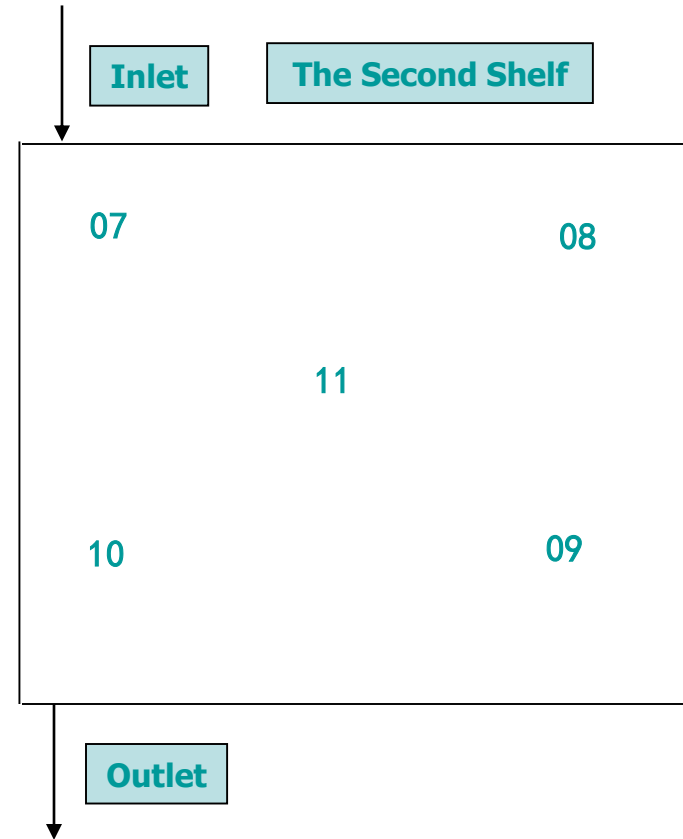
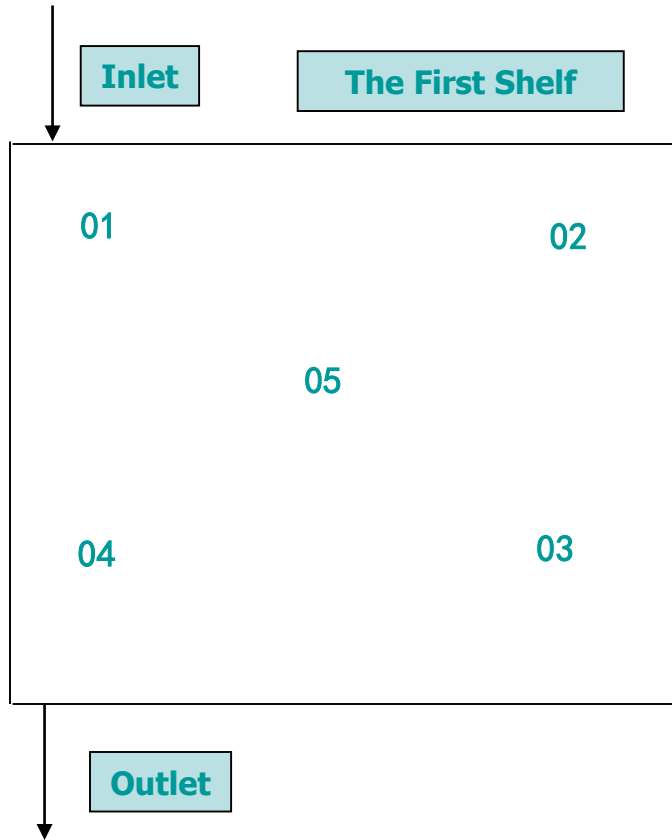
**Helium Leak Detector
For leakage test**



Temperature Uniformity Test



The image displays the Kaye Validator Thermal Validation System. At the top left is the GE logo. The main title is "Kaye Validator[®] Thermal Validation System". Below this, a central image of the device is overlaid with a menu of six buttons: "Define Setups", "Calibrate Sensors", "Run Qualification", "Password Maintenance", "Create Reports", and "Quit". In the foreground, there are two pieces of hardware: a vertical unit and a smaller horizontal unit with a screen. To the left of these units are two vials, one of which is labeled "SALINE".



Shelves Thermocouples Location



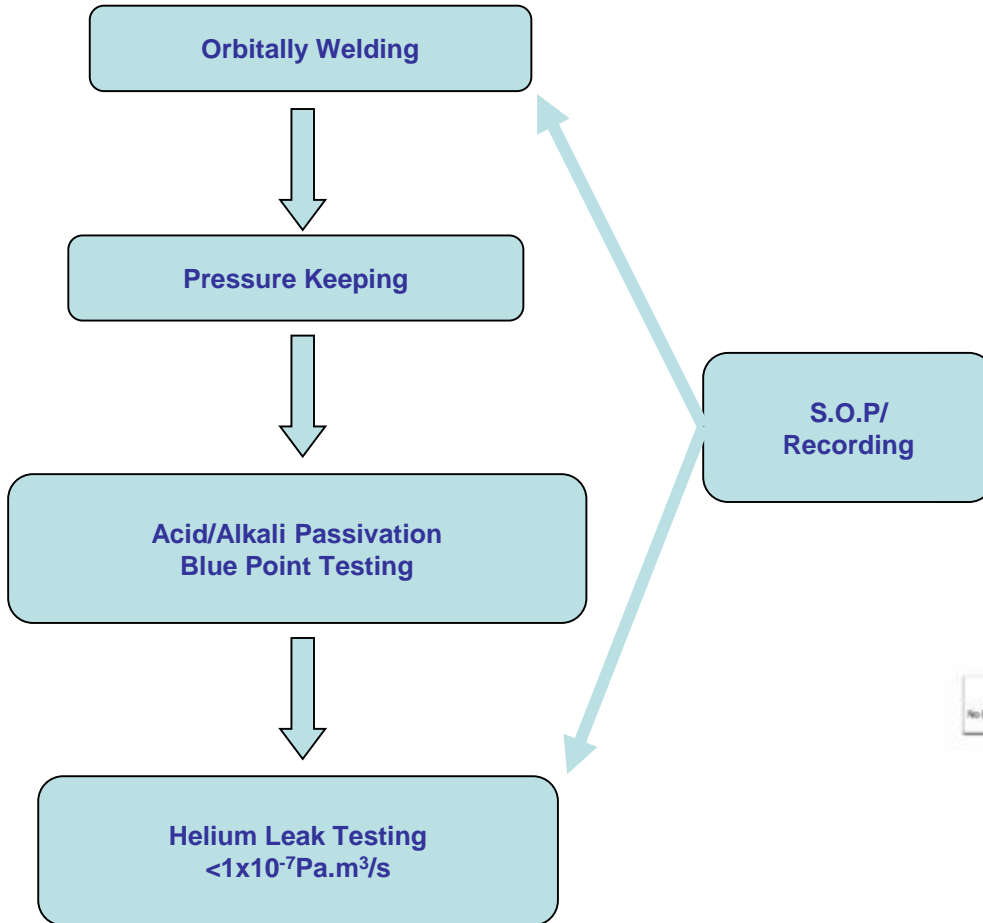
Filter Integrity Test (Water Intrusion Test)



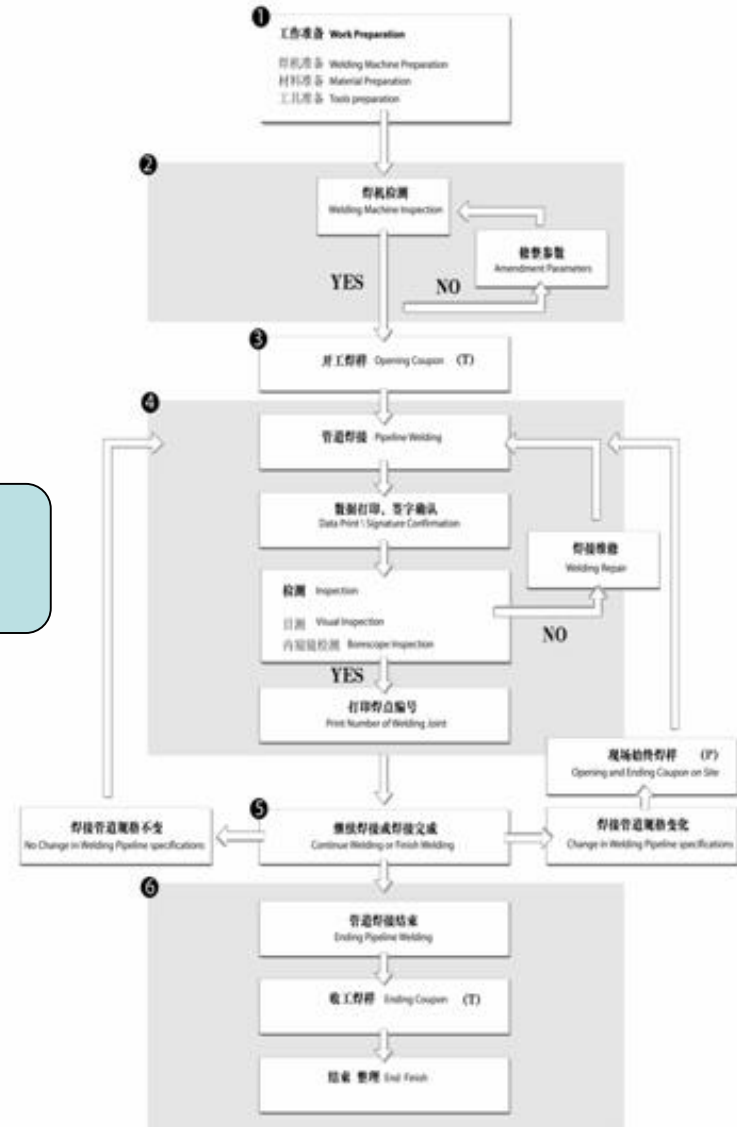


TIG Automatic Welding Machine

Piping Welding Process



管道焊接SOP流程图 Pipeline Welding SOP flow chart





Boroscope Inspection with Photos and Video Records



100% Boroscope of all welds



Documents

- User Requirement Specification (URS) or Technical Specification
- Qualification Project Plan (QPP)
- Quality Plan (QP)
- Design Specification (DS)
- Design Qualification (DQ)
- Installation Qualification (IQ)
- Operation Qualification (OQ)
- Factory Acceptance Test (FAT)
- Site Acceptance Test (SAT)
- Performance Qualification (PQ)
- Traceability Matrix



Other Documents of Equipment

- Installation Instruction
- Operation Instruction
- Maintenance Manual
- Main components List
- Spare Parts List
- Materials Certificate
- Instruments Calibration Certificate



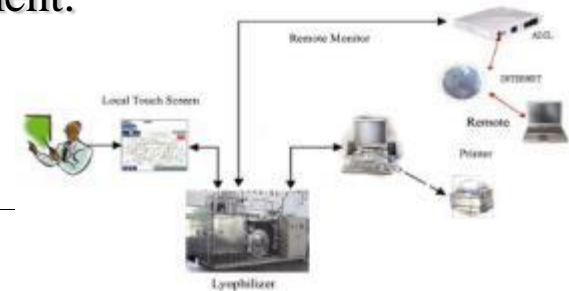


Whole Life After-Sales Service

For many years, we have successfully established well-running after-sales service mechanism and system which make us earn customers' satisfaction and make us stay ahead of the competition.

Prior Delivery

- ❖ Complete documentations with full details of the equipment.
- ❖ Supply of spare parts and accessories
- ❖ Standard IQ and OQ documentation package, as additional options to assist customers with equipment validation.





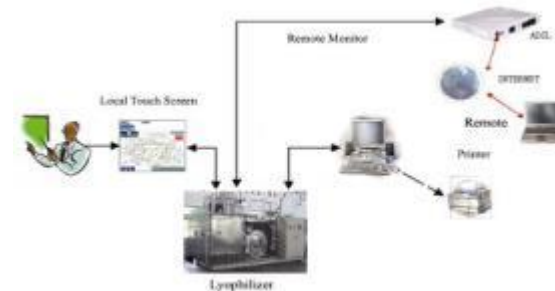
Whole Life After-Sales Service

Post Delivery

- ❖ Installation and start-up of new equipment
- ❖ Site Acceptance Test
- ❖ Product Training Courses

During Warranty

- ❖ Locally-based after-sales service
- ❖ As local assistance, there are also factory-trained technicians



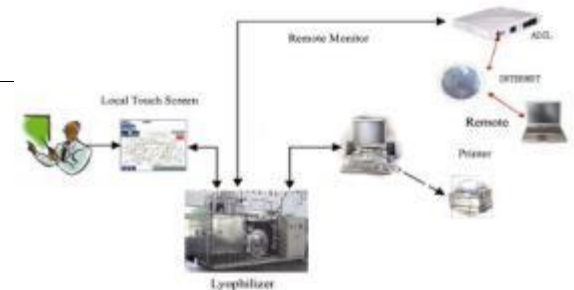


Whole Life After-Sales Service

- ❖ Preventative maintenance / Corrective repairs
- ❖ Remote problem solving (via telephone, internet, etc)

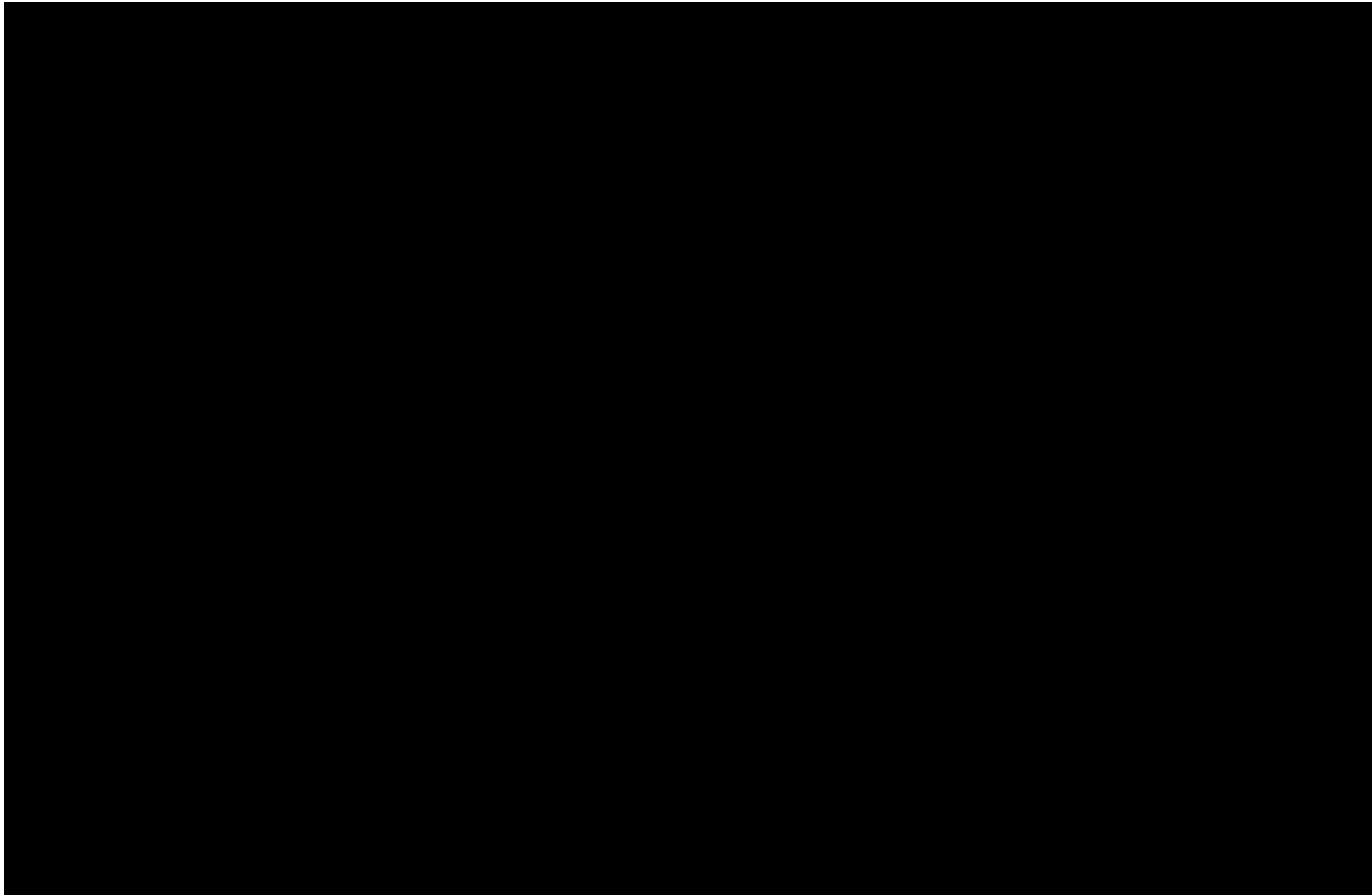
Lifetime Service

- ❖ Modification of existing equipment to optimize its performance
- ❖ Sales and supply of spare parts and accessories
- ❖ Product training courses



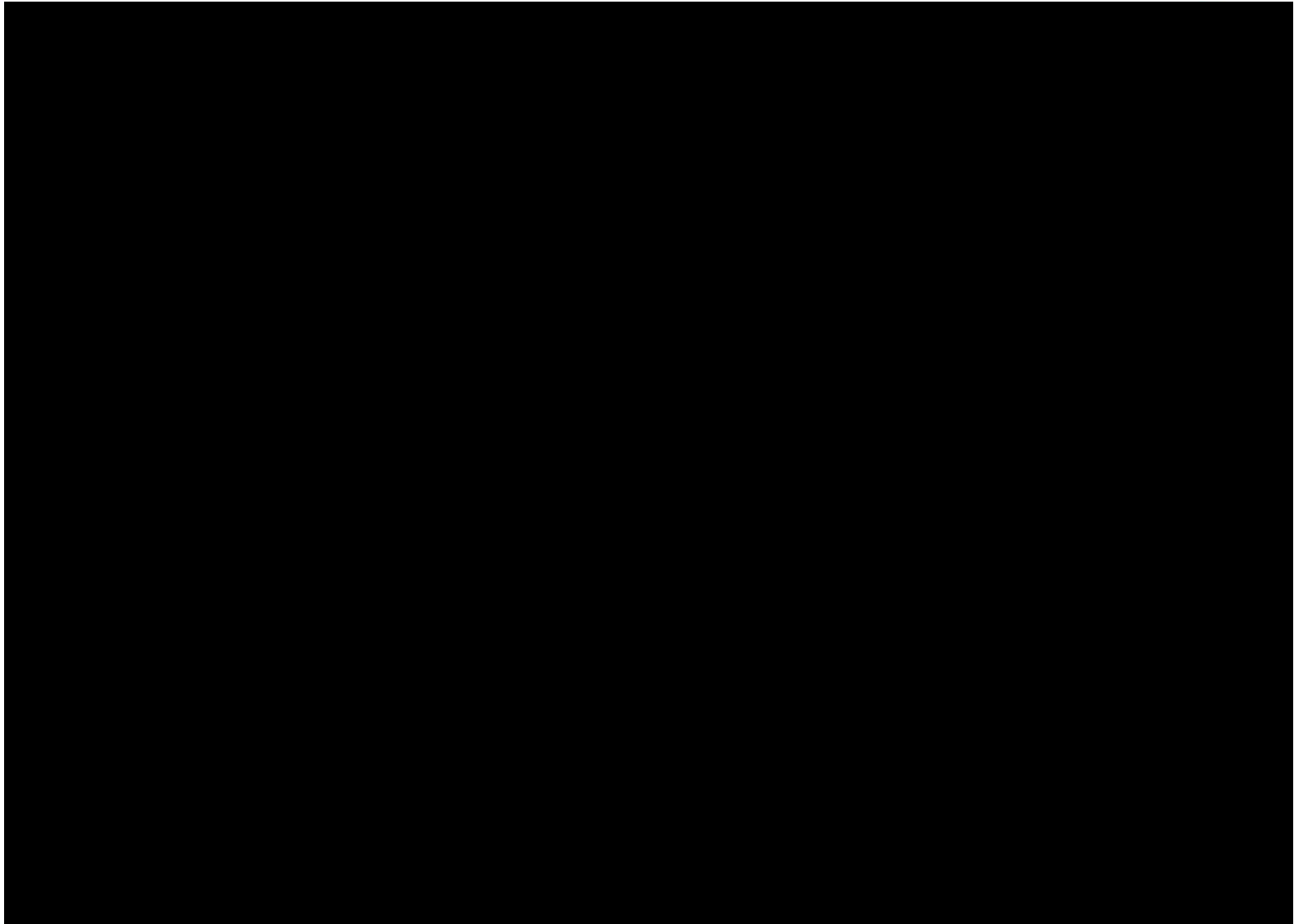


Total solution for pharmaceutical equipment





Total solution for pharmaceutical facilities



A group of ducks and geese are standing on a grassy area in front of a building with a grey metal grid facade. The word 'Tofflon' is written in large, red, 3D letters on the building. The scene is set against a clear blue sky.

Tofflon

Looking forward to serve your project
Thank You for your time!