WE OPEN THE DOOR TO OUR CUSTOMERS

Criofarma

DAL 1962 TORINO ITALY

I.E.C.Q.

ISO 9001 - EN 729

Impianti di liofilizzazione - Apparecchiature per l'industria farmaceutica

Freeze Drying Equipments - Engineered Solutions For Phamaceutical Industry

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LYOPHILIZER FROM CRIOFARMA CUSTOM BUILT WITH HIGHSTANDARD QUALITY

CRIOFARMA

Is one of the leading manufacturers of freeze-drying equipments for pharmaceutical food and biotechnology industries since 1962. In the specialized field of pharmaceuticals and biological products CRIOFARMA enjoys an international reputation for experience quality, performance, safety, validation and flexibility.

The name CRIOFARMA is synonymous with future-oriented progress and research freeze-drying technology.

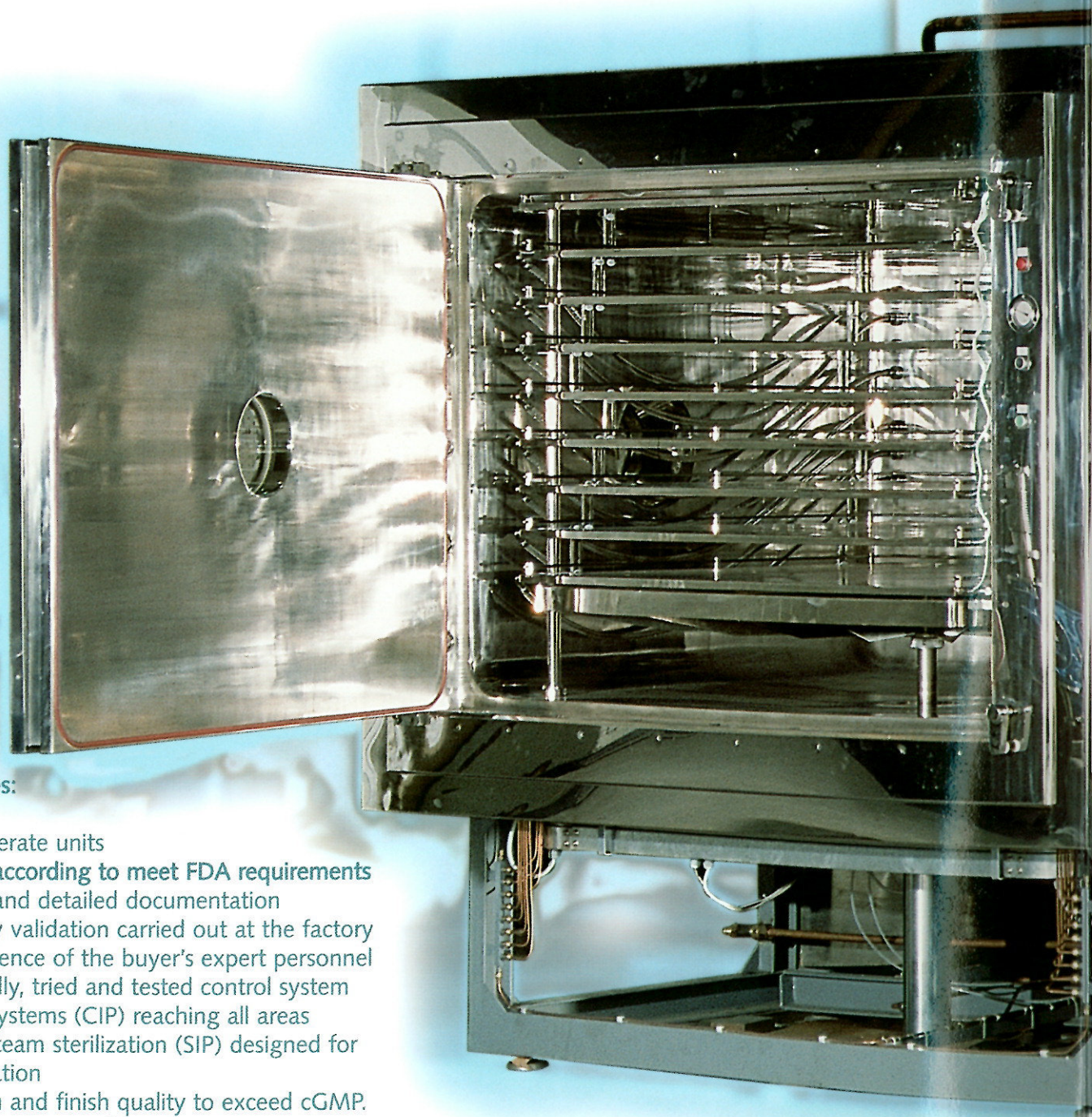
GLOBAL QUALITY SYSTEM

It is imperative that pharmaceutical manufacturers meet the very highest standards of product quality and integrity: Good Manufacturing Practice is only the starting point for CRIOFARMA. Our goal is to contribute positevely along with our competitors to the formation of an appropriate validation approach. We work closely with our customers every step of the way to make sure that validation is straightforward and trouble free.

As General Principles of Validation - FDA 1987 says:

"...establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting pre-determined specifications and quality attributes" .

Every detail of CRIOFARMA lyophilizers is throughly proven, tested and supported with documentary proof.



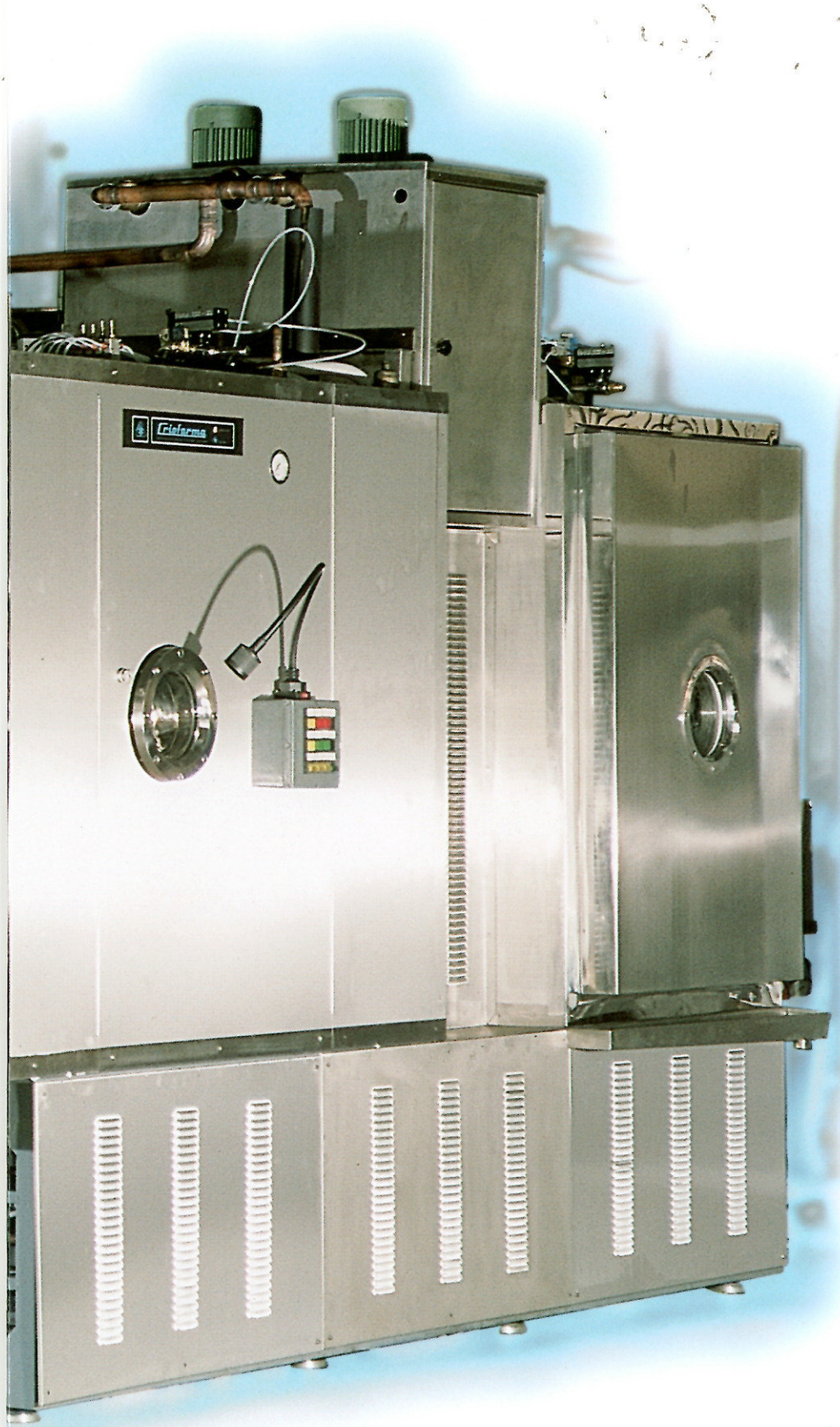
Main features:

- Easy to operate units
- **Designed according to meet FDA requirements**
- Extensive and detailed documentation
- Preliminary validation carried out at the factory in the presence of the buyer's expert personnel
- User friendly, tried and tested control system
- Cleaning systems (CIP) reaching all areas
- Through steam sterilization (SIP) designed for easy validation
- Fabrication and finish quality to exceed cGMP.
- High performance refrigeration system
- Compact design

CUSTOM SOLUTIONS FOR PHARMACEUTICAL INDUSTRY

MATCHING CUSTOMERS REQUIREMENTS

Our very long term experience since 1962 is so high that every CRIOFARMA freeze-drying system is a totally engineered solution to customers processing needs. Working closely with our customers and with our research, validation and production personnel we are able to provide the better layout and processing solutions for the customers requirements.



CUSTOM-MADE SYSTEMS

A wide range of machines are customised to meet customers requirements. Experience in design for sterile applications according to meet cGMP and all regulatory guidelines. Customised solutions from pilot plant (0,5 sq. m) up to industrial production plant of 60 sq. m. or more.

SAFETY

Naturally we have a deep sense of accountability towards safety and the environment. This manifest itself in every aspects of our work from the SIP and CIP device to our imaginative control system concept design for which both operators and products in process are always safety conditions.

LOADING AND UNLOADING SYSTEMS

CRIOFARMA is able to provide custom designed solution for loading systems of bulk product, vials or ampouls:

- Loading at constant level
- Loading shelf by shelf or all shelves at one time
- Double or single door solutions
- Intermediate storage before and after lyophilization
- Protective environments during loading and unloading

STERILIZATION IN PLACE (S.I.P.)

Many of the CRIOFARMA freeze-dryers are manufactured for high technology applications requiring sterilization. Designs are continually improving supported by intensive validation studies. All the CRIOFARMA freeze dryers can be easily sterilized with sterilization medium (steam is still the internationally preferred medium). Our validation staff can support our customers in any step of the O.Q. (Operation Qualification) and P.Q. (Performance Qualification) of the S.I.P. validation tests.

SINCE 1962 AN OPEN MIND FOR SPECIAL SOLUTIONS

CLEANING IN PLACE (C.I.P.)

CRIOFARMA offers several option to CIP using condensing steam alone, spray balls or rotating nozzles. The cleaning medium drain fully from the drying and condensing chamber and the drain is easily accessed from the inspection door.

FILTER INTEGRITY TEST

Included in the standard package is an air/nitrogen in let filter with valves manifold permitting in-situ integrity test after filter sterilization (SIP).

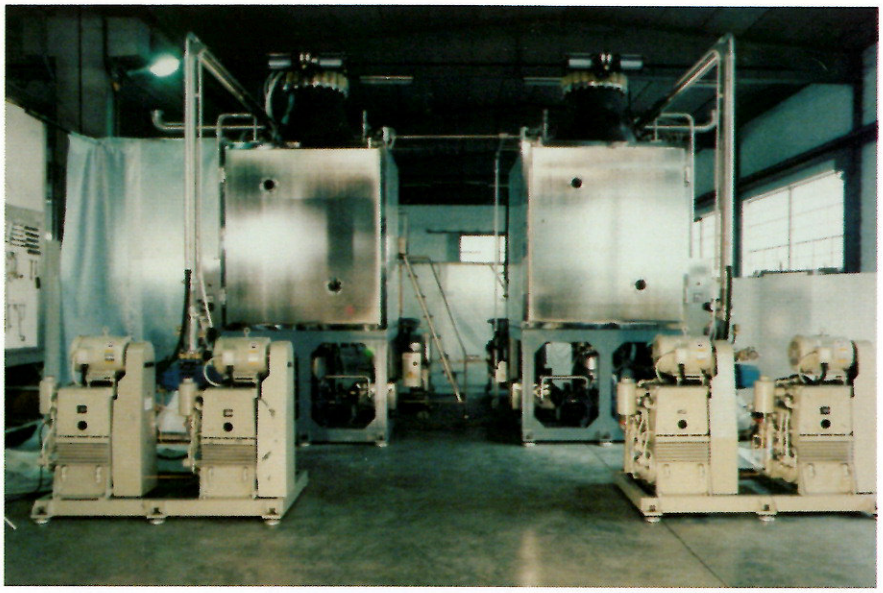
VALIDATION

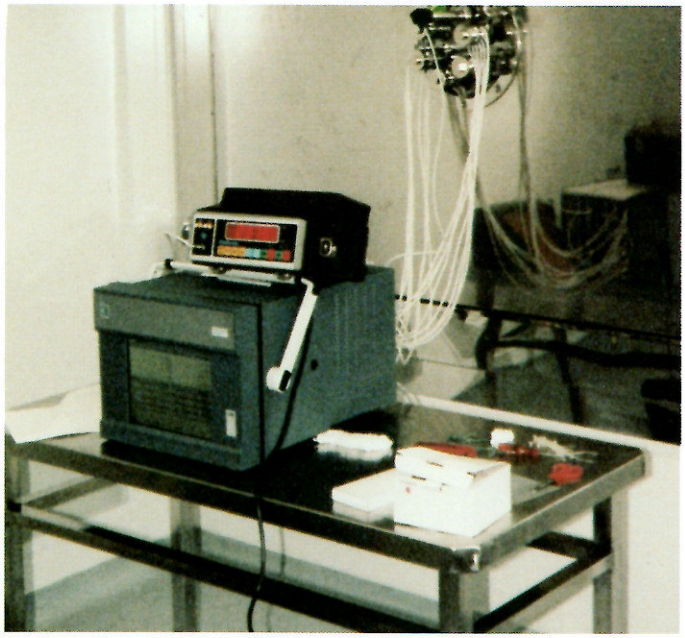
CRIOFARMA support our customers in the I.Q. (Installation Qualification), OQ (Operation Qualification) phase or even in parts of the P.Q. (Performance Qualification) phase providing the drawings, instructions, calibrations, protocols and other documentation to help our customer get in to production on time.

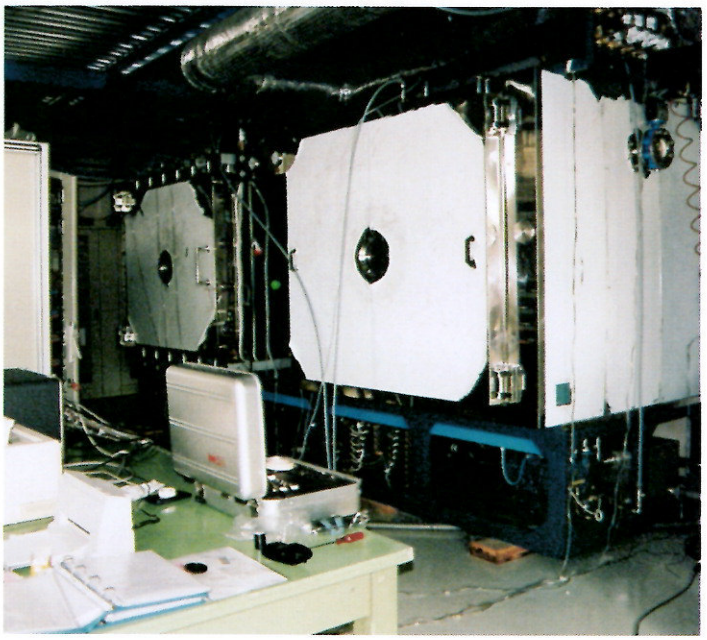
ADVANCED RESEARCH PROGRAM (R&D)

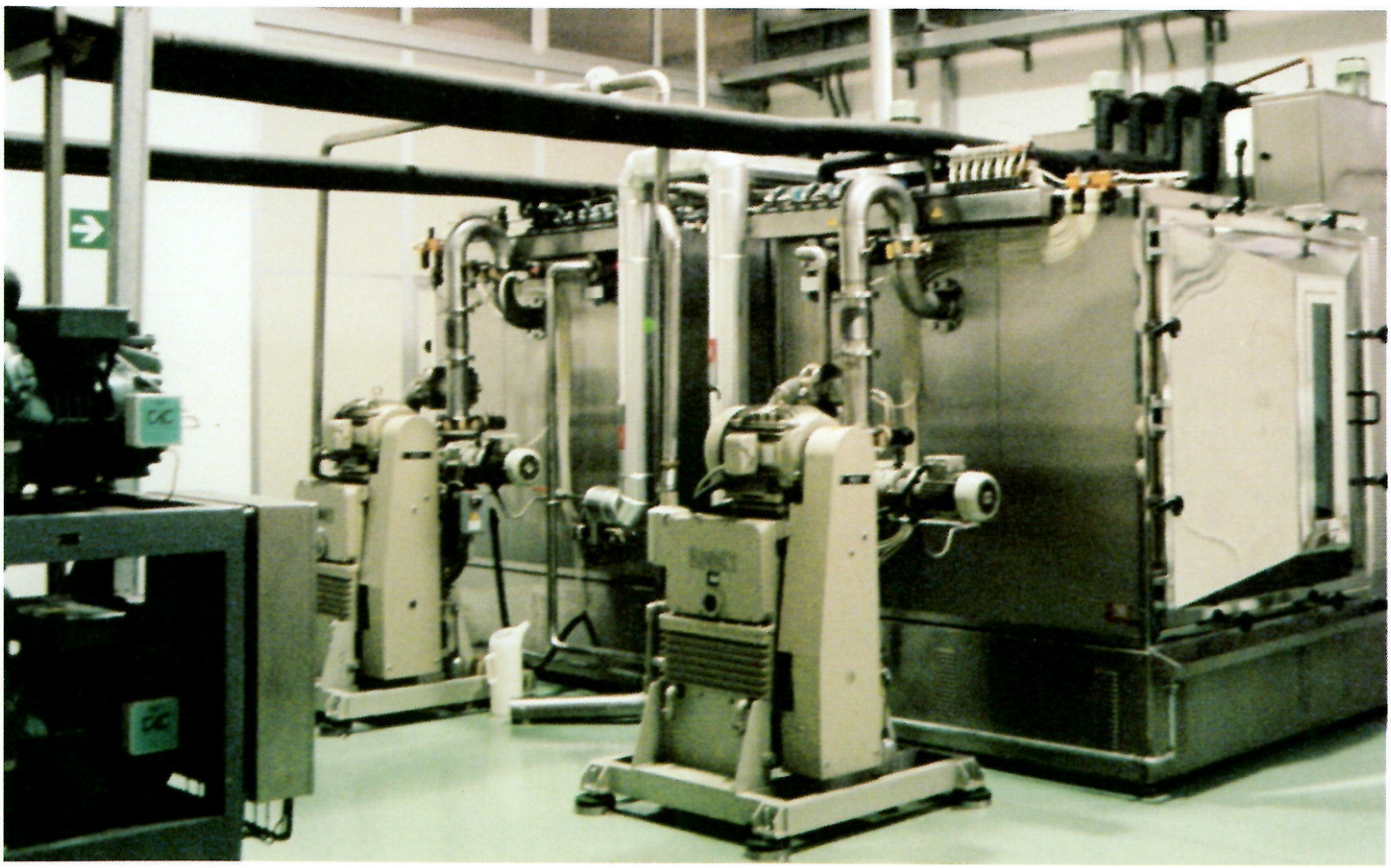
CRIOFARMA has been providing during the years important Research and Development in the freeze drying process in cooperations with University and scientist along the world.

CRIOFARMA continuos R&D allow to our customers to be at any time at the border line with the continuous progress in the freeze drying process and equipments.









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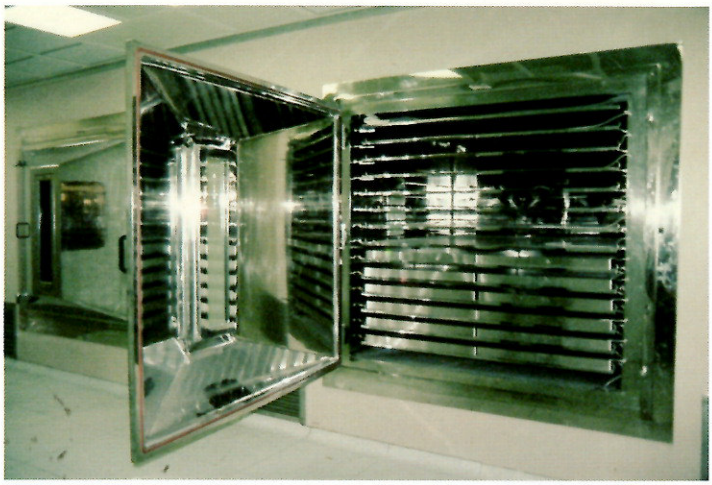

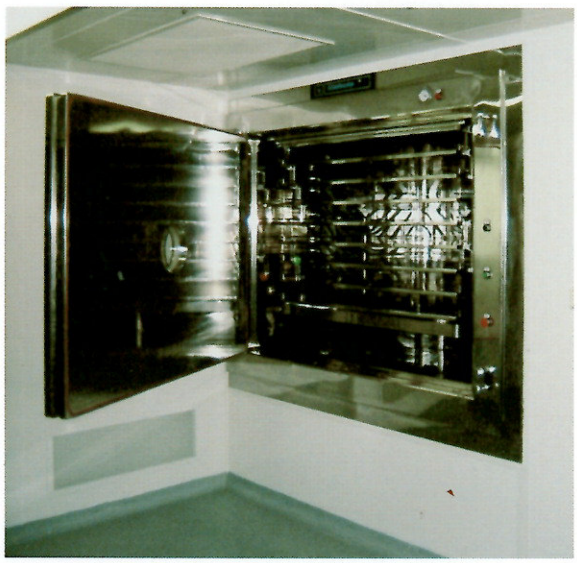
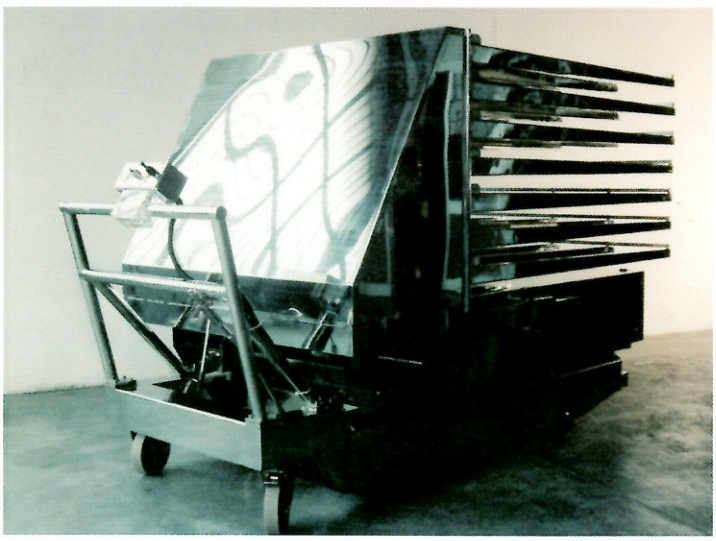
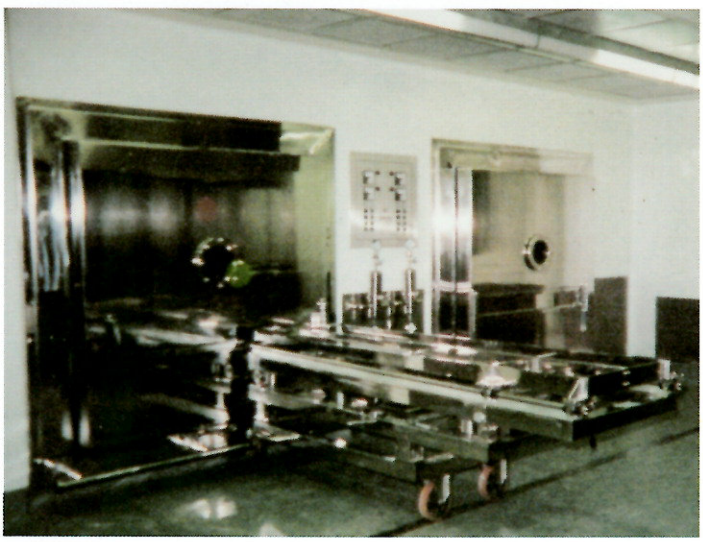

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