# Maintaining safe production and protecting investments

As a reliable partner at your side, we help you maintain and optimize the productivity of your equipment throughout its entire life cycle.

#### Our service includes:

- · Consultative service
- Delivery, installation, commissioning, and qualification
- · Control and process modifications
- · Technical modifications
- · Software modifications
- · Operator and maintenance training
- Phone support
- Supply of replacement parts & consumables



### With passion for the future

Whether you are producing the cures of today or discovering the cures of the future, preventing contamination from occurring is a common challenge.

We are there to support you in ensuring a productive and contamination-free research or production environment. Our portfolio of biopharmaceutical production equipment meets your specific challenges and fulfills strict compliance requirements while achieving high performance, maximum productivity and streamlined processes.

We produce GMP washers, sterilizers, closure processing systems, isolators and sterile transfer systems to meet each facility's specific needs.



Getinge is a global provider of innovative solutions for operating rooms, intensive care units, sterilization departments and for life science companies and institutions. Based on our firsthand experience and close partnerships with clinical experts, healthcare professionals and medtech specialists, we are improving the everyday life for people-today and tomorrow.

Contact · Getinge Infection Control AB · P. O. Box 69 · SE-305 05 Getinge Sweden · Phone: +46 (0) 10 335 00 00 E-mail: info@getinge.com

www.getinge.com



## Biopharmaceutical production

Stringent demands for sterility in the production of patient cures



Products manufactured by the biopharmaceutical industry serve as the first and last lines of defense in patient care. Manufacturers require maximum uptime, service and protection against microbial and particulate contamination in order to ensure the efficiency of life-saving medicinal products produced from chemical and biological sources.





#### Component and equipment processing

Components must be thoroughly cleaned and sterilized according to specific validated processes in order to avoid cross-contamination with the final product during production. Our portfolio of cGMP washers and sterilizers has been designed to help our customers ensure compliance with specific cGMP requirements and process demands.



Isolators

### Protection when handling active pharmaceutical substances

Today's drugs contain a significant proportion of active pharmaceutical ingredients (API) and highly potent active pharmaceutical ingredients (HPAPI). During the formulation and production of drug products, operators must be protected from these substances. Getinge's isolation technology and washing systems protect your personnel and the environment, and help ensure safe handling of active ingredients.



DPTE® Transfer systems (Courtesy of Octapharma)

#### Transfers of material without breaking containment

Safe transfer of aseptic items and toxic material requires secure handling without breaking the integrity of the system. The patented DPTE® system is based on the interaction of two separate units – "Alpha" and "Beta" – each fitted with a door, a lock and a sealing function, to ensure safe contamination-free transfer to and from your filling line.

#### Qualification of your facilities

We support the qualification of your equipment from the planning stage in compliance with ISPE guidelines and GMP principles. On request, we provide you with qualification protocols or our staff can carry out the necessary tests.

FAT

• PQ

• DQ

- Requalification of your equipment (calibrations)
- IQ and OQ (SAT)



#### **Calibrations**

Regular calibrations of your equipment and measuring instruments are indispensable for the safety and integrity of your products, and they are an important contribution to the quality assurance of your production.