



# GMP Pre-Qualification of Separators Ex Works

Flexible and safe on the  
GEA pharmaceutical test bay

# Customer Specific, Economical and Safe

For manufacturers of pharmaceutical products, the plant qualification in conformity with the GMP rules is the pre-requisite for obtaining and conserving the manufacturing permit.

The Factory Acceptance Test (FAT) is an important GEA service including documentation which is prepared after the preliminary GMP test carried out in the factory in Oelde. This is verified in the form of an installation test (IQ), a functional test (OQ) and the documents. The pharmaceutical test bay of GEA offers flexible FAT concepts that ensure a simplified acceptance by authorities and quicker commissioning of its centrifuge package units on site.

The pharmaceutical test bay permits the centrifuge package unit to be tested for observation of the quality requirements determined prior to installation, and to be documented in conformity with the GMP rules.

If and when possible, parts of IQ and OQ tests are integrated in the process. This minimises the risk during on-site validation and commissioning and saves time and money.

## FATs after completion of the preliminary plant test

FATs are carried out only after completion of the preliminary test/qualification test with presentation of the test protocols and certificates. Depending on the requested scale and depth of test, you can choose between three FAT concepts. A FAT protocol documents that all components function correctly and the specific requirements on product quality and production quantity are met.

## Quality and safety ensured by state-of-the-art engineering

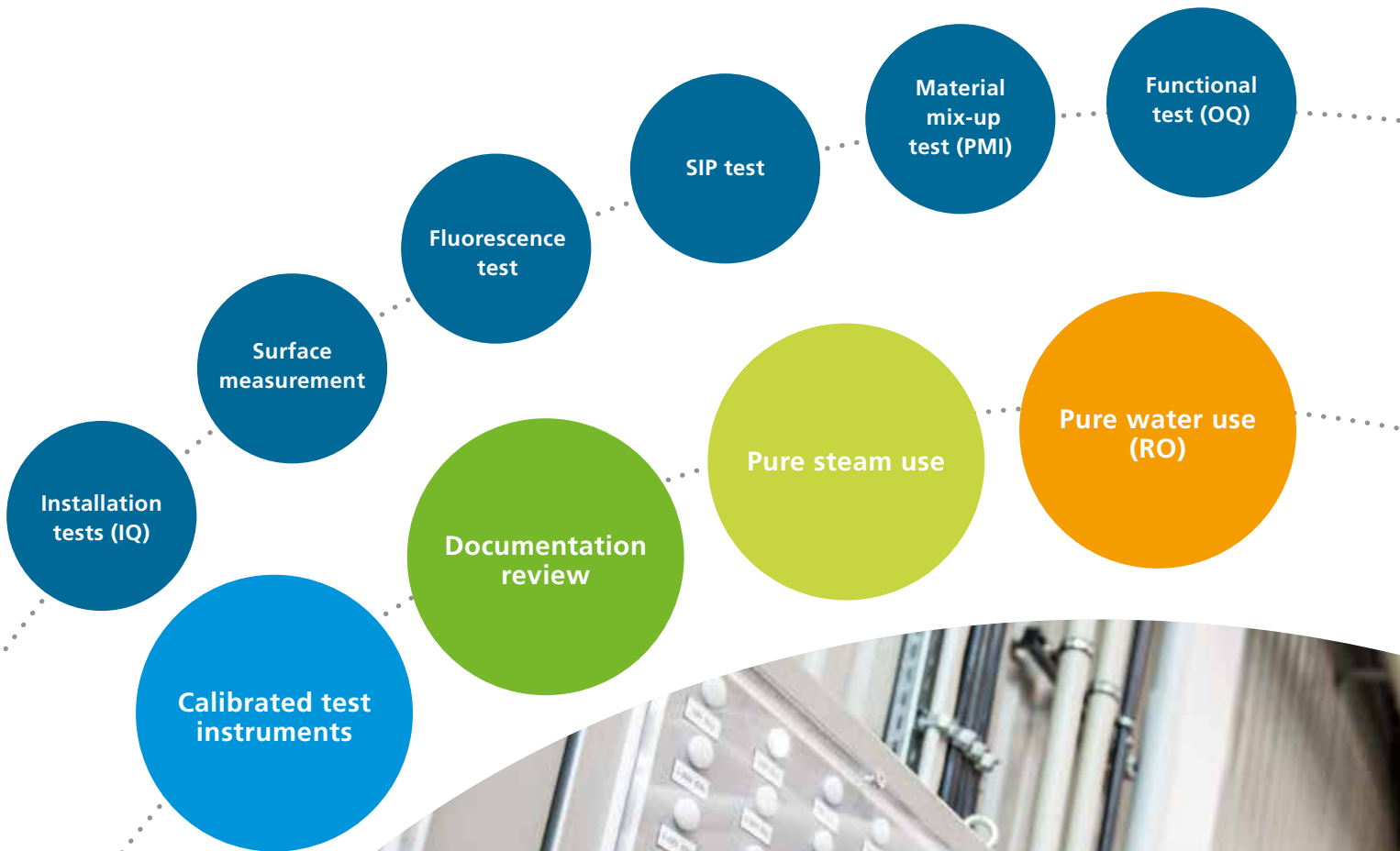
The tests are carried out under real conditions including the use of pure water systems and clean steam systems as well as calibrated test instruments.

## The advantages at a glance

- Customer-specific FAT tests
- Easy and quick correction possibilities
- Early review of GMP documentation
- Tests do not have to be repeated at customer site
- Certainty that the plant is in compliance with the specifications
- Certainty of GMP approval by authorities
- Quicker validation and commissioning by pre-qualified skids

AFTER SUCCESSFUL COMPLETION OF THE TESTS, THE SHIPMENT IS RELEASED FOR THE INSTALLATION OF THE PLANT IN YOUR WORKS.

# Flexible components for the customized GMP preliminary tests

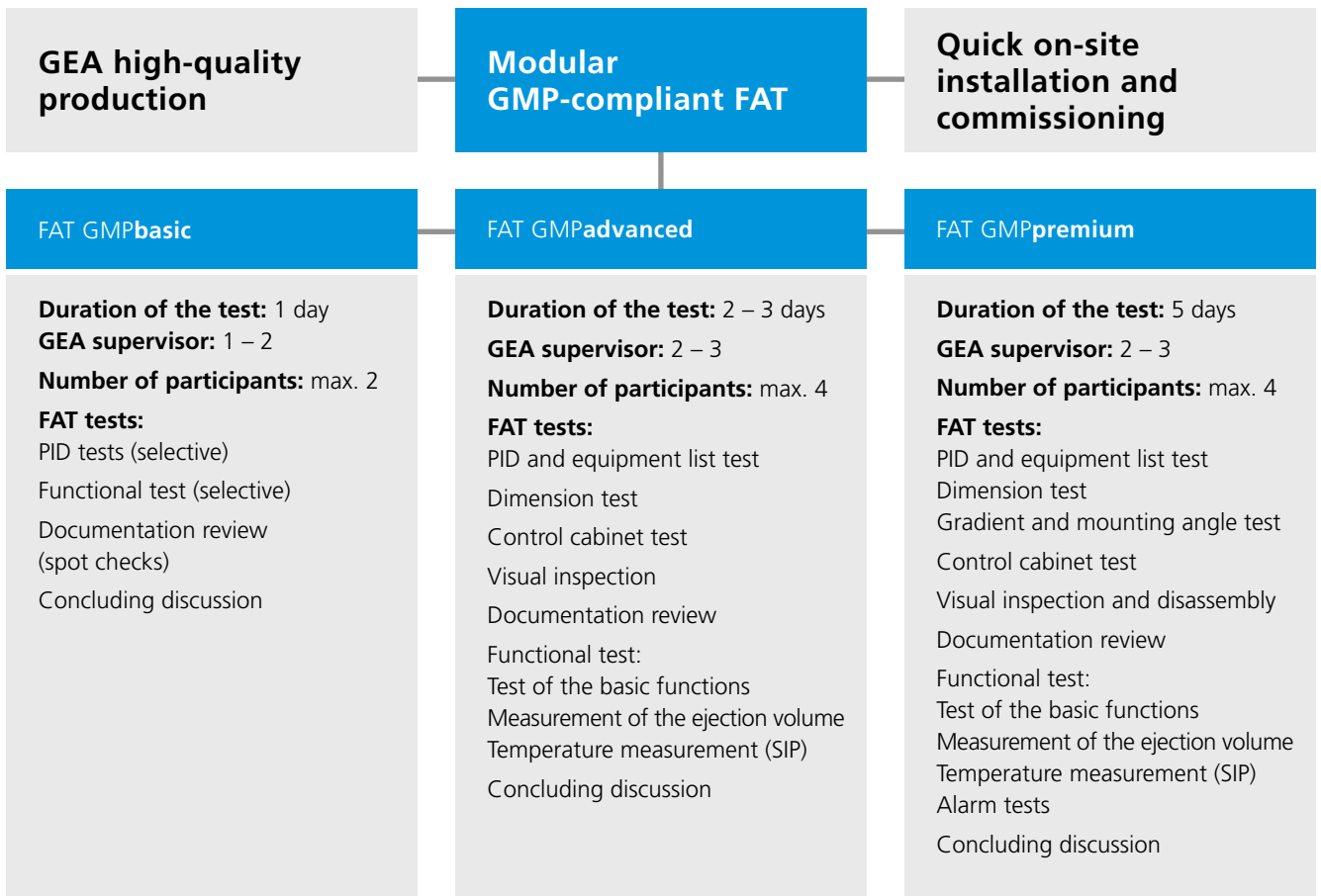




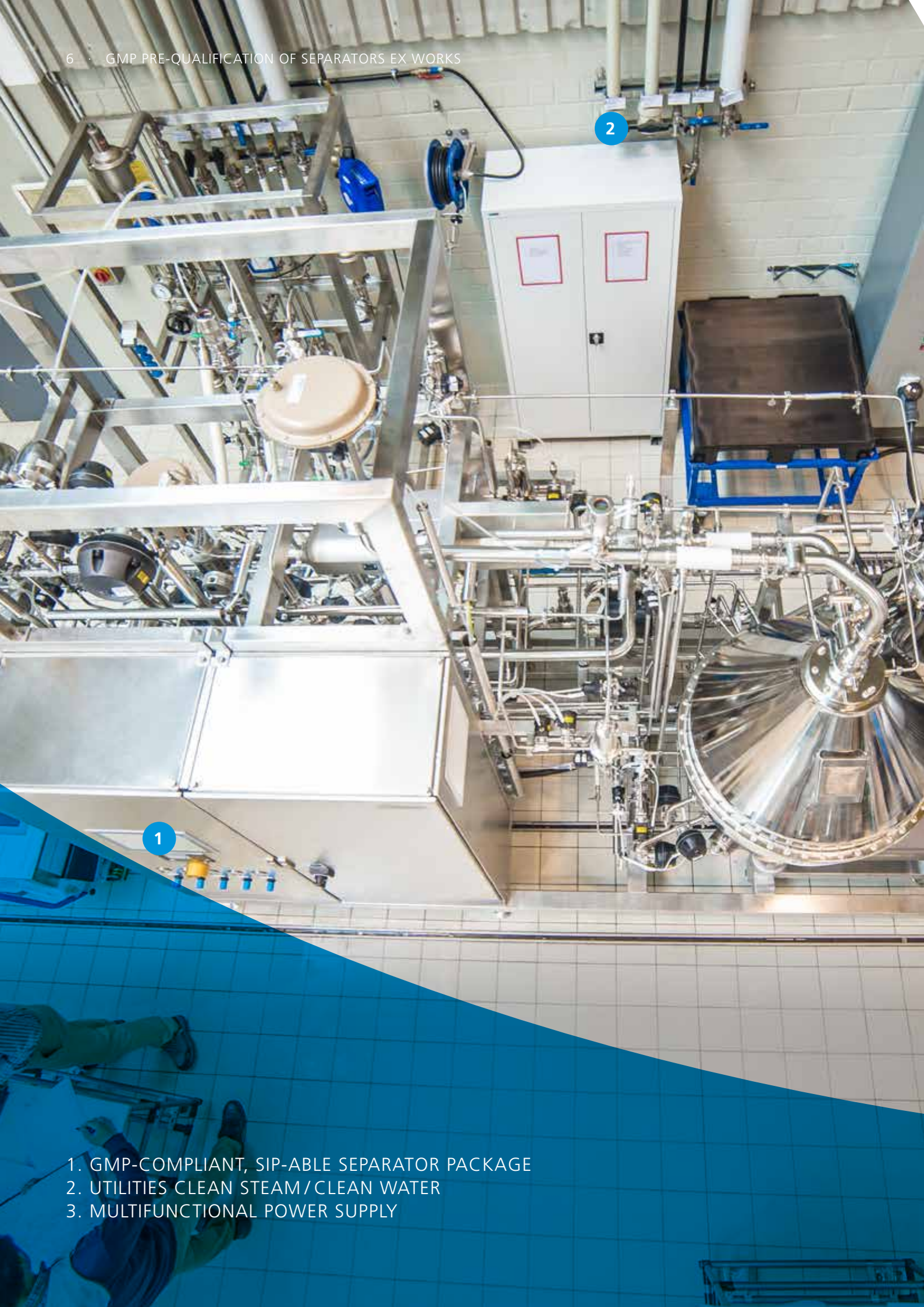
” THE DETAILED TESTS  
GIVE THE SECURITY OF  
PERFECT INSTALLATION  
ON SITE – RENDERING  
VALUABLE KNOW-HOW  
FOR PLANT HANDLING  
IN ADDITION.

# Simplified GMP Release and Quick Installation by Modular FAT Packages

On account of the modularly designed FAT packages, our experienced team of experts together with you ensure that your separator package unit from GEA satisfies the requirements of national and international approval and control authorities in compliance with the current GMP standards and FDA/PIC guidelines.



*Individual FAT tests in conformity with customer specifications are possible naturally.*



1

2

- 1. GMP-COMPLIANT, SIP-ABLE SEPARATOR PACKAGE
- 2. UTILITIES CLEAN STEAM / CLEAN WATER
- 3. MULTIFUNCTIONAL POWER SUPPLY

# Reliably Securing Top Pharmaceutical Product Quality

As a rule Factory Acceptance Tests (FATs) are carried out under real conditions with the use of pure water/steam applying state-of-the-art technology. A key factor for sustainable, GMP-compliant assurance of quality of pharmaceutical intermediate and end products.

As worldwide leading manufacturer of mechanical separation technology, GEA is well acquainted with the subject of quality and qualification. All our testing devices and instruments are subjected to regular calibration and servicing in conformity with the applicable standards, with which we ensure top accuracy in the pharmaceutical test bay.

With our FATs you receive the documented proof that all components of your centrifugal package unit have been installed correctly, the plants operate within the given parameter limits, and thus reliably and reproducibly manufacture your pharmaceutical intermediate and end products in the requested quality right from the initial start-up.





## We live our values.

Excellence • Passion • Integrity • Responsibility • GEA-versity

GEA is a global technology company with multi-billion euro sales operations in more than 50 countries. Founded in 1881 the company is one of the largest providers of innovative equipment and process technology. GEA is listed in the STOXX® Europe 600 Index. In addition, the company is included in selected MSCI Global Sustainability Indexes.

### GEA Germany

GEA Westfalia Separator Group GmbH

Werner-Habig-Straße 1  
59302 Oelde, Germany

Tel +49 2522 77-0  
Fax +49 2522 77-2089

sales.germany@gea.com  
gea.com