

**GERRESHEIMER**



# Irradiated ophthalmic dropper bottles - Validation

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## Gerresheimer 2017

### A leading partner for the pharma & healthcare industry

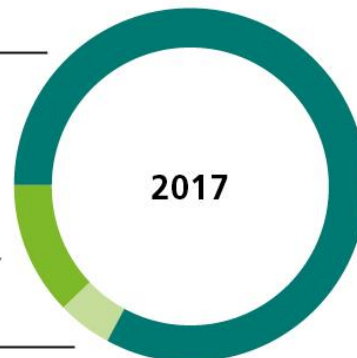
- Revenues 2017: EUR 1,348m
- International presence: Europe, Americas, Asia
- High quality customer base: Global blue chip customers
- Employees: about 10,000
- Head office: Duesseldorf, Germany
- Listing: Frankfurt Stock Exchange

### Percentage of revenues by market segment

Pharma and Healthcare 83 %

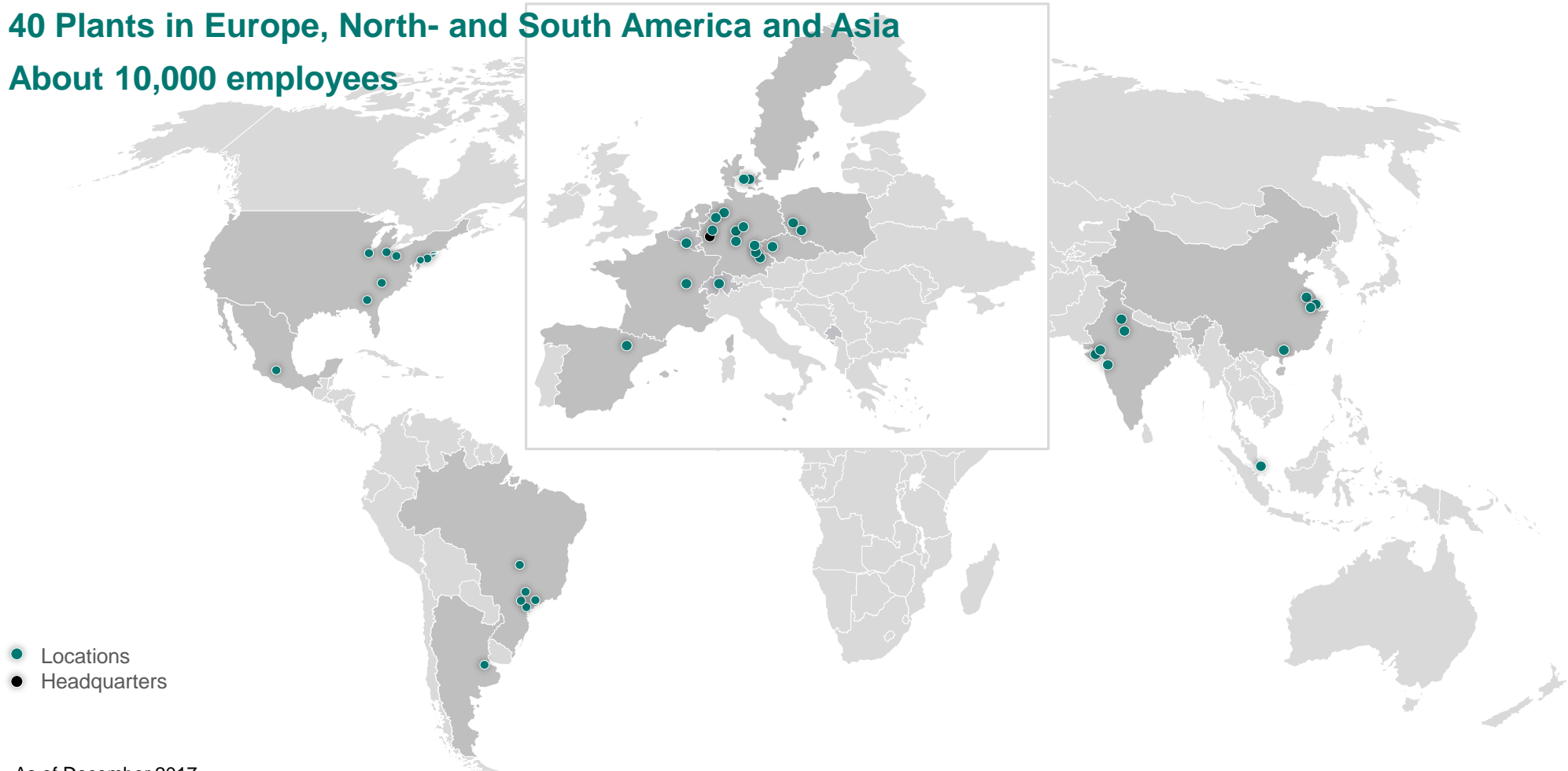
Cosmetic 12 %

Other 5 %



# Gerresheimer is a global player

**40 Plants in Europe, North- and South America and Asia**  
**About 10,000 employees**



As of December 2017

# Our Organization with 3 divisions

## Plastics & Devices Andreas Schütte



## Primary Packaging Glass Dr. Lukas Burkhardt



## Advanced Technologies Andreas Schütte



## Irradiated ophthalmic dropper bottles

### Eye preparation – Ophthalmic; European Pharmacopeia

- Eye preparations are sterile liquid, semi-solid or solid preparations intended for administration upon the eyeball and/or to the conjunctiva, or for insertion in the conjunctival sac.

Where applicable, containers for eye preparations comply with requirements of material used for manufacture of containers (3.1 and subsections) and containers (3.2 and subsections)

- Eye preparations are prepared using materials and methods designed to ensure sterility and to avoid the introduction of contaminants and the growth of micro-organisms.



## Full solution for irradiated products



- Production in clean-rooms ISO 7.
- Measurement on bioburden acc. to ISO 11137
- The bioburden for product: < 9 cfu/product
- Gamma irradiation acc. VDmax 17,5 kGy
- Certificated sterilization partners.
- Dosimetric validation / revalidation (dose mappings)
- Validation / revalidation of microbiology (dose audits)
- Physical and chemical tests of product properties after irradiation





# Methods of sterilization

Radiation (gamma and e-beam)

- EN ISO 11137-1:2006 Sterilization of health care product – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
- EN ISO 11137-2:2013 Sterilization of health care product – Radiation – Part 2: Establishing the sterilization dose
- EN ISO 11137-3:2007 Sterilization of health care product – Radiation – Part 3: Guidance on dosimetric aspects



## Products requiring sterility

Medical Devices

Pharmaceuticals

- injectable and inhalation drugs
- **nasal, ophthalmic and some topical products**
- In vitro Diagnostics—for health care related testing
- Prepared Media – for microbiology testing





## Advantages of radiation sterilization

- Supervision of the irradiating company as the approved supplier
- Transport from Gerresheimer to sterilization company and then to the place designed by customer
- Managing validation process as well as revalidation
- Lower costs relate to validation process as well as irradiation service
- The dose of VDmax 17,5 has less physical impact on the packaging material



# Features

- Validated process of irradiation using method Vdmax 17,5
- Gamma validation is done in accordance with the relevant ISO standards 11137, 11737 and 13004
- Physical and chemical tests of product properties after irradiation
- Monitoring of bioburden level
- Standardization of products designed to being irradiated



## We have passed the validation process of the gamma irradiation, which was based on:

- Dose substantiation of a irradiation dose of 17,5 kGy (Method Vdmax 17,5)
- Bioburden estimation and performance of verification dose experiment (bioburden and sterility test)
- Dose mapping within established scope: Min. Dose 17,5 kGy – max dose 50 kGy



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**Thank you for your attention!**