FRESENIUS KABI

Product Partnering

Fact Sheet (9)

Development & Clinical Trial Supply

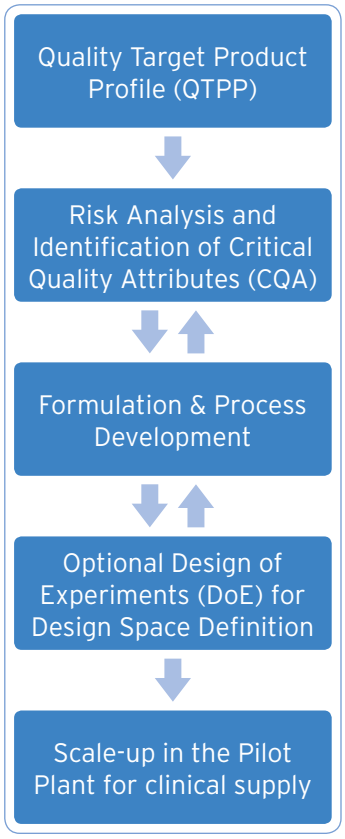
Fresenius Kabi Product Partnering offers services and expertise based on a decades-long track record of successful development of sterile pharmaceuticals.

Our development centers have teams of scientists and engineers with strong academic and industry backgrounds related to all types of sterile pharmaceuticals. By taking advantage of our extensive knowledge on the function of various excipients, we help our customers to transform an idea into a product.

For lipophilic and low-soluble APIs, we build on our knowledge base with emulsions and liposomal formulations to develop safe intravenous administration forms. For lyophilizates, we combine formulation knowledge with cryo-microscopy methods to find a suitable lyophilization process.

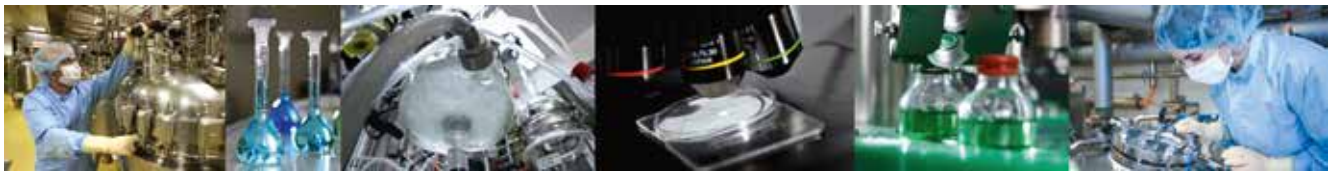
Various compatibility studies allow us to identify the best container closure system, such as ampoules, vials, bottles, pre-filled syringes or bags, to meet the requirements of the product and of the market.

Sophisticated developmental assays help us to optimize process parameters to guarantee a smooth scale-up and consistent product quality following the Quality by Design (QbD) guideline.



Preclinical and Clinical Trial Supply

Our pilot plant in Graz, Austria and our commercial plants are fully compliant with international quality standards (incl. FDA-GMP, EU-GMP), offering supply for preclinical and global clinical studies in various container closure systems. Our plant in Neufahrn, Germany is the ideal partner for aseptic compounding and can also offer blinding of study medication for clinical trials.



Services

Formulation Development for Sterile Pharmaceuticals

- Aqueous solutions
- Aseptic solutions
- Emulsions
- Liposomal formulations
- Suspensions
- Lyophilisates

Formulation and Process Development

- Analytical method development
- Compatibility studies for container closure systems, stainless steel, silicone and Teflon tubing, etc.
- Thermal stability studies
- ICH and ambient photo stability
- Extractables & leachables
- Lyophilization development
- Process optimization by DoE

Clinical Trial Supply for Global Studies

FDA & EMEA approved plants for clinical supply in the US and Europe

cGMP batch sizes: 5 L to 1000 L

Secondary packaging and blinding of study medication for clinical studies

Containers for clinical supply:

- Vials: 10 to 100 mL
- Bottles: 50 to 1000 mL
- Ampoules: 1 to 20 mL
- Pre-filled syringes: 1 to 50 mL
- Bags (PVC free): 50 to 1000 mL

product.partnering@fresenius-kabi.com / phone: +49 6172 686 1240 / www.freseniuskabi-productpartnering.com