Navigating you through drug development

Fit-for-Phase Nanomedicine Solutions

In the nanomedicines landscape Ardena is a leading fit-for-phase solutions partner. With expertise encompassing scalable formulation, process, and analytical development, we enable our customers to scale up to clinical schedules in time. As we keep track of your candidate at every stage of the development process, the drug development process is steered and development risks are reduced. In addition to taking responsibility for the technology transfer of the existing process and implementation of cGMP manufacturing, we also synthesize your lipids, polymers and other building blocks. The Ardena services platform includes state-of-the-art bioanalytical competencies to support your clinical program and the experience to facilitate regulatory approval.

ARDENA

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Nanomedicine development

Our expertise comprises the following types of nanoparticles:

- Liposomes
- Silica nanoparticles
- Crystalline nanosuspensions
- Polymeric micelles and polymeric nanoparticles
- Iron oxide nanoparticles
- Gold nanoparticles

GMP production

In our cGMP-compliant manufacturing facilities we can produce volumes up to multiple liters, using batch-type and continuous-flow processes. We also work with highly potent APIs and can deliver nanosuspensions and nanoparticle solutions as sterile finished drug products in vials or syringes. Other production techniques include:

- Continuous flow processing
- Tangential flow filtration
- High-temperature processing
- Magnetic separation
- Single-use manufacturing systems
- Wet milling
- Spray drying

Analytics

To support product development and to perform quality control of GMP-produced drug products, we utilise state-of-the-art analytical techniques such as:

- Dynamic light scattering, small-angle X-ray scattering and laser diffraction
- Asymmetric flow field-flow fractionation - multi-angle laser light scattering (AF_4-MALLS)
- Size exclusion chromatography
- Zeta potential measurements
- Transmission and scanning electron microscopy
- Nuclear magnetic resonance, infrared and Raman spectroscopy
- Advanced dissolution techniques
- HPLC/UPLC

Dossier development and strategic regulatory support

Having advanced a wide range of nanomedicine formulations into the clinic, we are used to developing new manufacturing techniques and analytical procedures under fierce regulatory scrutiny. Our deep understanding of the regulatory landscape gives your nanomedicine project the greatest chance of winning approval.

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