GMP/GCP SERVICES

STATENS SERUM INSTITUT

A Century in Biopharmaceuticals

Statens Serum Institut has more than 100 years of experience in research, development and manufacturing of biopharmaceuticals. Vaccine Development have produced more than 20 biophamaceuticals and contributed to more than 30 clinical trials the last 15 years

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GMP/GCP SERVICES

Pre-Clinical and Clinical Supply

Our pilot plant facilities support manufacturing of biopharmaceuticals for early clinical development projects with specific focus on.

- Pilot plant facilities certified by the Danish Medicines Agency
- Handling multi-product contract manufacturing in state-of-the-art cGMP facility
- Flexibility through high reliance on disposable technology, and readily available additional utility points
- Handling of BSL 2 and GMO I, possibility for GMO II
- Risk based quality management

Pilot Plant Capacity

- Cell banking laboratory and storage facilities
- Class C upstream facility
- 5L to 30L stirred tank bioreactors and possibility for single use reactors
- Class C downstream facility with class A LAF zone

Formulation and stability

SSI performs formulation screening and stability studies of optimized biopharmaceutical candidates with and without adjuvant including SSIs liposomal adjuvant CAF01.

- Classical or fast track formulation screening
- Facilitate technology transfer and requirements for fill and finish contact
- Stability studies according to ICH guidelines including development of stability protocols and reports

Support to pre-clinical and clinical trials

- Set-up of pre-clinical trials including assistance on trial design and vendor selection
- Assist in the preparation of Clinical Development Plans for new products
- Clinical trial set-up including assistance on trial design, site selection, regulatory and ethics committee submissions according to relevant ICH guidelines and national law
- Clinical trial conduct and monitoring according to ICH guideline on Good Clinical Practice
- Reporting of pre-clinical and clinical trial according to relevant ICH guidelines

QA and regulatory services

Our highly skilled QA professionals are issuing all documents related to manufacture and controls, perform batch record reviews and QP releases. All quality assurance procedures are cGMP compliant. All clinical trials conducted according to cGCP. To further help you meet your project goals we provide regulatory guidance.

Project Management

Each project is led by a dedicated project manager and supported by a multidisciplinary team. The project manager can assist in development of work packages and budget for grant applications.

The project manager is responsible for detailed timeline planning, milestone tracking, and will manage internal and external stakeholder expectations. We focus on frequent communication with the client to facilitate project implementation and progress.

Contact

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