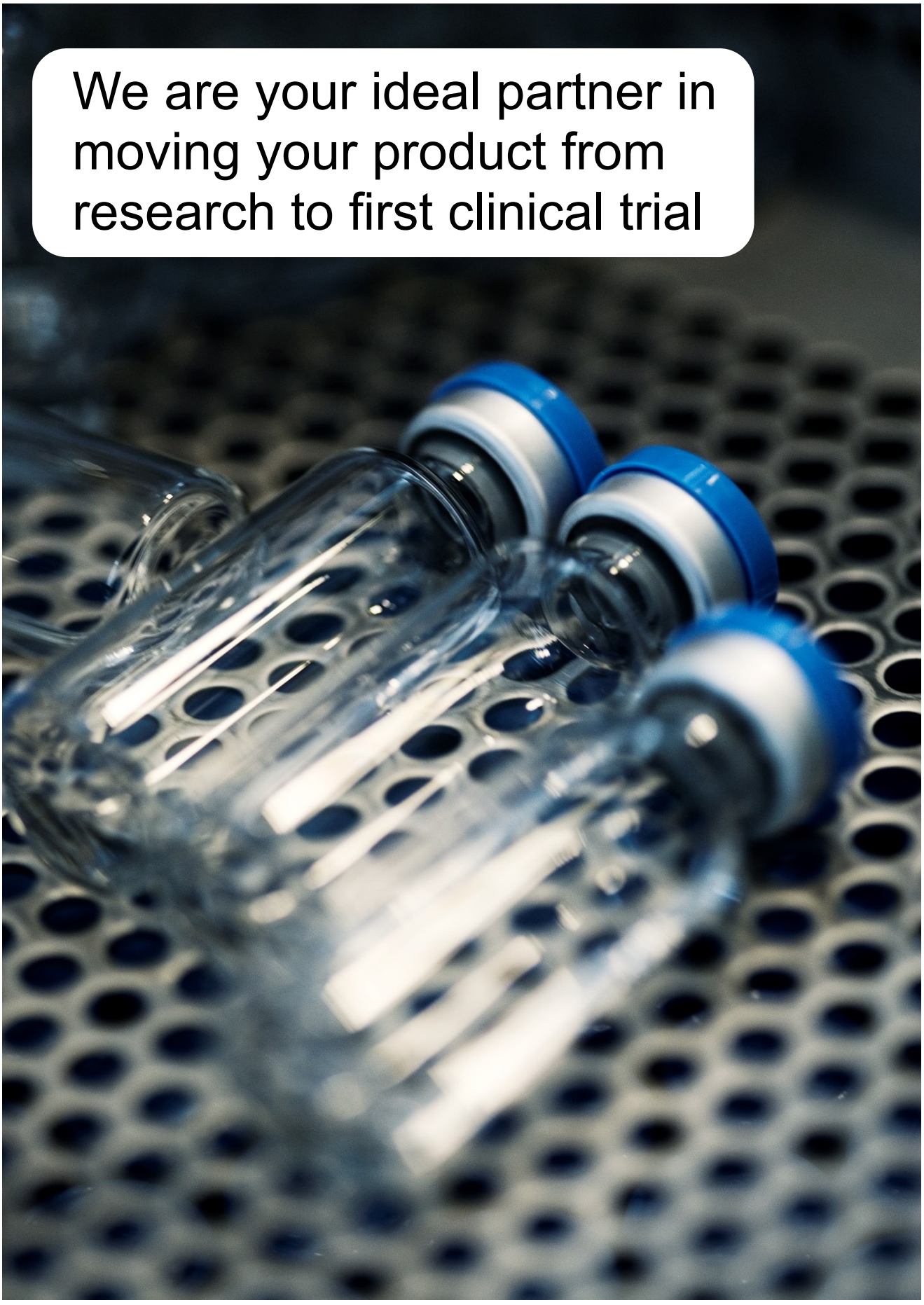
ONE STOP SHOP

STATENS SERUM INSTITUT



GXP SERVICES

The Vaccine Development Department at Center for Vaccine Research is your ideal partner in supporting your steps from research vaccine through development to an IMP for the first clinical study. We facilitate all aspects from GMP produced IMP through GLP support, labeling and shipment (GDP) to GCP clinical study and IMPD for submission to authorities.

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
- ◊ 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 30 L 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 adjuvants CAF®01, CAF®09b and CAF®10b.

- ◊ 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 responsible person that assist for timeline planning, milestone tracking, and will manage internal and external stakeholder expectations. We frequently communication with you to facilitate project implementation and progress.

Contact

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