CHIMIA REPORT/COMPANY NEWS

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Companies present themselves and their products

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Need help to bring your science to life?

CARBOGEN AMCIS is a leading provider of drug development and commercialization services to pharmaceutical and biopharmaceutical companies across all development stages. Built up with a portfolio of specialist services customer gets the highest degree of flexibility possible.

Highly Potent API

CARBOGEN AMCIS has more than 15 years of experience in the development and manufacture of highly potent Active Pharmaceutical Ingredients (API) up to category 4+ (<0.05 µg/m³). The services range from lab scale in dedicated equipment to multiple 100 kg scale GMP manufacturing in multi-purpose equipment – including chromatography. More than 40% of CARBOGEN AMCIS projects are highly potent projects.

ADC & Bioconjugation

CARBOGEN AMCIS offers tailored ADC & Bioconjugation projects out of one hand: The service ranges from synthesis of the active compound, to drug linker synthesis, conjugation processes to the final drug product formulation process.
CARBOGEN AMCIS' state-of-the-art clean room suite is fully cGMP qualified. A dedicated team of experts will advise you on conjugation strategy and downstream processing.

Chromatography

Very experienced chromatography experts guide you through a vast range of in-house solutions to tailor an optimal program around your needs. Depending on your requirements and on the existing data available, CARBOGEN AMCIS can develop a new chromatographic method or transfer and scale-up an existing processes to the plant. Isolation of intermediates and products are supported by concentration techniques like efficient and mild (continuous) short path distillation, tangential flow filtration (TFF) or freeze drying.

Process Development and Analytical Services Group

The CARBOGEN AMCIS services range from process development including analytical support with very broad variety of analytical techniques to enable process and product characterization from the lab to pilot and routine manufacturing. Process development is based on the principles of quality by design (QbD) including all related topics such as impurity profile identification, fate and purge of impurities and/or genotoxic impurities assessment and of course validation of related analytical methods according to customer's needs.

Crystallization

Defining the best crystalline form of an API is crucial in drug development, since it has a significant impact on the effectiveness of the formulation and, therefore, the bioavailability of the finished dosage form. CARBOGEN AMCIS is able to provide state of the art services from standardized solubility screenings, salt screenings to polymorphism screening. Process development capabilities around robustness of crystallizations, solid-liquid separation development and scale-up modelling of crystallizations complements the service portfolio.

Stability Studies and Reference Standard Certification Service

Stability studies and forced degradation tests are important components for drug development, the assessment of storage or shipment conditions, expiration date, and packaging. The services contribute to a thorough understanding of the physicochemical behavior, degradation pathways and the intrinsic stability of a new molecule.

Flow Chemistry

Scale-up can be tough even for reactions that are well established in the lab. With profound expertise in the field of flow chemistry CARBOGEN AMCIS has the capability to help you controlling conditions and handling the risk as reactive volumes are small at any time. The range of applicable conditions such as temperature and pressure is becoming larger than in classical batch reactors. Not only will the experience in this method allow a safer reaction and easier scale-up - the technique provides in many cases higher yields and improved impurity profiles.

Project Management and CMC-Support

CARBOGEN AMCIS dedicated Project Management group, supported by critical chain project management (CCPM) based tools is making sure, that offered services are delivered in time.
Together with their in-house regulatory affairs group, allows CARBOGEN AMCIS to advice their customers on development of a tailored program strategy based on sensitivity to risk & cost.

Drug Products

CARBOGEN AMCIS has developed a comprehensive range of services for the formulation of New Molecular Entities (NMEs) and aseptic production of parenteral drugs for preclinical and clinical trials (phases I, II and III). From developing formulations and processes for highly potent APIs including Cytotoxics, Cytostatics, Peptides, Biologics to Drug Delivery Systems both for liquid and lyophilized forms. A new state-of-the-art facility will open in Q1 2023 in France to allow larger capacities and supply CARBOGEN AMCIS customers with clinical batches for phase III clinical trials and small-scale for commercial.

Marketed Molecules

CARBOGEN AMCIS marketed molecules are supplied for their customers into all major markets (US, EU, Japan, Korea, Australia, etc.) and comprise various therapeutic indications. ~50% are oncology products among others modern antibody therapies. Conversely, ~50% of the drug supply is still focusing on treatment of classic diseases. The CARBOGEN AMCIS mission is to helping their customers create a better world by developing and manufacturing complex and challenging active substances that are able to improving the quality of life of our fellow human beings, or even can save their lives.

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