Peptide manufacture can now be accomplished at comparatively low cost, and large-scale production is open to any well-equipped specialist. This has significantly boosted the attractiveness of peptides as potential drugs. Peptides have made their mark as a drug class in various areas: adult-onset diabetes, obesity, oncology and dementia, for example. Medicinal products are now commercially available in the first three areas, with others undergoing clinical trials.

BACHEM PRODUCT LINES

RESEARCH CHEMICALS

Bachem's Research Chemicals are mainly used to make peptides and to advance biochemical knowledge. The new online catalog provides enhanced search functionality and a unique shopping experience. The catalog is being continually updated with new and innovative products.

NEW CHEMICAL ENTITIES (NCES)

There are a large number of peptide drug candidates in clinical development. Furthermore, over 70 peptides have already been approved as a treatment for various diseases. Bachem is pursuing the largest number of peptide projects worldwide.

GENERICS

After a drug loses its patent protection, generic copies are produced. Peptide-based pharmaceuticals are somewhat different in this regard because a generic peptide will usually not have the same formulation as the innovator product. It must therefore be navigated through a demanding approval pathway and generic drug makers turn to Bachem for support during this process.

The number of peptides with market approval has grown steadily and now stands at 76. In addition, there are well over 100 projects in various stages of clinical testing and an estimated 450 are in pre-clinical development. As a result, it is safe to assume that a growing number of peptides will be approved as medicines in the coming decades.

Peptides used in many therapeutic approaches

Peptides are currently drawing a great deal of attention as potential medicinal substances. A glance at the pre-clinical pipeline reveals that some 450 products are being seriously examined as potential candidates for clinical development. About half of these projects are being undertaken in the United States, with Europe accounting for roughly 35% and Asia 15%. Asia is catching up, with Japan in the lead.

Just five years ago diabetes was the most intensively researched primary indication. Since then, many peptides such as Exenatide, Liraglutide and Semaglutide have come to market as highly effective drugs. It is not surprising, therefore, that endocrine and metabolic indications have dropped to fourth place among indications for new peptide-based drugs.

The focus of research in peptide-based drug candidates today is on oncology and treatment of infections and dementia. Peptides are also a timely topic to potentially treat other diseases.

Services in support of research increasingly important

It can take over ten years for a drug to move from the pre-clinical phase to application for approval. Throughout this onerous and complex development process, Bachem supports customers with a broad range of products and services. Even very early in the development process, customers are concerned with gaining a thorough understanding of the selected molecule and determining whether it is the best possible candidate for the targeted indication. This puts Bachem in an ideal position to provide hundreds of similar molecules for the selection process.

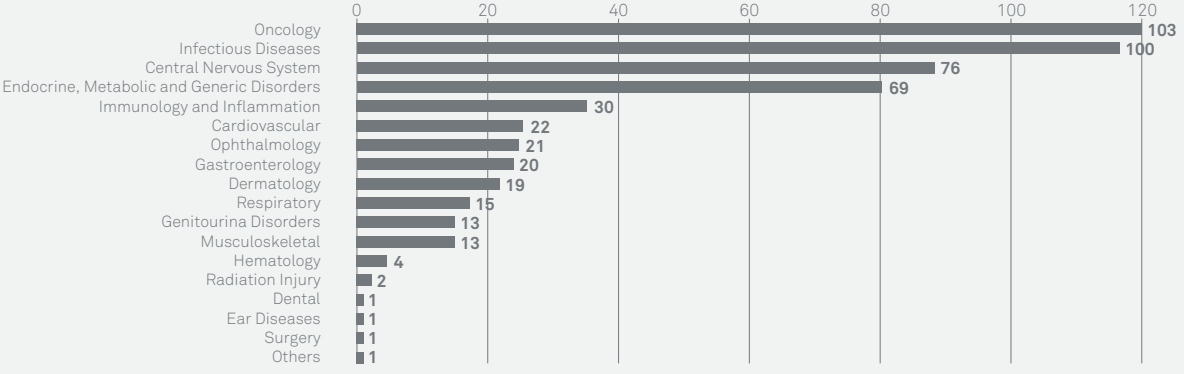
Once the right candidate has been identified, the production process is developed and optimized. Yields are increased and impurities reduced. Also of key importance is careful optimization for the intended commercial batch size and by use of suitable equipment. Here Bachem is an ideal partner thanks to its employees' years of experience in process development and validation.

The entire palette of analytical test procedures must be specifically developed and subsequently validated. This is extremely important not only for quality control and release of the products, but also for process optimization and monitoring. Various stability studies yield findings on the stability of the molecule. Degradation products are identified, characterized and often synthesized. The same applies to impurities specific to the process.

Important work is also required in compiling the approval documents. Despite harmonization efforts, requirements still differ from one country to another. Bachem has many years of global experience with regulatory documents and authorities. This sets Bachem apart from competitors in a positive way.

All of the services described above are important prerequisites for successful drug development. Bachem offers customers all of these services and many more, from synthesis of potential lead candidates to commercial production of the active substance.

GLOBAL PIPELINE OF PRE-CLINICAL NCES BY THERAPEUTIC CATEGORY



Source: Medtrack