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HPAPI development at a glance



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HPAPI development at a glance

The pharmaceutical industry's journey to improve patients' health has enhanced the number of more effective HPAPIs (High Potent Active Pharmaceutical Ingredient) in development pipelines. Traditionally, HPAPIs were exclusively concomitant with oncology therapeutics. Today, there is a rapid extension of HPAPI for several indications, classes of molecules, and new chemical entities that cover a much broader range of the developmental pipeline, including programs being evaluated for inflammatory and antimicrobial/antibacterial indications. In the race, the industry has continued to improve its capacity to assemble, deliver, and harness the power of better medicines. The process development and production of highly potent API with desired quality levels require highly specialized capabilities ¹.



Emerging Trends in the HPAPI Space

One of the key trends involved in the [HPAPI](#) market is the increasing tendency to outsource HPAPI projects to third party service provider (CDMOs). There are many reasons companies choose outsourcing, including the misalignment of production scale or facility utilization dynamics, risk management, and availability of contemporary approaches to HPAPI controls. The majority of the CDMO has HPAPI capabilities, making it challenging for companies to decide which partner best meets their requirement. A large CMO is an obvious choice as they offer the highest production volumes, but, given the nature of HPAPIs – higher potencies mean that smaller dosage-unit volumes are required – the market trend has been toward smaller-scale specialist partners.

HPAPI and Cytotoxic Drugs Manufacturing Market (3rd Edition), 2020-2030.²

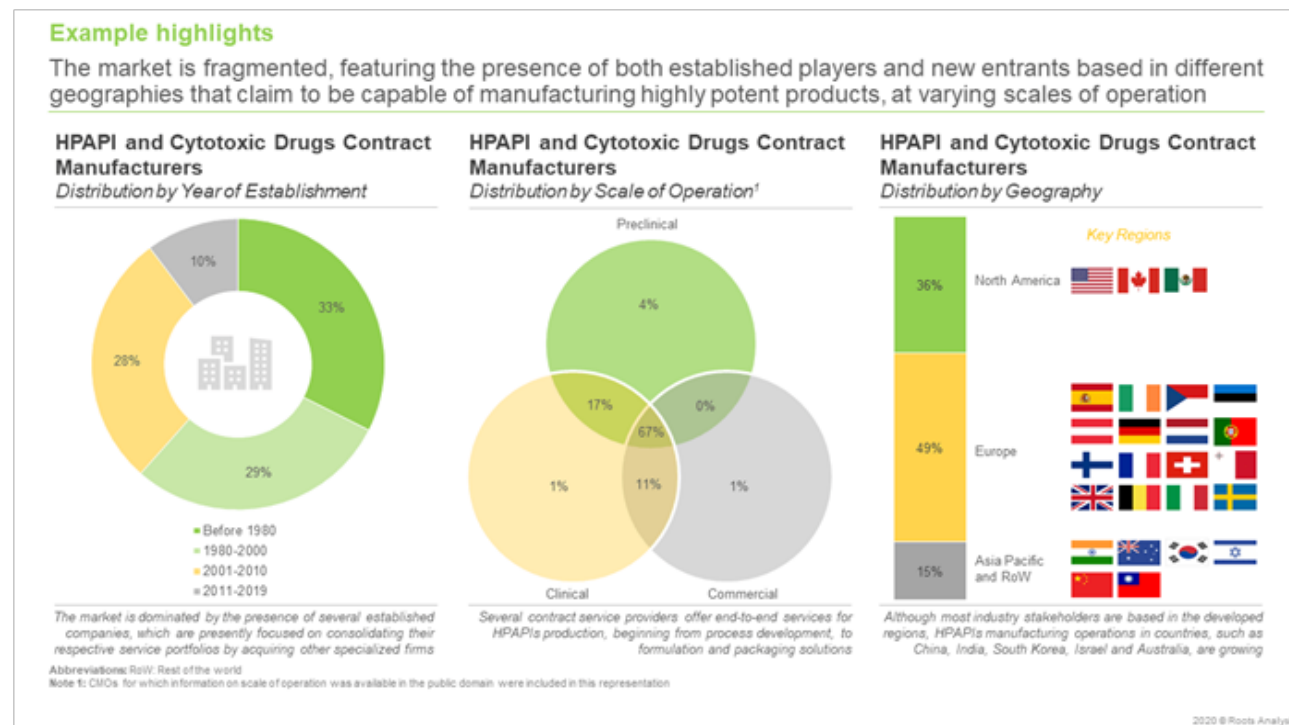


Figure 1 | Manufacturing highly potent products at varying scales of operations

To manage hastened timelines for HPAPI products, biotech companies often take advantage of working with [CDMOs](#) who can develop both drug substance and product., innovator biotech leaders mostly move to take benefit from working with CDMOs that have proficiency in developing both drug substance and a drug product and can depend on a single development partner across pre-clinical, clinical, and commercial production. To benefit from a breakthrough indication/ Fast track indication or accelerated approval pathway, small or virtual companies shorten timelines for their HPAPI products by carefully selecting a CDMO partner that can help rapidly progress HPAPI NCEs to clinical or commercial development.

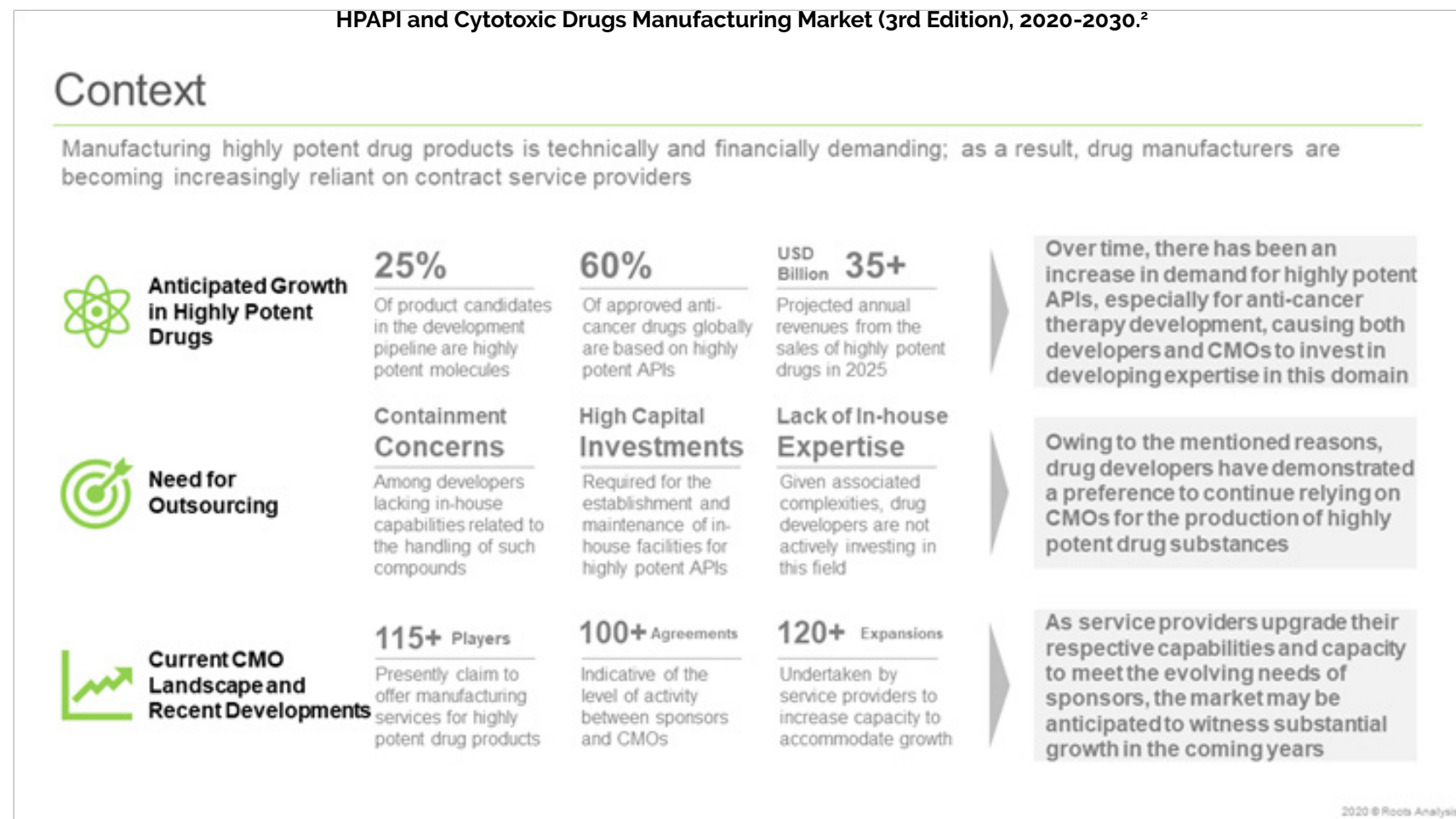


Figure 2 | Drug manufacturers are becoming increasingly reliant on contract service providers

Outsourcing has evolved from being a transactional need to a strategic function

Other important trending factors in the HPAPI category are the drug linkers or payloads for antibody-drug conjugates (ADCs). The ADC market grows fast (30% until 2024) and is often associated with accelerated pathways. The “need for speed” is even more crucial, and it is challenging to find a CDMO partner with in-depth experience across high potency small molecules, large-molecule biologics (monoclonal antibody and conjugation), as well as the final product. Experience with high-potency handling, robustness, scalability, and a track record of quality and delivery are vital differentiators that play an even more prominent role in the combined technologies for ADCs than when a purely small molecule-oriented chemical experience is essential³.

How Aurigene Pharmaceutical services can help

Our [integrated development and](#) manufacturing teams support the seamless process development and optimization of these complex drug substances at every step of the development phase. Our team can cater to all levels of requirements ranging from small to medium or large-scale production. In addition to installing isolators as process equipment and advanced cleaning and trace analytical testing methods, we further minimize the risk by the inclusion of highly skilled experts in toxicology to assess the product safety while undertaking a project. Managing shortened timelines from concept to commercialization makes Aurigene Pharmaceutical Services a preferred partner for global pharma and biotech companies. Accelerating access to affordable medicines for patients worldwide, our teams often play a pivotal role in bringing HPAPI products to the clinic and market faster.

At Aurigene, we also respond to the changing market landscape and evolving technologies by continuous improvement. A strong focus lies in the investment in state-of-the-art measures to handle HPAPIs safely and continuously upgrade our capabilities. One of the latest examples is the expansion of our injectable drug development capabilities. Contact us to find out more on how we can accelerate your next project.

Reference:

1. Maryam Mahdi, Getting a Handle on High Potency, <https://themedicinemaker.com/discovery-development/getting-a-handle-on-high-potency> (2020)
2. HPAPI and Cytotoxic Drugs Manufacturing Market (3rd Edition), 2020-2030, https://www.rootsanalysis.com/reports/view_document/hpapi-and-cytotoxic-drugs-manufacturing/299.html
3. Maurits Janssen, HPAPI Drug Manufacturing Trends, https://www.contractpharma.com/issues/2020-05-01/view_features/hpapi-drug-manufacturing-trends/ (2020)

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