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**Andrea Confetti,** Exclusive Synthesis BU Leader - **Dipharma Francis**

### WHAT ARE YOUR COMPANY'S TARGET MARKETS? CAN YOU PLEASE DESCRIBE THESE MARKETS IN TERMS OF THEIR MARKET SIZE, SEGMENTS AND TRENDS?

We aim to reinforce and expand our positioning in the Small Molecules custom synthesis market, using our extensive GMP experience dealing with a diversified advanced pool of technologies ranging from preclinical to commercialization. We see custom synthesis as a specific segment of CDMO that analysts describe with a double-digit growth rate shown across the last decade (i.e. from 12 billion $ in 2012, up to 22 billion $ in 2018).
This strong growth reflects the changes in business strategy implemented by Pharma companies, who are more and more relying on CDMOs while focusing the efforts on their core capabilities and strengths. Moreover, there is evidence of a significant increase in the number of promising New Molecular Entities (with 48 approvals by FDA in 2019, after the peak of 59 in 2018). The Small Molecules keep playing a prominent role, as well as they more frequently obtain orphan designation and fast-track status. Additionally, since the pharmaceutical industry is facing an increasing pressure to reduce the costs and to accelerate the development and commercialization of novel medicines, CDMOs are expected to contribute to the improvement of operational productivity and efficiency.
All above factors led the large Pharmaceutical companies to join the medium and small ones in fast-tracking the outsourcing trend. We believe this is an opportunity perfectly fitting Dipharma's capabilities and credentials.

### WHICH ARE THE MOST RELEVANT KEY SUCCESS FACTORS IN THESE MARKETS AND HOW DID THE KEY SUCCESS FACTORS CHANGE IN THESE MARKETS OVER THE LAST DECADE?

The pharmaceutical industry operates under the most stringent standards and, as today outsourcing is the strategic way for accelerating their drug development timelines, they choose their preferred partners shortlist using increasingly selective criteria on top of those standards.
Therefore, besides mastering state of the art technologies, a successful CDMO can differentiate its value proposition by sharpening its pool of soft but essential skills like reliability and creative flexibility, on top of must-have tangibles like innovation, safety and commitment to sustainability.

Nowadays, Pharma companies can't afford unplanned delays or failures. They require the production of more effective process solutions in order to quickly deliver outstanding drug development, therefore we put particular emphasis on the reliability and the right level of sense of urgency. We do our utmost to keep our customer timely involved and updated on how the project progresses, by means of a dedicated and duly coordinated team, with strong background in project management and communication skills, able to guarantee a successful new product introduction (NPI) and technology transfer.
There are many ways to implement innovation, such as proactively offering solutions and creatively identifying alternate options for our customers. The Pharma players currently invest a significant part of their financial resources in the R&D pipeline. Therefore, they seek to engage earlier than ever a CDMO capable of supporting them developing new chemical process routes and with Intellectual Property protection. At Dipharma we aim to create a supportive environment to build trust and confidence into our regular relationship with customers. We employ a solid R&D group focused on offering them the most efficient chemical process solution for their desired molecule and our IP department is instrumental in suitably protecting the processes that we set up for our customers throughout the development and registration stages, including the supply of non-infringement advice on their patent landscape.
Furthermore, as during the last decade the complexity of projects continued to increase, as well as the demands from regulatory authorities, more pharmaceutical companies are seeking CDMOs that can provide robust, reliable regulatory affairs (RA) support. Dipharma's RA department guarantees to our customers the development of high-quality dossiers including the updating of dossiers for marketed products, ensuring ongoing compliance.

As the needs of our customer may evolve along the life of a project bringing unexpected challenges, our ability to flexibly adapt and reallocate resources according to identified needs becomes a powerful tool for our success.
Safety ranks as undisputed number 1 in our values.
Our expertise in safety dates back to the beginning of our activity as a civil explosive manufacturer and it has been reinforced through the development of further hazardous processes currently in our technology portfolio.
With reference to sustainability, in the last decade most pharmaceutical companies have committed to important measures to minimize their impact on climate, waste and water treatment through their own operations, as well as those of their suppliers. Dipharma makes every year substantial investments to better preserve the environment and we work hard to reducing waste and air emissions, energy consumption, water use and to recovering solvents and other valuable materials.
Last but not least, as a third-generation family-owned company, we have a long history of stability, commitment and financial solidity.

### WHAT CHANGES DID YOU IMPLEMENT IN ORDER TO MEET AND EXCEED THE EMERGING KEY SUCCESS FACTORS?

We have acquired an American-based CRO in 2018, immediately initiating its upgrade to become a GMP CDMO site, in order to strengthen our value proposition with a global presence. We could thus provide a wider range of services along the lifecycle of a molecule, from medicinal chemistry to its launch and beyond it.
Our large experience in dealing with Health authorities, with first FDA inspection held in 1970, has significantly helped the path of integrating the refocused US facility into the existing Quality frame of Dipharma group.

On the organization side, at the end of the last year we rolled out two Business Units reflecting the evolution of our business model focused on the sustainable growth of our Catalogue APIs and Exclusive Synthesis activities.
At the same time, we implemented a new Global Sales organization, to leverage the synergies with the newly created BUs and to enhance worldwide coverage. Specific sales specialists are dedicated to each business (generic APIs and CDMO activities), with local sales offices in Europe, in the USA and in China.