PCAS: Transformation to excellence

PCAS has more than five decades of experience developing and manufacturing fine chemicals and active ingredients. With 900 employees, seven production sites in Europe and North America, and more than 100 scientists dedicated to R&D and scale-up operations, PCAS is committed to support its pharmaceutical customers from clinical requirements through commercialization. The company, headquartered in Paris, is transforming itself year after year to better serve life sciences organizations looking for a reliable partner for drug substances. The current favorable trends for outsourcing in the industry are fueled not only by emerging pharma but also by a growing willingness among the Big Pharma to adopt strategic rather than tactical outsourcing. This will continue to favor the top tier CMOs that can demonstrate critical features like:

- a high level of quality & environmental compliance
- a capability to offer strong technical capabilities and excellence in problem-solving to scale up complex chemistry
- a broad and global experience in regulatory affairs
- a flexible manufacturing structure with significant capacity
- a stable financial foundation with healthy long-term vision

PCAS is today adapting its organization in order to position the group as a leading CMO for the long term, capitalizing on its strengths like back integration to develop and produce Regulatory Starting Materials and their precursors. Also, PCAS is implementing a major investment program to up-grade and expand its four FDA-inspected API facilities. During 2015-2018, PCAS will invest approximately 60 M€ for manufacturing expansion and reinforcement of its cGMP compliance level for finishing steps, liquid/solid separation and drying units.

Quality compliance to meet tomorrow’s regulations is a critical concern within PCAS and has triggered several important decisions, like a total revamping in 2016 of the drying unit of the Limay (Paris) GMP facility in addition to the installation of a 3 m² filter dryer. The PCAS Aramon (South of France) GMP site will also receive 6 M€ investment to complete the construction of new finishing suites for API manufacturing. Besides investments to meet the highest quality requirements for API, the group will increase its production capacity with a new workshop at its Couterne (Normandy, France) facility, which will start qualification in March 2016. This new multi-purpose production unit will comprise large scale cryogenic capabilities and high performance distillation. The Limay (Paris) API facility will increase total reactor capacity by 20m³ over the next 24 months. Finally, the PCAS Finland GMP site located in Turku has started the installation of a new automatic plant control system (PCS) of the reactors and critical equipment. Temperature, pressure, stirring speed, additions, distillation, as well as dryers and centrifuges will soon be connected to the PCS system, which allows for both high quality and low cost on routine manufacturing.

Managing the complexity of increasingly sophisticated chemical structures is also a challenge that PCAS has been addressing for decades with today typical projects comprising eight to twelve chemical steps to scale-up, rapidly, in a highly regulated environment.

Customers can rely on significant R&D resources with 100 scientists spread over three research centers and multiple pilot units, for smooth scale-up and appropriate analytical capabilities supported by regular investments and the implementation of UPLC technology over the sites. Good science is a permanent focus to support rapid development, and the Protéeus Biocatalysis Research Center, which is specialized in protein science and gene engineering to create or optimize great biocatalytic systems in Nîmes (South of France) is helping our customers to access very innovative manufacturing solutions combined with state of the art chemistry. The latest methodologies like QbD are now widely used to ensure an enhanced process understanding and facilitate regulatory filings.
Contingency plan and supply chain security are also key concerns of the pharmaceutical industry. PCAS is in position to offer a back-up API production site involving a reasonable regulatory impact. More important today, is also the capacity of the group to integrate critical raw material or Regulatory Starting Materials in order to secure the API supply chain.

In addition to the two facilities in France for RSM production, Couternon for solids and Bourgoin-Jallieu (Lyon) mainly for liquids, PCAS is now adapting its Canadian plant near Montreal to produce complex RSMs. The Montreal site, historically working for the electronic chemicals, is located less than four hours drive from Boston and is well equipped for scaling-up multi-steps synthesis. A process and analytical group dedicated for life sciences is now built and can rely on kilo-lab, pilot and production equipment capable to produce up to 500 kg or even more for certain chemicals.

Overall, PCAS is adapting and focusing its whole organization, with the goal to get better every day and to continually improve in making complex ingredients and satisfying its pharmaceutical customers.