India Pharma Outlook
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PHARMACEUTICAL STARTUPS

JITESH DEVENDRA DR. S. DEVENDRA CHAITANYA DEVENDRA

AXXELENT PHARMA SCIENCE

A GO-TO PARTNER IN THE CONTRACT DEVELOPMENT & MANUFACTURING INDUSTRY

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COVER STORY

IPharma Outlook TOP 10 PHARMACEUTICAL STARTUPS - 2022

> WELL POSITIONED IN THE SPACE OF CDMO, AXXELENT OFFERS COMPREHENSIVE SOLUTIONS FOR VARIOUS DOSAGE FORMS FROM DEVELOPMENT TO MANUFACTURING OF ORAL SOLID DOSAGE, INJECTABLES, OPHTHALMIC, ORAL LIQUIDS AND TOPICALS

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The Pharmaceutical Industry in India ranks third in the world in terms of volume and fourteen in terms of value. Catering to approximately 20 percent of generic medicines sold globally with US being a key market, India has positioned itself as having the highest number of US-FDA inspected facilities outside of the US. Besides the US market, Indian Pharmaceutical companies are also making their presence felt in the other highly developed regulated markets and emerging markets. According to India Briefing, India is home to 3000 drug companies and more than 10,000 manufacturing units. We are seen as a reliable and trustworthy partner to service the global needs as evidenced during the Pandemic and rightly earned the title of 'Pharmacy of the World'.

With numerous schemes launched by Government of India under the 'Make In India' initiative, several start-up companies have come up to further strengthen India's contribution to the global market. With lower R&D and manufacturing costs, scientific talent pool, focus on innovation, access to centres for clinical trials and initiatives laid out by the Government, the Indian Pharmaceutical industry is poised for significant growth. Focused on Contract Development and Manufacturing (CDMO) of Pharmaceutical Products is Axxelent Pharma Science (Axxelent), a specialty pharma company focussed on B2B offerings via CDMO, Partnerships, and out licensing for Regulated markets.

Bridging Industry Gaps with Unique Offerings

Well positioned in the space of CDMO, Axxelent offers comprehensive solutions for various dosage forms from development to manufacturing of Oral Solid Dosage, Injectables, Ophthalmic, Oral Liquids and Topicals. This is one of the biggest advantages for its customers as the firm not only provides development to commercial but also manage the supply chain for our customers. With a Regulatory team in-house, it makes it smooth for the customers to file the dossier with the Regulatory agencies. Customers also look for the expertise of the team in complying with the guidelines of various regulatory agencies to name a few, US FDA, EU-GMP, UK MHRA , Health Canada, TGA Australia and ANVISA Brazil.

"In the CDMO space customers look for reliable partners with highest quality of service. Customers look at various capabilities and expertise a CDMO partner brings to meet their requirements. While each customer has their own expectations, we manage it by being flexible and understanding of their business requirements. Once a project is received, proactive and transparent communication on project progress builds the foundation of the relationship. Confidentiality is a non-negotiable aspect of this business. Protecting and respect for the customers IP is liked a sacred fruit. Combining the capabilities, expertise, communication and protecting the IP of the customers along with ethical practices in development and manufacturing is on what Axxelent has built its core values", briefs Chaitanya Devendra (Executive Director & Chief Business Officer).

Axxelent also has the capability and expertise to develop and technology transfer of dosage forms like, Solid Orals (Tablets, Capsules & Pellets – Immediate Release /Modified Release), Liquid orals (Solutions, Syrups & Suspensions), Topicals (Creams, Gels and Ointments) Parenteral (Liquid and Lyophilised Injections, Prefilled syringes, and Ampoules) and Ophthalmics/Otic (with and without Preservative).

"With over two decades of specialization in the field of Contract Development for various stringent regulatory markets, we provide end to end solution from Product development to commercial which includes Formulation development, Analytical method development & Analytical method validation and product can be transferred to Customer site or to our own manufacturing site at Sri city. With our vast experience, we have put together various systems and practices in place like SOP's, stage gate review, through which the development activities will be carried out as per ALCOA Principle", speaks Dr.Sampathkumar Devarajan (Executive Director,R&D).

Prior to Project initiation, thorough knowledge on the product development will be gained and the contents are put together in document titled 'Product Development Plan (PDP)' which covers literature/patent aspects, Drug substance, Dosage form, Analytical, Clinical & Regulatory strategy and timelines. "By having PDP in place, we know our targets and activities to be done for that particular product thereby accelerating the Research and Development process and provide a cost effective product to customer", adds Dr.Sampathkumar

A Step Ahead of All

The firm has its Contract Manufacturing facility located in Sri City, Andhra Pradesh, which has two blocks - One block is Non-Sterile (Phase-1) and the second one is Sterile block (Phase-2). Phase 1 will commence in November 2022, and this block has capability to produce OSD – Tablets, Capsules & Powder, Oral Liquids and Semi-solids. The Phase-2 which is the Sterile block will be equipped to produce Injectable with Lyophilization & PFS capability and Ophthalmic/Optic products.

The development and production plant design and capability has been made specifically to handle - Complex Oral Solid formulations – including Modified Release products like Controlled Release Pellets in form of MUPS Tablets, Delayed Release Tablets, Delayed Release Pellets in Sachet, Sustained Release Pellets in Capsules and Suspensions with Narrow Particle Size Distribution; Injectables with Lyophilization technology & PFS; Ophthalmic products including Preservative Free Technology; Topical Ointment and Cream capability including development and characterization of emulgel based products.

Axxelent is also known for its Business Models that suit to the customer's needs. The firm is flexible in its business models which range from a pure CDMO to Partnerships to Out-licensing in-house developed IP's. The transparency in their operating model is what has been highly appreciated by their customers. The firm is now focusing on complex molecules and incremental innovation that bring competitive advantage for our customers in the market place. "Proving end-to-end solutions – From drug substance to drug product. If a Customer approaches Axxelent with a product where API is a challenge, we provide them with solutions as we have a good supply chain network and relationships with our API partners who either have the API or can develop it exclusively for our partner. Our diversified go to market strategy has led to less dependency on one market. Ability to secure supplies for products where there are limited number of suppliers there by making it challenging is what we believe is one of the USP of Axxelent", shares Chaitanya Devendra,

Charting the Path Ahead

Having started its R&D operation in 2020 at IIT Research Park Chennai, Axxelent started with area of approx. 5000 sqft, and today, the firm has expanded to 10,000 sq feet. The firm's manufacturing unit which is a greenfield project in Sri City which also happens to be in a SEZ (Special Economic Zone) has commenced its operations in Nov'2022. The facility was initially designed for Oral Solids. We then extended our service offerings to Oral Liquids, Topicals and Sachets. Original plan to commence our Phase-2 was in 2024 but given the requirement from our customers to manage the projects from R&D to Manufacturing we advanced our plans by one year. Phase-2 which is the Sterile block will commence operations in March 2023. We have partners and customers from North America,Europe and APAC region which will be serving the regulated markets.

"At Axxelent, our team is well versed in handling inspections from regulatory agencies. With our pipeline of projects and with inspections initiated in India by various regulatory agencies, we are aiming to have the accreditations in CY of 2023 starting with India GMP EU GMP, UK MHRA,TPD Health Canada followed TGA Australia and USFDA in CY of 2024." Adding further about future plan, Dr.Sampathkumar says, "Our future roadmap is to develop in-house patented technologies that can can result in a differentiation for existing marketed products. The other area of focus is to expand on our current dosage form offerings as well as newer therapeutic areas . There is a plan laid out for this which will be implemented in 2026 post our commercialisation of Phase-1 and Phase-2. Our current area in Sri City has the expansion area to incorporate Phase-3." PO

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In appreciation of its exceptional diligence and inimitable approach to fulfill the end-to-end requirements of the customers.

Sudhakar Singh

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Managing Editor
India Pharma Outlook