HEALTHCARE & LIFE SCIENCES REVIEW

PHARMA BOARDROOM

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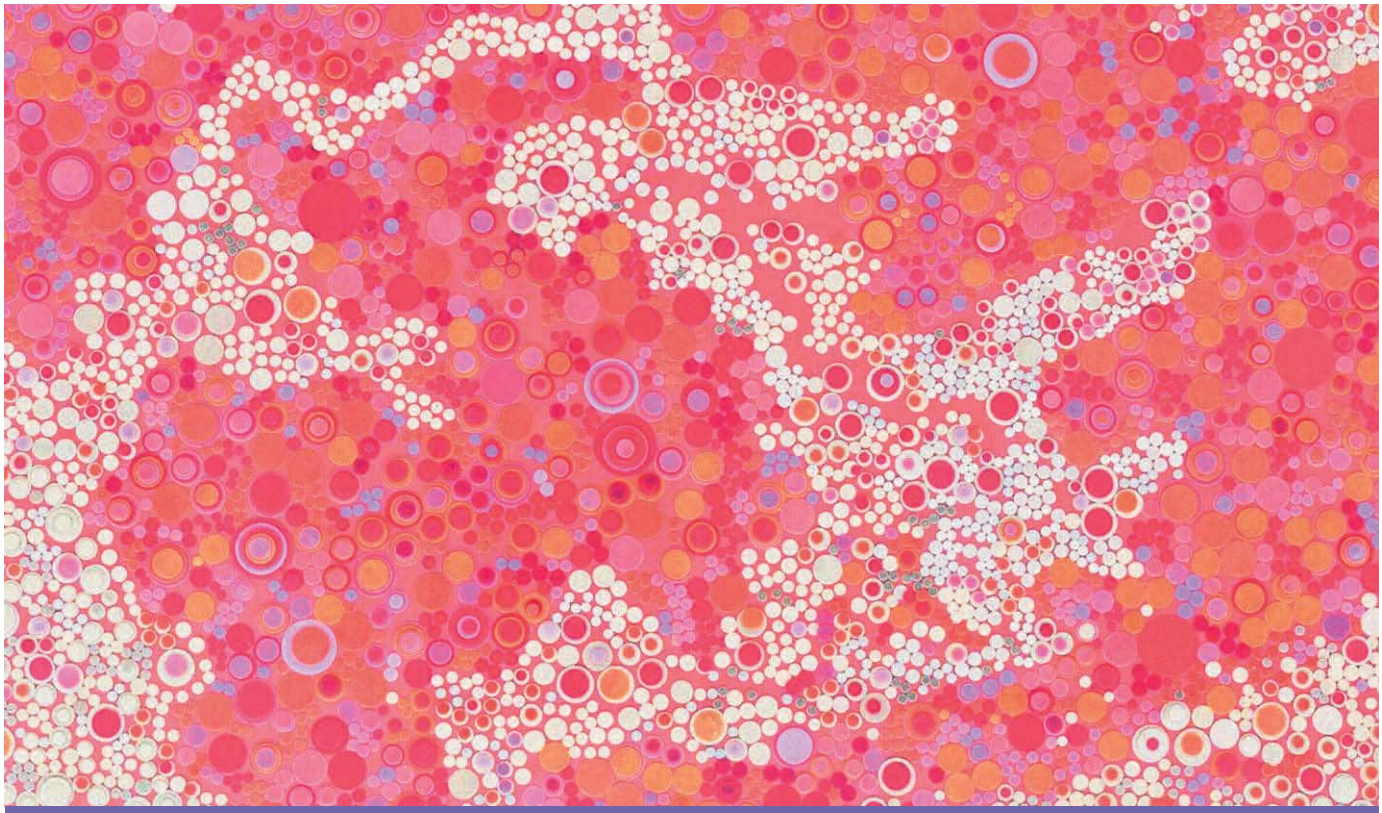

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INDIA

JULY 2018

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India

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AMPLIFIED CONTENT

BHUPENDRA SANGANI
CEO, Galentic, India

LUCA VISINI
Managing Director, Eli Lilly, India

DEEPAK BIREWAR
Chairman & Founder, Inventys Research, India

MOHAL SARABHAI
Managing Director, ASENCE Group, India

IN BRIEF

@OaknetHealth

We are very glad to inform that the interview of our beloved MD, Mr. R. S Raghav got published at the Premier Healthcare life science web portal @pharmaboardroom on 24.05.2018 #OaknetHealthcare #PharmaInterview #InternationalPharmaMagazine

Read the interview

@pharmaboardroom

Meeting US FDA Standards Across the Board in India #India #Indianpharma #FDA

Read the article

@LaurusLabs

Dr.Satyanarayana Chava, Founder and CEO, Laurus Labs speaks with @pharmaboardroom about the company and its future plans. #LaurusLabs #DrSatyanarayanaChava #Pharmaboardroom

Read the interview

@pharmaboardroom

Binish Chudgar of Intas, the largest privately-owned #pharma company in #India, talks growth models, M&A, #biosimilars, compliance and price erosion in the US #generics market

Read the interview

JANMEJAY VYAS
chairman, Dishman Group

DR. DEEPAK BIREWAR
founder and chairman, Inventys Research

approval for Tesaro's ovarian cancer drug, which Dishman will produce at its Bavla facility in Gujarat. "When the clinical trials of this drug were happening, Dishman was the API supplier alongside being a key supplier to Tesaro; now that this cancer drug has been approved the volume will jump significantly. Given the relationship and the trust that we have established over the years with the US FDA, they allowed us to start the supply of APIs to Tesaro already," remarks Dishman's chairman JR Vyas. "We have been working with the world's leading innovators for over a decade, although currently most of our CDMO efforts are centered on innovators' mature products," adds Dr. Deepak Birewar, founder and chairman of the dynamically growing CDMO Inventys Research. "For a few of our products, we started cooperating with our customers even before these products' introduction into the market: we therefore developed the laboratory samples and are now about to enter the launch and growth phase for those products. As we own an integrated site, we can offer full gamut of services from lab chemistry to scale-up and chemical process development to plant design, construction, and operation conforming to world class GMP standards," he explains. "In the meantime, several companies outside India have already shown a great interest in partnering with us, as they want to leverage our expertise in scaling up technology and efficiently designing/constructing state-of-the-art world-class automated manufacturing capacities. As part of these potential partnerships, we would still own these upcoming plants, but they would be the main investors in these projects. For us, this kind of agreement represents a smart way to increase our overall production capacity without having to allocate substantial resources to this effort," he stresses.

> **"SEVERAL COMPANIES OUTSIDE INDIA WANT TO LEVERAGE OUR EXPERTISE IN SCALING UP TECHNOLOGY AND EFFICIENTLY DESIGNING/CONSTRUCTING STATE-OF-THE-ART WORLD-CLASS AUTOMATED MANUFACTURING CAPACITIES**
>
> — **JR Vyas** DISHMAN

Over the past decade, India also witnessed the rise of niche, specialized service providers, which share the same focus on the most stringent pharma ecosystems in the world as their glorious predecessors. "I realized that there was no contract manufacturer dedicated to effervescent products based out of India or the US,

> **WITHOUT INNOVATION, YOU ARE NOT EVEN A CONTENDER IN TODAY'S FAST CHANGING WORLD OF GLOBAL COMPETITION**
>
> — **Deepak Birewar**
> INVENTYS RESEARCH

holding basic technologies and still focusing on low added-value products will struggle to comply with rising quality standards. In this regard, the only way forward is to continue climbing up the value chain and stimulate companies' innovation drive - and we are doing this with over 20 percent of our employees who work in Research & Technology," reveals Hiremath. "Without innovation, you are not even a contender in today's fast changing world of global competition," confirms Inventys Research's Dr. Deepak Birewar. "In 2017, we invested more than seven percent of our revenues in our R&D, which represents a remarkable commitment for a company of our size and sets us on top of the list of our competitors. If we actually consider the resources channelled to Inventys' new R&D & Pilot plant facilities over the past three years, those investments equal to our one year's revenue! As a matter of fact, almost all our profits (and some more) of the last ten years have been invested in R&D & related facilities," he concludes.

ADJUSTING TO A NEW NORMAL

Indian pharmaceutical exports have grown more than five-fold over the past two decades, but the increase only reached 2.5 percent during the fiscal year ending March 31 2018, according to Pharmexcil. More worryingly, the value of Indian pharma exports to North America dropped by 8.04 percent to USD 4.83 billion during the 11 months up to February 2018. North America, including the US, contributes to over 30 percent of the India's overall exports in terms of value.

> **THE LEVEL OF REGULATORY SCRUTINY THAT A PHARMACEUTICAL COMPANY HAS TO COPE WITH OFTEN DEPENDS ON THE SIGNIFICANCE OF ITS MARKET SHARE IN THE RELEVANT COUNTRY**
>
> — **Binish Chudgar** INTAS

"The level of regulatory scrutiny that a pharmaceutical company has to cope with often depends on the significance of its market share in the relevant country – especially when it comes to the US FDA. In this regard, it truly makes a difference whether a company holds only a handful of products or ships 50+ INNs from a given plant; when holding a small market share, regulators would typically not go into full details, but compliance inspections suddenly reveal themselves extremely stringent and in depth once a company has a substantial position," considers Chudgar of Intas. In the meantime, recent inspections seem to indicate that stringent regulatory scrutiny has been broadened to encompass API manufacturing plants, in addition to the formulation plants primarily targeted in the first place.

"I see quality compliance as a learning curve, while one should bear in mind that regulatory standards are also constantly evolving. Across our multiple manufacturing plants, Intas has successfully passed 50+ US FDA inspections over the past two decades, and the US FDA inspects one of our plants every six months on average," he adds. As part of the findings of IPA's Quality Forum - set up in 2015 with the vision of helping the Indian pharma industry achieve excellence in quality - progress has evidently already been made over the past three years: while Indian manufacturers accounted for 50 percent of all warning letters issued by the US FDA to non US-sites in 2015 – Chinese sites making up only 13 percent of the total – this number decreased to 29 percent in 2017 for India-based sites and grew to 35 percent for China-based sites.

In the meantime, regulatory and compliance issues do not seem to have utterly cooled down the eagerness of leading international companies to acquire India-based manufacturers and/or service providers, especially in very sophisticated product areas. For example, Swedish CDMO Recipharm completed the acquisition of India-based CDMO Kemwell in 2016 and acquired a majority stake in Nitin Lifesciences, an Indian sterile injectables CMO. In the same year Baxter agreed to purchase India-based Claris Injectables (including its three Ahmedabad-based manufacturing plants) for USD 625 million.

"Looking forward, I however expect that Indian companies will continue suffering from increasing scrutiny pressure in the coming years, leading them to significantly step up their investments related to quality and regulatory controls. In the meantime, some variable costs, such as electricity supply, are much more expensive in India than in Europe," considers Alexandre