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Span Diagnostics sets up bioprocess facility

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Manufacturing raw materials and biologics has not traditionally been the stronghold of Indian companies. Additionally, import taxes, regulatory delays, and rising competition from the East have long been affecting the diagnostic industry in an adverse manner. Addressing this critical lacuna in the system, Surat-based Span Diagnostics decided to build state-of-the-art systems to increase their competency in manufacturing antigens, antibodies and other reagents used in diagnostics.

Towards the end of 2008, Span applied for a Biotechnology Industry Partnership Program (BIPP) grant. Its main objective was to bulk produce monoclonal antibodies in vitro by using bioreactors as well as recombinant and native antigens using fermentors. The grant was received as a soft loan of Rs 2.1 crore, in installments, wherein all but one has now been received. The total cost of the project is estimated to be Rs 7.85 crore.
The new cGMP compliant bioprocess facility will help in large-scale production of raw materials for diagnostics. At present, the new BioSafety Level (BSL)1 laboratory is engaged in production of antibodies for blood grouping reagents. The BSL2 and BSL3 laboratories, which are ready, will be utilized for large scale production of microbial antigens. These laboratories will also be utilized for large-scale production of recombinant antigens.

Mr Pranav Naik, marketing manager, Span Diagnostics said, "This is one of the largest 'first-of-its kind' bulk-production facility for indigenous manufacturing of monoclonal antibodies and microbial antigens under cGMP conditions in India. What makes this facility unique is the fact that it has been built specifically for the diagnostics industry."

Mr Naik further said that getting the right technical consultancy firm for establishing cGMP compliant facility and technical support was difficult, which resulted in some delays. "However, earlier many such ideas could not be pursued because of financial constraints and risks, which are "sine qua non" (indispensable) for all biotech entrepreneurs. Now, through, BIPP scheme and BIRAC, we get support for innovative and novel ideas in the form of grant/soft loans for taking them up to the "proof-of-concept" stage. This helps us to mitigate the high risk in the beginning of such projects, and carry out clinical trials and establish a manufacturing facility."

Mr Naik says that they hope to work with academic institutions for the speedy conversion of R&D projects into marketable products, by providing the right manufacturing set up. Another important application for the new facility, which Span hopes to capitalize on, is for contract manufacturing for other companies. Being compliant with quality management system as per ISO 13485, Span hopes to fill the gap in market, when it comes to manufacturing essential raw materials for diagnostics.

The facility is not product specific, but rather built in such a manner that it can be refined according to current requirements. Depending on the need, Span plans to apply for certifications from the USFDA and other agencies. By achieving this self reliance, Span hopes to reduce the dependance on imports of materials used in the manufacture of in vitro diagnostic products for India and abroad, thus saving crores of rupees currently spent to meet the captive need for manufacture of immunodiagnostic kits and reagents."