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2012: The year ahead

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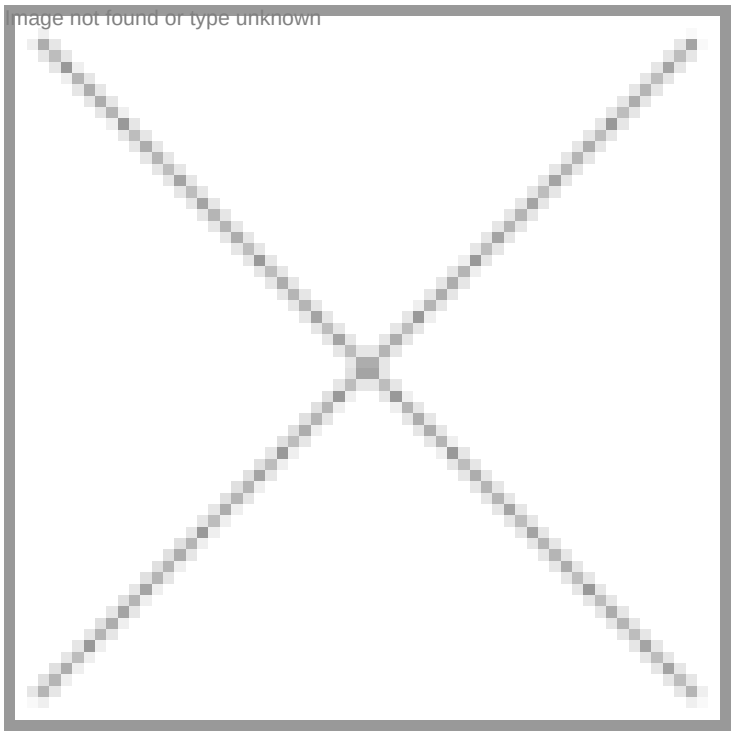

Industry leaders speak about the trends in the biotechnology industry and business expectations for the coming year

Drkiranmazumdarshaw Image not found or type unknown	The global biotech space has seen heightened activity in the biosimilars space with several new partnerships being announced. The growing presence of innovators in pursuit of biosimilars highlights the serious challenges in drug innovation. This will put added pressure on USFDA to relook its regulatory process and also urge the roll out of the long-awaited guidelines for biosimilars. Future trends in innovation are being seen in the area of new drug delivery devices, combination therapies, cancer vaccines and companion diagnostics. Radical cost-cutting in healthcare budgets coupled with escalating drug development costs pose serious challenges. Governments reeling under the financial burden of healthcare are likely to bring down orphan disease allowances which will make it even more challenging. Drug companies will be compelled to focus on cost efficiency and innovation efficiency. Indian companies must take advantage of this new market environment.â€? **-Dr Kiran Mazumdar Shaw,** CMD, Biocon India

Sujankdhar Image not found or type unknown	The year 2011 was a mixed bag from the perspective of a service provider organization, such as Abexome, that offers bioanalytical services to the biopharmaceutical industry. We saw a slowness in decision-making in many service contracts, and some projects were shelved by our clients. It appeared that some of the new entrants in the biopharmaceutical scenario were at a crossroad whereas the larger organizations consolidated their development pipeline. Development of therapeutic proteins like Erythropoietin or G-CSF was no longer in the pipeline and next generation biologics such as PEG-GCSF, Darbepoetin and the mAbs became more sought after molecules. This year we expect to launch assay kits for many biosimilars. As the experienced biopharma organizations move ahead with their next-generation pipeline, more contracts are expected for service providers like Abexome Biosciences. **-Dr Sujan K Dhar,** CEO, Abexome Biosciences
Satyadash Image not found or type unknown	The industry is poised for tremendous growth in all areas of biotechnology. The news regarding formation of BIRAC with early stage funding schemes and support services is a welcome news and will give much-needed boost to early stage start-ups. India needs to streamline its regulatory approval system both for biopharma and the agri-biotech sector as the growth prospects hinge on the establishment of a clear regulatory landscape. ABLE will work closely with both the industry and the government to facilitate growth of the biotechnology sector.â€? **-Dr Satya Dash,** COO, Association of Biotech Led Enterprises (ABLE)
Drramanandanadig Image not found or type unknown	Biotechnology will continue to make giant strides in offering succor to the needy by developing newer recombinant drugs, vaccines and innovative alternate therapies with stem cells. Need for innovative solutions in healthcare will continue to fuel further developments and let India lead from the front. Innovative alternates are emerging in the field of stem cell therapies, and with continued support and guidelines from the government and strict implementation of the regulatory policies, we can look forward for novel therapeutic offerings from cellular therapies. **-Dr Ramananda Nadig,** CEO, Khoday Stemcell Research & Medical Center
Ajaybharadwaj Image not found or type unknown	Anthem Biosciences had a very successful 2011. Our business grew nicely and profitably. But the creases on our brow never eased throughout the year, because of the extreme volatility in the global markets, and the dismal domestic situation. To make far-reaching plans and have reliable forecasts, industry needs stability. The situation doesn't look better as we welcome the new year. It appears we are in store for more volatility globally and inertia from our government planners. Anthem, however, is committed to investing further and trying to expand its geographical spread of business. **-Mr Ajay Bharadwaj,** CEO, Anthem Biosciences
Daprasanna Image not found or type unknown	The year 2011 was tough for the CRO industry in India. It became unattractive due to regulatory uncertainty. Indian CROs having a strong backlog survived. Those with operations outside India managed to keep their head above water. Market in India saw negative growth. Overcapacity has forced investors in CRO space to look for exit. Silver lining for 2012 is that inspections by the DCGI and FDA in most cases confirmed GCP and GLP compliance, showing confidence in quality. Scaling to $50 million revenue, differentiating through unique competency, diversifying country risk are areas Indian CROs will have to work for to survive 2012.â€? **-Mr D A Prasanna,** chairman and MD, Ecron Acunova

Drkrathishbopanna Image not found or type unknown Image not found or type unknown	Self-regulated environment with important checkpoints and balances will help in building this industry. It is the responsibility of professional societies, medical professionals, industry bodies, government and regulatory bodies to work in tandem to build confidence in society. Research is important for this country and outcomes define treatments, and it should be our responsibility to foster this path for disease and drug innovations.â€? **-Dr Krathish Bopanna,** president & executive director, Semler Research
Mranilpanwar Image not found or type unknown	With low-cost manufacturing capabilities and strengths in small molecule generics Indian companies are well positioned to benefit from the estimated 48 biologics that are slated to go off patent in the next decade. Indian market could become preferred destination for clinical trials because of cost advantages, availability of patient population, GCP-trained investigators and quicker recruitment. Regulators may strengthen systems and processes to ensure quicker approval of studies and more robust monitoring of clinical trials. Both industry and regulators need to make efforts to educate the media and society on conducting of clinical trials and bioequivalence studies and regulations.â€? **-Mr Anil Panwar,** CEO, Fortis Clinical Research
Mrpraveengupta Image not found or type u	We had a great year of business in genomics space with growth in agribio and clinical genomics segments. For 2012, Premas' life sciences division is expecting to continue its growth of Illumina business along with establishing its newly launched products from Trinean, ACDBIO, Biomatrica and many more. We are hoping that the 12th five-year funds are released well in time to enable initiation of new projects. We are also hoping for adoption of NGS by the clinical segment.â€? **-Mr Praveen Gupta,** executive director, Premas Biotech
Mrjigneshbhate Image not found or type u	I see 2012 as a year where general bioinformatics will further get segmented into sub-categories, such as text-mining, tool development and micro-array services, and winners will emerge in each category. Companies will move up the value chain offering higher-end services like systems biology to its customers.â€? **-Mr Jignesh Bhate,** CEO, Molecular Connections
	We are always optimistic at ReaMetrix about the prospects of biotechnology. In 2011 we laid the foundation for potentially changing the way medical diagnostics can be practiced through the development of a unique lab-in-a-box. We are happy with the initial feedback and we believe that the impact of this platform will go beyond the area of diagnostics and have an effect on other areas of life sciences as well. We expect to see the results of our work begin to bear fruits in 2012 and make an impact in the global arena. We hope to see more such path breaking innovations in 2012 from our community.â€? **-Dr Sridhar Ramanathan,** executive director, operations, ReaMetrix
Mrkvbalasubramania Image not found or type u	The year 2011, although good for the vaccine industry in terms of rise in demand, also witnessed increased competition with entry of more players and regulatory trouble for some players. The year 2012 can be expected to be better with hepatitis B vaccine now fully in the UIP program and pentavalent vaccine taken up by some states, besides increased scope for animal vaccines in disease control programs.â€? **Mr K V Balasubramaniam,** MD, Indian Immunologicals