

## The technology that started it all

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The underlying principles in all major biotech processes can be traced back to recombinant DNA technology, which was first invented in the 1970s

### Genesis

Dr Stanley Cohen and Dr Herbert Boyer published a series of papers in 1973-74 on the process by which pieces of DNA could be transferred between organisms using splicing enzymes. In December 1980, patents on gene cloning were issued to Stanford University and the University of California, where they taught.

### The Technology

Recombinant proteins are produced by transferring a human gene to an expression system. The human gene is isolated and then ligated or joined to a piece of plasmid vector, a piece of DNA that can replicate independently. Plasmids naturally occur in bacteria and hence can easily be transferred to a suitable host. The protein which is transferred also needs to be ligated with a promoter or a piece of DNA, upstream, from the host cell that will induce the production of that protein. When the host reproduces, the protein gene is replicated along with the plasmid.

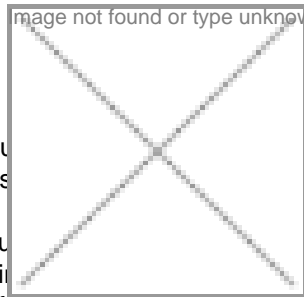
### The Impact

Prior to the advent of recombinant DNA technology, proteins for treating disorders had to be obtained from either cadavers or animal sources. These methods were unsafe and extremely difficult to be adapted on a large scale. Also a subset of patients existed who would develop allergies to the foreign insulin. Today, the global market for recombinant insulin alone is \$14 billion with the global insulin market forecasted to grow at the rate of 20 percent during 2010-15.

In 1973, when two scientists proposed a mechanism to combine DNA from two different organisms, not only did they give rise to a new technology but the biotechnology industry.

Today the underlying principles of all major biotech processes, ranging from recombinant proteins to vaccines to Bt Cotton, can be traced back to the recombinant DNA technology, discovered by Dr Stanley Cohen and Dr

The best way to describe recombinant DNA technology is that it is essentially a cut and paste mechanism that involves isolating parts of DNA from different organisms using enzymes (called restriction enzymes), and then joining them together to get recombinant DNA (by using a class of enzymes called ligases). These restriction enzymes allow for the DNA to be cut in such a way that their



The resultant recombinant DNA can be expressed in another host organism such as a bacteria or yeast. On replication, the organism produces a recombinant protein that would not have been possible. This recombinant protein is similar in nature to the natural

produced under natural conditions. The recombinant protein, but can be produced in large quantities

Initially, the lack of understanding of the technology led to criticism and false scares of genetically modified monsters. However, once it became possible to produce a recombinant protein, several human disorders arising out of protein deficiencies could be treated more easily.

With this, production of therapeutic proteins, such as insulin for diabetes, human growth hormone for pituitary gland disorders, erythropoietin for anaemia, factor VIII for hemophilia and many more can be done easily on a large scale and made available to the common man.

Similarly, recombinant antigenic proteins for producing vaccines and recombinant insect proteins for GMOs could be produced. Today this technology has spread to such an extent that it is in use everywhere from university labs to large biotech companies.

In India, since the last two decades, a number of companies such as Biocon, Transgene Biotek, Virchow Biotech, Bharat Serums and Vaccines and Shreya Life Sciences are producing recombinant proteins and biopharmaceuticals.

**Manasi Vaidya** in Bangalore