

Lonza

Biotech by Lonza

What's what Guide

This glossary is intended as a brief overview of biotechnology at Lonza. We have deliberately chosen terms which are closely related to the Group's biotechnology activities.

Biotech by Lonza

A what's what guide

An Introduction

Biotechnology is now one of the core activities at Lonza, with two dedicated business sectors: Lonza Biotec (microbial fermentation) and Lonza Biologics (fermentation based on mammalian cell cultures). The Group's involvement in the field of biotechnology dates back to the early eighties when a research group at the Visp (Switzerland) production site was asked to evaluate the potential synergies between organic fine chemical syntheses and bio-processes. Today, the Lonza Biotec and Lonza Biologics business sectors are focused mainly on custom manufacture of exclusive products for the pharmaceutical industry. Lonza aims to tap further into the huge growth potential of this field with a number of major projects currently in progress.

The demand for pharmaceutical active substances, especially biopharmaceuticals such as therapeutic proteins, will grow strongly in the coming years as a result of intensified research efforts and new scientific findings. While the goal of pharmaceutical research, namely the creation of an active substance with maximum efficacy and minimum side effects, has not changed, the methods of research and development of pharmaceutical substances have undergone a radical transformation. Genome research has made it possible to increase the selectivity of active substances, i.e. their ability to target a pharmacological effect at a specific site. Now, thanks to the sequencing of the human genome through the Human Genome Project, we can identify those genes that provide the information code for the proteins which regulate cell processes. While genes can be characterized as the database of life, proteins take on the role of software. Proteins control

almost all vital processes in the body. With increasing knowledge of the complex interactions involving the genes and proteins within cells, we can expect a dramatic increase in know-how relating to the sites of action relevant to certain illnesses.

The life sciences are gaining fresh impetus from the genome sequencing project and post-genomic research in cell biology. The value of the findings from this research is in their practical application to the production of useful small molecules and also, increasingly, of large complex biological molecules, particularly proteins. The growing complexity of these biological molecules places increasing demands on production techniques. Classic chemical synthesis is no longer adequate to the task of producing the extremely complex active substances being developed in increasing numbers on the basis of the advances in genome research. For these new biological therapeutics new production technologies exploiting genetic manipulation techniques and new methods of large-scale manufacturing, often using mammalian cell culture, have been developed. The culmination of this development so far is the harnessing of quasi-endogenous substances such as antibodies as well as other therapeutic proteins, for example human protein-C, a highly complex protein composed of over 500 amino acids and sugars, which plays a key role in the prevention of septic shock. Lonza is actively involved in these developments.

As a response to the growing complexity of pharmaceutical active ingredients, Lonza included biotransformation in its catalogue of services at an early stage. With

the help of specifically developed microorganisms, complex chemical syntheses were supplemented, considerably shortened, and simplified, especially in the area of chiral compounds. In the early eighties, a biotechnology research group was set up at Lonza to investigate the potential for harnessing synergies between organic syntheses and bioprocesses. With the start-up of the first 400-litre pilot fermentation plant in Visp in the mid-eighties, Lonza made a clear commitment to the further development of its biotechnology arm. At the end of the eighties, pilot production of L-Carnitine using microbial fermentation was developed. Today, Lonza is the market leader in the manufacture of L-Carnitine. In 1992 the fermentation and biotransformation plant in Kourim (Czech Republic) was acquired; this was significantly expanded in the period up to the mid-1990s. In 1997 a 15,000-litre plant in Visp was commissioned; one year later the fermentation capacity in Kourim was extended by 50,000 litres. In 1999 the new GMP-facilities for the production of L-Carnitine in Kourim were approved by the FDA. To deal with the expected increase in demand for our microbial fermentation products we are currently investing over CHF 100 million in the expansion of the Biotec plant in Kourim. This will bring an almost 50% increase in fermenter capacity to a total of nearly 500,000 litres. In Visp, we are investing over CHF 100 million in the construction of a biopharmaceutical plant to enable us to respond to different customer requests for biopharmaceuticals produced by microbial fermentation. This new installation, added to the existing microbial and mammalian cell culture fermentation capacity, will enable Lonza to cover the entire bandwidth of biopharmaceutical

production methods for the pharmaceutical industry.

Through the acquisition of the Biologics business sector, formerly Celltech Biologics, in Slough (UK) in 1996, the company was primed from an early stage to meet the challenges at the forefront of genome research. Lonza made development and production techniques available for the manufacture of therapeutic proteins and monoclonal antibodies on the basis of mammalian cell cultures before a significant demand had emerged. In 2001 the active ingredient of the product Xigris was approved by the FDA. In the same year, work began on the large-scale build-out for biopharmaceutical manufacture at the production site in Portsmouth (USA). This expansion will see some CHF 330 million invested up to the end of 2004, almost quadrupling the current fermenter volume by a total of 60,000 litres.

Lonza will continue to invest in research and development to maintain its capacity for flexible, customer-oriented production. In particular, the combination of chemical know-how and biotechnological processes in the area of customer manufacturing has proven extremely successful in the manufacture of active substances for the pharmaceutical industry.

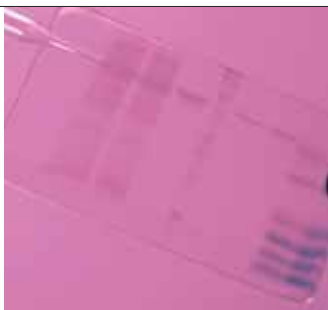
Active ingredients are substances which, in relatively small quantities, can have significant physiological effects, e.g. →vitamins, →enzymes or →active pharmaceutical ingredients.

Active pharmaceutical ingredients (API) are substances which are designed to have a specific therapeutic effect.

Air lift fermenter is a kind of →fermenter that uses sparged gas for mixing and does not require an impeller. →Lonza Biologics has air lift fermenters, with volumes of up to 5000 l, for mammalian cell culture.

Amino acids are organic compounds which are the →building blocks of →peptides and →proteins. These organic →molecules consist of one or more amino groups ($-\text{NH}_2$), a carboxyl group ($-\text{COOH}$) and other molecular groups specifically characterizing the particular amino acid. The amino acid building blocks are linked in chains creating peptides of different lengths such as dipeptides, oligopeptides and →proteins. The number and type of amino acids as well as the order in which they are arranged determines the properties of the peptide or protein. There are 20 different kinds of amino acid that make up the vast array of proteins in the human body, each protein having a special function. Amino acids of a protein are added in a genetically determined sequence, encoded by →DNA. Human →cells cannot produce all of these naturally occurring, essential amino acids, which must be obtained from dietary proteins. Unnatural amino acids whose specific molecules groups are not found in nature are important for the production of active substances for →pharmaceuticals. Amino acids can be manufactured by

extraction from existing proteins, by chemical synthesis or by microbial fermentation (→Lonza Biotec).

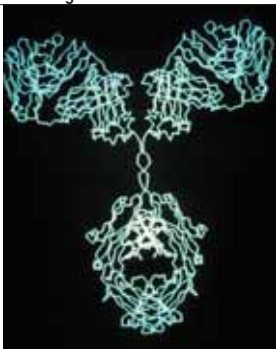


Analysis refers to the process of determining the identity and relative quantities of the constituents of a chemical or biological product or mixture. In general, chemical, physicochemical, biochemical or other biological methods are used.

Analytical systems are the instruments and associated materials used to carry out →analysis.

Antibiotics are substances with →antimicrobial effects produced naturally by →microorganisms. They are used to treat infections (→infectious disease) caused by →bacteria or fungi.

Antibody Molecule



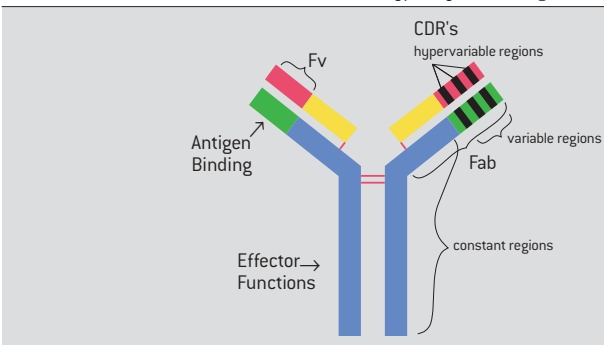
Antibodies constitute a class of complex →proteins produced by the immune system of higher →organisms in response to invading →antigens, e.g. for the destruction of pathogens (→pathogenicity) or the removal of a foreign substance. Antibodies are also known as →immunoglobulins.

CDR's (Complementary Determining Regions) - The specific amino acid sequences in the variable region which bind to antigen and determine antibody specificity

Variable region - Part of the antibody where the structure varies giving each antibody its specificity

Constant region - Part of the antibody which has a constant structure and contains effector functions which can influence other aspects of the immune system

Antibody fragments (Fab, Fv) - Antigen binding fragments which can be manufactured, typically in microorganisms



Antibodies, monoclonal, also called MAb, are →antibodies designed to bind specifically to a given →epitope. They are manufactured in large quantities to a high degree of purity. Monoclonal antibodies are used for research, diagnosis and therapy because of their ability to bind very specifically to a given target and to modify the function of →disease targets. Using →genetic engineering methods, monoclonal antibodies can be optimized for therapeutic applications, e.g. medicines for prevention of organ rejection after transplantation.

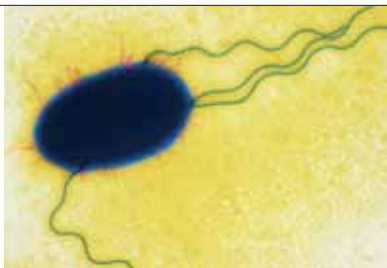
Antigens are substances capable of inducing a specific immune response and reacting with the products of that response, e.g. →antibodies or specifically sensitized T-cells. The term antigen has no genetic connotations.

Antimicrobials are chemotherapeutic agents produced chemically or by →biotechnological processes. Antimicrobials are used to treat →infectious diseases caused by →bacteria, fungi or parasites, as well as →viruses. Because bacterial infections are so common, antimicrobials, and particularly →antibiotics, are among the most frequently used →pharmaceuticals.

Assay is a test method for determining the presence, quantity or efficacy of a test substance such as the potency of a →drug or the purity of a compound.

Asymmetric synthesis is a special kind of →synthesis in which a desired →enantiomer is produced.

E.coli



Bacteria are viable, microscopically small, single-cell →microorganisms without a cell nucleus (→prokaryotes) which proliferate by means of each

→cell dividing to form two cells. Some bacteria are pathogens (→pathogenicity), others are inherent parts of the human body such as those which play a key role in the intestinal flora. Bacteria are also used for →fermentations and other →biotechnological processes.

Basic chemicals are usually produced in bulk quantities for further processing by the chemical industry.

Batch fermentation is a kind of →fermentation in which all growth substrates are added to the →fermenter at the beginning of the process together with the →cells or →microorganisms which are being cultivated. The products are harvested at the end of the fermentation period.

Bioassay is a technique (→assay) for determining the activity of a substance using biological systems such as living →organisms or →cells.

Biocatalysis is the chemical conversion of a substance (→educt) by →microorganisms or →enzymes (→biocatalysts).

Biocatalysts are biological agents such as →microorganisms or →enzymes that activate or speed up a chemical reaction.

Biochemistry is focused on the chemistry of living →organisms. It is the study of the structure, synthesis and interactions of natural →molecules.

Biocides are chemical substances, e.g. disinfectants, fungicides and bacteriocides, capable of killing →microorganisms.

Biology is the science of living →organisms.

Biopharmaceuticals are biotechnologically produced substances, such as →proteins, →peptides, →nucleic acids and other naturally occurring compounds, derived from living →cells for pharmaceutical applications. Lonza produces biopharmaceuticals such as monoclonal antibodies



(→antibody monoclonal) and other proteins using mammalian cell cultures (→Lonza Biologics). In the biopharmaceutical plant at Visp (→Lonza Biotec), which is due to come on stream in the first quarter of 2005, Lonza will produce biopharmaceuticals such as antibody fragments (→Fabs) and other proteins using microbial cultures.

Bioprocessing is a technique for the manufacture of a desired →product using →microorganisms, living →cells or →enzymes.

Bioreactor →fermenter

Biosafety comprises personal precautions as well as physical and biological containment measures to ensure the safe handling of biological agents such as →microorganisms and particularly →GMOs or their biosynthetic products to protect personnel, local population and environment from negative effects such as disturbances to the ecosystem. Biosafety is governed by a number of international and national guidelines, regulations and standards. Lonza has internal directives, policies and operating procedures on biosafety.

Biosynthesis means the production of an entire natural →molecule by a living →organism during growth and →metabolism. Unlike a →biotransformation, which acts on a starting substance or →educt, the biosynthesis is not dependent on educts or starting substances, but only on →nutrients.

Biotechnology is in the broadest sense the science of discovery and exploitation of biological processes and

methods for industrial and other purposes. Biotechnology is a multi-disciplinary science which uses →microorganisms, particularly →bacteria, yeast and fungi, or animal and human →cells to produce useful substances. →Genetic engineering has played a crucial role in modern biotechnology, and the recent unravelling of the sequence of the human →genome (→HUGO) has created much excitement within biotechnology.

Among the industrial →biotechnological processes we differentiate between classical biotechnology, e.g. brewing with yeast or cheese →fermentation with lactic bacteria, modern biotechnology, e.g. microbial production of natural compounds such as →antibiotics or →biotransformation, and the area of →genetic engineering, e.g. production of →proteins by recombinant organisms or cells. Classical biotechnological processes have been used for hundreds of years, especially for the production of alcoholic drinks, vinegar and products like cheese and yoghurt. In 1857 Louis Pasteur proved that microorganisms are responsible for these transformations. In the late 19th century pure cultures were introduced for the first time into industrial →fermentation processes, for example at the Carlsberg brewery in Copenhagen. A further milestone in biotechnology was achieved when Watson and Crick established the structure of →DNA in 1953. This information about genetic fundamentals resulted in the expansion of the palette of fermentation processes and the possibility to reprogramme microorganisms to produce a variety of →products.

Milestones in biotechnology

1680	Antoni van Leeuwenhoek first to see microorganisms with his microscope
1876	Louis Pasteur identifies microorganisms as a cause of failed beer fermentations
1897	Eduard Buchner discovers enzymes extracted from yeasts can convert sugar into alcohol
1928	Alexander Fleming discovers penicillin
1944	Large-scale production of penicillin begins
1953	James Watson and Francis Crick propose the DNA double-helix structure
1961	Genetic code (four base code for proteins) established
1973	First successful genetic engineering experiments
1975	Kohler and Milstein create the first hybridomas making monoclonal antibodies
1978	Genentech produces somatotropin (hGH), first human protein by recombinant DNA techniques
1980	Rank Hovis McDougall receives permission to market fungal food made by fermentation for human consumption in UK
1982	Genetically engineered insulin approved for use in diabetics in USA and UK
1984	Genetically engineered human growth hormone approved for treatment of dwarfism
1986	Human genome project launched by James Watson
1990	First gene therapy treatment for children with weak immune systems
1994	Gene for breast cancer found by University of Utah team
1997	Dolly is cloned, the first transgenic mammal produced by nuclear transfer
2000	Human genome project completed

Biotechnological processes are catalysed by living →cells or specific components of living cells such as →enzymes. Such processes (→biotransformations) can sometimes be used to supplement chemical technologies where a particular reaction is difficult or cannot be achieved by conventional chemistry. Biotechnological processes using →microorganisms, animal cells, →transgenic animals and plants are also used to produce therapeutic substances especially →proteins.

Microbial processes are simpler and less expensive than animal cell processes but are restricted to the production of smaller, simpler proteins. For the production of large complex proteins, which often need to be glycosylated (→glycosylation) to be biologically active, one is usually dependent on the more sophisticated synthetic machinery of mammalian cells. →Lonza Biotec focuses on microbial fermentation for biotransformations, and a →biopharmaceutical plant is being built at Visp which will be used for the production of →pharmaceutical proteins such as antibody fragments (→Fabs). →Lonza Biologics concentrates on the production of complex protein pharmaceuticals from large-scale mammalian cell culture.

Characteristics	Microbial Fermentation		Mammalian Cell Culture Fermentation
	E.coli	Yeast	
Cell growth doubling time	Rapid (30 min)	Rapid (90 min)	Slow (24hr)
Complexity of growth medium	Minimum	Minimum	Complex
Cost of growth medium	Low	Low	High
Expression level	High	Low-High	Low-Moderate

Biotransformation means selective chemical transformation, also called bioconversion, of a defined starting substance into a desired final →product with the aid of →biocatalysts, e.g. →microorganisms, which are often genetically modified, or isolated →enzymes.

BLA is the abbreviation for Biologics Licence Application. It is the process by which application is made to the Food

and Drug Administration (→FDA, →CBER), in the USA for approval to market a biological →drug.

Building Blocks are chemical or biotechnological compounds which can be combined with other compounds to form a new →molecule through chemical →synthesis or biotechnological methods (→biotechnological processes).

Bulk actives are →active pharmaceutical ingredients.

Capacity utilization refers to the percentage of available capacity used for production.

Catalysts are substances which allow or speed up reactions without being consumed or changed.

CBER is the abbreviation for Center for Biologics Evaluation and Research and is part of the →FDA. The CBER regulates biological products derived from living sources such as humans, animals, and →microorganisms in contrast to chemically synthesized →drugs (→see CDER).

CDER is the abbreviation for Center for Drug Evaluation and Research and is part of the →FDA.

Cell is the smallest viable component of a living →organism.

Cell banks are uniform pools of →cells, distributed into vials and preserved, typically, in the case of animal cells, by freezing in liquid nitrogen. Vials of cells taken from the

Cell banking

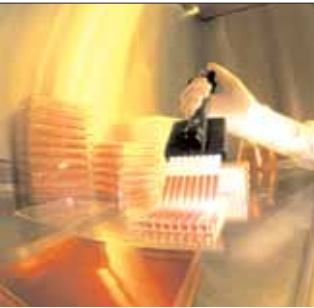


bank are used to initiate the manufacturing process (see →master cell banking).

Cell culture is a method for growing →cells isolated from living →organisms (→in vitro) under laboratory conditions.

Cell fusion means the fusion of two or more →cells to create a new cell containing the →genetic information of both fusion partners.

Cell line creation



Cell line comprises →cells from a defined origin. This uniform cell population can be continuously cultured →in vitro.

Cell therapy is a form of therapy in which →cells are grown or otherwise

manipulated in culture and then administered to a patient to treat a disease.

cGMP is the abbreviation for current Good Manufacturing Practice, comprising a set of general regulations mandated by regulatory agencies such as the →FDA and the →EMA. These regulations have to be followed in the testing and production of →pharmaceuticals. The stand-

ards comprise documentation and control of the product and production methods including facilities, equipment and personnel through a quality management system. Lonza's exclusively manufactured products (→production processes) are made under cGMP conditions when this is required by regulations. "Current" means that the production processes and quality systems are always up-to-date according to the regulations of the →FDA and other relevant authorities.

Chemistry is the science of substances, dealing with their structure, characteristics and reactions.

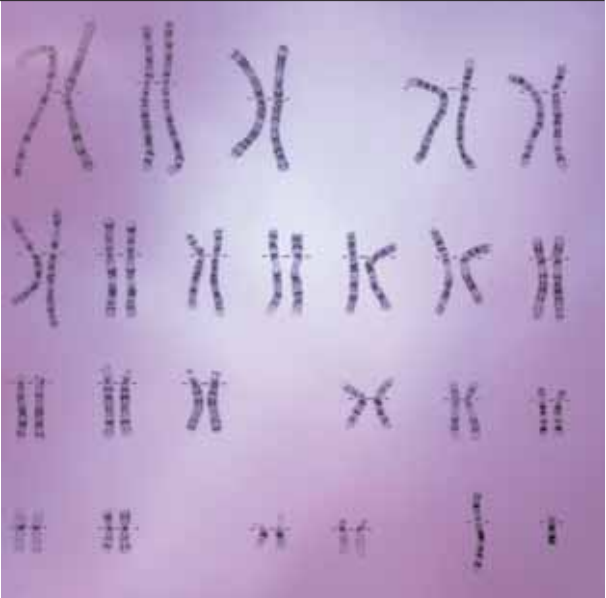
Chirality describes the property of some →molecules to exist in two forms, one being the mirror image of the other. This is rather like left- and right-handedness. Frequently only one chiral form of a →molecule has the desired chemical or biological activity and special techniques are used to produce these desired forms.

CHO stands for Chinese hamster ovary →cell. This is a type of cell line that can be grown continuously in →culture and is very widely used for the production of recombinant →proteins.

Chromatography is a widely used separation method in →biotechnology in which complex mixtures of →molecules are passed across a solid matrix which selectively retains particular substances. A large range of chromatography matrices are available which allow separations to be carried out based on size, electrical charge or a variety of other physical characteristics of the product of interest. For a →protein it is common to use several

different chromatography steps to achieve the desired level of purity.

Chromosomes



Chromosomes are the chemical packages of hereditary information, made up of long, coiled chains of →DNA. Human beings have 22 different pairs of chromosomes plus two x-chromosomes or one x- and one y-chromosome, depending on sex. The number of chromosomes varies from one species to another.

Clean room is a special working area that has a specified air quality in terms of the number of dust particles and the number of →microorganisms per cubic meter of air. A limit on the number of microorganisms on working sur-

faces is also specified. Clean rooms are maintained by special cleaning and disinfection regimens. The efficiency of these measures is regularly monitored. The air pressure in the clean room is higher than normal to prevent ingress of "dirty" air from outside the area. The personnel working in a clean room are specially trained, and a defined dress code is applied, with a changing area under increased air pressure. Access to a clean room is generally restricted. Clean rooms are widely used at Lonza. At →Lonza Biotec for example they are used for →master cell banking and the growth of inoculum cultures to protect microbial cultures from cross-contamination.

Clinical trials are human studies for evaluating the safety, efficacy and required dosage of a new →drug for human beings. Clinical trials normally include patients who are given an inactive substance, known as a placebo, which acts as a control against which the activity of the trial drug can be compared. The clinical trials are structured in three phases, which are mandated by the →FDA or other relevant national agency. Phase I is designed to evaluate whether the new drug is toxic or harmful to healthy human beings. Phase II is carried out in a limited number of patients with the aim of obtaining more information on safety and dosing and preliminary efficacy data. The purpose of phase III is to verify the dosage and efficacy of the new drug by carrying out statistically valid full-scale clinical trials.

Clone is a population of →organisms produced from a single parent →cell. The individual cells derived from a single clone are genetically identical.

CMO is the abbreviation for Contract Manufacturing Organization (→custom manufacturing).

Codon is a triplet of →nucleotides in →DNA or →RNA →molecules that codes for one of the 20 →amino acids in →proteins, or for a signal to start or stop protein production. Each →gene that codes for a protein is a series of codons that gives the instructions for building that protein.

Combinatorial biology comprises the set of →DNA technologies used for generating a large number of samples of new chemical substances, which are tested for therapeutic effects such as →pharmaceuticals. The technologies of combinatorial biology provide a more efficient method for discovery of potential pharmaceutical effects during the →screening process.

Combinatorial chemistry is based on the rapid →synthesis of large numbers of variants of →molecules by combining different molecular functions in a variety of combinations. This creates novel molecules which can be screened for their activity.

Commodity chemicals are compounds with low value, produced in high volumes. They are used for a broad spectrum of applications.

Continuous fermentation describes a process in which →culture medium is continuously added to the culture and spent culture fluid containing product is continuously removed from the reactor. This allows →fermentations to be run for prolonged periods compared with simple

batch processes. →Perfusion culture is a particular type of continuous culture in which →cells are prevented from being removed from the reactor in the spent culture fluid. This enables high cell densities to be achieved and hence, potentially, higher productivity.

Cosmeceuticals are bioactives used in cosmetics.

CTX stands for →clinical trials exemption certificate and is the mechanism in Europe by which approval is given to commence a →clinical trial.

Culture medium →medium

Custom manufacturing, sometimes also called exclusive manufacturing, means the production of intermediates and active substances exclusively for certain customers. Lonza has systematically focused on customers' requirements and originated the concept of custom manufacturing in the →pharmaceutical industry. With the concept "Leave it to Lonza", the company recognized the trend towards outsourcing in the pharmaceutical business more than 20 years ago and significantly influenced the market by providing an appropriate service.

Derivatives are substances derived from a chemical or biotechnological compound which are usually formed in a single reaction step and whose chemical structure is closely related to those of the parent substance.

Disease targets are genetic or biochemical processes in living →organisms in which the activity of a specific →molecule, usually a →protein, is involved in a disease.

The molecule or the processes in which it takes part can be targeted with therapeutic →drugs to prevent or treat the disease.

aaagtcctt ctgtagtcc ttacca
 catgagata tgctttaa tccaggt
 cttttcagg tgtgtaggg tgccctg
 gggcgaagt ggggtgtctg ggttct
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 gttaccctct gtcagcagat gtggga
 agctgtctcc tctgagtttc agtggtc

DNA is the abbreviation for deoxyribonucleic acid, which holds the →genetic information of every living creature. When →cells divide, the DNA in the cell is copied and each daughter cell receives one copy. The DNA contains four bases

– adenine, thymine, cytosine and guanine; the amount of thymine always equals that of adenine, and the amount of cytosine always equals that of guanine (A=T; G=C).

Double helix – The principal structure of →DNA, consisting of two complementary strands. The →nucleotides in each strand link to complementary nucleotides in the second chain of the double helix.

Downstream processing (DSP) describes the process steps in chemical or biotechnological manufacture following the reaction step, e.g. →fermentation, to recover and purify the →product. Various technologies, including →chromatography, are used for the concentration and isolation of the product.

Drugs are →pharmaceuticals in their final formulation.

Drug resistance is the ability of some →microorgan-

isms, particularly →bacteria, to withstand attack from certain drugs (→antimicrobials).

Drug substances are →active pharmaceutical ingredients before the product has been formulated and filled.

Educt is a chemical starting compound for a chemical or biocatalytical (→biocatalysis) conversion to a product.

EMA is the abbreviation for the European Agency for the Evaluation of Medicinal Products, whose regulations are effective for all →pharmaceuticals in Europe.

Enantiomers are two →molecules with the same composition and structure that are different in the arrangement of the elements around an asymmetric carbon molecule such that one molecule is the mirror image of the other. One enantiomer will rotate a beam of light clockwise (dextrorotatory or D-form) and the other rotates the light anticlockwise (laevorotatory or L-form) such as D-Carnitine and →L-Carnitine.

Enzymes are →proteins which act as biological catalysts (→biocatalyst), initiating all biochemical reactions. Enzymes are used in many biotechnological methods. Defects in enzyme activity in living →cells can be responsible for diseases (→disease targets).

Epitope is that specific part of an →antigen which is recognised by an →antibody and to which the antibody binds.

Escherichia coli, also known as E.coli, is a common intes-



tinal →bacterium in the human intestine. *E. coli* is the most studied bacterium of all and is used in many microbiological processes, as it can be genetically modified

for use in the production of human →proteins such as →insulin.

Eukaryotes are →organisms such as humans, animals, plants. Cells of eukaryotes are larger and more complex than →prokaryotic cells such as →bacteria. Eukaryotic cells have many structural features which are absent from prokaryotic cells; for example the →chromosomes of eukaryotes are contained in the nucleus, an organelle which does not exist in prokaryotes.

Excipients are ingredients other than the →active pharmaceutical in the dosage form. They may be added, for example, to improve the stability of the →pharmaceutical.

Expression is the formation of →proteins or →peptides in a →cell by transcription of the →genetic information and its translation into an →amino acid sequence according to the →genetic code.

Fab is a particular type of →antibody fragment which contains the regions which bind to the →antigen.

FCCB, the abbreviation for Federal Coordination Center for Biotechnology, is the Swiss governmental authority for

the registration and authorization of biological activities using pathogenic (→pathogenicity) →organisms and →GMOs.

FDA is the abbreviation for the Food and Drug Administration; the US →drug regulatory body whose regulations are effective for all →pharmaceuticals produced for use in the USA.

Fed-batch fermentation is a kind of →batch fermentation in which specific ingredients, usually growth substrates and/or →educts, are added during the course of the →culture to improve the productivity of the process; the products are harvested at the end.

Fermenters. Lonza Biotec, Kourim



Fermentation describes processes for cultivating →microorganisms or →cell cultures to get specific products. The technology of fermentation has existed for hundreds of years. In the first period of fermentation microorganisms were used to produce alcoholic drinks, dairy products and vinegar in brewing vats or wooden barrels. These microorganisms and their exact effects were not characterized. In the next period, starting around the mid-19th century, baker's yeast, lactic acid, citric acid and glycerol, among others, were made in closed, but non-sterile vats. Later on the use of pure cultures of microorganisms and increasing knowledge of their properties led to many new applications. Today fermentation technology is used to produce a wide range of natural products such as →amino acids and →antibiotics. The development of →genetic engineering has expanded the application of the technology to recombinant products such as →insulin and monoclonal antibodies (→antibody, monoclonal).

Viewing point of a fermenter. Lonza Biologics, Slough



Fermenter is a vessel for the cultivation of →cells under controlled conditions. These biological processes (→biotechnological processes) can be conducted with →microorganisms, animal or plant

cells. To obtain an optimal production process, the different parameters of the fermenter must be controlled: the concentration of the substrate, the temperature, the pH-value, the concentration of oxygen etc.

Final product formulation is the process whereby the →pharmaceutical is manufactured in the form in which it is to be delivered to the patient.

Fine chemicals are value-added intermediates and active substances used, for example, in →pharmaceuticals, crop protection agents and engineering plastics. They are usually produced in relatively small quantities for specific applications.

Genes are the 'blueprints' of life, they control the structure and function of →cells and →organisms and contain →genetic information. Individual genes, coding segments of the →DNA molecule, provide the instructions for making specific →proteins which form the framework and machinery of cells. The human being has 30 000 genes. The totality of the genes of an organism, holding all the genetic information, forms the →genome.

Gene amplification means the process of increasing the number of copies of a specific →gene in a →cell, usually to increase the productivity of the cell for the product coded by the gene.

Genetic characterization is the analysis of the →genetic information of a →cell or an →organism.

Gene expression means that the →gene is expressed, i.e. is functional, within the →cell. Gene expression technology is used to create →cell lines →or microorganisms producing a specific →protein, e.g. for a therapeutic use, by transferring the gene that codes for the protein to a relevant production cell line in which it will be

expressed at a high level. →Lonza Biologics has developed a highly efficient gene expression system for mammalian cells known as the →GS Expression System.

Gene mapping is used to determinate the relative positions of different →genes on →chromosomes and the distances between them.

Gene sequencing describes the method used to identify the sequence of →nucleotides in the →DNA molecule.

Gene technology →gene engineering

Gene therapy is the modification of the →genetic information of a patient's →cells with the purpose of replacing or supplementing defective or missing parts of cellular →DNA.

Genetic code is the term used to describe the →genetic information of the →DNA. It is a linear code based on combinations of four →nucleotides, akin to letters in a code, read in groups of 3 – so called triplet →codons. Each codon codes for an →amino acid in the amino acid sequence of →peptides and →proteins.

Genetic engineering refers to all methods used for the isolation of →DNA →molecules of a living →organism, and their →analysis, modification and introduction into a →cell. Such methods include the →recombination of genetic material (→gene), including recombination of →DNA from different species; methods for the insertion of recombinant DNA (→recombinant DNA technology) into an organism, either the original one, or one in which

this DNA does not naturally occur; and methods for the replication and expression of this DNA in its new environment. Genetic engineering has made it possible to manufacture →proteins which have therapeutic value. These include naturally-occurring proteins, e.g. hormones, →enzymes and blood factors. The coding sequence (→gene sequence) of the human gene controlling the production of the protein is introduced into bacterial or mammalian cells which can then be used to produce substantial quantities of these naturally rare, but vital, molecules. It is also possible to produce proteins that have been altered by gene modification to provide improved therapeutic properties for example humanised monoclonal antibodies (→antibody, monoclonal).

Genetic information is encoded in the →DNA and is responsible for the molecular structure of all →proteins of a living →organism and their production inside the →cells (→genetic code).

Genetics is a part of →biology, which is concentrated on the rules of inheritance. Gregor Mendel discovered the basic principles by which →genes are inherited. Molecular genetics uses the techniques of →molecular biology to investigate genetics.

Genome means the totality of the →genetic information within every →cell of a living →organism.

Genotype has the same meaning as →genome.

Genome research is focused on the sequencing of the →genome, including the human genome (→HUGO).

Genome research will decode the →genes and also lead to an understanding of how genes interact in living →organisms.

GILSP means Good Industrial Large-Scale Practice, guidelines for handling genetically modified →organisms (→GMOs) at large scale.

GLP means Good Laboratory Practice. This refers to the general requirements laid down by regulatory authorities covering the standards to which laboratory testing of →pharmaceuticals should be carried out, for example toxicology.

Glycosylation is the addition of carbohydrate (sugar) residues to a →protein which is then called a glycosylated protein or glycoprotein. In mammalian →organisms, glycosylation of proteins is often essential for biological activity. In contrast to higher organisms, e.g. mammals, fungi, plants, →bacteria are incapable of glycosylation. The ability of a particular →cell or →microorganism to correctly glycosylate a protein can dictate whether it will be useful for making proteins by →genetic engineering.

GMOs are genetically modified →organisms that have changed in their biochemical features because of changes made to their genetic material (→DNA). Genetic modifications are obtained using →genetic engineering techniques.

GMP →cGMP

GMWP means Good Microbiological Working Practice,

including internationally agreed working standards in a microbiological laboratory, e.g. standards of hygiene and care.

Growth rate is the rate of change in the number of →cells in a growing →culture in relation to time.

GS Expression System stands for glutamine synthetase →gene expression system which is proprietary to →Lonza Biologics. This system is a highly efficient mammalian expression system which combines the use of selection via glutamine independence (imparted by GS) with a powerful viral promoter to allow the rapid creation of highly productive →cells. The GS system has been successfully used by over 60 →biotechnology and →pharmaceutical companies worldwide.

High-throughput screening describes a highly developed process of →screening in which automated →assays are used for determination of therapeutic activities of a large number of substances.

Host system is a →cell or an →organism which is used for the →expression of foreign →DNA (→virus, →plasmid). In →genetic engineering, different factors determine the choice of a host such as the requirement for →glycosylation and the complexity of the product. Typical host systems include →bacteria such as →Escherichia coli, yeast such as Saccharomyces cerevisiae and →mammalian cells such as →CHO and NS0 (mouse myeloma).

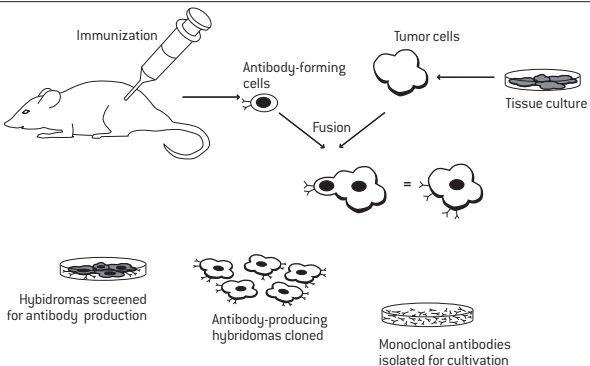
HUGO is the abbreviation for Human Genome

Organisation which is an international organization started in 1988 and focused on the sequencing of the human →genome and the dissemination of resulting data and materials. Thanks to this programme →genes can be identified which provide the information code for the →proteins making up the machinery of →cells. With increasing knowledge of the complex interactions of the cells' genes and proteins, as well as post-genomic research in cell biology, a dramatic increase is expected in know-how relating to the sites of action relevant to certain illnesses. Large-scale sequencing of →DNA is revealing gene function and mapping genes that are defective in human diseases (→disease target).

Humanization means the engineering of an →antibody →protein sequence to make it more human-like and therefore less antigenic (→antigen) during therapeutic use. This has been particularly important because many monoclonal antibodies (→antibody, monoclonal) were initially developed as mouse proteins using →hybridoma technology.

Hybridoma is a →cell line resulting from the fusion of a

Monoclonal Antibody Production



continuously dividing cancer →cell with a normal blood cell (lymphocyte) secreting a specific →antibody, to produce an immortal hybridoma cell line manufacturing a specific antibody or monoclonal antibody (→antibody, monoclonal). Typically the cells used to create hybridomas have been derived from mice. Because of their extremely high specificity such monoclonal antibodies are indispensable tools in research and diagnostics. Humanized monoclonal antibodies serve as highly effective medicines.

ICH stands for International Conference on Harmonisation and comprises international guidelines for the standards and measures necessary to develop →biopharmaceuticals.

Ig is an abbreviation of →Immunoglobulin.

Immunoglobulins are special kinds of →proteins also known as →antibodies and which play an important role in the immune system.

IND stands for Investigational New Drug application and describes the process in the USA for gaining approval from the →FDA to carry out →clinical trials on a new →drug.

Inclusion bodies are particles of recombinant →protein produced within →cells of →microorganisms in an insoluble, denatured form. The proteins must be re-natured outside the cell before they can be used for the desired applications. In general this is only possible for less complex proteins.



Infectious diseases such as cholera, typhoid, influenza, are caused by →bacteria and →viruses and can be transmitted from one person to another.

Insect cells are used as an efficient method for expressing →proteins with the baculovirus →expression system. Baculovirus is in the family Baculoviridae, a diverse group of large doubled-stranded →DNA →viruses that infect insects, arachnids and crustaceans. They are extremely species-specific and neither infect vertebrate life forms nor propagate in →mammalian cell cultures. Insect cell systems are used most frequently for the rapid expression of research quantities of proteins in →drug discovery programmes.

Insulin is a hormone normally produced in the pancreas of humans and mammals. Diabetics cannot produce the vitally important insulin. Insulin is the first →recombinant →drug produced by →genetic engineering and was introduced in 1982. It is produced by using →bacteria into which the human insulin →gene has been introduced. Prior to this insulin was produced by extraction from animal pancreases.

Interferons are →proteins secreted in human and other animals during viral infections (→viruses) and they have antiviral and immunological properties. Today these proteins can be produced by genetically engineered (→genetic engineering) →bacteria and →mammalian cell culture and they are used in a number of therapeutic areas, such as cancer, viral disease, multiple sclerosis.

Intermediates are chemical compounds, generally made

by biotechnological methods (→biotechnological processes) or from chemical →synthesis, which can be used to synthesise useful products.

In vitro refers to an experiment performed outside a living →organism.

In vivo refers to an experiment performed in a living →organism.

L-Carnitine is a vitamin-like compound also known as →vitamin B₇ that is synthesised by the adult human body. The main applications of L-Carnitine are in the area of sports nutrition, food, →pharmaceuticals and feed-stuffs. Lonza is the leading manufacturer of L-Carnitine using →biotechnological processes.

Lonza – The name Lonza originates from the Lonza River in Valais where the company was founded as Elektrizitätswerk Lonza in 1897 with the goal of generating hydroelectric power for the manufacture of electrochemical products. In the following decades, Lonza Group developed its product range to encompass fertilizers, basic organic chemicals and intermediates. In the 1960s, Lonza Group entered into the petrochemical market by commissioning a naphtha cracker. Through acquisitions in the USA, Lonza Group entered the performance chemical sector for biocides and oleochemicals. The operations in Italy added the sector of dibasic acids and derivatives, which are mainly used for selected polymer applications. From the mid-1970s, Lonza Group continuously upgraded the transformation of key raw materials into higher-value-added products. In the early eighties, a biotechnol-

ogy research team was asked to work on the harnessing of synergies between organic syntheses and bioprocesses (→biotechnological processes), which marked the start of Lonza's biotechnology activities. In the following years, Lonza invested and expanded in this area and built up today's biotechnology business sectors →Lonza Biotec and →Lonza Biologics. In November 1999 Lonza Group was de-merged from algroup. Lonza Group has become a successful independent company focused on chemical and biotechnological activities. Today, Lonza Group has positioned itself as a pre-eminent supplier to the →life sciences industry. Lonza Group Ltd is the holding company and is quoted on the Swiss stock exchange.

Lonza Valais Works, Visp



Lonza Biologics is one of the →biotechnology business sectors of Lonza Group which produces exclusive therapeutic →proteins including monoclonal antibodies (→antibody, monoclonal) using →mammalian cell cultures. Lonza Biologics offers a full service: from →cell

line construction and process development to large-scale (→scale up) manufacturing and regulatory support. The research center of Lonza Biologics is located in Slough (UK) and there are production sites in Slough and Portsmouth (USA). With the large-scale expansion in Portsmouth, which is currently under construction and due to come on stream in mid-2004, Lonza will quadruple its existing capacity for mammalian cell culture fermentation. The main market for Lonza Biologics is the →pharmaceutical and biotechnology industry.

Lonza Biotec is one of the →biotechnology business sectors of Lonza Group, a world leader in the manufacture of exclusive fine chemicals and biologically active substances using microbial →fermentation. Lonza Biotec offers →cGMP →custom manufacturing and process development, focusing on microbial fermentation for the →life sciences industry. The research activities of Lonza Biotec are located in Visp (CH), and production in Kourim (CZ). With the new biopharmaceutical plant at the Visp site which is currently under construction, Lonza will be able to produce complex →peptide →molecules such as antibody fragments (→Fabs) by microbial fermentation. Lonza Biotec will then be able to offer the production of →pharmaceuticals (small molecules) and →biopharmaceuticals (→proteins, →peptides).

Lonza Exclusive Synthesis manufactures exclusive fine chemicals on the basis of advanced chemical →synthesis for the →life sciences industry. Research and production are located in Visp (CH); there is another production site in Conshohocken, PA (USA).

Lonza Organic Fine Chemicals is focused on combined chemical and biotechnological processes, e.g. for the production of →vitamins, and offers a broad catalogue of organic intermediates for a wide range of applications.

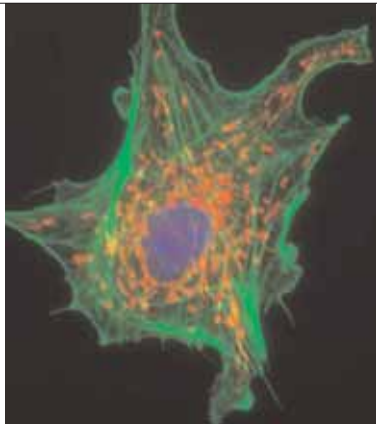
Lonza Performance Chemicals provides →antimicrobial and associated products and services to the personal care, household hygiene, industrial and institutional hygiene, water treatment, wood protection, food emulsifier and industrial aids markets.

Life sciences link life and science. In this context, life refers to human beings, animals, plants and →microorganisms, and the sciences to research into and understanding of life as a constantly changing process. The life sciences industry uses these findings to preserve and improve the quality of life through applications in the fields of diagnostics, →pharmaceuticals, nutrition, agro-science and hygiene.

MAb is an abbreviation for monoclonal antibody (→antibody, monoclonal).

Mammalian cell

Mammalian cells are →eukaryotes. They are used for the manufacture of a range of →pharmaceutical →proteins and →vaccines. (→Lonza Biologics)



Master cell bank is a single pool of →mammalian cells or →microorganisms, prepared from a selected parent cell (→clone), distributed into vials and preserved under defined conditions (typically in liquid nitrogen for animal cells and in glycerol cultures at -80°C for bacterial cultures). A vial is thawed to grow sufficient cells to create a large number of vials of the working cell bank. Vials from this are used to initiate each new production batch. The master and working banks are rigorously tested for a wide range of characteristics; genetic stability, absence of contaminant →organisms etc. When a working cell bank is exhausted a new one is generated from the master cell bank.

Medium, also known as culture medium, is a formulation of →nutrient substances used in the culture of →microorganisms, animal →cell or plant cell cultures. Significant effort goes into the optimisation of culture media to maximise productivity of →fermentation processes.

Metabolism comprises all biochemical processes in a living →organism.

Microbiology is the branch of →biology that deals with →microorganisms.

Microorganisms include →bacteria, yeasts, fungi and →viruses. Some of these →microorganisms can initiate diseases, while others are very useful for →biotechnological processes.

Molecules are made up of at least two atoms, held together by chemical bonds. Molecules consisting of

more than approximately 1000 atoms are called macromolecules. The molecular structure results from the kind of chemical binding which forms specific configurations of the atoms in the molecules.

Molecular biology is a branch of →biology that focuses on understanding the behaviour of living systems at the molecular level, specifically in relation to →DNA, →RNA, and →proteins.

Mutations are changes in the genetic material of a living →cell. They can occur spontaneously during the process of replication of →genetic information before cell division or as a result of damage to the →DNA. Mutations can also be deliberately induced in the laboratory. The damage to the DNA may be caused by chemicals or irradiation of the genetic material.

NCE stands for new chemical entity.

NDA is the abbreviation for New Drug Application, which is an application to the →FDA for the approval of (usually) a non-biological →drug.

Niacin is an important →vitamin of the B-complex (vitamin B₃). Lonza is the world's leading producer of this supplementary food and feed additive (see →Lonza Organic Fine Chemicals).

Nucleic acids are long-chained →molecules (→DNA and →RNA) which encode and control the synthesis of →proteins in living →organisms.



Nucleotides are the structural components of →DNA and →RNA.

Nutraceuticals are bioactive additives for food products. The term nutraceuticals was created to link →pharmaceuticals and nutrition.

Nutrients are substances, such as →amino acids, carbohydrates, minerals, fatty acids or →vitamins, which enable growth and normal functioning and sustain life.

Oleochemicals are oil products and chemicals derived from biological fats and oils. The most important oleochemicals are fatty acids, fatty esters, fatty alcohols, fatty amines and glycerine.

Oligonucleotides, also called oligos, are short chains of →nucleotides which have been linked together in a specific number and configuration. A number of oligonucleotides are in development as therapeutic agents.

Organisms consist of one (uni-cellular) or many (multi-cellular) organized →cells.

Parent cell cultures, PCCs, are the initial →clones of a microbial production strain for →master cell banking. For safety reasons the parent cell cultures are stored also in strain collections and customer →cell banks. Parent cell cultures in Lonza's strain collection are documented regarding their origin and/or their construction as production strains, as well as their phenotypic (→phenotype) and genotypic (→genotype) features, and other relevant aspects, e.g. →pathogenicity, biohazard status, toxins.

Pathogenicity is the potential of a → microorganism, e.g. a → virus or → bacterium, to cause → infectious diseases in humans.

Peptides consist of two or more → amino acids, defined as anything smaller than about 50 amino acids. Peptides can be produced chemically and biotechnologically. Lonza makes peptides by microbial fermentation (→ Lonza Biotec) and chemical synthesis (→ Lonza Exclusive Synthesis); the kind of production technology deployed depends on different characteristics of the desired products. Peptides consisting of fewer than 10 amino acids are usually called oligopeptides. Larger peptides are known as polypeptides or → proteins.

Perfusion fermentation is a kind of continuous → culture in which → nutrients are added continuously to the culture and the product is harvested at the same rate, while retaining → cells within the reactor (→ fermenter).

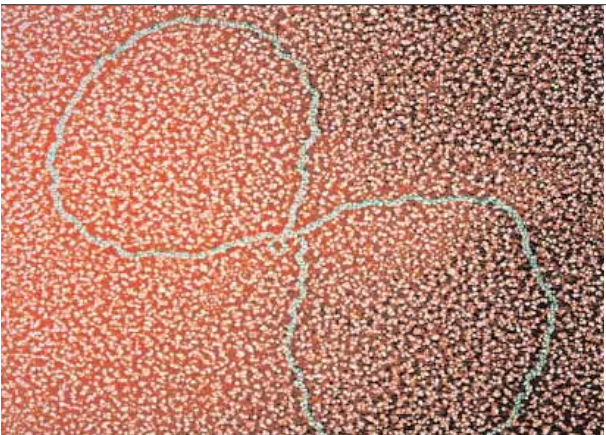
Pharmaceuticals are → drug substances which are intended to preserve health and treat disease.



Phenotype describes the overall characteristics of an →organism; its morphology, physiology and behaviour.

Plasmids are independent, self-replicating →DNA molecules, commonly found in bacterial (→bacteria) →cells. Plasmids and their →genetic information are inherited as part of the →host's →genome, but are separate from chromosomes. Naturally occurring plasmids are used by →microorganisms to mobilise genetic information between →organisms, e.g. antibiotic resistance (→antibiotics). In →biotechnology plasmids or →vectors can similarly be used to deliberately transfer →genes from one organism to another.

DNA Plasmid



Post-translational modification describes changes that may occur to a →protein in a →cell after →translation has taken place to produce a defined →amino acid sequence. A common example is →glycosylation - the addition of sugar →molecules to the protein.

Prokaryotes, in contrast to →eukaryotes, are mainly single-cell →organisms (such as →bacteria) with a simpler structure than eukaryotes.

Production technologies at Lonza include a wide spectrum of technological processes: highly developed chemical syntheses in the →Lonza Exclusive Synthesis business sector, combined chemical and biotechnological processes (→biotechnological processes) at →Lonza Organic Fine Chemicals, production of fine chemicals and biologically active ingredients by microbial fermentation at →Lonza Biotec, and production of monoclonal antibodies (→antibody, monoclonal) and other therapeutic →proteins using mammalian cell cultures at →Lonza Biologics. Almost all Lonza's production technologies are customized (→custom manufacturing). The range of production technologies also includes specific services such as →screening, process development, →scale up, →downstream processing and regulatory support.

Proteins are polypeptides with a high molecular weight and complex three-dimensional structure, consisting of more than 50 →amino acids. Proteins vary in size and can contain many hundreds of amino acids. The wide range of →cell types reflects the variety of protein →molecules found in them. In the human body there are about 50 000 to 100 000 different proteins and they have various essential functions; they can act as structural proteins, e.g. for muscle structure, as →enzymes or →antibodies, and as hormones such as →insulin. Today, as a result of →genetic engineering, several therapeutic proteins can be produced by →biotechnological processes.

Proteomics is a new field of study within →biotechnology, which is being used to identify the detailed →protein architecture of →cells, providing an improved understanding of the molecular basis of particular diseases and information which can be linked back to →gene function. These advances are radically improving our understanding of the role of cellular proteins and pathways in disease processes, providing an increasing number of targets (→disease targets) for the development of novel medicines.

Purification refers to the separation of a desired substance from a mixture. In →biotechnology, purification is usually the separation of a desired substance, e.g. a →protein, from culture →medium and →cell components, typically by →chromatography.



Quality assurance, QA, is a concept defining the conditions required for quality-conscious working practices. Quality assurance embraces all measures designed to ensure that the products meet the standards of quality appropriate to their intended use and encompasses all aspects of →cGMP.

Quality control, QC, comprises sampling, specification and testing procedures, as well as organization, documentation and release of →products. It is part of →GMP.

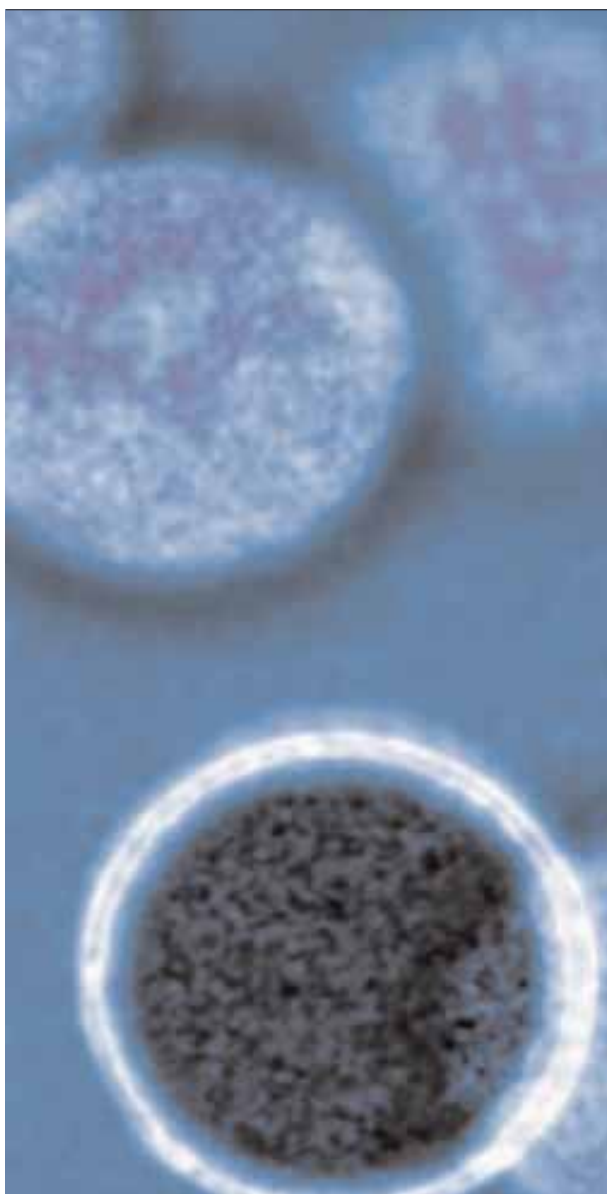
Proper testing ensures that the product always meets the specifications registered with the regulatory authorities. Quality control tests are carried out on raw materials, intermediates and end-products in specially equipped laboratories. Chemical, physical and biological →assays are carried out.

Recombination means the new combination of →genes in an →organism. →In vitro recombination is a →genetic engineering technique that involves the uniting of specific →DNA fragments from different sources in a test tube and reintroducing them into a →cell or →microorganism which is then called a recombinant organism.

Recombinant DNA technology comprises methods to recombine the →DNA of different sources (→bacteria, animals, plants, humans), e.g. by →genetic engineering in a →host organism. The new strains can be used in production processes by the →biotechnology industry.

Lonza Biologics, Slough





Recombinant DNA technology requires DNA extraction, →purification and transfer to →cell or target →organism.

Responsible Care® is the term for the chemical industry's worldwide environmental, economic and social program. By signing the agreement, companies commit themselves to continuous improvement of their performance in safety, health and environmental protection, irrespective of any applicable statutory requirements.

Ribosome is a structure within →cells which acts as the site for →protein synthesis.

RNA is the abbreviation for ribonucleic acid. It forms a complex family of biochemical →molecules some of which (messenger RNAs) carry a copy of the →genetic information during the process of →gene →expression to make a particular →protein molecule. The RNA molecules are the key links in the chain: →DNA makes RNA makes protein.

Scale up means the construction and operation of production plants on the basis of data extracted from lab and pilot facilities.

Screening means the systematic sampling of strains of →microorganisms or →cell lines or biological activities in search of specific characteristics, e.g. →pharmaceutical effectiveness. Screening may also be used to identify →drug candidates which interact with a chosen cell or biological activity. →High-throughput screening makes it possible to analyse large numbers of microorganisms or compounds in a very short time.

Secondary metabolism is the part of the →metabolism which is not essential for growth or maintenance, unlike primary metabolism. Secondary metabolism is most active under conditions of limited growth or even absence of growth. Products of secondary metabolism, some of which are of pharmacological importance, are called →secondary metabolites. The best known examples are →antibiotics such as penicillin.

Secondary metabolites are products of the →secondary metabolism of →microorganisms and plants. These metabolites are often produced in tiny amounts, many are often poorly water-soluble, have a very complex structure, sometimes with several chiral centers (→chirality), and they are usually highly biologically active. Most of the →pharmaceuticals – e.g. anticancer →drugs, immunomodulators, →antibiotics – are secondary metabolites or derivatives of secondary metabolites.

Substrate describes the →nutrient(s) which →microorganisms or →cells utilise during →culture. Substrate or nutrient is the starting material for →metabolism.

Synthesis refers to the manufacture of chemical compounds on the basis of specific chemical or biochemical reactions.

Therapeutic vaccines →vaccines

Transcription is the process by which →genetic information contained in →DNA is transcribed or copied into a →molecule of →RNA, called messenger RNA. Transcription is the first step in →protein →synthesis.

Transfection is a process for transferring or introducing →recombinant →genetic information into a recipient →cell or →host →organism.

Transgenic animal →transgenic organism

Transgenic organism, transgenic animals or transgenic plants, are →organisms living with an altered →gene or additional genes as a result of →genetic engineering.

Transgenic plant →transgenic organism

Translation describes the process by which →genetic information encoded in messenger →RNA in the form of a →nucleotide sequence (→genetic code) is converted into a sequence of →amino acids in a →peptide chain or →protein. This process is mediated by the →ribosomes.

Vaccines contain →antigens prepared from live, killed or weakened pathogenic (→pathogenicity) →organisms or made as recombinant →proteins. They are used to stimulate the production of →antibodies to give immunity against specific diseases.

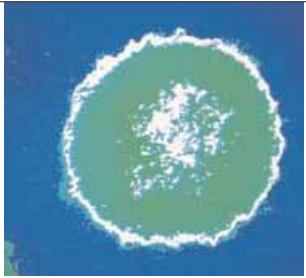
Vectors transmit →DNA into →cells. They are constructed by cutting and joining DNA from different →organisms. →Plasmids or →viruses are often used as vectors.

Vitamin is a general term for a number of essential substances which the human body cannot synthesise itself and which therefore have to be obtained from the diet. It is generally accepted that there are 13 vitamins which can be broadly distinguished as either water-soluble –

e.g. vitamin C and the B-complex vitamins such as →Niacin or the vitamin-like substance →L-Carnitine – or fat-soluble, such as vitamin A.

HI-Virus

Virus is a non-cellular, non-self-replicating →organism, which needs the genetic system of living →host →cells for reproduction. Viruses are quite specific in their ability to infect particular cells and particular organisms.



Working Cell Banks, WCB →master cell banks

World Health Organisation, WHO, is an agency of the United Nations, founded in 1947 for the purpose of promoting health. Its headquarters are in Geneva. The risk groups of →microorganisms are based on WHO classifications.



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