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USE OF BIOTECHNOLOGY IN DRUG PRODUCTION / A REVIEW ARTICLE

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Abstract:
Since the early 1970s, biotechnological advancements have progressed under established guidelines and local laws. Comprehensive examinations have revealed no unexpected or unmanageable characteristics in recombinant organisms. This technology has proven invaluable, enabling numerous medical advancements through therapeutic proteins that are otherwise unattainable. In developed countries, biotechnology has emerged as a significant economic force, driving substantial industry growth during the biotechnological revolution.

Keywords: Biotechnology, Drug Production, Medical Challenges

REVIEW ARTICLE: Biotechnology workers face medical challenges due to specific risks associated with hosts, vectors, DNA, and physical processes. To date, worker illnesses have been prevented through engineering controls, work practices, vaccinations, and biocontainment measures tailored to specific risks.

METHODS: A management structure exists to assess potential risks for each new experimental protocol ongoing evaluations of environmental risk including persistence, spread, natural trade-offs, host cell characteristics, host range specificity of transfer agents, and gene introduction nature determine the safety of environmental releases across various materials. It is critical to consider these factors to minimize unforeseen impacts on affected environments and species.

INTRODUCTION

1.1 Definition of Biotechnology

Biotechnology involves applying biological systems to technical and industrial processes, encompassing conventional and genetically engineered organisms. Classical biotechnology includes methods like hybridization and interbreeding, used historically to produce various goods from bread and beer to antibiotics. Recently, biotechnology has been employed to treat sewage, human wastewater, and toxic industrial waste[1].

1-2 Modern Biotechnology

Modern biotechnology integrates principles from chemistry and biological sciences with engineering and computer science to produce goods, services, and manage environments. Techniques like genetic material manipulation and cloning enable the creation of genetically modified organisms (GMOs) and engineered clones, marking significant advancements since the 1960s[2].

A-Early Risk Recognition: Since the early 1970s, scientists have recognized both the potential of genetic engineering and its associated risks, leading to calls for global moratoriums on specific experiments. Concerns included the escape of vectors and potential environmental hazards posed by genetically modified microorganisms. Protective measures for laboratory workers were also implemented to mitigate unknown risks[3].

B- Asilomar Conference and Guidelines: In February 1975, the Asilomar Conference in California produced initial consensus guidelines to manage biotechnological risks through biological and physical containment strategies. These guidelines evolved into the National Institutes of Health (NIH) Guidelines in 1976, categorizing research by risk level and imposing corresponding restrictions[4].

1-3 Evolution of Biotechnological Regulations

The NIH Guidelines (NIHG), regularly updated, have become a standard in the United States, requiring compliance from federally funded organizations. These regulations expanded to include containment considerations and approvals for technologies like gene therapy and large-scale production facilities. The US Office of Science and Technology Policy (OSTP) published the Coordinated Framework for Biotechnology Regulation in 1986, aiming to ensure public and environmental safety and minimize regulatory overlaps[5].

A-Growth of the Biotechnology Industry*:* The NIH Guidelines and coordinated framework facilitated the US biotechnology sector's growth into a multibillion-dollar industry. By 1994, the industry employed over 100,000 people, supported by a robust supply chain providing essential supplies, equipment, and services[6].

B-Global Concerns and Regulations: Despite growth, significant global concerns persist regarding biotechnology's safety. The Council of the European Communities developed guidelines to protect workers and environments, mirrored by international organizations like the WHO, ISO, and FAO, which have established standards and guidelines for biotechnology products[7].

1-4 Biotechnology Workers

Biotechnology spans research laboratories and involves interdisciplinary professionals such as molecular and cell biologists, immunologists, geneticists, biochemists, and biochemical engineers. These workers face real and potential risks associated with recombinant DNA (rDNA) technology[8]. Approximately 30 to 40% of the workforce in commercial biotechnology companies, including those in academia, medicine, and government institutions, are exposed either directly or indirectly to these hazards include according to [9] .

A-Hazards and Risks: Laboratory workers encounter a range of hazards including hazardous chemicals, recombinant and non-recombinant biohazards, human blood-borne pathogens, zoonotic diseases, and radioactive materials used in experiments. Musculoskeletal disorders and repetitive strain injuries are also common due to extensive computer and microscope [10]. In manufacturing, operators handle hazardous chemicals and, depending on the process, may be exposed to radionuclides. Biotechnology manufacturing processes typically use closed systems to minimize exposure risks, with biomedically focused facilities adhering to Current Good Manufacturing Practices (CGMP) and biosafety guidelines to safeguard workers[8]. Healthcare workers, including clinical laboratory technicians, encounter gene therapy vectors and laboratory specimens, while agricultural workers face exposure risks during pesticide application, planting, harvesting, and processing of genetically modified organisms. Both groups rely on engineering controls, personal protective equipment (PPE), training, and medical supervision to mitigate these risks according to [11].

B- Expected Risks in Biotechnology**:** Biomedical biotechnology involves cultivating modified cells or organisms in monoculture bioreactors to produce desired products. For example, in mammalian cell cultures, proteins are secreted into nutrient media and purified using separation methods like chromatography. Fermentation with E. coli hosts involves product production within cell membranes, necessitating physical disruption of cells to harvest products, potentially exposing workers to endotoxins. Antibiotics added to media can lead to allergic sensitivities, with aerosol exposure posing a general risk[12]. Control measures include sealed or filtered (0.2 microns) vessel penetrations, exhaust gas filtration, and biological inactivation of effluents to manage aerosol emissions. Other industry-related risks include noise, mechanical hazards, thermal burns, and exposure to corrosive materials, all controlled through stringent safety protocols.

C- Agricultural Biotechnology: Genetic engineering in agriculture accelerates plant trait development, reducing reliance on pesticides and fertilizers. Techniques like the particle gun and non-tumorigenic bacterial tumors are used to introduce engineered DNA into plant cells. Regenerated plants undergo rigorous testing in closed growth chambers and greenhouses to assess genetic stability and environmental impact, supporting regulatory approvals for open field trials[13] .

1-5 Modern Drug Manufacturing Methods Based on Biotechnology include :

A-Human Insulin and Insulin Crystals: Biotechnology's impact on pharmaceutical manufacturing began notably with Genentech's 1978 achievement: modifying Escherichia coli bacteria to produce human insulin. Previously sourced from animal pancreases, animal-derived insulin posed allergy risks due to its non-identical nature. Genentech's method involved integrating artificial genes for insulin's protein chains into plasmids, which were then introduced into E. coli to induce human insulin production[13].

B-Human Growth Hormone: Before recombinant DNA technology, human growth hormone (HGH) was extracted from human pituitary glands, posing supply challenges. In 1979, Genentech used reverse transcription of pituitary mRNA to create a DNA sequence for HGH, integrating it into E. coli. Despite complexities in synthesizing the lengthy HGH DNA strand, this method marked a breakthrough in HGH production[14].

C-Human Blood Clotting Factors: Development of Factor IX: Historically, blood clotting factors were sourced from human blood donations, risking HIV transmission to hemophiliac patients until the mid-1980s. In 1986, using genetically engineered Chinese hamster ovary (CHO) cells, researchers produced Factor IX. By synthesizing cDNA from known Factor IX DNA sequences, researchers mapped and isolated the Factor IX gene on the X chromosome. Transfecting CHO cells with plasmids containing the Factor IX gene and methotrexate resistance genes ensured stable production[15]. Genetically Modified Farm Animals: Recombinant DNA techniques extended to farm animals, enabling production of pharmaceuticals like human hemoglobin from genetically modified pigs. While not transfusable due to species differences, purified hemoglobin from these pigs supports blood substitute manufacturing[16].

1-6 Biotechnology Products

Biotechnology revolutionized pharmaceutical production, yielding diverse products such as human insulin, growth hormone, vaccines such as Hepatitis B, interferons, and tissue plasminogen activators. Other innovations include insecticides, genetically modified foods suc as Flavr Savr Tomato, and enzymes like chymosin for cheese production [15]. Health Risks in Biotechnology: Workers in industrial biotechnology face health risks including infection from microorganisms, inflammatory responses to end toxins, sensitization to microbial components, allergies to biotechnological products, and adverse reactions to toxins produced during biotechnological processes [17].

CONCLUSION:

Biotechnology has reshaped pharmaceutical manufacturing by offering sustainable, cost-effective alternatives to traditional methods. Advances in cell culture and bioreactor technologies continue to drive innovation in healthcare and agriculture, promising future breakthroughs in complex compound production and environmental stewardship.

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