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VACCINE: APPEARANCE AND FURTHER DEVELOPMENT

Vaccines are medicines that are used in medical practice for the purpose of the specific prevention of infectious diseases. They are the result of a complex and lengthy production process.

The first vaccination. On May 14, 1796, an English doctor and a researcher, Edward Jenner (1749-1823) conducted the first procedure, which subsequently revolutionized medicine, opening a new preventive direction. We are talking about vaccination against smallpox, which tens of thousands of years ruthlessly taking millions of lives**.** The village doctor Jenner noticed that peasants who work with cows infected with cowpox do not get sick with dangerous smallpox. Therefore, for the prevention of smallpox, he came up with the idea of introducing into the human body a safe vaccinia virus, to which people quickly develop immunity that protects against smallpox. It was on May 14, 1796 that Jenner instilled cowpox in the boy and proved that he became immune to smallpox. It was from the Latin name of the disease "cowpox" (in Latin - variole vaccine) that the name "vaccine" came from, and in Latin vaccinus means "cow" (from the word "vacca" - "cow").

Research stage

1. Vaccine development and production

A stage in the vaccine development process designed to identify natural or synthetic antigens that can help prevent disease or facilitate the treatment of an infectious disease. Such antigens can include both attenuated strains of the corresponding virus and individual parts thereof.

2. Preclinical studies

At this stage, a candidate vaccine manufactureres typically investigate tissue or cell culture systems and conduct animal studies to determine whether the vaccine candidate will elicit an immune response. Many vaccine candidates do not go to the next stages of development, because they do not meet the established criteria or are generally harmful to experimental animals.

I phase. The candidate vaccine is administered to a small group of volunteers (less than 100 people) in order to determine whether the candidate vaccine is safe and obtain the first data on adverse reactions. This phase is carried out on as healthy people as possible in order to exclude the possible influence of other factors.

II phase. The candidate vaccine is administered to hundreds of people. The purpose of this phase is to obtain information on safety, immunogenicity, immunization schedule and dose value.

III phase. Thousands or tens of thousands of people, different target groups, may be involved in this phase of the study. The objective of this phase is to continue to investigate the safety (rare adverse reactions sometimes do not appear in smaller groups) and efficacy of the candidate vaccine. The minimum number of participants for this phase is 3000 people. As for COVID-19 vaccines, at the present stage of vaccine development, many more people are attracted to this phase, because first of all, it is necessary to vaccinate people with comorbidities and in very large quantities. And

so the number of people in Phase 3 is many times greater to maximally identify rare adverse adverse reactions and guarantee the safety and efficacy of vaccinated people

3. Review of vaccine materials in the NRA for the purpose of its registration and approval of regulatory documents

If the vaccine has passed all three phases of the clinical study, the candidate vaccine developer submits an application with the appropriate package of documents for obtaining a marketing authorization (license) to the National Regulatory Authority.

4. Vaccine production

All stages of the vaccine manufacturing process, testing methods, reagents, industry standard samples must meet the standards defined by Good Manufacturing Practice (GMP) requirements. These strict quality requirements include: specific pharmaceutical quality systems, quality assurance measures and procedures, quality inspection at every stage of production, production processes that can allow to guarantee identification, sterility, batch-to-batch repeatability, vaccine efficacy and safety.

The production of vaccines involves numerous risks and problems, primarily due to the nature of such drugs. Measures to ensure the quality of vaccines must be carried out throughout the production process, including cold chain control from manufacturer to consumer. The creation of any new enterprise is worthwhile, and necessitates investments both in the construction of premises and the establishment of the production process itself (the acquisition or scientific development of modern technology), the training of qualified personnel. In addition, it is necessary to take into account that to start production it is necessary to have production strains (antigens) and carry out their constant support and control.

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