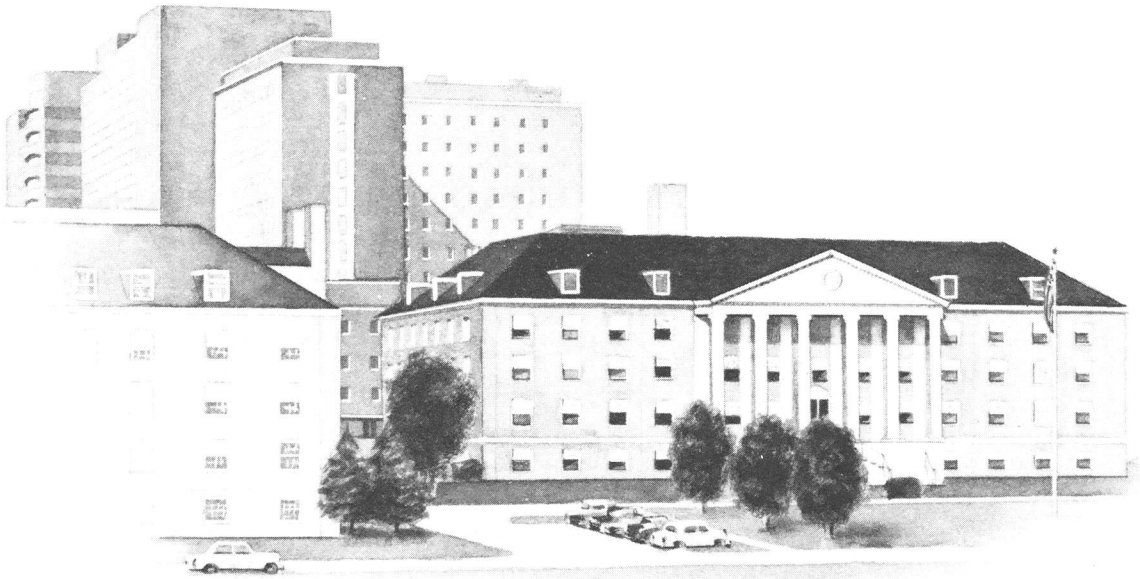
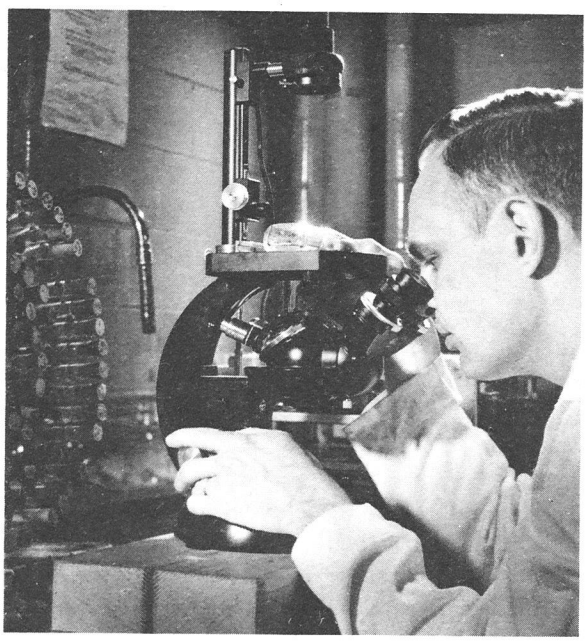


NATIONAL INSTITUTES OF HEALTH

U. S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service, National Institutes of Health

Division of Biologics Standards



Scanning tissue culture cells for presence of virus in safety testing of vaccine

Federal control of biological products for human use began with the passage of the "Biologics Control Act" in 1902. The present statute, though there have been some changes, is basically the same. It regulates the manufacture and sale of vaccines, toxins, antitoxins, blood derivatives, and analogous products applicable to the prevention and cure of diseases in man.

Many biological products are derived from virulent microorganisms, and all are potentially dangerous if improperly prepared and tested. Close surveillance of production and constant improvement of quality are essential. These are responsibilities of NIH. To meet increasing demands, the Division of Biologics Standards was created in June 1955, replacing the Laboratory of Biologics Control.

The Act provides for licenses of two types—establishment licenses and product licenses. Biologics produced under the Act can be imported, exported, or placed in interstate commerce only if they meet the Public Health Service's standards of safety, purity, and potency. The manufacturers give wholehearted cooperation to this authority, which ensures the greatest benefits with the least risk to the consuming public.

As designated by the Surgeon General, the specific aim of the Division is to develop an organization capable of exerting leadership in the field of biologics, based on the concept that their control should rest on a foundation of research. The staff conducts studies, for example, on the fundamental aspects of bacterial and viral infection. Results are contributing to the development of methods for the control of new products and are helping to improve the older ones. For instance, the Clinical Center Blood Bank, operated by the Division, provides an opportunity to improve techniques of blood collection, processing, and transfusion.

The Division is prepared to meet new needs occasioned by the expanding range of diseases to which biological products are applicable and the accelerated discovery of such products, particularly in the field of virology. The antibiotics and sulfa compounds have made little impression on the common virus infections. But principles utilized in the development of a successful poliomyelitis vaccine offer promise of solutions to such baffling problems as mumps, measles, and influenza. It is anticipated that potent biologics yet to be developed will greatly increase the Division's responsibilities.

The control functions of the Division are to recommend the licensing of manufacturers of biologics, to establish standards for a given product, and to see that such standards are maintained. This third function is performed through regular inspection of the manufacturing plants, review of protocols of the manufacturing process, and testing of the product. The tests employ animal inoculation, tissue culture, and other methods to ensure that the requirements for safety, purity, and potency are fulfilled.