

Recent Publications and Documents

Guidance for industry: active pharmaceutical ingredients

This document focuses on the manufacture of active pharmaceutical ingredients (APIs) and will provide guidance to industry on basic requirements expected when filing for or renewing new drug applications within the United States of America. It may also prove useful for the manufacture of excipients.

For the moment, the document is circulated as a draft for comments and is not meant for implementation. However, it will give a good indication of the requirements desired in the manufacture and control of APIs for drugs and biologicals, including chemical isolation and purification steps used for biological or fermentation processes and sterile APIs. It does not apply to medical gases, bulk packaged drug products in final dosage form, and radiopharmaceuticals.

Good manufacturing practices apply to all steps of the API manufacturing process, including the use of starting materials. Such practices include the validation of processes determined to affect the quality and purity of the active pharmaceutical ingredient.

Draft guidance for industry: manufacturing, processing or holding active pharmaceutical ingredients. Available from: Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville MD 20852, USA or through <http://www.fda.gov/cber>.

Guidance for industry: human plasma-derived biological products

The Food and Drug Administration has announced the availability of a draft guidance for industry for the establishment of descriptive information for human plasma-derived biologicals or animal plasma or serum-derived products. The guidance is intended to assist applicants in the preparation of the descriptive section of a licence application for such products. This action is intended to reduce

unnecessary burdens for industry without diminishing public health protection.

Draft guidance for industry for the submission of chemistry, manufacturing and controls and establishment description information for human plasma-derived biological products or animal plasma or serum-derived products. Available from: Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville MD 20852, USA or through <http://www.fda.gov/cber>.

WHO Expert Committee on Drug Dependence

The scale of drug dependence has grown dramatically in the past quarter-century. Preventing dependence and reducing the harm associated with the use of psychoactive substances is a challenge for health services and governments the world over. This WHO Expert Committee report categorizes the different types of harm that can result from psychoactive substances, whether illicit or legally available, and describes the steps that can be taken to treat health problems and stop them from occurring. The report looks at the cost and effectiveness of various treatment methods, drawing on evidence from research findings, and gives a detailed outline of the elements needed for an effective national treatment system. It addresses the question of whether dependent persons should be given a controlled supply of drugs and proposes for further review several substances that have potential for abuse. The Expert Committee's recommendations cover drug policies and treatment services, as well as training, information needs and research. The report lays the foundation for realistic but sound strategies in national and international efforts to reduce the health damage caused by the use of psychoactive substances.

WHO Expert Committee on Drug Dependence. Thirtieth report. WHO Technical Report Series, No. 873, 1998. ISBN 92 4 120873 2

WHO Expert Committee on Biological Standardization: Forty-sixth report

This report represents the recommendations of a WHO expert committee commissioned to coordinate a range of research and other activities required to assure the purity, potency, safety and stability of biological products used in medicine. The report covers the development and adoption of detailed requirements for the manufacturing, licensing and control of vaccines and other biologicals. The committee also coordinates the establishment of international biological reference materials for use in clinical assays, pharmaceutical research and quality control.

The report is divided into three parts. The first provides a brief discussion of general issues that shape the committee's work. Issues discussed include procedures for establishing and distributing reference materials and the rationale for issuing or revising requirements for specific products. The second part summarizes activities relating to the status of some 36 biological reference preparations categorized as antibiotics, antibodies, antigens and related substances; blood products, cytokines, endocrinological substances and toxins.

The third and most extensive part contains detailed revised requirements for the production and control of yellow fever vaccine and amended general requirements for the sterility of biological substances, modified to reflect new procedures for conducting a sterility test for mycoplasmas. Also included are a list of laboratories approved by WHO for the production of yellow fever vaccine and a summary protocol for the routine batch release of virus vaccines.

WHO Expert Committee on Biological Standardization. Forty-sixth report. WHO Technical Report Series, No. 872 1998. ISBN 92 4 120872 4.

Use of antimicrobials in food-producing animals

In October 1997, the World Health Organization convened a meeting to examine the question of whether the use of antimicrobials in livestock production contributes to the escalation of antimicrobial resistance in humans. Timely public health action is needed to control medical problems related to the widespread application of antimicrobials outside the medical sphere. On the agenda were such issues as the development, licensing and use of antimicrobials in livestock production, and clinical microbiology, resistance monitoring and medical infectious disease control.

The meeting reviewed antimicrobial use and the known and potential consequences in food animal production. General recommendations were proposed for action by national control authorities and collaboration within the medical, veterinary and agricultural sectors. It was agreed that WHO should take the lead in coordinating international efforts in resistance monitoring. As a matter of urgency, microbiological laboratories capable of developing networks on resistance monitoring should be strengthened. In this way, countries will be able to ascertain and monitor the prevalence of resistant bacteria in food-producing animal products.

The use of antimicrobials in animals must balance the possible benefits to livestock production against the medical risk and public health consequences deriving from their use. It was emphasized that antimicrobial agents should not be used as a substitute for adequate hygiene in animal husbandry. No antimicrobial should be administered to a food animal unless it has been evaluated and authorized by the national authorities, and prescription and practice standards should be strictly applied.

The medical impact of the use of antimicrobials in food animals: available from the Division of Emerging and Other Communicable Diseases, Surveillance and Control. WHO, Geneva. WHO/EMC/ZOO/97.4.