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# VACCINE MANUAL

The production  
and quality control  
of veterinary vaccines  
for use in  
developing countries





In December 1991, at FAO Headquarters in Rome, the Animal Production and Health Division held an Expert Consultation on the Quality Control of Veterinary Vaccines in Developing Countries. The purpose of the consultation was to bring together experts in various aspects of vaccine production and quality control, to consider existing problems and likely future developments in the application of vaccines for the control of animal disease and to make recommendations in this important field. The consultation recommended that FAO lead the way in forging a closer cooperation among international organizations in the development of a more coherent approach to vaccine quality control; this manual is FAO's response to that recommendation. Written by some of the most highly regarded international experts in the field, the manual is principally concerned with providing guidelines and recommendations for the application of modern methods of vaccine production and evaluation, and also presents information on the state of veterinary vaccine development.

# **VACCINE MANUAL**

**The production  
and quality control  
of veterinary vaccines  
for use in  
developing countries**

**Noel Mowat  
and  
Mark Rweyemamu**

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# Introduction

In December 1991 at FAO headquarters in Rome, the Animal Production and Health Division held an Expert Consultation on the Quality Control of Veterinary Vaccines in Developing Countries.<sup>1</sup>

The purpose of the consultation was to bring together experts in various aspects of vaccine production and quality control to consider present problems and likely future developments in the application of vaccines for the control of animal disease and to make recommendations for further improvements in this important field.

One of the most important conclusions reached at the end of the consultation was: "Discussions at this meeting have repeatedly highlighted duplication of recommendations and procedures from international organizations. WHO, OIE and FAO have previously prepared guidelines and recommendations for various aspects of animal vaccine preparation and quality control. There appears to be a lack of co-ordination or cooperation in undertaking these activities."

As a consequence of this, the following general recommendation was made: "This meeting recommends that a closer co-operation be established with other international organizations to develop a more coherent approach on guidelines for vaccine quality control and to this end *urges FAO to take the initiative*." This manual represents one of FAO's responses to that recommendation.

FAO has been very fortunate in obtaining contributions from some of the best

recognized international experts in the field of veterinary vaccine development, both at the theoretical and the "hands on" practical level. In producing this manual, the intention has been to compile the latest information on all aspects of the production and quality control of vaccines which are primarily intended for use in domestic livestock and, where appropriate, to take into consideration the particular conditions of production and application in the developing countries.

While it is principally concerned with providing guidelines and recommendations for the application of modern methods of vaccine production and evaluation (and as such can have no *mandatory* significance), the manual attempts to bring together information on the state of the art in veterinary vaccine development, with some of the chapters presenting a "definitive" text on certain topics.

It is hoped that the Overview will prove to be of exceptional interest to the majority of readers. Many of the contributions in this section indicate the remarkable impact that modern biotechnology is having on a wide range of topics related to veterinary vaccines. They include work on understanding the mechanisms of immunity and protection against disease, as well as the exploitation of genetic engineering and molecular biology for the development of more effective vaccines, and also cover the particular problems and practical aspects of vaccines for fish and those required for the control of multicellular parasites. There is also a very useful contribution from the Office international des Épidémiologies (OIE) summarizing its functions and activities to promote the standardization of vaccine quality at the international level.

<sup>1</sup> For the proceedings of the expert consultation, see: FAO. 1993. *Quality control of veterinary vaccines in developing countries*. Animal Production and Health Paper No. 116. Rome.



Part 2 of the manual deals with the planning and management aspects of vaccine production and control. Under present-day conditions of financial constraint and limited budgets, efficient planning and management of resources according to modern practice is of paramount importance – and nowhere is this more relevant than in the developing countries. This section is therefore concerned with the design and maintenance of production facilities and equipment, the principles of financial management, the registration and licensing of veterinary immunoprophylactics, the logistics of vaccine manufacture as related to working in the developing countries, and the pros and cons of one solution to setting up vaccine production under such conditions, namely the role of private industry in transferring modern vaccine technology to developing countries.

The next section, Part 3, is devoted to the practical aspects of vaccine production and covers the basic laboratory facilities and services necessary, the application of modern fermentation technology, the preparation of inactivated antigens, the freeze-drying of vaccines, the need for adjuvants in modern vaccines and the requirements for the bottling, packing and distribution of the final product. All of these chapters provide much of the “hard” practical information necessary for running an efficient vaccine production unit.

The final section, Part 4, deals with the major topics of quality assurance and quality control. Chapters cover good laboratory and manufacturing practice, the essential documentation required of a modern unit, the assessment of the safety and potency of vaccines and the statistical interpretation of the results of those tests. There is also a useful chapter on the role and contribution made by the internationally recognized regional laboratories which have responsibilities for the diag-

nosis and characterization of the causative organisms of disease outbreaks of major economic importance, such as foot-and-mouth disease, and also the provision of advice on the most appropriate vaccines and the required standards of efficacy.

At present, animal husbandry and production industries, particularly in the developing countries, are attempting to meet the demands for increased food production from expanding human populations with expectations of higher standards of living.

Infectious disease is a major constraint to the development of improved livestock production, to which the solution for many of the developing countries must be prevention by means of efficient immunization programmes. In a frequently changing environment in which the conditions favour the rapid spread of disease and the possible emergence of new strains of organisms, greater dependence has to be placed on the use of modern biological science to counter these threats. More effective vaccines, produced by up-to-date methods as economically as possible, can make a significant contribution to the control of animal disease. By bringing together some of the latest information and guidelines on modern vaccine technology, this manual is intended to help achieve these aims.