

Seed Lot Culture Technique The Microbiology Network

This report presents the recommendations of a WHO Expert Committee commissioned to coordinate activities leading to the adoption of international recommendations for the production and control of vaccines and other biological substances, and the establishment of international biological reference materials. Following a brief introduction, the report summarizes a number of general issues brought to the attention of the Committee. The next part of the report, of particular relevance to manufacturers and national regulatory authorities, outlines the discussions held on the development and adoption of new and revised WHO Recommendations, Guidelines and guidance documents. Following these discussions, a WHO guidance document on Regulatory assessment of approved rDNA-derived biotherapeutics was adopted along with WHO Guidelines on the stability evaluation of vaccines for use under extended controlled temperature conditions and on WHO good manufacturing practices for biological products. In addition, revised WHO Recommendations to assure the quality, safety and efficacy of recombinant human papillomavirus virus-like particle vaccines were also adopted by the Committee. Subsequent sections of the report provide information on the current status and proposed development of international reference materials in the areas of antibiotics; biotherapeutics other than blood products; blood products and related substances; in vitro diagnostic device reagents; and vaccines and related substances. A series of annexes are then presented which include an updated list of all WHO Recommendations, Guidelines and other documents on biological substances used in medicine (Annex 1). The above four WHO documents adopted on the advice of the Committee are then published as part of this report (Annexes 2-5). Finally, all additions and discontinuations made during the 2015 meeting to the list of International Standards, Reference Reagents and Reference Panels for biological substances maintained by WHO are summarized in Annex 6. The updated full catalog of WHO International Reference Preparations is available at: <http://www.who.int/bloodproducts/catalogue/en/>.

Progress in the field of plant cell and tissue culture has made this area of research one of the most dynamic and promising not only in plant physiology, cell biology and genetics but also in agriculture, forestry, horticulture and industry. Studies with plant cell cultures clearly have bearing upon a variety of problems as yet unsolved in basic and applied research. This was the compelling reason for assembling such a comprehensive source of information to stimulate students, teachers, and research workers. This book comprises 34 articles on regeneration of plants, vegetative propagation and cloning; haploids; cytology, cytogenetics and plant breeding; protoplasts, somatic hybridization and genetic engineering; plant pathology; secondary products and a chapter on isoenzymes, radiobiology, and cryobiology of plant cells. Particular attention has been paid to modern, fast-growing and fascinating disciplines - e.g. the induction of haploids, somatic hybridization and genetic manipulation by protoplast culture, which possess an enormous potential for plant improvement.

Laymen often consider modern laboratory research to be based on an endless array of sophisticated technologies whose complex capabilities are as important to the outcome of any project as the inventiveness and creativity of the scientists who

employ them. Scientists at times may share this point of view until they are confronted by unexpected findings that demand new approaches, and they discover that yesterday's "sophisticated tools" are today's "blunt instruments." This experience provides a more sobering view of the current state of our scientific methods. It also serves as an impetus for the further development of technology that prepares us for the next stage of advance. Immunologists were confronted by such a technological crises in the late 1970s when they finally were forced to admit that poly clonal antibodies, although quite sensitive reagents, were not specific enough to answer many of the questions then confronting virologists and tumor biologists. The answer to the need for specificity came with the development of monoclonal antibody technology. In the last ten years there have been considerable advances in monoclonal antibody techniques. Today these reagents are much more versatile than they were initially and can be applied to a broad range of problems. Still, most workers who are using these antibodies are convinced that their potential is far from exhausted, and that at least in some fields we are currently in the early stages of learning how to use them properly.

An Essential Guide

Seed-Borne Diseases of Agricultural Crops: Detection, Diagnosis & Management

Viruses and Virus Diseases of Vegetables in the Mediterranean Basin

WHO Expert Committee on Biological Standardization

Code of Federal Regulations

Applied and Fundamental Aspects of Plant Cell, Tissue, and Organ Culture

This Book was written to serve those interested in seed pathology. It is designed to serve as a textbook as well as a reference book for students, teachers, and researchers, and for seed health testing, seed production, and plant quarantine personnel. It is to be used as a guide to the literature. Much of the illustrative material has come from the authors' files used for teaching or from their own research. Teachers will want to supplement this book with examples from their own experience and research or with information and data from other seed pathology programs. The authors hope that this book, in addition to being of value to seed and plant pathologists, will be useful to agriculturalists interested in crop production. It was written in part to stimulate research in seed pathology and its importance to the role of seedborne inoculum in the epidemiology and control of plant diseases.

This adaptation of Bentley's Textbook of Pharmaceutics follows the same goals as those of the previous edition, albeit in a new look. The content of the old edition has been updated and expanded and several new chapters, viz. Complexations, Stability Testing as per ICH Guidelines, Parenteral Formulations, New Drug Delivery Systems and Pilot Plant Manufacturing, have been included, with an intention to make the book more informative for the modern pharmacists. The book has six sections: Section I deals with the physicochemical principles. Two new chapters: Complexations and ICH Guidelines for Stability Testing,

have been added to make it more informative. Section II conveys the information regarding pharmaceutical unit operations and processes. Section III describes the area of pharmaceutical practice. Extensive recent updates have been included in many chapters of this section. Two new chapters: Parenteral Formulations and New Drug Delivery Systems, have been added. Section IV contains radioactivity principles and applications. Section V deals with microbiology and animal products. Section VI contains the formulation and packaging aspects of pharmaceuticals. Pilot Plant Manufacturing concepts are added as a new chapter, which may be beneficial to readers to understand the art of designing of a plant from the pilot plant model.

This manual provides all relevant protocols for basic and applied plant cell and molecular technologies, such as histology, electron microscopy, cytology, virus diagnosis, gene transfer and PCR. Also included are chapters on laboratory facilities, operation and management as well as a glossary and all the information needed to set up and carry out any of the procedures without having to use other resource books. It is especially designed for professionals and advanced students who wish to acquire practical skills and first-hand experience in plant biotechnology.

Potato Seed Production for Tropical Africa

Validation Approaches and Global Requirements, Second Edition

Proceedings of the International Workshop on Rice Seed Health, 16-20 March 1987

Principles of Seed Pathology (1987)

Sixty-Third Report

MMWR

Laboratory Techniques in Rabies Diagnosis, Research and Prevention provides a basic understanding of the current trends in rabies. It establishes a new facility for rabies surveillance, vaccine and antibody manufacturing. It offers clarity about the choice of laboratory methods for diagnosis and virus typing, of systems for producing monoclonal and polyclonal antibodies and of methods for testing potency of vaccines and antibodies. The book covers advancements in the classical methods described as well as recent methods and approaches pertaining to rabies diagnosis and research. Supplies techniques pertaining to rabies diagnosis and research Provides an update on the conventional and modern vaccines for rabies prevention Offers updates on the full length antibodies and antibody fragments for post exposure prophylaxis of rabies Presents technique descriptions that can be used to be compared to industry protocols to identify and establish potential new techniques Manual and is a supplement to the United States Pharmacopeia (USP) for pharmaceutical microbiology testing, including antimicrobial effectiveness testing, microbial examination of non-sterile products, sterility testing, bacterial endotoxin testing, particulate matter, device bioburden and environmental monitoring testing. The goal of this manual is to provide an ORA/CDER harmonized framework on the knowledge, methods and tools needed, and to apply the appropriate scientific standards required to assess the safety and efficacy of medical products within FDA testing laboratories. The PMM has expanded to include some rapid screening techniques along with a new section that covers inspectional guidance for microbiologists that conduct team inspections. This manual was developed by members of the Pharmaceutical Microbiology Workgroup and includes individuals with specialized experience and training. The instructions in this document are guidelines for FDA analysts.

When available, analysts should use procedures and worksheets that are standardized and harmonized across all ORA field labs, along with the PMM, when performing analyses related to product testing of pharmaceuticals and medical devices. When changes or deviations are necessary, documentation should be completed per the laboratory's Quality Management System. Generally, these changes should originate from situations such as new products, unusual products, or unique situations. This manual was written to reduce compendia method ambiguity and increase standardization between FDA field laboratories. By providing clearer instructions to FDA ORA labs, greater transparency can be provided to both industry and the public. However, it should be emphasized that this manual is a supplement, and does not replace any information in USP or applicable FDA official guidance references. The PMM does not relieve any person or laboratory from the responsibility of ensuring that the methods being employed from the manual are fit for use, and that all testing is validated and/or verified by the user. The PMM will continually be revised as newer products, platforms and technologies emerge or any significant scientific gaps are identified with product testing. Reference to any commercial materials, equipment, or process in the PMM does not in any way constitute approval, endorsement, or recommendation by the U.S. Food and Drug Administration.

The Beaudette strain of egg-embryo adapted fowl pox vaccine supplied by Veterinary Research Institute, Ipoh was cloned for its ability to grow in tissue culture. The virus was found produce a constant cytopathic effect after 6 passages in tissue culture. The resulting virus was subjected to there cycles of purification by the limiting dilution technique in tissue culture. The ninth passage virus was used as the master-seed for the production of the working seed by the seed-lot system. The seed virus tested for its sterility, purity, identity, safety and antigenicity. [Authors' abstract].

Biology of Populus and Its Implications for Management and Conservation

Federal Register

Fundamental Methods

Isozymes in Plant Genetics and Breeding

Ex Situ Storage of Seeds, Pollen and in Vitro Cultures of Perennial Woody Plant Species

XIX World Congress, Montreal, Quebec, Canada, August 5-11, 1990

Ascochyta blights consistently affect large areas of grain legume production (pea, lentil, chickpea and faba bean) in all countries where they are cultivated. These diseases are capable of causing large yield losses. This book considers the state-of-the-art by taking a comparative approach of Ascochyta blight diseases of cool season food and feed legumes. Topics considered are pathogen diversity, legume genetics and breeding, and integrated disease management.

Wheat Diseases and Their Management addresses biotic and abiotic constrains to wheat production. Besides detailed illustrations and descriptions of the most important diseases of wheat in the world, it offers an updated view on the reemergence of some old diseases and the occurrence of new races of the pathogen. It deals with the sustainability of wheat production through precision agriculture and focuses on the importance of conservation tillage. The book also deals with pillars of integrated disease management which would be eco-friendly and reduce severity of diseases and

yield losses, with acquired Latin-American experiences of more than 40 years.

Seeds provide an efficient means in disseminating plant virus and viroid diseases. The success of modern agriculture depends on pathogen free seed with high yielding character and in turn disease management. There is a serious scientific concern about the transmission of plant viruses sexually through seed and asexually through plant propagules. The present book provides the latest information along with the total list of seed transmitted virus and viroid diseases at global level including, the yield losses, diagnostic techniques, mechanism of seed transmission, epidemiology and virus disease management aspects. Additional information is also provided on the transmission of plant virus and virus-like diseases through vegetative propagules. It is also well known that seed transmitted viruses are introduced into new countries and continents during large-scale traffic movements through infected germplasm and plant propagules. The latest diagnostic molecular techniques in different virus-host combinations along with disease management measures have been included. The book shall be a good reference source and also a text book to the research scientists, teachers, students of plant pathology, agriculture, horticulture, life sciences, green house managers, professional entrepreneurs, persons involved in quarantines and seed companies. This book has several important features of seed transmitted virus diseases and is a good informative source and thus deserves a place in almost all university libraries, seed companies and research organizations.

1985-1999

Bibliography of Agriculture

Maintaining Cultures for Biotechnology and Industry

The Code of Federal Regulations of the United States of America

Seed Technology and Its Biological Basis

The Plant Disease Bulletin

Vaccinology: An Essential Guide outlines in a clear, practical format the entire vaccine development process, from conceptualization and basic immunological principles through to clinical testing and licensing of vaccines. With an outstanding introduction to the history and practice of vaccinology, it also guides the reader through the basic science relating to host immune responses to pathogens. Covering the safety, regulatory, ethical, and economic and geographical issues that drive vaccine development and trials, it also presents vaccine delivery strategies, novel vaccine platforms (including experimental vaccines and pathogens), antigen development and selection, vaccine modelling, and the development of vaccines against emerging pathogens and agents of bioterror. There are also sections devoted to veterinary vaccines and associated regulatory processes. **Vaccinology: An Essential Guide** is a perfect tool for designed for undergraduate and graduate microbiologists and immunologists, as well as residents, fellows and trainees of infectious disease and vaccinology. It is also suitable for all those

involved in designing and conducting clinical vaccine trials, and is the ideal companion to the larger reference book *Vaccinology: Principles and Practice*.

As a group of organisms that are too small to see and best known for being agents of disease and death, microbes are not always appreciated for the numerous supportive and positive contributions they make to the living world. Designed to support a course in microbiology, *Microbiology: A Laboratory Experience* permits a glimpse into both the good and the bad in the microscopic world. The laboratory experiences are designed to engage and support student interest in microbiology as a topic, field of study, and career. This text provides a series of laboratory exercises compatible with a one-semester undergraduate microbiology or bacteriology course with a three- or four-hour lab period that meets once or twice a week. The design of the lab manual conforms to the American Society for Microbiology curriculum guidelines and takes a ground-up approach -- beginning with an introduction to biosafety and containment practices and how to work with biological hazards. From there the course moves to basic but essential microscopy skills, aseptic technique and culture methods, and builds to include more advanced lab techniques. The exercises incorporate a semester-long investigative laboratory project designed to promote the sense of discovery and encourage student engagement. The curriculum is rigorous but manageable for a single semester and incorporates best practices in biology education.

Seedborne pathogens are problematic in all soybean growing areas. Culture dependent methods, the current standard, may only detect a small portion of the microorganisms in a seed lot. Next generation amplicon sequencing of fungal and bacterial DNA revealed over two dozen seedborne microorganisms. Five fungi and bacteria were found using culture methods from the same seed lot.

Current Laboratory Techniques in Rabies Diagnosis, Research and Prevention

Development of Tissue-culture

Volume II

The Plant Disease Reporter

High-Tech and Micropropagation VI

Soybean Seed Quality and Vigor

In recent years, the field of pharmaceutical microbiology has experienced numerous technological advances, accompanied by the publication of new and harmonized compendial methods. It is therefore imperative for those who are responsible for monitoring the microbial quality of pharmaceutical/biopharmaceutical products to keep abreast of the latest changes. *Microbial Limit and Bioburden Tests: Validation Approaches and Global Requirements* guides readers through the various microbiological methods listed in the compendia with easy-to-follow diagrams and approaches to validations of such test methodologies. Includes New and Updated Material Now in its second edition, this work is the culmination of research and discussions with technical experts, as well as USP and FDA representatives on various topics of interest to the pharmaceutical microbiologist and those responsible for the microbial quality of products, materials, equipment, and manufacturing facilities. New in this edition is an entire chapter dedicated to the topic of

biofilms and their impact on pharmaceutical and biopharmaceutical operations. The subject of rapid methods in microbiology has been expanded and includes a discussion on the validation of alternative microbiological methods and a case study on microbial identification in support of a product contamination investigation. Substantially updated and revised, this book assists readers in understanding the fundamental issues associated with pharmaceutical microbiology and provides them with tools to create effective microbial contamination control and microbial testing programs for the areas under their responsibility.

The 7th edition of the European Pharmacopoeia was published July 15 2010 and consists of a two-volume main edition. It is complemented by non-cumulative supplements that are to be kept for the duration of the 7th Edition. Two supplements were published in 2010 and three supplements will be published in each 2011 and 2012. It contains information on all types of active substances used to prepare pharmaceutical products: various chemical substances, antibiotics, biological substances, vaccines for human or veterinary use, immunosera, radiopharmaceutical preparations, herbal drugs and homoepathic preparations. Over 1800 specific and general monographs are included.

Developments in Plant Genetics and Breeding, 1A: Isozymes in Plant Genetics and Breeding, Part A focuses on the advancements in the processes, methodologies, and approaches involved in the study of isozymes, including its role in plant genetics and breeding. The selection first elaborates on the historical perspectives of plant isozymes, plant genetics, and isozyme systems to study gene regulation during development. Discussions focus on the use of isozyme and similar comparisons to study differential gene regulation, gene preservation, dissemination of cultivars, propagation of cultivars and breeding lines, and studies on the effect of viral infection and hormones on isozyme expression. The text then examines allozymes in gene dosage studies, gene mapping, and plastid isozymes. The manuscript takes a look at the genetics of mitochondrial isozymes, evolution of plant isozymes, and detection of somatic variation. Topics include evolution of isozymes in plants, generation of isozymes, glutamate dehydrogenase, glutamate-oxaloacetate transaminase, and malate dehydrogenase. The text also ponders on enzyme activity staining, isozymic variation and plant breeders' rights, genetic purity of commercial seed lots, and use of isozymes in plant disease research. The selection is a valuable reference for researchers interested in the role of isozymes in plant genetics and breeding.

Microbial Limit and Bioburden Tests

Wheat Diseases and Their Management

Vaccinology

European Pharmacopoeia

Proceedings, International Union of Forest Research Organizations, Working Party S2.02-15, White Pine Provenances and Breeding

Recombinant DNA Technical Bulletin

This volume of *Advances in Virus Research* focuses on mycoviruses. The authors and reviews represent the most current and research in the field. A broad range of research is presented from research experts. Contributions from leading authorities in updates on all the latest developments in the field

Poplar is increasingly recognized as an excellent model tree for the study of tree growth and its underlying physiology and genetics. Studying trees of the genus *Populus* (poplars, cottonwoods, aspens), which in their native ecosystems play a major role in the recovery of sites after disturbances, new insights have been gained into plantation culture and the development of improved cultivars. The chapters in this publication, authored by an international group of researchers, one section deals with systematics, genetics, breeding, manipulation and biotic interactions of populus, while the other deals with stress response and the physiology of growth and development. This report presents the recommendations of a WHO Expert Committee commissioned to coordinate activities leading to the development of international recommendations for the production and control of vaccines and other biologicals, and the establishment of international biological reference materials. Following a brief introduction, the report summarizes a number of general issues brought to the attention of the Committee. The next part of the report, of particular relevance to manufacturers and national regulatory authorities, outlines the discussions held on the development of revised WHO Recommendations and Guidelines for a number of vaccines, blood products and related substances. Specific discussion areas included the development of WHO guidance on the quality, safety and efficacy of vaccines (oral, live, attenuated); recombinant malaria vaccines; diphtheria vaccines (adsorbed); tetanus vaccines (adsorbed); diphtheria and tetanus vaccines based on diphtheria and tetanus vaccines; and Japanese encephalitis vaccines (live, attenuated). Subsequent sections then provide information on the current status and proposed development of international reference materials in the areas of vaccines and related substances; blood products and related substances; in vitro diagnostic device reagents; biotherapeutics other than blood products and antibiotics. A series of annexes are then presented which include an updated list of WHO Recommendations, Guidelines and Technical Documents on biological substances used in medicine (Annex 1), followed by a series of WHO Recommendations and Guidelines on the advice of the Committee (Annexes 2-7). All additions made during the meeting to the list of International Standards and Technical Reagents for biological substances maintained by WHO are then summarized in Annex 8.

Cell and Tissue Culture Techniques for Cereal Crop Improvement

Pharmaceutical Microbiology Manual

Proceedings of a Workshop

Morbidity and Mortality Weekly Report

Bentley's Textbook of Pharmaceutics - E-Book

Rice Seed Health

Edited by a renowned seed biologist with a team assembled from the most respected seed laboratories worldwide, *Seed Technology and Its Biological Basis* illustrates the commercial value of seeds as a major resource. The editors provide a sweeping overview of

the current state-of-the-art in seed technology and its biological basis. The book is invaluable to researchers and professionals in both the industrial and academic sectors. The Code of Federal Regulations is the codification of the general and permanent rules published in the Federal Register by the executive departments and agencies of the Federal Government.

The global population is increasing rapidly, and feeding the ever-increasing population poses a serious challenge for agriculturalists around the world. Seed is a basic and critical input in agriculture to ensure global food security. Roughly 90 percent of the crops grown all over the world are propagated by seed. However, seed can also harbour and spread pathogens, e.g. fungi, bacteria, nematodes, viruses etc., which cause devastating diseases. Seed-borne pathogens represent a major threat to crop establishment and yield. Hence, timely detection and diagnosis is a prerequisite for their effective management. The book "Seed-Borne Diseases of Agricultural Crops: Detection, Diagnosis & Management" addresses key issues related to seed-borne/transmitted diseases in various agricultural crops. Divided into 30 chapters, it offers a comprehensive compilation of papers concerning: the history of seed pathology, importance of seed-borne diseases, seed-borne diseases and quarantine, seed health testing and certification, detection and diagnosis of seed-borne diseases and their phytopathogens, host-parasite interactions during development of seed-borne diseases, diversity of seed-borne pathogens, seed-borne diseases in major agricultural crops, non-parasitic seed disorders, mechanisms of seed transmission and seed infection, storage fungi and mycotoxins, impact of seed-borne diseases on human and animal health, and management options for seed-borne diseases. We wish to thank all of the eminent researchers who contributed valuable chapters to our book, which will be immensely useful for students, researchers, academics, and all those involved in various agro-industries.

Sixty-sixth Report

Influencing Factors, Measurement, and Pathogen Characterization

Microbiology

Seed-borne plant virus diseases

A Laboratory Experience

Plant Cell, Tissue and Organ Culture

To retain their usefulness, cultures that manufacture economically valuable products must be uncontaminated, viable, and genetically stable. *Maintaining Cultures for Biotechnology and Industry* gives practical advice necessary to preserve and maintain cells and microorganisms important to the biotechnology and pharmaceutical industries in ways that ensure they will continue to be able to synthesize those valuable metabolites. This book covers not just those strains currently being used but also those yet to be discovered and engineered. This text is essential for anyone working with cultures who wants to avoid the frustration of losing strains and needs to be able to devise and evaluate new strategies for preservation. Written by hands-on experts in their respective fields Contains helpful tables and protocols for preserving or maintaining cells, cultures and viruses Discusses means to preserve cells by freezing, lyophilization, drying, cyoprotection, spore storage, continuous propagation and subculturing when absolutely necessary, and others Gives information needed to test cultures for stable retention of important characteristics Gives principles needed to devise and evaluate preservation strategies for newly identified and newly engineered cells and organisms Lists culture sources for each class of organism Includes information for characterizing and monitoring recombinant organisms, especially important because of their propensity for genetic stability Discusses the history of the continually evolving field of culture preservation Examines the importance of genetically stable cultures as it relates to maintaining patent positions

Special edition of the Federal Register, containing a codification of documents of general applicability and future effect ... with ancillaries.

This volume, fifth in the series High-Tech and Micropropagation, contains 24 chapters arranged in the following three sections: I. Vegetables and Fruits: garlic, *Amaranthus*, *Brassica oleracea*, pepper, watermelon, cassava, banana, *Myrtus communis*, passionfruit, *Polymnia sonchifolia*, pepino, and spinach. II. Grasses: bamboos, *Caustis dioica*, *Dendrocalamus*, *Miscanthus x giganteus*, sugarcane. III. Trees: *Aegle marmelos*, *Eucalyptus*, *Fraxinus excelsior*, *Juglans cinerea*, *Pinus virginiana*, *Prosopis*, and *Ulmus*. This book is of use to research workers, advanced students, and teachers in the fields of horticulture, forestry, botany, and plant biotechnology in general, and also to individuals interested in industrial micropropagation.

Plant Disease Reporter

Ascochyta blights of grain legumes

Methods of Hybridoma Formation