Afrikanische Arzneipflanzen und Jagdgifte. Chemie, Pharmakologie, Toxicologie

Hans Dieter Neuwinger, Wissenschaftliche Verlagsgesellschaft mbH Stuttgart, Germany, 1998. 960 pp., DM 178.-; ISBN 3-8047-1550-8

With its detailed review of more than 270 common, but potentially toxic or medicinally interesting African plants, this book is outstanding in that it combines skilfully and concisely, in a single volume, a variety of information on the nature of these plants and on their use as hunting poisons.

The book is well organized and is divided into sections which deal with the respective plant families.

Each monograph covers a variety of subjects. The information includes both species and native name, habitat, a comprehensive botanical description of the plant and a study of its pharmacological and toxicological effects. The use of the plant as either a medication or as a hunting poison and the symptoms of the poisoning caused by the substance are described.

The monographs are illustrated by geographical and plant drawings and by structural formulae. Some beautiful plant pictures are also included.

A list of references is provided for each monograph and these should prove useful if more details on some specific subject were needed.

Furthermore, this book also includes several short but interesting chapters dealing with various topics such as larva poisons, poisons used for fishing and an impressive list of references on the traditional African medicines.

This book is a very good reference and should be recommended to medical practitioners, pharmacists, biologists, botanists and chemists. It deserves to be translated from German to English to ensure a wider distribution.

Fortunately, there are some people, who because of their passion, do not let knowledge such as this to be lost.

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Validation Fundamentals: How To, What To, When To Validate

William Gibson, Keith Powell-Evans (Editors), Interpharm Press, Buffalo Grove, IL, USA (1998)

The authors present a book which is intended to give an elementary introduction into the philosophy of validation as well as a guidance on how to do it.

In the first Chapter (pp. 1–36) 'What is validation?' validation is defined as 'the means by which the members of the pharmaceutical industry demonstrate to themselves, to governmental regulators and to the general public that they have taken, are taking and will take the best possible actions to secure the integrity of their products'. It is outlined that five validation categories are presently established: Process validation, Equipment and utilities validation, Computer validation, Analytical and Cleaning validation. A flow chart shows how each of these categories is broken down into the four qualification stages: Design Qualification (DQ), Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ). In further subchapters, the scope of the validation master plan as well as of the protocols of the various qualification stages is outlined.

Chapter two (pp. 37–50) gives a short overview on the history of validation. This summary is focused on the developments in the USA and the UK. With one exception, the contributions made by WHO or other European countries are not mentioned.

In Chapter 3, the following questions are raised: 'Why do we validate? How much does it cost?' The basic answer to the first question is given by the statement that 'the manufacturer is directed by GMPs and cGMP guidelines which he is bound to follow'. This is enforced by reference to the FDC Act, Section 401(a)(2)(B). The next statement however, 'Information on cost, efficiency and necessity are recorded in a familiar and understandable way' can not be deduced from the definition of validation given in the first chapter nor from the GMP or cGMP guidelines. It describes an often observed tendency of people involved in the validation business to penetrate all areas of pharmaceutical industry even if there is no direct link to the manufacture of drug products. The discussions on the cost of validation are not really helpful.

Chapter 4 deals with the question 'Who is responsible for Validation?'. A major role is assigned to the 'dedicated working party' which 'is convened to define, instigate, progress, collate, co-ordinate and, ultimately, approve the entire effort including all the documentation generated'. This working party includes preferably the following staff members: 'Head of quality assurance, Head of Engineering, Validation Manager, Production Manager' and Specialist validators from all areas. This team 'provides direction as well as controls the interdepartmental flow of information'.

In Chapter 5 the question is raised 'How does validation affect you?'. As already mentioned in Chapter 3 'only competent, qualified persons shall be active' in validation. 'This means trained personnel'. In Chapter 6 (pp. 79–97) 'Validation policy, Strategy Protocols and the Validation Report', the various issues mentioned in the headline are discussed at length. In addition, flow charts on protocol development, on the application of the validation process as well as on validation development conceptual activities are given. This information is completed by forms on the pages 1–4 of the validation report.

Chapter 7 (pp. 99–116) gives an answer to the question 'What Activities support the Validation Effort?' A series of