# INTRODUCTION

This book has been prepared in address the requirements of that section of the *Guide to the Knowledge and Practical Experience Required by Qualified Persons in the Pharmaceutical Industry* (the "Study Guide") concerned with pharmaceutical microbiology reproduced below:

The Qualified Person must understand the significance of the presence of bacteria, yeasts, moulds, viruses and toxins in pharmaceutical raw materials, products and production environments. In addition, they must understand how to prevent contamination by good product design, GMP and control over starting materials, intermediates, finished products, production plant and processes, people and the environment.

Applicants will be expected to demonstrate an understanding of the following:

· sources and types of micro-organisms as related to pharmaceutical production;

· production of sterile products and associated environmental controls;

· bacterial endotoxins and pyrogens - sources, removal and testing;

· microbiological test methods for use in routine production;

· microbiology of water, its production and distribution systems;

· microbiology of non-sterile production environments and products;

· sterilisation and disinfection methods;

· interpretation of microbiological data;

· validation of microbiological test methods;

· microbiological specifications;

· selection and use of preservatives.

In addition, applicants will be expected to have an awareness of the following:

· microbiological test methods used in product development;

· biological test methods and interpretation of results;

· rapid methods of microbiological testing.

This book has been prepared on the principle of devoting each page to one particular key topic; the key topic being identified at the head of the page.

This book neither uses the headings of the Study Guide nor the sequence of the Study Guide. In my experience of delivering didactic training in pharmaceutical microbiology I have found that these headings and this sequence do not build up progressively in a way that assists learning. Therefore, in order to assure the reader that the coverage is appropriate, the section(s) of the Study Guide addressed by each key topic is/are addressed on the page opposite each key topic.

Within each key topic I have endeavored to provide the information which a QP should know in as simple and easily digestible a manner as possible. In recognition that this format offers a very limited depth of information, the page opposite to that covering each key topic lists published references on that topic and where supporting information may be available on the internet, this has been identified too.

I envisage this book to be useful in several ways:

- As a quick guide for QP candidates preparing themselves for their assessment board
- As a refresher guide for QP's when faced with hopefully rather rare actual or potential microbiological problems
- As a starting point for QP's who may wish to explore pharmaceutical microbiology in greater depth than just the requirements of the Study Guide
- As a starting point for microbiology graduates entering the pharmaceutical industry who may well be unfamiliar with the peculiarities of its problems and technologies.

I hope you find it useful too.

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