Qualified Persons involved in the manufacture of pharmaceuticals

Study Guide

The knowledge and practical experience required by Qualified

Contents

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Preface

The three professional bodies requi re an applicant for certification of eligibility for nomination as a Qualified Person to demonstrate a thorough understanding of the foundation knowledge elements, to apply their knowledge of Pharmaceutical Quality System (PQS) principles, and to demonstrate understanding of the additional knowledge requirements. The applicant will be required to demonstrate this by reference to the products and processes for which they are claiming qualifying experience, which will apply wholly or in part to the Manufactur e & Importation Authorisation (known as a Licence herein) detailed on the application. The applicant will also be expected to demonstrate an ability to translate those principles and requirements to other dosage forms or scenarios currently outside their direct experience.

1.0 The Qualified Person involved in the manufacture of pharmaceuticals: background.

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3.0 Additional knowledge requirements for the Qualified Person

d. Mathematics and statistics

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e. Medicinal chemistry and therapeutics

g. Pharmaceutical microbiology

h. Analysis and testing

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i. Pharmaceutical packaging

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j. Active Substances and Excipients

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7.0 Summary

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