

Preface

This volume presents a systematic approach to understanding the essential elements required for a successful GMP analytical chemistry department to function as an efficient and effective organization. It describes in detail a department structure which allows for the necessary processes to become available to all its personnel. This department structure facilitates the free flow of information and interactions within the department. The environment and culture created by this approach encourages and rewards the sharing of ideas, skills, and abilities among department personnel.

The essential elements such as SOPs, regulatory guidances/guidelines, project teams, technical and department processes, statistical concepts, outsourcing, mentoring and hiring the best are among the many topics that are discussed in detail and how they can be implemented to build an efficient and effective analytical department.

Essential Elements for a GMP Analytical Chemistry Department can be an asset to all companies that perform GMP analytical method development, validation, analyses, etc. This book is an essential addition to the library for all start-ups, generic pharmaceutical companies, and contract research organizations. In addition, it can be an important subject as part of a university Pharmaceutical Technology program.

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