

Introduction To Pharmaceuticals Ashok Gupta

David Sedaris plays in the snow with his sisters. He goes on vacation with his family. He gets a job selling drinks. He attends his brother's wedding. He mops his sister's floor. He gives directions to a lost traveler. He eats a hamburger. He has his blood sugar tested. It all sounds so normal, doesn't it? In his newest collection of essays, David Sedaris lifts the corner of ordinary life, revealing the absurdity teeming below its surface. His world is alive with obscure desires and hidden motives -- a world where forgiveness is automatic and an argument can be the highest form of love. Dress Your Family in Corduroy and Denim is another unforgettable collection from one of the wittiest and most original writers at work today.

This book explains both the basic science and the applications of biotechnology-derived pharmaceuticals, with special emphasis on their clinical uses. The foundations of pharmaceutical biotechnology lie mainly in the capability of plants, microorganism, and animals to produce low and high molecular weight compounds useful as therapeutics. Pharmaceutical biotechnology has flourished since the advent of recombinant DNA technology and metabolic engineering, supported by the well-developed bioprocess technology. A large number of monoclonal antibodies and therapeutic proteins have been approved, delivering meaningful contributions to patients' lives, and the techniques of biotechnology are also a driving force in modern drug discovery. Due to this rapid growth in the importance of biopharmaceuticals and the techniques of biotechnologies to modern medicine and the life sciences, the field of pharmaceutical biotechnology has become an increasingly important component in the education of pharmacists and pharmaceutical scientists. This book will serve as a complete one-stop source on the subject for undergraduate and graduate pharmacists, pharmaceutical science students, and pharmaceutical scientists in industry and academia.

To facilitate the development of novel drug delivery systems and biotechnology-oriented drugs, the need for new excipients to be developed and approved continues to increase. Excipient Development for Pharmaceutical, Biotechnology, and Drug Delivery Systems serves as a comprehensive source to improve understanding of excipients and forge new avenue

Caste, Business, and Industry in a Modern Nation

Practical Pharmaceutics

An Introduction to P-Glycoprotein

A Textbook of Pharmacognosy and Phytochemistry

Pharmaceutical Applications of Raman Spectroscopy

For First Year Diploma in Pharmacy

Despite considerable technological advances, the pharmaceutical industry is experiencing a severe innovation deficit, especially in the discovery of new drugs. Innovative Approaches in Drug Discovery: Ethnopharmacology, Systems Biology and Holistic Targeting provides a critical review and analysis of health, disease and medicine, and explores possible reasons behind the present crisis in drug discovery. The authors illustrate the benefits of systems biology and pharmacogenomics approaches, and advocate the expansion from disease-centric discovery to person-centric therapeutics involving holistic, multi-target, whole systems approaches. This book lays a path for reigniting pharmaceutical innovation through a disciplined reemergence of pharmacognosy, embracing open innovation models and collaborative, trusted public-private partnerships. With unprecedented advances made in the development of biomedically-relevant tools and technologies, the need is great and the time is now for a renewed commitment towards expanding the repertoire of medicines. By incorporating real-life examples and state-of-the-art reviews, this book provides valuable insights into the discovery and development strategies for professionals, academicians, and students in the pharmaceutical sciences. Analyzes the reasons behind historical drug failures to provide valuable insights on lessons learned Uses current scientific research to promote learning from traditional knowledge systems and through the integration of traditional and western medicines Discusses advances in technologies and systems biology to support the transition from formulation discovery to therapeutic discovery

This book covers the recent innovations relating to various bioactive natural products (such as alkaloids, glycosides, flavonoids, anthraquinones, steroids, polysaccharides, tannins and polyphenolic compounds, volatile oils, fixed oils, fats and waxes, proteins and peptides, vitamins, marine products, camptothecin, piperines, carvacrol, gedunin, GABA, ginsenosides) and their applications in the pharmaceutical fields related to academic, research and industry.

The Qualified Success And General Appeal Of Medicinal Chemistry Is Not Only Confined To The Indian Subcontinent, But It Has Also Won An Overwhelming Popularity In Other Parts Of The World. Specific Care Has Been Taken To Maintain And Sustain The Fundamental Philosophy Of The Textbook Embracing Rigidly The Original Pattern And Style Of Presentation With A Particular Expatiated Treatment Of Synthesis Of Potential Medicinal Compounds For The Ultimate Benefits Of The Teachers And The Taught Alike. The Present Thoroughly Revised And Skilfully Expanded Fourth Edition Essentially Contains Three New And Important Chapters, Namely : Molecular Modeling And Drug Design (Chapter 3), Adrenocortical Steroids (Chapter 24), And Antimycobacterial Agents (Chapter 26) So As To Make The Textbook More Useful To Its Readers. With The Advent Of Thirty Chapters The Present Updated Form Of Medicinal Chemistry Will Prove To Be An Asset For M. Pharm./B. Pharm. Degree Students, M. Sc. Pharmaceutical Chemistry, M.Sc. Applied Chemistry And M. Sc. Industrial Chemistry Throughout The Indian Universities. Medicinal Chemistry Appears As A Newly Designed And Artistically Presented In A Two-Colour Scheme So As To Facilitate A Distinctly More Effective Use Of The Book. This Highly Readable, Lucid, Handy, And Exceptionally Knowledgeable Textbook Will Definitely Win A Better, Bigger, And Confident Place For Itself Amongst Its

Valued Readers.

Dress Your Family in Corduroy and Denim

Dosage Form Design Considerations

Regulatory Affairs in the Pharmaceutical Industry

Perspectives and Promotion

Pharmaceutics-II

Polymer Gels

Alginates in Drug Delivery explores the vital precepts, basic and fundamental aspects of alginates in pharmaceutical sciences, biopharmacology, and in the biotechnology industry. The use of natural polymers in healthcare applications over synthetic polymers is becoming more prevalent due to natural polymers' biocompatibility, biodegradability, economic extraction and ready availability. To fully utilize and harness the potential of alginates, this book presents a thorough understanding of the synthesis, purification, and characterization of alginates and their derivative. This book collects, in a single volume, all relevant information on alginates in health care, including recent advances in the field. This is a highly useful resource for pharmaceutical scientists, health care professionals and regulatory scientists actively involved in the pharmaceutical product and process development of natural polymer containing drug delivery, as well as postgraduate students and postdoctoral research fellows in pharmaceutical sciences. Provides a single source on the complete alginate chemistry, collection, chemical modifications, characterization and applications in healthcare fields Includes high quality illustrations, along with practical examples and research case studies Contains contributions by global leaders and experts from academia, industry and regulatory agencies who are pioneers in the application of natural polysaccharides in diverse pharmaceutical fields

I-Dispensing Pharmacy - II-Dispensed Medications - a-Monophasic Liquid Dosage Forms - b-Biphasic Liquid Dosage Forms - c- Semi-solid Dosage Forms - III - Sterile Dosage Forms

Natural bioactive compounds from medicinal plants are inexplicably diverse in chemical structure and biological properties. The unmet therapeutic requirements for various diseases serve as a guide for researchers to study natural compounds. These studies are intended to isolate, identify the structural characterization and eventually discover the pharmacological activity of natural compounds from their plant sources with the goal of treating specific diseases. Bioactive Phytochemicals: Drug Discovery to Product Development explores the scope and approaches of drug discovery from natural products. Chapters in the book cover information about the cultivation, collection and processing of medicinal plants, the methods and high throughput techniques for isolation and characterization of bioactive phytochemicals and pharmacological screening for activity, formulation and quality control. Information about the regulations specified for natural medicinal products in different region of the world is also presented, followed by a concluding chapter devoted to the role of natural herbal products for treatment of human diseases such as cancer, cardiovascular diseases, diabetes, obesity, inflammation and neurological disorders. Each chapter concludes with a general reference section, which is a bibliographic guide to more advanced texts. The contributing authors for this volume are drawn from a rich blend of experts in various areas of herbal medicine which encompass herbal drug discovery to product development. The concise and organized layout along with a broad coverage of phytochemistry and drug discovery makes this book a suitable reference for students of medicinal chemistry, researchers and industry professionals interested in herbal product development.

Nanobiomaterials in Cancer Therapy

Lachman/Lieberman's

Anticancer Drug Development

PHARMACEUTICS-I

REVIEW OF PHARMACOLOGY.

Ethnopharmacology, Systems Biology and Holistic Targeting

Importance And Scope Of Medicinal Plants 1 2. Classification Of Crude Drugs 6 3. Drug Adulteration 16 4. Biogenesis Of Phyto-Pharmaceuticals And Basic Metabolic Pathways 45 5. Chemical Nature Of Phytoconstituents 62 6. Extraction Techniques 74 7. Industrial Production And Analysis Of Phytoconstituents 79 8. Marine Pharmacognosy 99 9. Indigenous System Of Medicines 107 10. Plant Tissue Culture 130 11. Pharmaceutical Enzymes 136 12. Primary Metabolites 141 12.1 Carbohydrates 141 12.2 Proteins 166 12.3 Lipids 175 13. Secondary Metabolites 207 13.1 Alkaloids 207 13.2 Glycosides 228 13.3 Tannins 245 13.4 Terpenoids 252 13.5 Resins And Resin Combinations 262 14. Plant Fibres 267 15. Natural Dyes 273 Question Papers

Pharmaceuticals and Personal Care Products Waste Management and Treatment Technology: Emerging Contaminants and Micro Pollutants provides the tools and techniques for identifying these contaminants and applying the most effective technology for their remediation, recovery and treatment. The consumption of pharmaceuticals and personal care products (PPCPs) has grown significantly over the last 35 years, thus increasing their potential risk to the environment. As PPCPs are very difficult to detect and remove using conventional wastewater treatment methods, this book provides solutions to a growing problem. Includes sampling, analytical and characterization methods and technology for detecting PPCPs in the environment Provides advanced treatment and disposal technologies for the removal of PPCPs from wastewater, surface water, landfills and septic systems Examines the pathways of PPCPs into the environment

Effective from 2008-09 session, U.P.T.U. has introduced the subject of manufacturing processes for first year engineering students of all streams. This textbook covers the entire course material in a distilled form.

Evaluation of Herbal Medicinal Products

Innovative Approaches in Drug Discovery

Recent Progress and Future Applications

Introduction to Pharmaceutics, Vol. I , 3e

Introduction to Pharmaceutics, Vol.II (According to the Education Regulation 1991), 4e

Manufacturing Process

Raman spectroscopy has advanced in recent years with increasing use both in industry and academia. This is due largely to steady improvements in instrumentation, decreasing cost, and the availability of

chemometrics to assist in the analysis of data. Pharmaceutical applications of Raman spectroscopy have developed similarly and this book will focus on those applications. Carefully organized with an emphasis on industry issues, *Pharmaceutical Applications of Raman Spectroscopy*, provides the basic theory of Raman effect and instrumentation, and then addresses a wide range of pharmaceutical applications. Current applications that are routinely used as well as those with promising potential are covered. Applications cover a broad range from discovery to manufacturing in the pharmaceutical industry and include identifying polymorphs, monitoring real-time processes, imaging solid dosage formulations, imaging active pharmaceutical ingredients in cells, and diagnostics.

P-glycoprotein (P-gp), encoded by the multidrug-resistance (MDR)-1 gene is one of the best studied efflux transporters that is linked to multidrug resistance in cancer chemotherapies. P-gp belongs to the ATP-binding cassette (ABC) transporter family of proteins that utilizes energy derived from hydrolysis of ATP to efflux endogenous and exogenous xenobiotics, metabolites and toxins from the intracellular space to the outside, thereby providing a general protective role. P-gp is expressed on the apical plasma membrane of all major drug eliminating organs such as the intestine (enterocytes), liver (bile canaliculi), kidney (proximal tubules), brain (endothelia of blood-brain barrier) and in certain tumor types. In the intestine and BBB, P-gp limits entry of drugs by actively pumping drugs back into the lumen or blood, respectively. In the liver and kidney, P-gp actively effluxes drugs, endogenous substances and metabolites into bile or urine, thereby removing them from the body. Upregulation of P-gp in tumor cells is noted in several cancers and is a hallmark for drug resistance. Additionally, P-gp is also shown to play a role in neurogenesis and maintaining homeostasis in the brain. Alteration of P-gp expression is observed in neurodegenerative diseases, highlighting its importance in maintaining normal brain health. Due to its central role in defining oral pharmacokinetics, systemic clearance, tissue exposure, organ health and chemoresistance, much of the research has been focused on modulating P-gp. Chemical inhibitors, formulation-based and epigenetic approaches are applied to modulate P-gp activity with a goal to improve oral pharmacokinetics, increase tumor and brain penetration, minimize organ toxicity and potentially treat neurodegenerative diseases. Although enormous research on P-gp has been published, a book chapter exclusively and comprehensively covering diverse aspects of P-gp, including the recent developments in the field, is required. With much enthusiasm from the publisher, we have collaborated to bring together wide-ranging topics on P-gp. This book contains 12 chapters covering the structure, function, regulation, distribution and expression of P-gp, its pharmacological importance in health and disease and role in pharmacokinetics and drug-drug interactions. Also included are computational approaches to identify selective inhibitors and tactics to modulate P-gp function using chemical inhibitors (synthesized or isolated from marine sources), formulation strategies or epigenetic approaches. The last chapter describes various methods to quantify P-gp expression levels and function in in vitro, in situ and in vivo settings. It is our sincere hope that this material will serve as an important desk reference for students, researchers and clinical scientists in academia, medical research and the pharmaceutical industry working in various fields such as pharmacology, pharmacy, toxicology, medicinal chemistry, pharmaceutical sciences, pharmacokinetics and computational biology. Finally, we wish to acknowledge the contributions of all the authors who passionately contributed to this book. We also extend our gratitude to the editorial staff and production manager at Nova publishers. Lastly, but most importantly, we thank our families for their continued support during this journey.

This book summarizes the recent advances in the science and engineering of polymer-gel-based materials in different fields. It also discusses the extensive research developments for the next generation of smart materials. It takes an in-depth look at the current perspectives and market opportunities while pointing to new possibilities and applications. The book addresses important topics such as stimuli responsive polymeric nanoparticles for cancer therapy; polymer gel containing metallic materials; chemotherapeutic applications in oncology; conducting polymer-based gels and their applications in biological sensors; imprinted polymeric gels for pharmaceutical and biomedical purposes; applications of biopolymeric gels in the agricultural sector; application of polymer gels and their nanocomposites in electrochemistry; smart polyelectrolyte gels as a platform for biomedical applications; agro-based polymer gels and their application in purification of industrial water wastes; polymer gel composites for bio-applications. It will be of interest to researchers working in both industry and academia.

Advances in Pharmaceutical Biotechnology

Targeting Chronic Inflammatory Lung Diseases Using Advanced Drug Delivery Systems

The Theory and Practice of Industrial Pharmacy

India's New Capitalists

Pharmaceutical Quality Assurance

R.C.C. Designs (Reinforced Concrete Structures)

Among the highlights of this book are the use of nanotechnology to increase potency of available insecticides, the use of genetic engineering techniques for controlling insect pests, the development of novel insecticides that bind to unique biochemical receptors, the exploration of natural products as a source for environmentally acceptable insecticides, and the use of insect genomics and cell lines for determining biological and biochemical modes of action of new insecticides.

In order to do business effectively in contemporary South Asia, it is necessary to understand the culture, the ethos, and the region's new trading communities. In tracing the modern-day evolution of business communities in India, this book uses social history to systematically document and understand India's new entrepreneurial groups.

Biopolymer-Based Formulations: Biomedical and Food Applications presents the latest advances in the synthesis and characterization of advanced biopolymeric formulations and their state-of-the-art applications across biomedicine and food science. Sections cover the fundamentals, applications, future trends, environmental, ethical and medical considerations, and biopolymeric architectures that are organized in nano, micro and macro scales. The final section of the book focuses on novel applications and recent developments. This book is an essential resource for researchers, scientists and advanced students in biopolymer science, polymer science, polymer chemistry, polymer composites, plastics engineering, biomaterials, materials science, biomedical engineering, and more. It will also be of interest to R&D professionals, scientists and engineers across the plastics, food, biomedical and

pharmaceutical industries. Provides in-depth coverage of methods for the characterization of the physical properties of biopolymeric architectures Supports a range of novel applications, including scaffolds, implant coatings, drug delivery, and nutraceutical encapsulation systems Includes the use of experimental data and mathematical modeling, thus enabling the reader to analyze and compare the properties of different polymeric gels

Bioactive Natural Products for Pharmaceutical Applications

Drug Discovery to Product Development

Perspectives on Quality, Safety and Efficacy

Pharmaceutical Chemistry - I

Drug Store and Business Management

The third edition of the now popular and successful book includes Board Question Papers 2010 to 2017. The book is written, presented and published to meet the requirements of students of diploma in pharmacy. Written in a lucid and simple language, it attempts to demystify and simplify the basic concepts for the students of pharmacy for proper understanding of the subject and to get a sure success in the state board examinations.

Nanobiomaterials in Cancer Therapy presents the major applications of nanobiomaterials in oncology, offering an up-to-date overview of the latest research in this field. Utilizing nanobiomaterials, novel therapeutic approaches enable significant improvements in drug-loading capacity, formulation stability and drug efficiency. In this book, leading researchers from around the world share their expertise and unique insights. The book covers the fabrication methods of platforms for multimodal and combinatorial therapeutic options, along with simultaneous and real-time cancer imaging, and innovative approaches for oncology by passive or active pathways of multifunctional nanocarriers. The work also classifies and discusses engineered nanobiosystems for cancer therapy, prevention, and low cancer recurrence or relapse. This book will be of interest to postdoctoral researchers, professors and students engaged in the fields of materials science, biotechnology and applied chemistry. It will also be highly valuable to those working in industry, including pharmaceuticals and biotechnology companies, medical researchers, biomedical engineers and advanced clinicians. A comprehensive resource for researchers, practitioners and students working in biomedical, biotechnological and engineering fields A valuable guide to recent scientific progress and the latest application methods

Discusses novel opportunities and ideas for developing or improving technologies in nanomedicine and nanobiology

"This book presents a structural approach to the evaluation of herbal medicinal products for quality, safety and efficacy. There has been an enormous growth in the market for herbal medicinal products in the last twenty five years. However the rediscovery of natural substances with therapeutic potential has raised questions of quality, safety and efficacy on the part of the consumer and also from health professionals. This book brings together current thinking and practice in these areas highlighting current research. In the light of increasing legislation to enforce better standards for these products and the demand by legislators and the public for assurance of safe and effective use, this book seeks to provide a state-of-the-art review, which informs and guides those who seek to promote their use. This book also gives an overview of the place of ethno pharmacology in the development of herbal medicinal products and discusses good agricultural and collection practices, marker analysis and stability testing which contribute to assessment of good quality of these materials." -- Publisher description.

Medicinal Chemistry

Insecticides Design Using Advanced Technologies

Emerging Contaminants and Micro Pollutants

Biomedical and Food Applications

Bioactive Phytochemicals

Pharmaceutics

This book is based on the principles, limitations, challenges, improvements and applications of nanotechnology in medical science as described in the literature. It highlights various parameters affecting the synthesis of bio-nanomaterials and exclusive techniques utilized for characterizing the nanostructures for their potential use in biomedical and environmental applications. Moreover, biodegradable synthesis of nanomaterials is regarded as an important tool to reduce the destructive effects associated with the traditional methods of synthesis for nanostructures commonly utilized in laboratory and industry and as well as academic scale of innovative research foundation.

Dosage Form Design Parameters, Volume I, examines the history and current state of the field within the pharmaceutical sciences, presenting key developments. Content includes drug development issues, the scale up of formulations, regulatory issues, intellectual property, solid state properties and polymorphism. Written by experts in the field, this volume in the Advances in Pharmaceutical Product Development and Research series deepens our understanding of dosage form design parameters. Chapters delve into a particular aspect of this fundamental field, covering principles, methodologies and the technologies employed by pharmaceutical scientists. In addition, the book contains a comprehensive examination suitable for researchers and advanced students working in pharmaceuticals, cosmetics, biotechnology and related industries. Examines the history

and recent developments in drug dosage forms for pharmaceutical sciences Focuses on physicochemical aspects, preformulation solid state properties and polymorphism Contains extensive references for further discovery and learning that are appropriate for advanced undergraduates, graduate students and those interested in drug dosage design

This practical manual contains 31 exercises covering all topics included in pharmaceutics courses. The content is discussed in very simple language and intense detail. At the end of the manual a few pages have been left blank for notes to be made by students. The page facing every exercise has also been left blank and students can write calculations, methods of preparation in their own language etc. on these pages.

Pharmaceutics-I

Practical Manual of PHARMACEUTICS--II

Applications of Nanobiomaterials

Bio-manufactured Nanomaterials

Pharmaceuticals and Personal Care Products: Waste Management and Treatment Technology

Pharmacognosy

Targeting Chronic Inflammatory Lung Diseases Using Advanced Drug Delivery Systems explores the development of novel therapeutics and diagnostics to improve pulmonary disease management, looking down to the nanoscale level for an efficient system of targeting and managing respiratory disease. The book examines numerous nanoparticle-based drug systems such as nanocrystals, dendrimers, polymeric micelles, protein-based, carbon nanotube, and liposomes that can offer advantages over traditional drug delivery systems. Starting with a brief introduction on different types of nanoparticles in respiratory disease conditions, the book then focuses on current trends in disease pathology that use different in vitro and in vivo models. The comprehensive resource is designed for those new to the field and to specialized scientists and researchers involved in pulmonary research and drug development. Explores recent perspectives and challenges regarding the management and diagnosis of chronic respiratory diseases Provides insights into how advanced drug delivery systems can be effectively formulated and delivered for the management of various pulmonary diseases Includes the most recent information on diagnostic methods and treatment strategies using controlled drug delivery systems (including nanotechnology)

The third edition of this popular and textbook in drug store and business management includes questions from papers in recent examinations. It has been written to meet the requirements of students working towards a diploma in pharmacy. Written in a easy to understand language, it attempts to demystify and simplify the basic concepts in order for students to fully understand the subject and ensure success in their examinations.

Introduction to Pharmaceutics, Vol. I , 3eIntroduction to Pharmaceutics, Vol.II (According to the Education Regulation 1991), 4ePharmaceutics-I Practical Note Book CBS Publishers & Distributors Pvt Limited, India

Practical Note Book

Pharmaceutics - I

Perspectives and Applications

Excipient Development for Pharmaceutical, Biotechnology, and Drug Delivery Systems

Alginates in Drug Delivery

Biopolymer-Based Formulations

Here in a single source is a complete spectrum of ideas on the development of new anticancer drugs. Containing concise reviews of multidisciplinary fields of research, this book offers a wealth of ideas on current and future molecular targets for drug design, including signal transduction, the cell division cycle, and programmed cell death. Detailed descriptions of sources for new drugs and methods for testing and clinical trial design are also provided. One work that can be consulted for all aspects of anticancer drug development Concise reviews of research fields, combined with practical scientific detail, written by internationally respected experts A wealth of ideas on current and future molecular targets for drug design, including signal transduction, the cell division cycle, and programmed cell death Detailed descriptions of the sources of new anticancer drugs, including combinatorial chemistry, phage display, and natural products Discussion of how new drugs can be tested in preclinical systems, including the latest technology of robotic assay systems, cell culture, and experimental animal techniques Hundreds of references that allow the reader to access relevant scientific and medical literature Clear illustrations, some in color, that provide both understanding of the field and material for teaching Quality Control in Pharmacy - Errors in Analysis - Impurities in Pharmaceutical Substances and Limit Tests - Water - Solubility of Pharmaceuticals - Acids, Bases and Buffers - Antioxidants - Gastrointestinal Agents - Topical Agents - Dental Products - Inhalants - Expectorants, Emetics and Respiratory Stimulants - Major Intra and Extracellular Electrolytes - Official Compounds of Iron - Official Compounds of Iodine - Official Compounds of Calcium - Radiopharmaceuticals and Contrast Media - Antidotes in Poisoning - Identification Tests for Ions and Radicals - Appendix - Index - Bibliography

Regulatory Affairs in the Pharmaceutical Industry is a comprehensive reference that compiles all the information available pertaining to regulatory procedures currently followed by the pharmaceutical industry. Designed to impart advanced knowledge and skills required to learn the various concepts of regulatory affairs, the content covers new drugs, generic drugs and their development, regulatory filings in different countries, different phases of clinical trials, and the submission of regulatory documents like IND (Investigational New Drug), NDA (New Drug

Application) and ANDA (Abbreviated New Drug Application). Chapters cover documentation in the pharmaceutical industry, generic drug development, code of Federal Regulation (CFR), the ANDA regulatory approval process, the process and documentation for US registration of foreign drugs, the regulation of combination products and medical devices, the CTD and ECTD formats, and much more. Updated reference on drug approval processes in key global markets Provides comprehensive coverage of concepts and regulatory affairs Presents a concise compilation of the regulatory requirements of different countries Introduces the fundamentals of manufacturing controls and their regulatory importance