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Lyophilized Biologics and Vaccines Dushyant Varshney, Manmohan Singh, 2015-05-19 This book provides a detailed account of the most recent developments, challenges and solutions to seamlessly advance and launch a lyophilized biologics or vaccine product, based on diverse modalities, ranging from antibodies (e.g., monoclonal, fused), complex biologics (e.g., antibody drug conjugate, PEGylated proteins), and vaccines (e.g., recombinant-protein based). The authors adeptly guide the reader through all crucial aspects, from biophysical and chemical stability considerations of proteins, analytical methods, advances in controlled ice nucleation and quality-by-design approaches, alternate drying technology, to latest regulatory, packaging and technology transfer considerations to develop a stable, safe and effective therapeutic protein, vaccine and biotechnology products. *Lyophilized Biologics and Vaccines: Modality-Based Approaches* is composed of four sections with a total of 17 chapters. It serves as a reference to all critical assessments and steps from early pre-formulation stages to product launch: Provides recent understanding of heterogeneity of protein environment and selection of appropriate buffer for stabilization of lyophilized formulations Details the latest developments in instrumental analysis and controlled ice nucleation technology Explains in-depth lyophilized (or dehydrated) formulation strategies considering diverse modalities of biologics and vaccines, including plasmid DNA and lipid-based therapeutics Details an exhaustive update on quality-by-design and process analytical technology approaches, illustrated superbly by case studies and FDA perspective Provides the latest detailed account of alternate drying technologies including spray drying, bulk freeze-drying and crystallization, supported exceptionally by case studies Provides a step-by-step guide through critical considerations during process scale-up, technology transfer, packaging and drug delivery device selection, for a successful lyophilization process validation, regulatory submission and product launch Chapters are written by one or more world-renowned leading authorities from academia, industry or regulatory agencies, whose expertise cover lyophilization of the diverse modalities of biopharmaceuticals. Their contributions are based on the exhaustive review of literature coupled with excellent hands-on experiences in laboratory or GMP setup, making this an exceptional guide to all stages of lyophilized or dehydrated product development.

Lyophilization of Biopharmaceuticals Henry R. Costantino, Michael J. Pikal, 2005-12-05 Humans have been experimenting with lyophilization, or freeze-drying, as a method to preserve biological structures for over a thousand years. This comprehensive volume, intended for scientists in both academia and industry, covers a wide range of topics relevant to the formulation of peptide and protein drugs in the freeze-dried state.

Freeze-drying of Pharmaceuticals and Biopharmaceuticals Felix Franks, Tony Auffret, 2008 Aimed at product and process developers in the biopharmaceutical industry and academia, this is the first book to describe freeze-drying, as related to the pharmaceutical industry.

Handbook of Polymer Testing Roger Brown, 1999-01-21 The Handbook of Polymer Testing: Physical Methods provides virtually currently used techniques for measuring and testing the physical properties of polymers. A concise but detailed technical guide to the physical testing methods of synthetic polymers in plastics, rubbers, cellular materials, textiles, coated fabrics, and composites, the book analyzes

Lyophilization Thomas A. Jennings, 1999-08-31 Finding consistent, analytical discussions of processes and principles of lyophilization can be challenging and often frustrating. The first resource to gather information about the field, *Lyophilization: Introduction and Basic Principles* is still the book to have on lyophilization. Presenting information in an easy-to-read style, the book comprehensively and authoritatively covers the field. Using plain, unpretentious language, author Thomas A. Jennings pulls together information from diverse sources to provide an authoritative compendium of the lyophilization process and its basic principles. He provides important discussions about the nature of the container-closure system and the equipment, tools, and environments required. Case studies and examples of solutions illustrate the many ways problems can be addressed in the lyophilization process. The book covers: Properties of lyophilized materials Product formulation requirements and the thermal properties of formulations Importance of process water Phase changes Thermal analytical methods Freezing, primary, and secondary drying processes Effect of vacuum freeze-dryers, both now and in the future Including over 150 illustrations, global symbols, and more than 350 references, this book is the complete guide to lyophilization, its analytical methods, measurement of process parameters, and equipment.

Amorphous Food and Pharmaceutical Systems Harry Levine, 2007-10-31 During the past decade, the importance of amorphous water-soluble substances has been increasingly recognised within the food and pharmaceutical industries. In response, *Amorphous Food and Pharmaceutical Systems* brings together current leading experts to contribute to this unique cross-disciplinary account of the subject. Coverage includes: water-compatible amorphous solids (physical, chemical behaviour), low water content systems (water as plasticizer); applications in food and pharmaceutical sciences and industries (processing and stability) along with state-of-the-art technology in food and pharmaceutical systems. This timely publication will be welcomed by academic and industrial researchers and professionals in the pharmaceuticals, food, materials and

polymer sciences.

The Schools of Design Quentin Bell, 2023-07-21 First published in 1963, *The Schools of Design* is a history of English Art Education. The story of the genesis of English art schools is one of the fierce conflicts in which private feuds mingle with questions of principle. It is a story of administrative chaos and open scandal in which some long-forgotten figures are involved; others – such as Haydon, Gladstone, Alfred Stevens, Dyce, Stafford Northcote, Etty and Henry Role – appear in a new role. In itself this forms an entertaining study full of incident and drama. Many of the problems that presented themselves in the 1840s are still with us today and no one who is interested in the place of art in our society can afford to neglect the lessons of the Schools of Design. This book will be of interest to students of art and history.

Schools of Art, 1884

King Cole Elizabeth Bonython, 1982

The Nationalization of Culture Janet Minihan, 1977

The Opening of the Crystal Palace John Ruskin, 1854

Another Reason Gyan Prakash, 2020-06-16 *Another Reason* is a bold and innovative study of the intimate relationship between science, colonialism, and the modern nation. Gyan Prakash, one of the most influential historians of India writing today, explores in fresh and unexpected ways the complexities, contradictions, and profound importance of this relationship in the history of the subcontinent. He reveals how science served simultaneously as an instrument of empire and as a symbol of liberty, progress, and universal reason--and how, in playing these dramatically different roles, it was crucial to the emergence of the modern nation. Prakash ranges over two hundred years of Indian history, from the early days of British rule to the dawn of the postcolonial era. He begins by taking us into colonial museums and exhibitions, where Indian arts, crafts, plants, animals, and even people were categorized, labeled, and displayed in the name of science. He shows how science gave the British the means to build railways, canals, and bridges, to transform agriculture and the treatment of disease, to reconstruct India's economy, and to transfigure India's intellectual life--all to create a stable, rationalized, and profitable colony under British domination. But Prakash points out that science also represented freedom of thought and that for the British to use it to practice despotism was a deeply contradictory enterprise. Seizing on this contradiction, many of the colonized elite began to seek parallels and precedents for scientific thought in India's own intellectual history, creating a hybrid form of knowledge that combined western ideas with local cultural and religious understanding. Their work disrupted accepted notions of colonizer versus colonized, civilized versus savage, modern versus traditional, and created a form of modernity that was at once western and indigenous. Throughout, Prakash draws on major and minor figures on both sides of the colonial divide, including Mahatma Gandhi, Jawaharlal Nehru, the nationalist historian and novelist Romesh Chunder Dutt, Prafulla Chandra Ray (author of *A History of Hindu Chemistry*), Rudyard Kipling, Lord Dalhousie, and John Stuart Mill.

With its deft combination of rich historical detail and vigorous new arguments and interpretations, Another Reason will recast how we understand the contradictory and colonial genealogy of the modern nation.

The Indian Metropolis Norma Evenson,1989

The London and Westminster Review ,1835

The History and Philosophy of Art Education Stuart Macdonald,2004 Investigating the study of art and design education in Italy, France, Britain, Germany and the United States, this text traces the philosophies of teachers from the age of the guilds and the academies, setting them in the context of the general education theories of their times.

The Moral Economy of Labor James Bernard Murphy,1993-01-01 This concerns the dignity and the degradation of labour. Work has great power to undermine or to foster happiness. Bernard feels the moral dimension of labour has been neglected in political theory and practice and he aims to restore productive labour to its place in moral and political debate.

Goethe's Travels in Italy Johann Wolfgang von Goethe,Alexander James William Morrison,1885

The Origins of Culture Sir Edward Burnett Tylor,1970

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