

2. Quality management system of the manufacturer

2.1. The quality management system of the manufacturer

2.1.1. Brief description of the quality management system run by the company and reference to the standards used

The quality management system of **xxx Co., Ltd. xxx Plant** is established referring to **Ministerial Ordinance on Standards for Manufacturing Control and Quality Control for Drugs and Quasi-drugs (GMP Ordinance)**, relevant regulations/normations, **Current Good Manufacturing Practice Regulations in the US (cGMP)** and **PIC/S GMP GUIDE**, **Quality Manual of xxx Co., Ltd. xxx Plant** serves as the highest level document in the document system of the site, and various written standards and procedures have been prepared under this manual.

These documents include quality policy, quality management organization, document control, personnel qualifications/hygiene control/education & training, manufacturing control, quality control, hygiene control of premises and equipment, qualification of premises and equipment, validation/maintenance, change control, deviation control, handling of quality information and quality defects, etc., recall procedure, self-inspection, management review.

The Quality Manual refers to the current version of **ISO 9000 Series**.

2.1.2. Responsibilities related to maintaining of quality system including review management

The organization related to the quality management system at this manufacturing site is shown in **Appendix 5. GMP Organization Chart of xxx Co., Ltd. xxx Plant**. Senior management and other management are responsible for this.

Head of Quality Assurance supervises activities related to manufacturing control and quality control, to ensure appropriate and smooth conduct of such activities. **Head of Quality Assurance** is responsible for change control, deviation control, handling of quality information and quality defects, etc., product recall, and internal audit, and so on.

2.1.3. Information of activities for which the site is accredited and certified

This manufacturing plant (**xxxxxxx**) is accredited. Hierarchy of the certificate is given in **Appendix 6. ISO 9001**.

Date of certification:

Scope of certification:

Name of certifying bodies:

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HACCP User's Manual Donald A. Corlett, 1998-06-30 Now there is a single easy reading reference to help you plan implement and audit a HACCP Hazard Analysis and Critical Control Point program HACCP User's Manual provides comprehensive information on new and existing HACCP systems current U S Food and Drug Administration FDA and U S Department of Agriculture USDA regulations and procedures for application of the system as well as sanitation standard operating procedures SSOPs With more than 30 years experience in the food industry Don Corlett is eminently qualified to guide you step by step through the process of tailoring and operating a HACCP system to fit your operation In HACCP User's Manual you find expert tips for getting started details on how to develop and implement a HACCP plan and how to operate the HACCP system including organization of record keeping techniques

Chemical Technicians' Ready Reference Handbook Gershon J. Shugar, Jack T. Ballinger, 1996-06 The definitive reference of laboratory safety analytic procedures and instrumentation techniques for the modern chemical laboratory Cited in BCL3 the new edition contains expanded chapters on gas chromatography GC and high performance liquid chromatography HPLC and physical properties and testing methods with a new chapter on thermal analytic methods as well as on electrophoresis Also includes up to date information on the role of chemical laboratory technicians and chemical process operators in industry and current data on laboratory safety chemical waste disposal government regulations and ISO 9000 Explains in detail the day to day procedures techniques and formulas of today's chemical laboratory The new edition 2nd was 1981 emphasizing the importance of safety has been expanded to include additional information on material safety data sheets chemical waste disposal Right to Know regulations and the National Fire Protection Association codes Also new is material on such topics as gas chromatography high performance liquid chromatography infrared spectroscopy atomic absorption spectroscopy and computers in the laboratory

Laboratory Control System Operations in a GMP Environment David M. Bliesner, 2020-04-27 Develop an understanding of FDA and global regulatory agency requirements for Laboratory Control System LCS operations In Laboratory Control System Operations in a GMP Environment readers are given the guidance they need to implement a CGMP compliant Laboratory Control System LCS that fits within Global Regulatory guidelines Using the Quality Systems Approach regulatory agencies like the FDA and the European Medicine Agency have developed a scheme of systems for auditing pharmaceutical manufacturing facilities which includes evaluating the LCS In this guide readers learn the fundamental rules for operating a CGMP compliant Laboratory Control System Designed to help leaders meet regulatory standards and operate more efficiently the text includes chapters that cover Laboratory Equipment Qualification and Calibration Laboratory Facilities Method Validation and Method Transfer Laboratory Computer Systems Laboratory Investigations as well as Data Governance and Data Integrity The text also includes chapters related to Laboratory Managerial and Administrative Systems Laboratory Documentation Practices and Standard Operating Procedures and

General Laboratory Compliance Practices Additionally a chapter outlining Stability Program operations is included in the text In addition to these topics it includes LCS information and tools such as End of chapter templates checklists and LCS guidance to help you follow the required standards Electronic versions of each tool so users can use them outside of the text An In depth understanding of what is required by the FDA and other globally significant regulatory authorities for GMP compliant systems For quality assurance professionals working within the pharmaceutical or biopharma industries this text provides the insight and tools necessary to implement government defined regulations

Chemical Technicians' Ready Reference Handbook, 5th Edition Jack Ballinger, Gershon Shugar, 2011-06-24 THE DEFINITIVE CHEMICAL PROCESS INDUSTRY REFERENCE FULLY REVISED Updated to reflect the latest developments in operational procedures for today's sophisticated chemical technologies Chemical Technicians Ready Reference Handbook Fifth Edition remains the undisputed classic in the field Expanded to include coverage for process operators this authoritative resource contains in depth details on chemical safety laboratory procedures chemical nomenclature basic electricity laboratory statistics and instrumental techniques Step by step directions for performing virtually every laboratory task are also included in this practical guide COMPREHENSIVE COVERAGE INCLUDES Chemical process industry workers and government regulations Chemical plant and laboratory safety Chemical handling and hazard communication Handling compressed gases Pressure and vacuum Mathematics review and conversion tables Standard operating procedures Laboratory glassware pH measurement Basic electricity Sampling Laboratory filtration Recrystallization The balance Gravimetric analysis Preparation of solutions Process analyzers Plumbing valves and pumps Physical properties and determinations Extraction Distillation and evaporation Inorganic and organic chemistry review Chemical calculations and concentration expressions Volumetric analysis Chromatography Spectroscopy Atomic absorption spectroscopy

Modern Computer Arithmetic Richard P. Brent, Paul Zimmermann, 2010-11-25 Modern Computer Arithmetic focuses on arbitrary precision algorithms for efficiently performing arithmetic operations such as addition multiplication and division and their connections to topics such as modular arithmetic greatest common divisors the Fast Fourier Transform FFT and the computation of elementary and special functions Brent and Zimmermann present algorithms that are ready to implement in your favourite language while keeping a high level description and avoiding too low level or machine dependent details The book is intended for anyone interested in the design and implementation of efficient high precision algorithms for computer arithmetic and more generally efficient multiple precision numerical algorithms It may also be used in a graduate course in mathematics or computer science for which exercises are included These vary considerably in difficulty from easy to small research projects and expand on topics discussed in the text Solutions to selected exercises are available from the authors

FDA Compliance Program Guidance Manual United States. Food and Drug Administration, 1999-12 [CGMP's/food Plant Sanitation](#) Wilbur A. Gould, 1990 A textbook training manual and reference for people in the food industries who are or may be responsible for

sanitation in a processing plant Surveys the major concerns describes the principles and practices of maintaining sanitation and presents the pertinent regulations The date of the first edition is not noted the second includes new chapters on metal detection and training programs and updates references and regulations Available from CIT Publications Inc 2619 Maryland Ave Baltimore MD 21218 4547 Annotation copyright by Book News Inc Portland OR **Potato Production, Processing and Technology** WA Gould,2013-11-28 This compilation focuses on the events of growing processing quality control color as well as freezing canning chip and dried production This potato processing operations book written in terms the nonprofessional plant worker will understand is a must reference for all food processors technologists executives students etc as well as a valuable addition to the company technical reference library Included are figures tables and charts throughout the book Instructor's Resource Manual to Accompany Raven and Johnson Biology, Second Edition Linda R. Van Thiel,1989 *Fundamentals of Food Processing and Technology* WA Gould,2013-12-01 This book was written to summarize some of the fundamentals to be considered in the food processing and technology area It is an outgrowth of Dr Goulds workshops on this subject This text is an excellent starting point for students of food processing technology and individuals working in the processing arena The challenge for today s food processor is to produce food that is needed improve quality and efficiency and develop new businesses that will add value to the preserved product **Technical Manual** American Association of Blood Banks,1996 **Statistical reference book of international activities** United States. National Institutes of Health,1982 FDA Compliance Program Guidance Manual, Section IV (Veterinary Medicine) United States. Food and Drug Administration,1980 Principles of Transfusion Medicine Ennio Claudio Rossi,1996 This is a practical guide for safe and effective use of blood as a drug It has a practical focus with a format that blends transfusion science with clinical concerns and includes contributions from the areas of pathology internal medicine surgery anaesthesiology and paediatrics This new edition includes 15 new chapters and the Organization of Blood Services section has been restructured to guide the reader through the intensified regulatory environment and the use of computers a control devices The text also discusses how blood banks can meet the FDA s tight new guidelines using audit and error management as the key to process control **CLSC Exam Certification Guide** Kevin Downes,Tim Boyles,1999 The Cisco LAN Switch Configuration CLSC exam is one of the tests required for certification as a Cisco Certified Network Professional CCNP or Cisco Certified Design Professional CCDP When you re ready to test your skills complete your knowledge of the objectives and prepare for exam day you need the preparation tools found in CLSC Exam Certification Guide from Cisco Press **Gamete Research** ,1989 *FDA Compliance Policy Guides Manual* ,1989 **Manual of Industrial Microbiology and Biotechnology** Arnold L. Demain,Julian E. Davies,Ronald M. Atlas,1999 The editors have enlisted a broad range of experts including microbial ecologists physiologists geneticists biochemists molecular biologists and biochemical engineers who offer practical experience not found in texts and journals This comprehensive perspective makes MIMB a valuable how

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