

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

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

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 (ISO 9001) 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

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