

1.6 Document Overview

[Provide a description of the document organization.]

2 METHODOLOGY

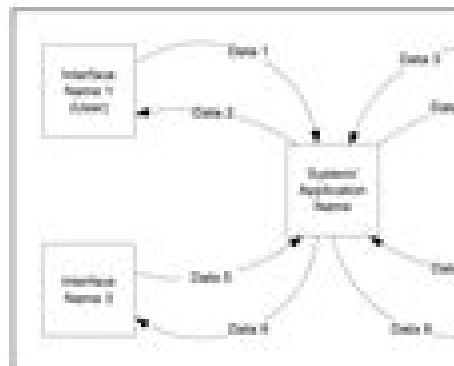
[Describe the overall approach used in the determination of the modeling method(s) so non-technical readers can convey.]

3 FUNCTIONAL REQUIREMENTS

4.1 Context

[Provide a context diagram of the system, with explanation of a system refers to the connections and relationships environment.]

Exhibit 2 - Generic Context Diag



4.2 User Requirements

[Provide requirements of the system, user or business, to classes/categories of users. Provide the type of user characteristics of each set of users. List the functional req user requirement. As the functional requirements are de functional requirements are traced to the user requirement functional requirements is not mandatory in the traceability parent requirements are already traced to them.

User requirement information can be in text or process flow class that shows what inputs will initiate the system functionality.

what outputs are expected to be generated by the system. The scenarios should be comprehensive, to the extent that all user types and all major functions are covered. Give each user requirement a unique number. Typically, user requirements have a numbering system that is separate from the functional requirements. Requirements may be labeled with a leading "U" or other label indicating user requirements.]

4.3 Data Flow Diagrams

[Decompose the context level diagrams to determine the functional requirements. Data flow diagrams should be decomposed down to the functional primitive level. These diagrams are further decomposed during design.]

4.4 Logical Data Model/Data Dictionary

[Create the initial Logical Data Model. Describe data requirements by providing data entities, decomposition, and definitions in a data dictionary. The data requirements describe the business data needed by the application system. Data requirements do not describe the physical database and are not at the level of identifying field names.]

4.5 Functional Requirements

[List the functional requirements of the system.]

4.5.1 Functional Requirements Group 1

[List the functional requirements for each functional requirements group.]

Exhibit 4 - Sample Requirements Group 1

Section/ Requirement ID	Requirement Definition
FR1.0	The system shall [parent requirement group 1].
FR1.1	The system shall [child parent requirement].
FR1.1.1	The system shall [child requirement].
FR1.1.2	The system shall [child requirement].

4.5.2 Functional Requirements Group 2, Etc.

5 OTHER REQUIREMENTS

[Describe the non-behavioral requirements.]

5.1 Interface Requirements

[Describe the user interfaces that are to be implemented by the system.]

Writing Functional Specification Documents

Linda R. Timms



Writing Functional Specification Documents:

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Basics of Pharmaceutical Manufacturing and Quality Operations Erfan Syed Asif, Shahid Bader Usmani, 2024-03-14 This book provides guidance on how to meet the requirements of the pharmaceutical industry as a beginner It includes procedures for production and packaging batch auditing as well as all quality measures used in the pharmaceutical industry This book also provides questions and answers with each chapter for institutes and trainers providing basic training to the new graduates and new comers to the industry Basics of Pharmaceutical Manufacturing and Quality Operations A Comprehensive Guide is primarily written for anyone in the pharmaceutical industry interested in development and manufacturing of active pharmaceutical ingredient API and finished pharmaceutical manufacturers in both sterile and non sterile areas The book is a simple concise and easy to use reference tool covering basic quality concepts required by the pharmaceutical educational institutions and professional certification bodies It describes details of all GXP activities that are directly related to Quality Safety and Efficacy of the products manufactured under the umbrella of Quality Operations common testing methods which are used in any modern industry Requirements of Validation and Qualification of equipment facilities and processes integral segments of Drug product manufacturing storage and distribution practices The material provides stepwise guidance on how to evaluate audit qualify and approve a pharmaceutical product to enhance the GMP within the industry The book is written with the idea of providing basic knowledge to undergraduate students who are preparing to enter the industry at the end of their graduation The book would also be beneficial for institutions conducting pharmaceutical technology study courses in terms of GMP and GLP applications Features Provides readers and front line health care product manufacturers all the information they need to know to develop a GMP oriented industry with trained and skilled personnel and manufacture products that meet GMP and regulatory requirements Provides stepwise guidance on how to evaluate audit qualify and approve a pharmaceutical product and packaging material to enhance the GMP within the industry Includes significant processes and steps in production for all common dosage forms Explains how in process and finished products are released Provides an ideal and effective tool for anyone starting Quality Assurance Quality control Production responsibilities

The Linux Development Platform Rafeeq Ur Rehman, Christopher Paul, 2003 Two leading Linux developers show how to choose the best tools for your specific needs and integrate them into a complete development environment that maximizes your effectiveness in any project no matter how large or complex Includes research requirements coding debugging deployment

maintenance and beyond choosing and implementing editors compilers assemblers debuggers version control systems utilities using Linux Standard Base to deliver applications that run reliably on a wide range of Linux systems comparing Java development options for Linux platforms using Linux in cross platform and embedded development environments

Software Requirements & Specifications Mr. Rohit Manglik, 2023-05-23 Focuses on requirement engineering processes use case modeling and creating specifications that guide software design and validation **Joint Requirements**

Engineering Georg Herzworm, Sixten Schockert, Werner Mellis, 2000 Software development is becoming increasingly complex and dynamic The Requirements Engineering process has to integrate know how from customers and developers and focus on the essentials Quality Function Deployment QFD fulfils these needs The objective of QFD is a software which does not include all that is technically possible but only the features that are important for success Requirements engineering with QFD is goal oriented fast flexible and customer focused Communicating as IT Professionals Jay Liebowitz, William W.

Agresti, G. Reza Djavanshir, 2006 The authors focus on how written and oral communications are the integrative elements for success between people and IT IT and other employers want their people to be able to communicate well individually in project teams and organizationally The book is consciously written in an easy flowing familiar manner with warm up and exercises sprinkled throughout the chapters **Anatomy of a Robot** Charles Bergren, 2003-04-22 This work looks under

the hood of all robotic projects stimulating teachers students and hobbyists to learn more about the gamut of areas associated with control systems and robotics It offers a unique presentation in providing both theory and philosophy in a technical yet entertaining way The Elements of C Programming Style Jay Ranade, Alan Nash, 1993 Novice and experienced C programmers alike will discover precise and direct programming rules explained with examples and detailed discussions In addition more than 300 sample programs are included that demonstrate how to produce clear concise software constructs that are executable and elegant How to Write Computer Manuals for Users Susan J. Grimm, 1982

New York Court of Appeals. Records and Briefs. New York (State)., *Software Project Management Kit For Dummies?* Greg Mandanis, Allen Wyatt, 2000-05-11 The seasoned programmer and novice alike find this reference the ideal resource for getting a project off to the right start Friendly practical advice is combined with the latest software in this For Dummies edition Follow your expert guide through planning development testing and implementation the first steps to your project s success Then get your hands on scheduling assigning resources and estimating costs and best of all making your software happen The book s CD ROM includes trial versions of Microsoft Project 2000 Soffrant TRACK and Cost Xpert as well as templates and a wealth of other planning tools **Writing and Analyzing Effective Computer System Documentation**

Ann Stuart, 1984 *Proceedings 3, COMPSAC79, the IEEE Computer Society's Third International Computer Software & Applications Conference, November 5, Tutorial, November 6-8, 1979, Conference, the Palmer House, Chicago, Illinois ,1979*

Designing, Writing, and Producing Computer Documentation Lynn Denton, Jody Kelly, 1993 This comprehensive

step by step guide shows both novices and documentation pros how to make all their task oriented documents and libraries more useful attractive and accessible They ll learn to quickly locate and logically organize source information then write revise and edit the material for maximum clarity *A Program Guide for CIM Implementation* Leonard Bertain, Lee Hales, 1987 **ZUM ... the Z Formal Specification Notation** , 1995 **Software Lifecycle Management** William C. Cave, Gilbert W. Maymon, 1984 **Organizing and Documenting Data Processing Information** Thomas Robert Gildersleeve, 1977 Legal Care for Your Software Daniel Remer, Robert Dunaway, 1992 This guide for computer software writers and publishers covers the major changes in the copyright and trademark laws It discusses such topics as nondisclosure beta tests and evaluation agreements trademarks patents licensing agreements and trade secrets

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