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Policy: A Device Master Record will be prepared and maintained for all devices (products) manufactured or under development.

Purpose: To prescribe the responsibilities for preparing Device Master Records (DMR) and to ensure the completeness of DMR indexes (indices).

Scope: All equipment specifically including medical devices manufactured by the Company are covered under this procedure.

Definitions: **Device Master Record (DMR)** - A compilation of records containing the description, design, formulation, specifications, complete manufacturing procedures, quality assurance requirements, and labeling of a finished device. In addition to the device specifications, a DMR contains documents that cover typical manufacturing activities including procurement, assembly, labeling, testing, and inspection and packaging.

DMR Index - Table of contents for the master record of a device, can contain information on the breakdown of the device into assemblies and/or manufacturing steps. Called a "document plan" during planning and early development of a new product.

Procedure:

1.0 PREPARATION OF DEVICE MASTER RECORD

1.1 Upon completion of the design phase of a device, a formal document plan will be initiated and will be called the Device Master Record. The configuration and structure of the master record is determined by the Engineering and Manufacturing managers.

After agreement, the master record will be created, document numbers assigned, status of drawings indicated and the record approved by Engineering and Manufacturing. See ENG104-1 DEVICE MASTER RECORD CONTENTS for a listing of items that may appear in a Device Master Record.

1.2 Upon compilation of all documents to be included in the Master Record, a ENG104-2 DEVICE MASTER RECORD INDEX shall be prepared to identify all items in the record and location(s) of these records.

1.3 Complete specifications of the device will be prepared and included as part of the Master Record (see ENG104-3 DEVICE SPECIFICATION EXAMPLE). The device or product specification is a specific document that briefly describes and

Engineering Procedure Template

RS Peters



Engineering Procedure Template:

This book delves into Engineering Procedure Template. Engineering Procedure Template is a vital topic that must be grasped by everyone, ranging from students and scholars to the general public. This book will furnish comprehensive and in-depth insights into Engineering Procedure Template, encompassing both the fundamentals and more intricate discussions.

1. The book is structured into several chapters, namely:
 - Chapter 1: Introduction to Engineering Procedure Template
 - Chapter 2: Essential Elements of Engineering Procedure Template
 - Chapter 3: Engineering Procedure Template in Everyday Life
 - Chapter 4: Engineering Procedure Template in Specific Contexts
 - Chapter 5: Conclusion
2. In chapter 1, this book will provide an overview of Engineering Procedure Template. The first chapter will explore what Engineering Procedure Template is, why Engineering Procedure Template is vital, and how to effectively learn about Engineering Procedure Template.
3. In chapter 2, the author will delve into the foundational concepts of Engineering Procedure Template. The second chapter will elucidate the essential principles that need to be understood to grasp Engineering Procedure Template in its entirety.
4. In chapter 3, this book will examine the practical applications of Engineering Procedure Template in daily life. This chapter will showcase real-world examples of how Engineering Procedure Template can be effectively utilized in everyday scenarios.
5. In chapter 4, the author will scrutinize the relevance of Engineering Procedure Template in specific contexts. The fourth chapter will explore how Engineering Procedure Template is applied in specialized fields, such as education, business, and technology.
6. In chapter 5, the author will draw a conclusion about Engineering Procedure Template. This chapter will summarize the key points that have been discussed throughout the book.

The book is crafted in an easy-to-understand language and is complemented by engaging illustrations. This book is highly recommended for anyone seeking to gain a comprehensive understanding of Engineering Procedure Template.

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