

medical device development process

medical device development process is a complex, multi-stage journey that transforms an initial concept into a fully functional, regulatory-compliant medical product. This process involves a combination of engineering, clinical research, regulatory strategy, and quality management to ensure safety and efficacy. From ideation to commercialization, each phase requires meticulous planning and execution to meet stringent industry standards. Understanding the medical device development process is crucial for manufacturers, developers, and stakeholders aiming to bring innovative healthcare solutions to market. This article explores the comprehensive stages involved, highlighting critical activities such as design control, prototyping, clinical evaluation, and regulatory approval. Additionally, it covers post-market surveillance and the importance of continuous improvement in maintaining device performance and patient safety. The following sections provide a detailed overview of the key components of the medical device development process.

- Concept and Feasibility
- Design and Development
- Regulatory Compliance and Approval
- Manufacturing and Quality Assurance
- Clinical Evaluation and Trials
- Post-Market Surveillance and Support

Concept and Feasibility

The initial phase of the medical device development process begins with concept generation and feasibility assessment. During this stage, innovators identify unmet clinical needs and develop ideas that could address these challenges. This step involves brainstorming, market research, and preliminary technical evaluation to assess the practicality of the proposed device.

Identifying Clinical Needs

Understanding the target medical problem is fundamental to the development process. Developers collaborate with healthcare professionals, patients, and market analysts to pinpoint specific issues that require innovative solutions. This user-centered approach ensures that the device concept is relevant and has potential clinical value.

Feasibility Studies

Feasibility studies evaluate the technical, financial, and regulatory viability of the device concept. This includes assessing available technologies, potential design challenges, cost estimates, and regulatory pathways. Early risk analysis is also performed to identify possible obstacles and safety concerns.

Design and Development

The design and development phase is critical in transforming a concept into a tangible prototype. It encompasses detailed design, engineering, and iterative testing to refine device functionality and safety. Strict adherence to design controls and documentation is required to comply with regulatory

standards such as FDA's 21 CFR Part 820 or ISO 13485.

Design Inputs and Specifications

Design inputs define the device requirements based on user needs, regulatory demands, and safety considerations. These inputs serve as the foundation for developing detailed design specifications, including performance criteria, materials, and usability features.

Prototyping and Iterative Testing

Prototyping allows developers to create physical or digital models of the device. These prototypes undergo rigorous bench testing to evaluate functionality, durability, and safety. Iterative refinement based on test results ensures that design issues are addressed before advancing to clinical evaluation.

Risk Management

Throughout design and development, risk management processes identify, analyze, and mitigate potential hazards associated with the device. This systematic approach aligns with ISO 14971 standards and is integral to ensuring patient safety and regulatory compliance.

Regulatory Compliance and Approval

Securing regulatory approval is a pivotal step within the medical device development process. Regulatory bodies such as the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA), and others enforce strict guidelines to verify device safety and effectiveness before market

entry.

Regulatory Pathways

The choice of regulatory pathway depends on the device classification and intended use. Common pathways include Premarket Notification 510(k), Premarket Approval (PMA), and the European CE marking process. Understanding these pathways early helps streamline development and reduce time to market.

Submission Preparation

Preparing regulatory submissions involves compiling comprehensive technical documentation, including design history files, risk analyses, preclinical and clinical data, and manufacturing information. This documentation must demonstrate conformity with applicable standards and regulatory requirements.

Manufacturing and Quality Assurance

Manufacturing is an essential phase that translates the developed design into mass-produced medical devices. Quality assurance systems ensure that each device meets stringent quality standards and regulatory compliance through controlled processes and audits.

Good Manufacturing Practices (GMP)

Adherence to Good Manufacturing Practices guarantees that devices are produced consistently and controlled according to quality standards. This includes validated processes, qualified personnel, and

proper facility conditions to minimize defects and risks.

Quality Management Systems (QMS)

A robust Quality Management System, typically aligned with ISO 13485, supports continuous monitoring and improvement of manufacturing processes. QMS encompasses document control, corrective and preventive actions (CAPA), and supplier management to uphold product quality.

Clinical Evaluation and Trials

Clinical evaluation is a vital component of the medical device development process aimed at verifying safety and effectiveness in human subjects. Clinical trials generate evidence necessary for regulatory submissions and market approval.

Clinical Study Design

Designing clinical studies involves selecting appropriate protocols, endpoints, and patient populations. Studies may range from pilot feasibility trials to large-scale pivotal trials, depending on device risk classification and regulatory expectations.

Data Collection and Analysis

Accurate data collection and statistical analysis are critical to demonstrating device performance. Clinical data must be systematically documented, monitored, and analyzed to identify benefits and potential adverse effects.

Post-Market Surveillance and Support

After regulatory approval and market launch, ongoing post-market surveillance ensures continued device safety and performance. This phase involves monitoring real-world use, managing complaints, and implementing improvements based on feedback.

Monitoring and Reporting

Manufacturers are required to track adverse events, device malfunctions, and user feedback. This information is reported to regulatory authorities and used to assess risk over the device lifecycle.

Product Maintenance and Upgrades

Post-market activities include software updates, recalls if necessary, and design enhancements to improve device functionality and patient outcomes. Maintaining compliance with evolving standards is essential for sustained market presence.

Customer Support and Training

Providing adequate training and support to healthcare providers and users ensures proper device use and maximizes therapeutic benefits. Educational programs and technical assistance are integral to successful device adoption.

Key Steps in the Medical Device Development Process

Summarizing the essential actions involved in the development journey helps clarify project management and resource allocation. These key steps include:

- Identifying unmet clinical needs and market opportunities
- Conducting feasibility and risk assessments
- Developing detailed design inputs and specifications
- Creating and testing prototypes through iterative cycles
- Preparing and submitting regulatory documentation
- Establishing compliant manufacturing and quality systems
- Executing clinical trials and collecting evidence
- Implementing post-market surveillance and customer support

Frequently Asked Questions

What are the key stages in the medical device development process?

The key stages include concept development, feasibility analysis, design and development, verification and validation, regulatory approval, manufacturing, and post-market surveillance.

How important is regulatory compliance in medical device development?

Regulatory compliance is critical to ensure the device meets safety and efficacy standards set by authorities like the FDA or EMA, enabling legal marketing and protecting patient safety.

What role does risk management play in the medical device development process?

Risk management identifies, evaluates, and mitigates potential hazards throughout the device lifecycle to ensure patient and user safety and compliance with standards such as ISO 14971.

How does the design control process impact medical device development?

Design control ensures systematic documentation, traceability, and verification of design outputs against inputs, helping to deliver a safe and effective final product.

What are common challenges faced during medical device development?

Challenges include navigating complex regulatory requirements, ensuring biocompatibility, managing design changes, maintaining quality control, and meeting market needs.

How can software development be integrated into the medical device development process?

Software development must follow specific standards like IEC 62304, including rigorous testing, validation, and documentation to ensure the software's reliability and safety.

What is the role of prototyping in medical device development?

Prototyping allows developers to create functional models for testing design concepts, usability, and performance before full-scale production.

How does user feedback influence the medical device development process?

User feedback helps identify design improvements, usability issues, and unmet needs, leading to enhanced device functionality and patient outcomes.

What documentation is essential during the medical device development process?

Essential documentation includes design history files, risk management files, verification and validation reports, clinical evaluation reports, and regulatory submissions.

How has emerging technology impacted the medical device development process?

Emerging technologies like AI, 3D printing, and IoT have accelerated innovation, enabled personalized devices, improved data collection, and enhanced device functionality.

Additional Resources

1. Medical Device Development: A Regulatory Overview

This book provides a comprehensive guide to the regulatory requirements essential for medical device development. It covers the entire product lifecycle from concept through commercialization, emphasizing compliance with FDA and international standards. Readers gain insight into risk management, quality systems, and documentation necessary for successful device approval.

2. Design Controls for the Medical Device Industry

Focused on design control processes, this book explains how to implement effective design control systems as required by regulatory bodies. It includes practical examples and case studies to illustrate best practices in design verification, validation, and change management. The text is invaluable for engineers and project managers involved in device design.

3. Medical Device Technologies: A Systems Based Overview Using Engineering Standards

This book explores the application of engineering standards in the design and development of medical devices. It provides a systems approach to understanding device functions, safety, and performance. The author integrates technical, clinical, and regulatory perspectives to offer a holistic view of medical device technology.

4. Risk Management in Medical Device Development

This title delves into the critical role of risk management throughout the medical device development process. It outlines methodologies such as FMEA and fault tree analysis to identify and mitigate potential hazards. The book also discusses compliance with ISO 14971 and how effective risk management enhances product safety and market acceptance.

5. Clinical Evaluation of Medical Devices: Principles and Case Studies

Focusing on clinical evaluation, this book covers methods for assessing safety and performance through clinical investigations. It provides guidance on designing clinical trials, data collection, and regulatory submission requirements. Case studies illustrate practical challenges and solutions in clinical evaluation.

6. Software Development for Medical Devices: A Practical Guide

This practical guide addresses the unique challenges of software development in medical devices. It covers software lifecycle processes, validation, and compliance with standards such as IEC 62304. The book is tailored for software engineers and quality professionals working in regulated medical device environments.

7. Quality Management Systems in Medical Device Companies

This book outlines the establishment and maintenance of quality management systems compliant with ISO 13485. It discusses documentation, auditing, and continuous improvement strategies essential for medical device manufacturers. Readers learn how to align quality processes with regulatory expectations and business goals.

8. Biomedical Engineering and Medical Device Design

A comprehensive textbook, this title integrates principles of biomedical engineering with practical aspects of medical device design. It covers biomechanics, materials, and electronic systems, offering a multidisciplinary approach. The book also highlights innovation and emerging technologies in device development.

9. Project Management for Medical Device Development

This book provides tools and techniques for effective project management tailored to the medical device industry. Topics include planning, risk assessment, team coordination, and regulatory timelines. It helps professionals navigate complex development projects to deliver compliant and market-ready devices on schedule.

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medical device development process: *Development of FDA-Regulated Medical Products*
Elaine Whitmore, 2012-02-15 Translating promising discoveries and innovations into useful, marketable medical products demands a robust process to guide nascent products through a tangle of scientific, clinical, regulatory, economic, social, and legal challenges. There are so many human and environmental elements involved in shepherding medical advances from lab to launch that the field of medical product development has been referred to as an ecosystem. The purpose of this book is to help provide a shared foundation from which cross-functional participants in that ecosystem can negotiate the product development labyrinth and accomplish the goal of providing both groundbreaking and iterative new medical products. The book is intended for anyone in industry, the public sector, or academia—regardless of functional specialty, workplace, or seniority—who is interested in medical product development. The years since the publication of the previous edition of this book have seen profound changes in the actions and attitudes of patients, insurers,

manufacturers, and the Food and Drug Administration regarding the streamlining of medical product development and approval. What those years have not seen is a concomitant increase in innovative treatments with profound benefits to patients. Despite enormous investments in research by both private and public sources and a surge in scientific and technological advances, new medical products barely trickle into the marketplace. For a variety of reasons, applied sciences necessary for medical product development are not keeping pace with the tremendous advances in basic sciences. Not surprisingly, industry and academia are under substantial pressure to transform discoveries and innovations from the laboratory into safe and effective medical products to benefit patients and improve health. This evolution—from bench to bedside—has become known as translational research and development, and this approach is what this book illuminates. I have been working in medical device design and design assurance for over 10 years...Elaine Whitmore really gets this right...The point is that quality regulations are not going to go away, and those responsible for healthcare product development will have to lead the charge to keep up the momentum in their organizations. I am going to have to buy several copies of this for my clients! Joseph P. Sener, P.E.

medical device development process: Development of Biopharmaceutical Drug-Device

Products Feroz Jameel, John W. Skoug, Robert R. Nesbitt, 2020-03-13 The

biotechnology/biopharmaceutical sector has tremendously grown which led to the invention of engineered antibodies such as Antibody Drug Conjugates (ADCs), Bispecific T-cell engager (BITES), Dual Variable Domain (DVD) antibodies, and fusion proteins that are currently being used as therapeutic agents for immunology, oncology and other disease conditions. Regulatory agencies have raised the bar for the development and manufacture of antibody-based products, expecting to see the use of Quality by Design (QbD) elements demonstrating an in-depth understanding of product and process based on sound science. Drug delivery systems have become an increasingly important part of the therapy and most biopharmaceuticals for self-administration are being marketed as combination products. A survey of the market indicates that there is a strong need for a new book that will provide “one stop shopping” for the latest information and knowledge of the scientific and engineering advances made over the last few years in the area of biopharmaceutical product development. The new book entitled Development of Biopharmaceutical Drug Device Products is a reference text for scientists and engineers in the biopharmaceutical industry, academia or regulatory agencies. With insightful chapters from experts in the field, this new book reviews first principles, covers recent technological advancements and provides case studies and regulatory strategies relating to the development and manufacture of antibody-based products. It covers topics such as the importance of early preformulation studies during drug discovery to influence molecular selection for development, formulation strategies for new modalities, and the analytical techniques used to characterize them. It also addresses important considerations for later stage development such as the development of robust formulations and processes, including process engineering and modeling of manufacturing unit operations, the design of analytical comparability studies, and characterization of primary containers (pre-filled syringes and vials). Finally, the latter half of the book reviews key considerations to ensure the development and approval of a patient-centered delivery system design. This involves the evolving regulatory framework with perspectives from both the US and EU industry experts, the role of international standards, design control/risk management, human factors and its importance in the product development and regulatory approval process, as well as review of the risk-based approach to bridging between devices used in clinical trials and the to-be-marketed device. Finally, case studies are provided throughout. The typical readership would have biology and/or engineering degrees and would include researchers, scientific leaders, industry specialists and technology developers working in the biopharmaceutical field.

medical device development process: Production Management and Process Control

Beata Mrugalska, 2023-07-19 Proceedings of the 14th International Conference on Applied Human Factors and Ergonomics (AHFE 2023), July 20-24, 2023, San Francisco, USA

medical device development process: Medical Devices Seeram Ramakrishna, Lingling Tian,

Charlene Wang, Susan Liao, Wee Eong Teo, 2015-08-18 Medical Devices and Regulations: Standards

and Practices will shed light on the importance of regulations and standards among all stakeholders, bioengineering designers, biomaterial scientists and researchers to enable development of future medical devices. Based on the authors' practical experience, this book provides a concise, practical guide on key issues and processes in developing new medical devices to meet international regulatory requirements and standards. - Provides readers with a global perspective on medical device regulations - Concise and comprehensive information on how to design medical devices to ensure they meet regulations and standards - Includes a useful case study demonstrating the design and approval process

medical device development process: Applied Human Factors in Medical Device Design

Mary Beth Privitera, 2019-06-15 *Applied Human Factors in Medical Device Design* describes the contents of a human factors toolbox with in-depth descriptions of both empirical and analytical methodologies. The book begins with an overview of the design control process, integrating human factors as directed by AAMI TIR 59 and experienced practice. It then explains each method, describing why each method is important, its potential impact, when it's ideal to use, and related challenges. Also discussed are other barriers, such as communication breakdowns between users and design teams. This book is an excellent reference for professionals working in human factors, design, engineering, marketing and regulation. - Focuses on meeting agency requirements as it pertains to the application of human factors in the medical device development process in both the US and the European Union (EU) - Explains technology development and the application of human factors throughout the development process - Covers FDA and MHRA regulations - Includes case examples with each method

medical device development process: A Hand Book on Medical Devices Dr. Juturi Ravi

Kumar Reddy, 2023-06-29 Medical devices have revolutionized the practice of medicine, enabling earlier and more accurate diagnoses, minimally invasive treatments, and improved quality of life for patients. These devices assist in the prevention, diagnosis, monitoring, treatment, and management of various medical conditions. They range from simple, handheld devices to sophisticated, complex systems that integrate advanced technologies. The importance of medical devices lies in their ability to bridge the gap between medical knowledge and patient care, translating scientific advancements into practical applications. This book aims to provide a comprehensive overview of medical device development and applications. It will delve into various aspects, including design principles, regulatory considerations, clinical validation, manufacturing processes, quality assurance, and post-market surveillance. Each chapter will focus on specific topics within the broader domain of medical devices, providing insights, case studies, and practical guidance for professionals involved in this field.

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Elisabetta Ceretti, Joaquim De Ciurana Gay, Ciro Angel Rodriguez, Jorge Vicente Lopes Da Silva, 2016-10-24 *Biomedical Devices: Design, Prototyping, and Manufacturing* features fundamental discussions of all facets of materials processing and manufacturing processes across a wide range of medical devices and artificial tissues. Represents the first compilation of information on the design, prototyping, and manufacture of medical devices into one volume Offers in-depth coverage of medical devices, beginning with an introductory overview through to the design, manufacture, and applications Features examples of a variety of medical applications of devices, including biopsy micro forceps, micro-needle arrays, wrist implants, spinal spacers, and fixtures Provides students, doctors, scientists, and technicians interested in the development and applications of medical devices the ideal reference source

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Process Control Beata Mrugalska, Waldemar Karwowski, Tareq Z. Ahram, 2024-10-09 Drawing on contributions from various manufacturing fields, this book offers a comprehensive perspective by combining theoretical concepts with practical applications. It emphasizes future developments, the integration of technologies, and the crucial role of humans in manufacturing companies. Production Management, Manufacturing, and Process Control presents cutting-edge strategies and innovations

for creating people-centered manufacturing processes. It explores how culture influences cognition and behavior, providing readers with valuable insights into relevant theories. This book also explores risk management, human performance improvement, and the current challenges in quality and information systems management. Sustainable global manufacturing practices that balance global market access with strong domestic engineering ecosystems are covered in detail, and this book also addresses the optimization of production processes, including the use of machine learning for fault diagnosis. This is an ideal read and a valuable resource for students, graduates, teachers, researchers, and professionals in industrial management, business management, safety fields, manufacturing, risk management, and quality management.

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medical device development process: Handbook on Advanced Design and Manufacturing Technologies for Biomedical Devices Andrés Díaz Lantada, 2014-07-08 The last decades have seen remarkable advances in computer-aided design, engineering and manufacturing technologies, multi-variable simulation tools, medical imaging, biomimetic design, rapid prototyping, micro and nanomanufacturing methods and information management resources, all of which provide new horizons for the Biomedical Engineering fields and the Medical Device Industry. *Advanced Design and Manufacturing Technologies for Biomedical Devices* covers such topics in depth, with an applied perspective and providing several case studies that help to analyze and understand the key factors of the different stages linked to the development of a novel biomedical device, from the conceptual and design steps, to the prototyping and industrialization phases. Main research challenges and future potentials are also discussed, taking into account relevant social demands and a growing market already exceeding billions of dollars. In time, advanced biomedical devices will decisively change methods and results in the medical world, dramatically improving diagnoses and therapies for all kinds of pathologies. But if these biodevices are to fulfill present expectations, today's engineers need a thorough grounding in related simulation, design and manufacturing technologies, and collaboration between experts of different areas has to be promoted, as is also analyzed within this handbook.

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neuromodulation procedures as well as technical specifications of various implantable devices. All of the contributors to Neuromodulation represent leading experts in the field. The editors are internationally renowned in their respective fields of neuromodulation, pain management, functional neurosurgery and biomedical engineering. Neuromodulation will be the first and foremost authoritative text on neuromodulation therapies and will establish the gold standard that defines the field for years to come.

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randomized trial, and reliability study. Medical researchers will benefit from greater confidence in their ability to initiate and execute their own investigations, avoid common pitfalls in translational orthopedics, and know what is needed in collaboration. Further, this title is an indispensable tool in grant writing and funding efforts. The practical, straightforward approach helps the aspiring investigator navigate challenging considerations in study design and implementation. The book provides valuable discussions of the critical appraisal of published studies in translational orthopedics, allowing the reader to learn how to evaluate the quality of such studies with respect to measuring outcomes and to make effective use of all types of evidence in patient care. In short, this practical guidebook will be of interest to every Medical Researcher or Orthopedist who has ever had a good clinical idea but not the knowledge of how to test it. - Focuses on the principles of evidence-based medicine and applies these principles to the design of translational investigations within orthopedics - Provides a practical, straightforward approach that helps investigators navigate challenging considerations in study design and implementation - Details discussions of the critical appraisal of published studies in translational orthopedics, supporting evaluation with respect to measuring outcomes and making effective use of all types of evidence in patient care

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medical device development process: *Mission-Critical and Safety-Critical Systems Handbook* Kim Fowler, 2009-11-19 This handbook provides a consolidated, comprehensive information resource for engineers working with mission and safety critical systems. Principles, regulations, and processes common to all critical design projects are introduced in the opening chapters. Expert contributors then offer development models, process templates, and documentation

guidelines from their own core critical applications fields: medical, aerospace, and military. Readers will gain in-depth knowledge of how to avoid common pitfalls and meet even the strictest certification standards. Particular emphasis is placed on best practices, design tradeoffs, and testing procedures. - Comprehensive coverage of all key concerns for designers of critical systems including standards compliance, verification and validation, and design tradeoffs - Real-world case studies contained within these pages provide insight from experience

medical device development process: *Secure and Smart Cyber-Physical Systems* Uttam Ghosh, Fortune Mhlana, Danda B Rawat, 2024-07-26 Cybersecurity is a paramount concern in both Internet of Things (IoT) and Cyber-Physical Systems (CPSs) due to the interconnected and often critical nature of these systems. The integration of AI/ML into the realm of IoT and CPS security has gained significant attention and momentum in recent years. The success of AI/ML in various domains has sparked interest in leveraging these technologies to enhance the security, resilience, and adaptability of IoT and CPS. *Secure and Smart Cyber-Physical Systems* provides an extensive exploration of AI/ML-based security applications in the context of IoT and CPS. Features Presents cutting-edge topics and research in IoT and CPS Includes contributions from leading worldwide researchers Focuses on CPS architectures for secure and smart environments Explores AI/ML and blockchain approaches for providing security and privacy to CPS including smart grids, smart cities, and smart healthcare Provides comprehensive guidance into the intricate world of software development for medical devices Covers a blueprint for the emergence of 6G communications technology in Industry 5.0 and federated-learning-based secure financial services This book covers state-of-the-art problems, existing solutions, and potential research directions for CPS researchers, scholars, and professionals in both industry and academia.

medical device development process: *Healthcare Entrepreneurship and Management* Arnab Chanda, Shubham Gupta, 2024-06-28 Post pandemic, the world is not the same place. There has been an increasing focus on healthcare and well-being, which has created a once-in-a-lifetime opportunity for healthcare innovations and startups. From adoption of a range of medical apps and telemedicine technologies to heightened public interest in smart wearables and medical devices, the demand for efficient healthcare delivery has been skyrocketing. This book aims to serve as a first-of-its-kind guide for skill development in conception to commercialisation of healthcare products and services. It covers the gamut from the study of healthcare challenges, such as understanding customer requirements, market needs, and competition, to the various steps of the healthcare product development process, such as defining value propositions and specifications, the creation of minimum viable product (MVP) to prototyping, and manufacturing. The authors also discuss key commercialisation and management strategies, including the development of a robust business plan, fund raising, intellectual property, creating barriers to entry, and launching healthcare startups. Medical product pricing, positioning, sales and distribution, and customer acquisition are also presented with real-life examples. This book serves as a key reference not only for biomedical engineers who are looking to launch their products or services in the market but also for budding entrepreneurs willing to explore opportunities in the healthcare domain. For example, engineers and managers working on the development of medical devices require knowledge of ethical guidelines, regulations, and approvals to effectively launch their products in the medtech industry. On the other hand, entrepreneurs looking to benefit from the booming healthcare industry will find this book helpful in understanding the fundamentals of medical product development and commercialisation to launch their ideas successfully.

medical device development process: *Advances in Production Management Systems. Production Management Systems for Volatile, Uncertain, Complex, and Ambiguous Environments* Matthias Thürer, Ralph Riedel, Gregor von Cieminski, David Romero, 2024-09-06 The six-volume set IFIP AICT 728-729 constitutes the refereed proceedings of the 43rd IFIP WG 5.7 International Conference on Advances in Production Management Systems, APMS 2024, held in Chemnitz, Germany, during September 8-12, 2024. The 201 full papers presented together were carefully reviewed and selected from 224 submissions. The APMS 2024 conference proceedings are

organized into six volumes, covering a large spectrum of research addressing the overall topic of the conference “Production Management Systems for Volatile, Uncertain, Complex, and Ambiguous Environments”. Part I: advancing eco-efficient and circular industrial practices; barriers and challenges for transition towards circular and sustainable production processes and servitized business models; implementing the EU green deal: challenges and solutions for a sustainable supply chain; risk analysis and sustainability in an uncertain system in a digital era. Part II: smart and sustainable supply chain management in the society 5.0 era; human-centred manufacturing and logistics systems design and management for the operator 5.0; inclusive work systems design: applying technology to accommodate individual workers’ needs; evolving workforce skills and competencies for industry 5.0; experiential learning in engineering education. Part III: lean thinking models for operational excellence and sustainability in the industry 4.0 era; human in command - operator 4.0/5.0 in the age of AI and robotic systems; hybrid intelligence - decision-making for AI-enabled industry 5.0; mechanism design for smart and sustainable supply chains. Part IV: digital transformation approaches in production and management; new horizons for intelligent manufacturing systems with IoT, AI, and digital twins. Part V: smart manufacturing assets as drivers for the twin transition towards green and digital business; engineering and managing AI for advances in asset lifecycle and maintenance management; transforming engineer-to-Order projects, supply chains, and systems in turbulent times; methods and tools to achieve the digital and sustainable servitization of manufacturing companies; open knowledge networks for smart manufacturing; applications of artificial intelligence in manufacturing; intralogistics. Part VI: modelling supply chain and production systems; resilience management in supply chains; digital twin concepts in production and services; optimization; additive manufacturing; advances in production management systems.

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