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An Analysis on Critical Regulative Issues Correlated with Medical Product Design Stages

Alper ÇALGÜNER

Gazi University, Architecture Faculty, Department of Architecture, 06570, Ankara, TURKEY

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Abstract

This research is a partially adaptive quest focusing on the local and universal systemic regulations and principles concerning medical equipment design and corporate apprehension levels on innovative processes. Considering the rapid changing variables in policy structures concerning medical equipment industries towards the content of user types and preferences, technological implementations, and marketing approaches; this study inquires the quality management modalities and primary product determination criteria. It is emphasized that product innovativeness does impact the nature of the medical product design process, and also sustainable innovative strategies endorsed by flexible and multi-disciplinary managerial modalities often present more unique and progressive opportunities of investigation than massive and conventional enterprises with larger endorsements and higher production capacities. Findings expose that focal aspects are transformed from empirical and quantifiable outcomes into qualifiably recordable and methodically observable ones in about 20 years.

1.INTRODUCTION AND RESEARCH PREFERENCES

The purpose of medical equipment is to be of assistance in the diagnosis, monitoring and even the treatment of patients' medical conditions (Khelood 2015; Polisena et al. 2014). Considering it is observable, convenient for quick feedbacks and measurable; medical equipment design can be identified as a suitable area for empirical researches. Since this area of study covers a substantially wide scale through industries conducting refined systematic methods that have been built upon a competent theoretical background, it continually requires a periodically updated comprehensive research and implementation process. Furthermore, as medical product industry acts as an internationally competitive, innovation-focused and dynamic sample theme that is closely correlated with research and support institutions, non-profit organizations, small and medium sized businesses, universities, scientific researchers, incubating enterprises, and corporate partnering relationships; it can be dealt as a unique point of issue for comparative researches conducted towards registering the observable impacts of innovation on designed products. The industry is also of particular interest to the study of new product development among manufacturers for more than two decades, "because the intense competition, high rate of growth, continuing technological innovation, customer sophistication, and relatively easy access to capital (thereby reducing barriers to entry) suggest a significantly above average level of new product development activity". (Rochford and Rudelius, 1997) Dozens of approaches on signifying the attitude of medical devices by product design perspectives are derived either through the standpoints of local and / or universal regulations (i.e. Maisel, 2004; Sharples et al., 2012; Hamrell, 2006; Pietzch et al., 2007), or on resultant consequences in the light of the User Centered Design (UCD) principles (Hallbeck, 2010), on the basis of usability testing principles (Carayon et al., 2010), through the categories of human error (Cooper et al. 2002), referring to experiences on the usage of ergonomic principles (Lauer et al., 2010). Grippingly, these researches have shown a substantial decline in quantity since 2013, which point out a satiety appertaining to a prevalent congruence on the used methods and attained findings. This circumstance, of necesstity, orients a researcher towards investigating and adapting retrospective methods and outcomes for diagnosing a specific approach to illustrate viable approaches for correlating medical device design context by local or universal regulations.

* Corresponding author: acalguner@gazi.edu.tr

As a function mainly involved in the development of new products, design challenges the natural organizational attitudes of preservation and resistance to change, generating a constant tension between the search for innovation and the necessity of relying on established ideas and solutions. (Deserti & Rizzo, 2014) This interaction between design and innovation processes forges the prevalent discussion on the variable roles of these activities through the operative stages of each other. A prior occasion of medical equipment design profession appears as it's capacity on exposing the tangible consequences of these processes by enabling this interaction that is convenient for being identified in a systemic regulative process. The most appropriate approach, is inferred to be conducted by licensed corporations. Appraising the efforts conducted by these corporations such as institutes, associations and centers that are appointed for defining and coordinating the procedure and standards of the medical product development stages, the generic structure of this study focuses on a broad conception of analyzing methods correlated with organizing medical device design processes.

Interpreting the common regulations and recent literature basing on the compilation above, it can be deducted that medical devices are usually supervised with complicated regulative arrangements in content of documentations related to Health Care Policy approaches that show variations depending on the device category, classified principally according to the predicted usage scenario, potential hazards, risk level, the position of contact with the user and systematic effects of the product. Focusing on the fragmentary intervals and the integrated stages along with the common evaluative criteria associated with medical device designing process, this study aims to contribute the previous methodical efforts for introducing the changing user types and preferences, technological implementations and marketing approaches basing on the innovativeness level of the designed product. Towards achieving the stated aims, importance is attached to tangential deductions correlated with new product frameworks, quality management modalities and primary product determination criteria.

The substructure of this research is constituted upon the study of Rochford and Rudelius (1997), in the means of using the method of classification, and the definitions of the classified titles that are used in the stated research. Two sets of information sources are determined by two regulatory documents that have been published with an approximate interval of two decades, for the utilization of the research. These documentary sets are used to provide keywords in order to be placed under the related titles that are derived from the methodological phases of Rochford and Rudelius.

Various approaches on procedures of organizing, analyzing and standardizing the definitions, procedures and protocols of product development activities in medical device production segments are discussed by studying on regulative documents. Intrinsic deductions are set forth in the light of the comparative discussions on the sample method and the common processes inferred from the relevant literature.

A Rough Outlook on the Regulative Processes and Institutional Approaches Concerning Medical Device Design Industry

The nature of medical device design settles around multi-purpose and multi-user access where it necessitates a regulative system through Health and Social Care Policies that would be ascendant in both local and international environments. That the policy documents and related corporations are matched up with each other in common for different approaches, the data is compiled bu quoting from recent studies in this section. While quite similar approaches may formulate some universal viewpoints, "Definitions and nomenclatures for medical devices are not internationally agreed upon, although this is being worked on by the Global Harmonization Task Force (GHTF), which was founded in 1992 by the European Union (EU), United States (US), Canada, Australia and Japan. (GHTF, 2005) These efforts have been facilitated by the passing of EU-wide harmonization legislation, the US Federal Drug Administration (FDA) Modernization Act, and through substantial adoption of GHTF recommended models by the Therapeutic Goods Administration (TGA) in Australia, the Therapeutic Products Directorate (TPD) in Canada, and by Japan's Ministry of Health, Labor, and Welfare (MHLW)." (Craven, 2006) The founding aim of GHTF seems to support a process of interpenetration towards the policy and regulatory documents, in the light of universal design criteria (i. e. focused function, safety, hygien), accelerating technological acquisitions and stimulating design innovation. Also "the U.S. Food and Drug Administration (FDA) is charged with

ensuring the safety and effectiveness of medical devices in the United States and regulates more than 1700 types of devices, 500 000 medical device models, and 23 000 manufacturers (Monsein LH. Primer on medical device regulation. Part I. History and background. Radiology. 1997;205:1-9. [PMID: 9314952] - Center for Devices and Radiologic Health. Accessed at www.fda.gov/cdrh /index.html. on 20 December 2003) (…) The safety and effectiveness of medical devices in the United States are under the purview of the FDA. The FDA's task is primarily risk assessment, which is performed through the processes of premarket and postmarket evaluation. The desire to rush a new product or technology to market must be balanced carefully against the desire to ensure the safety of those who will benefit from the device. The FDA, Congress, manufacturers, the public, and physicians each play a vital role in the safe and effective use of medical devices." (Maisel, 2004) "The Multidisciplinary Assessment of Technology Centre for Health care (MATCH) is a research collaboration that is working in conjunction with industrial collaborators to apply ergonomic methods to real case study projects with the ultimate aim of producing an industry focused guide to applying ergonomic principles in medical device development (…) MATCH is an Innovative Manufacturing Research Centre (IMRC) funded by the Engineering and Physical Sciences Research Council (EPSRC) and The Department of Trade and Industry (DTI). A collaboration between five UK universities, MATCH aims to support the health care sector by creating methods to assess the value of medical devices from concept through mature product. Although the MATCH research is being performed within an academic framework, the emphasis is on working with research partners such as the NPSA and industrial collaborators to solve real problems." (Martin et al., 2008)

Regulations about medical devices are intensely organized by specialized associations, focused research programs and national / international agencies. "Official sources of information on regulations and extensive guidance include the Medical Devices Directives (URL 1) and MEDDEV (URL 2) in the European Union, Device Advice (URL 3) in the USA, and via the websites of the other members of the Global Harmonization Task Force (URL 4). Industry-supporting websites and magazines, such as Medical Devicelink (URL 5), Medical Device Technology (URL 6) and publications of professional bodies such as the IEEE Engineering in Medicine and Biology Society (URL 7), are further useful sources of advice and information for medical technology developers (…) Health Technology Assessment (HTA) aims to provide information to support healthcare decisions and policy making at local, national and international levels. The University of York's Centre for Reviews and Dissemination (CRD) maintains an international database on behalf of the International Network of Agencies for Health Technology Assessment, including a list of HTA bodies worldwide and records of ongoing projects being conducted. (NHS HTA Program website, National Coordinating Centre for Health Technology Assessment (NCCHTA), UK, http://www.ncchta.org/ (accessed 10 March 2005).)" (Craven, 2006) These regulations must be considered at every stage of the development process (Pietzsch et al. 2009), along with models developed to facilitate MDD." (Medina et al., 2013)

2. METHODOLOGICAL AND EXECUTIVE APPROACH OF THE STUDY

Albeit of the convenient factors and adequate data for conducting a case study, having a high opinion of Breslin and Buchanan (2008) that case studies help focus on the transitions between theory and practice, and considering that conventional case studies typically serve for the researches conducted with little theory; this study have been envisaged as an adaptation of the research structure utilized in (Rochford and Rudelius, 1997) from a 13-stage model of the NPD process, adapted and modified from Cooper (1990) and Kleinschmidt et al. (1991) and the Booz, Allen, and Hamilton (1982) models. The stated research model is constructed upon developing and analizing propositions by suggesting related management actions involving the variables V1, V2, V3, V4 shown in Figure 1.

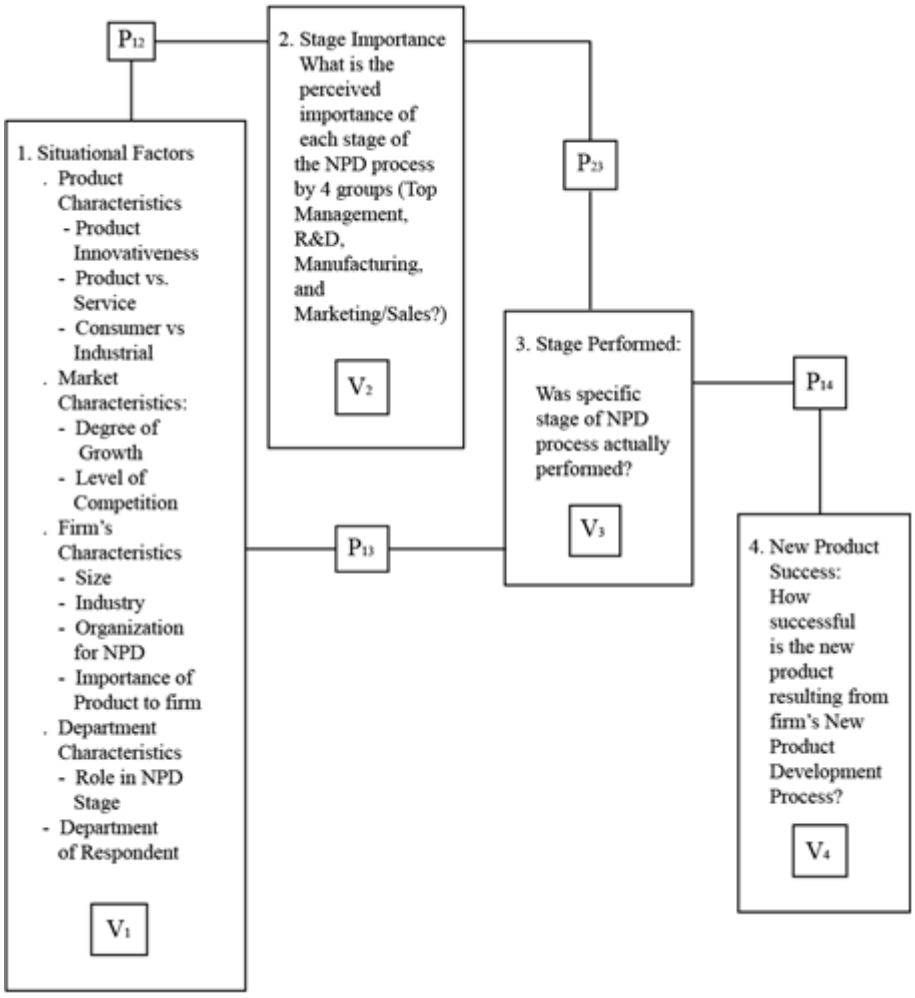

Figure 1: Research design of the NPD process linking situational factors, perception, and performance of new product stages and new product success. (Rochford and Rudelius, 1997)

The set of variables (V) and propositions (P) are defined on the basis of the original approaches and the vision identified by the intrinsic modality of this study. Importance is attached to the economic motility and innovative elasticity, making the studied document be assigned through both a production and procurement region of EU cuntries. Four sets of survey themes are designed for interpreting and discussing the variables under a taxonomic scheme. These themes are formulated to refer to the adaptated titles of 'designed product', 'analysis of EU approach', 'corporate information' and 'R&D activities'. The senses and contents of those variables and references are stated below:

Variable 1

The heading 'Situational Variables' refers to a complex but coordinated stack of sub variables, including the specialized conditions of the product, market, firm and department. For reporting the situational factors, as to ensure the scope of the heading, the focus points of the 'designed product' theme are cumulated around the design staff, utilized design support programs, samples of products, and value added by design.

Design staff: Existing structures and predictions about the designer contributions are classified according to their position and acquisition. Permanent designer staff models are designed to be investigated as well as part time or freelance designers or design teams, design focused project managing SMEs, and

engineering or mechanical design structures. The estimated returns about design staff are mainly recorded as characteristic or uncommon ways of benefiting from the probable economic contributions of designers.

Design support programs: These programs are found to be designed and conducted mainly by national policy structures. As to differentiate the types of support models, the queried patterns are scrutinized under two core statements: Direct and indirect design support programs. These terms are stated with their semantic explanations that are admitted in this study as follows: Direct design support programs are programs generated for supporting the steps of design process as 'developing original concepts and solution proposals', 'ergonomic analysis', 'determining materials and production methods' and 'prototyping' which are determined towards national design approach and defined in policy structures, in professional activities concerning design activity. İndirect design support programs are support structures generated towards activities containing or concerning design process, not by focusing on design activity.

Types and samples of products: On condition that all discussed devices are designed, produced and marketed for serving the entailments and requirements of the medical segment; they are characterized in this study according to the R&D expenses, production costs, expertise areas of usage, ensured standards and level of innovative technologies they reserve. The potential contributions of design staff varying primarily in education and specialization backgrounds will be deduced by this focus.

Value added by design: In conjunction with a wide range of discussions about the topic, the economical and reputable contributions of a designer to a company as well as the product is perceived as value added by design in this study.

In order to assure the particular aims of the research, the sample cluster is analyzed over the given viewpoints of the sectorial vision of the inclusionary managerial structure of the cluster, common resources for usage, and inclusive collaboration attempts. Particularly, specific occasions on mutual use of quality standards and consultancy services, activities of support and education institutes, testing and control centers, performance and security tests are interrogated.

The data on company information is organized by focusing on the determination techniques on product scale, imported / domestic stock rates, production capacity usage rates and erroneous production rates that are aimed to be queried. Besides, with reference to the R&D activities, the role of the specified staff and departments, utilized R&D supports and the endorsement proportions are designated in the survey context.

Variable 2 and 3

Rochford and Rudelius (1997) defined the stage importance variable as the importance of each stage of the NPD process as perceived by top management, R&D, manufacturing, and marketing/sales. Similarly, stage importance was considered an important variable as it is expected to influence whether a given stage in the new product process would be undertaken. In particular with this research, stage importance variable is rated according to the findings of the sequences concentrated on market and user group analyzing methods, product development strategies and prototyping techniques.

Variable 4

Considering the new product success, the research is designated to identify the feedback mechanisms, especially on international markets. Although the scope represents the prominent facts of this variable, this method partially fails in measuring the new product performance, especially in devices hosting high tech components. This deficiency is surpassed by omitting the quantitative data acquired for V4 to interpret only qualitative findings in the discussion section.

The research propositions are composed of four main modes of relationships among the four variables discussed above. Based on the model approach, these linkages appear as:

P1.2 Product innovativeness and stage importance: Regarding market research and data on previous efforts for satisfying a particular theme as the first stage of the product development activity, the whole process, up to the end of prototyping and after sales feedbacks, deals with the innovativeness level and qualities of the final product. Quantifying this relationship entails a manipulation over a range of defined product development steps above a set of completed research on measuring innovative output. (Dewangan and Godse, 2014; Lin et al., 2012; Mahroum and Al-Saleh, 2013) Sufficient assessments can be actualized by counting on vis-a-vis interviews as well as open ended survey queries.

P1.3 Product innovativeness and stage performed: A quantitative inference on the whole process reveal weakness in identifying the output of every completed step. Presuppositions comparative predictions by a deductive approach should mislead the research in attaining delusive findings about the analysis of the stage outputs.

P2.3 Stage importance and stage performed: The model approach, which highlights the importance of a given stage, should be an indicator of whether a stage was undertaken. Disagreement among departments concerning the importance of a particular stage may mean that a particular stage is not undertaken or sufficient resources are not directed to the stage to ensure that the activity is adequately completed. (Rochford and Rudelius, 1997) Not to mention, the significance of every stage is found to have determinative impacts on the partial outputs.

P3.4 Stage performed and new product success: For performing a factual discussion, it is deduced that corporate continuity is essential in assigning a consistent vision exhibiting new product success. Participating firms were asked to point out three fundamental criteria for launching a new product by evaluating a recent supported project that has been put on the market. The responses have bargained for providing any evidence that fixes a peculiar manner in clarifying the interactive relationship between the outputs of every stage and level of success considering design aims.

There are planned to be two sets of documentaries, representing the late 20th and early 21st century approaches, in order to make a comparison for determining the transition in the general contents and regulative criteria. 3 representative and inclusive texts are listed for each set, that are competent for fulfilling the requirements of the methodological formulation.

The first set of documentary that should be a base to find out common keywords or phrases defining a holistic scope of regulative items, are fixed to be;

- Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (90/385/EEC).

- Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

- Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

The second set of information, representing the early 21st century approach, is finalized as to be 'Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC' and 'Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU' that have been published in the Official Journal of the European Union, Volume 60.

As to make adjective deductions from the stated documentary through defining a rough frame of classified aspects for holding a view on the general approach towards medical equipment design, a taxonomic approach is applied on the theme. The titles that specified data from the documentary are placed under, are

formalized basing on Figure 1 [Research design of the NPD process linking situational factors, perception, and performance of new product stages and new product success (Rochford and Rudelius, 1997)].

Despite the hierarchical complexity through the interactive settlement of variables and propositions on Rochford and Rudelius' theme, peculiar requirements of this study entail an egalitarian approach towards the headings and sub headings, also by evaluating the whole and eliminating a part of those aspects in the light of research aims and available data used in this study. The stated selection process is carried on by considering the criteria below:

- Every selected title should be in direct relationship with the common context of the regulatory documentation that is reviewed in the study.

- The titles should be in correspondance with each other, by means of being referring and supporting each other title's theme and the anticipated content.

- The titles should include every keyword and phrase that is deducted from the regulatory documentation.

The determined criteria point out a set of titles to be correlated with the deducted keywords and phrases. In order to provide a proper and elucidatory correlation, it is decided to liberate the correlation of a keyword or phrase with one or more title.

Through those appointed decisions, the titles are appeared to be listed as below:

• Designed Product

• Analysis of EU approach

• Corporate information

• R&D activities

• Situational factors

• Market characteristics

• Product characteristics

• Product innovativeness

• Organization for NPD

• Role in NPD stage

• Stage importance

• Stage performed

• New product success

• Situational variables

• Specialized conditions

• Product characteristics

• User group analyzing methods

• Product development strategies

• Prototyping techniques

• Design staff

• Utilized design support programs / operational process plans

• Samples of products

• Value added by design

• Feedback mechanisms

• Measuring the new product performance

The derived keywords from the two sets to be classified, are stated on the table under the related titles:

	First Set	Second Set
Designed Product	Mass-produced Adapt Requirements Professional user and devices Mass-produced Industrial manufacturing processes Written prescriptions Authorised person Custom-made Benefits Public health Foreseeable risks and inconveniences Preparatory cleaning or disinfection Consumable components Regulation	Used safely with the materials, substances and gases Routine procedures Designed and manufactured Compatible Provisions Restrictions
Analysis of EU Approach	Regulation Regulation Quality Safety Clinical investigations Safety Clinical investigation Regulation Economic operators Users Specific processes Conformity assessment Clinical investigations Clinical evaluations Post-market surveillance Market surveillance Standards Technical specifications Legal certainty Technical documentation EU declaration of conformity	National legislations
Corporate Information	The health institution Competent authority Manufacturing Modification	
R&D Activities	Manufacturers Recording	

	Reporting Objectives Implications Risks Inconveniences Clinical investigations Clinical investigations Clinical investigation National law Clinical investigations Clinical evaluation Performance studies Performance evaluation Post-market performance Physico-chemical characterisation Toxicological testing	
Situational Factors	Analytical or clinical performance Performance evaluation plan Related reports Omissions	
Market Characteristics	Internal market Protection of health Small- and medium-sized enterprises Regulation Harmonise rules Market of medical devices Second-hand sales Post-market surveillance Post-market surveillance report Post-market surveillance data Evaluate Production phase Post-market surveillance system Frequency of occurrence Overall risk Benefit-risk ratio Risk acceptability	Clinical investigation (plan)
Product Characteristics	Regulation Quality Safety Common safety concerns	
Product Innovativeness	Benefit-risk determination Risk management Design and manufacturing information Instructions Labelling Identification of needs Identification of options	
Organization for NPD		
Role in NPD Stage	Ergonomic features of the device Technical knowledge Experience Education Training Use environment Medical and physical conditions	
Stage Importance	Post-market phase Post-market experience Technical documentation National competent authorities Market surveillance activities Post-market surveillance system Quality management system Post-market surveillance plan Post-market surveillance Preventive and/or corrective actions Update Technical documentation Risk assessment Performance evaluation Purposes of transparency	
Stage Performed		

New Product Success	Safety and performance results Assessment of risks Clinical benefits Discussion of clinical relevance Clinical state of the art Specific precautions Specific patient populations Implications for the investigational device Limitations of the investigation General safety and performance requirements Intended purpose	
Situational Variables	Clinical investigations Safety Dignity Well-being Clinical investigation Clinical data Valid Reliable Robust Nature Objectives Benefits Implications Risks Inconveniences Clinical investigations	
Specialized Conditions	Risk management system Clinical evaluation Clinical risks Clinical investigations Clinical evaluation Post-market clinical follow up Risk management Clinical evaluation Risk management Construction and material Reverse engineering Specific patient populations Individual subjects Protection of public health Manufacturers Risk management system Risk management Regular systematic updating Risk management plan Identify and analyse Known and foreseeable hazards Estimate and evaluate the risks Reasonably foreseeable misuse Risk control measures Safety principles Residual risk Residual risk	Injury risk Physical features Conditions of the devices Particles penetrating in the device inadvertently Risk management output
Product Characteristics		Interaction features of medical equipment and the body Medical fuctionality and performance Product Identification Fixture Hardware Software Implant Reactive Material Analytical susceptibility Diagnostic susceptibility Analytical genuineness Diagnostic specificality, Precision Repeatability Determination limits Known interference Control. Design calculations Test results.

		Design calculations Risk analysis Investigations Technical tests Benefit/risk profile Specific design characteristics
User Group Analyzing Methods	Clinical evaluation Favourable and unfavourable data Classification Intended purpose Manufacturer's claims Available clinical data Intended purpose Clinical evidence Systematic scientific literature review Health institution Documentation Target patient group's specific needs	Planning Clinical evaluation Methodology Literature review Documentation Literature review Clinical research Surveillance Clinical follow-up Presentment to the market Clinical evaluation report
Product Development Strategies	Physicochemical properties Intensity of energy Tensile strength Viscosity Surface characteristics Wavelength Software algorithms Similar deployment methods Similar principles of operation Critical performance requirements	Comprehensibility Drawings Diagrams Plans Definitions Explanations Handbooks Internationally accepted symbols Label and media of the instruction manual Format Content Legibility Position General definition of the device Alterations Documents Quality system, Characteristics of basic materials Features Limits of the device's performance Production method Design drawings Component diagrams Sub-parts Circuits Quality control Quality Assurance Techniques, Quality System Documentation, Quality Assurance Methods, Quality Programs, Quality records Inspection records Test and calibration data Quality reports Related staff Quality-system documentation Results of analyses Calculations Tests Pre-clinical and clinical evaluation Post-market Clinical follow-up plan Post- market clinical follow-up Quality policies and procedures Quality programmes Quality plans Quality manuals Quality records Documentation Quality system, Obligations Quality system Approved quality system
Prototyping Techniques	Supervision and control of the manufacture of devices Post-market surveillance	Safe design and production

	Vigilance activities Regulatory compliance Conditions of qualification	
Design Staff	International standards Administrative organisation and structure Confidentiality of information Device technologies Conformity assessment of devices Certification	
Utilized Design Support Programs / Operational Process Plans	Benefit-risk determination Risk management Instructions for use User training Manufacturer's post-market surveillance plan PMCF plan proposed Quality management system Quality of processes, procedures and devices Structure Responsibilities Procedures Processes Management resources Principles and actions Regulation Regulatory compliance Conformity assessment procedures Procedures for management of modifications	
Samples of Products		
Value Added by Design	Robust Transparent Predictable Sustainable regulatory framework High level of safety and health Innovation Regulatory approach Supervision of notified bodies Conformity assessment procedures Clinical investigations Clinical evaluation Vigilance Market surveillance Provisions ensuring transparency and traceability Improve health and safety Custom-made devices Technical documentation Technical documentation Conformity of the device Regulation Pre-clinical and clinical evaluation assessment report EU type examination report Serious incidents Field safety corrective actions	Design aim Diagnosis Prevention Monitoring Prediction Prognosis Treatment Alleviation of the disease. Diagnosis Monitoring Treatment Alleviation Compensation Injury Disability. Research Substitution Modification Anatomy Any physiologic or pathologic process or case. Providing information In vitro investigation Samples that are obtained from human body Organ Blood Tissue donations. Prevention or support pregnancy Hygiene Disinfection Sterilization Diagnosis Prevention Monitoring Treatment Alleviation Diagnosis Monitoring Treatment Alleviation Compensation Injury Handicap, Investigation Replacement Modification Anatomy

		Physiological process, Control of conception Transport and storage Choice of materials Toxicity Flammability Compatibility Materials used Biological tissues Cells Body fluids Intended purpose Risk posed by contaminants and residues Transport Storage Use of the devices Risks posed by substances leaking from the device. Risks posed by the unintentional ingress of substances into the device Risk of infection Easy handling Minimize contamination of the device Sterile The risk of injury Physical features Volume/pressure ratio Dimensional and where appropriate ergonomic features Risks connected with reasonably foreseeable environmental conditions Risks arising where maintenance or calibration are not possible Ageing of materials Loss of accuracy Measuring or control mechanism Minimize the risks of fire or explosion Sufficient accuracy and stability Measurement Monitoring Display scale Ergonomic principles Protect the patient and user Mechanical risks Resistance Stability Moving parts Analytical sensitivity Diagnostic sensitivity Analytical specificity Diagnostic specificity Accuracy Repeatability Reproducibility Control of known relevant interference Limits of detection Characteristics Performances Intended use Storage and transport conditions Temperature Humidity Measuring Monitoring Display scale Colour change Visual indicators Designed Manufactured Ergonomic principles Intended purpose Easy to use Intended lay user Risk of user error Handling of the device Interpretation of the results

Feedback Mechanisms		Elements Requirements Provisions Systematic and orderly manner Written policies Procedures Quality programmes Quality plans Quality manuals Quality records Performance evaluation studies Analysis Calculations Design Accommodated standards Common specifications Pharmaco-toxicological and clinical standards and protocols Testing Proprietary medicinal products Consultation results Test reports Calibration data Mandatory Specifications Technical Safety Features National Provisions Medical device vigilance systems
Measuring the New Product Performance	General safety and performance requirements Requirements for clinical investigations Clinical evaluation Post-market clinical follow-up Regulation Unannounced on-site audits Physical or laboratory tests Original certification Risk management Interaction between the device and the human body, Clinical performance Clinical evaluation guidance Performance evaluation guidance Performance of conformity assessment State of the art Clinical evaluation Performance evaluation Physico-chemical characterisation Microbiological Biocompatibility Mechanical Electrical Electronic or non- clinical toxicological testing Clinical data Clinical evaluation Physico-chemical characterisation Microbiological Biocompatibility Mechanical Electrical Electronic Non-clinical toxicological testing Risk management system Performance evaluation process Clinical risks Performance studies Performance evaluation Post-market performance follow-up Risk management Performance evaluation Inter-dependent Monitoring and measurement of output Data analysis Product improvement	Inspection Procedures Self adjustment Calibration Maintenance Safety Medical confidentiality Risk of use error Ergonomic features Design for patient safety Technical knowledge Experience Education Training Medical and physical conditions Professional, disabled or other users Eliminate or reduce risks Inherently safe design and construction Adequate protection measures Risks that cannot be eliminated Residual risks Shortcomings of the protection measures adopted. Design control Design verification Comparison test Conclusions of the examination Conditions of its validity Data needed for identification Inspections Tests Standardizations Calibrations Qualifications Demonstration of conformity Essential requirements Performance evaluation Bench testing Pre-clinical evaluation

DISCUSSION ON THE PARTICULAR ISSUES OF THE CASE

3. **A**

This research is conducted about 33 years after Booz, Allen, and Hamilton; and 18 years after Rochford and Rudelius models have published. Medical device design industry has rapid changing variables as user types and preferences, technological implementations, and marketing approaches. Besides, it shelters various stabilized aspects like safety, reliability and particular criteria on hygiene. One of the main findings of the model study emphasizing that product innovativeness does impact the nature of the new product development process, are secured by the deductions indicating the interaction of fragmentary or integrated process intervals with the indications concerning the success and innovativeness levels of product designs. Similarly, the differences between more and less successful products, are based on the innovativeness level of the product that have appeared towards the responses about the new product frameworks, quality management modalities and primary product determination criteria.

This research is conducted with respect to an organizational structure that ensures an occasion demonstrating strategic motility, flexible quantity of design staff, management intellect overlooking both high-tech and low-tech industrial circumstances with limited resources, and innovating ability for the researchers. It is fixed by the inferences that studies focusing on the viable lookups on the productivity levels of innovative medical design processes should submit literal proposals of conducting sophisticated new product development activities that are adequate to provide constant economical acquisitions. It is also espoused that sustainable innovative strategies endorsed by flexible and multi-disciplinary managerial modalities often present more unique and progressive opportunities of investigation than massive and conventional enterprises with larger endorsements and higher production capacities.

That there seems to be a general average of two decades between the publishing eras of the two sets, deductions have a potential to be a ground for a comparative evaluation through a radiply converted process, the classified keywords and phrases are discussed in terms of subtitles for design related issues, by being correlated with the main titles of the table. These correlated themes configuring the comparative evalualtion, serve a purpose of associating the perceptions, measures, focuses and criteria that the regulative documents comprise, which are provided for querying the validity and efficacy of current local and universal governance approaches on medical equipment design.

4. CONCLUSIONS

There are found to be 1160 keywords or phrases that are classified under 21 of the 26 titles for the first set, while the relatively recent second set included 1153 keywords or phrases located under 13 of 26 titles. The more intense aggregation on less titles of the second set point out a quantitative reduction through the active scale of the research universe, as well as a qualitative increase in terms of homogenity. Analitical, technical, corporate and situational determinants show a dominancy on the first set, while non-technical issues like product characteristics or value added by design appeared to be more observable on the current regulative set of documents. Unexpectedly, product development stages and feedback mechanisms are fixed to came into prominence in time, according to the dispersion of the data on table. The terms ‘requirement’, ‘regulation’, ‘investigation’, ‘evaluation’, ‘surveillance’, ‘specification’, ‘documentation’, ‘identification’, ‘determination’, ‘assessment’, ‘implication’, ‘limitation’, ‘management’, ‘updating’, ‘classification’, ‘supervision’, ‘qualification’, ‘organization’, ‘information’, ‘modification’, ‘examination’, ‘certification’, ‘interaction’ are detected to be used typically in the more outdated first set, however, the second set commonly include ‘provision’, ‘restriction’, ‘procedure’, legislation’, ‘investigation’, ‘risk’, ‘output’, ‘feature’,

‘interaction’, ‘identification’, ‘calculation’, ‘analysis / analytical’, ‘test’, ‘profile’, ‘susceptibility’, ‘genuineness’, ‘specificality / specification’, ‘precision’, ‘repeatability’, ‘determination’, ‘interference’, ‘control’, ‘benefit’, plan’, ‘document / documentation’, ‘comprehensibility’, ‘alteration’, ‘format’, ‘quality’, ‘qualification’ ‘legibility’, ‘position’, ‘characteristics’, ‘record’, ‘report’, ‘calibration’, ‘analysis / analytical’, obligation’, ‘safe (design) / safety’, ‘design aim’, ‘research’, ‘prediction’, ‘modification’, ‘prevention’, ‘monitoring’, ‘measurement’, ‘sensitivity’, ‘ergonomic’, ‘procedure’, ‘confidentiality’, ‘accuracy’. The most reiterant keywords are appeared to be ‘evaluation (18)’, ‘management (14)’, ‘surveillance (13)’, ‘regulation (12)’, ‘investigation (10)’, ‘assessment (7)’, ‘quality / qualification’ (6) in the first set, where the second set put forward ‘quality (21)’, ‘risk (15)’, ‘test (8)’, ‘feature (7)’, ‘analysis / analytical (7)’, ‘plan (6)’, ‘monitoring (6)’, ‘safe (design) / safety (5)’, ‘calculation (4)’, ‘record (4)’, ‘calibration (4)’, ‘procedure (4)’ in quantitative order. By having a rough look over the outcomes of the process, a generic deduction can be exposed, focusing on contextual qualities of prevalent keywords that also are constitutive findings of the research. This task enlightens an inclusive model of common approaches on regulative procedure over medical equipment design that are issued through a two decades interval. The dominant keywords are inferred to be more empirical and quantifiable in the first set, while the outcomes of the second set are observed as the process is constructed on qualifiably recordable and methodically observable sets of data. This inference can be clearly crosschecked and verified by fixing the ranking of ‘quality’ over the findings of the two sets. The determination can also be supported by the establishment of keywords as risk, test, plan, monitoring and analysis, that can be assessed as knotty-to-define components for defining by a linear model of explanation.

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