29 January 2020

DESIGN & DEVELOPMENT

SKILLS DEVELOPMENT
Experience
- 12 Years in Textiles: Operations Dyeing / Printing / Finishing (Various)
- 9 Years in Pharmaceuticals: Plant Operations with Beecham (now GSK)
- 3 Years in TQM Consultancy with PERA
- 23 Years in Consulting & Training with GPB

Education
- Colour Chemistry & Polymer Chemistry
- Psychology
- Business

Memberships
- TOPRA, RAPS, BPS
Background

GPB Management Consultancy: Formed 14 March 1994
G.P.B. Limited: Formed 2005

- Regulatory Affairs (RA) & Quality Assurance (QA)
  - CE Marking some 3,500 + devices
  - Major Countries Market Clearance
  - Management Systems
  - Supply Chain Management
  - Clinical Evaluation
    - CIP, CI Application
  - Issue Resolution
- Multi-Disciplinary Team / Board Memberships
- QAR / Advisors
- Training / Workshops
Examples of graduates worked with:

- Physiotherapists
- GP’s Consultants
- Biologists
- Microbiologists
- Toxicologists
- Physicists
- Astronomers
- Chemists
- Pharmacists
- Librarians
- Electronic Engineers
- Software Engineers
- Risk Analysts
- Various Researchers
- Electrical Engineers
- Mechanical Engineers
- Hydraulic Engineers
- Nurses
- Marketing
- Business
- Finance
- Statisticians
- Mathematicians
- IT
- Data Analysts
- Linguists
- Project Engineers
- Process Engineers
Medical Devices: Bandages, software tools to surgical robots
Challenges:

- Lack of innovation in conventional segments,
- Evolution of GAFAM (Google, Amazon, Facebook, Apple, and Microsoft)
  - increasing personalization,
  - data and tech leverage,
  - enhanced post-acute care coordination
  - increasing focus on value-based care models.
- Asia-Pacific:
  - key growth region
  - driven by adoption of emerging technologies in countries like Japan, China, Singapore, and India
  - 25% of global market by 2019
  - Overtake Europe as the second-largest market by 2022.
2020 To Tap growth Opportunities:

- Focus on smartphone-based solutions:
  - $2.11 billion opportunity by 2020.
  - Technologies such as AI, machine learning, AR/VR, Internet of Things (IoT), and big data analytics, coupled with existing smartphone tools like cameras and external sensors, are transforming smartphones into powerful and cost-effective diagnostic tools.

- Offer Software-as-a-Medical-Device (SaMD).
  - These will become the building blocks of platforms of care aimed at holistic solutions for diagnosis, surgery, surgical navigation, treatment planning, and disease management.
2020 To Tap growth Opportunities:

- Improve care-coordination and information exchange for patients to enhance their outcomes.
  - Medtech companies are building risk-sharing contracts that are enabled only by data-sharing models, to understand the role of vendor solutions in care and outcomes management as a part of the overall strategy to become partners with hospitals.
- Properly define the endpoints and measurement criteria to prevent disease adjacencies.
- Foster partnerships with smart home ecosystem:
  - participants to aid early diagnosis and disease management and hence, ensure better outcomes.
WHAT WE DO

Medical Devices
Complete Life-cycle Compliance

- Bespoke compliance services, for any or all life-cycle stages;
- Expert hands-on support to attain, maintain and retain those vital registrations, certificates & licenses for your markets;
- Work with us to ensure your devices are safe, perform as intended and your management systems remain fully compliant with regulations, national & global standards.

CLiC on any stage
**Medical Device Regulation (MDR)**

**MEDICAL DEVICES**
- Any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specified medical purposes.
- Devices for the control or support of conception;
- Products specifically intended for the cleaning, disinfection or sterilisation of Medical devices, accessories and products without an intended medical purpose as MDR Article 1 (2)

**INTENDED PURPOSE**
the use for which a device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements and as specified by the manufacturer in the clinical evaluation

**TECHNOLOGY**
- IP / POC
- MEDICAL PURPOSE
  - diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease
  - diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability
  - investigation, replacement or modification of the anatomy or of a pathological process or state
  - providing information by means of *in vitro* examination of specimens derived from the human body, including organ, blood and tissue donations
Devices shall:

- achieve the performance intended by their manufacturer;
- be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose;
- be safe and effective;
- not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art.
Design Pre-considerations

MEDICAL DEVICE DESIGN CONTROL CYCLE

1. Concept Design
2. Design Planning
3. Product Design
4. Design Verification
5. Design Validation
6. Design Transfer

- User Needs
- Design Inputs
- Design Process
- Design Outputs
- Verification
- Finished Device
- Design Transfer

Reviews:
- Design History File
Design & Development: Planning

Requirement:

- Plan and control the design and development of product.
- As appropriate, design and development planning documents shall be maintained and updated as the design and development progresses.
- During design and development planning, the organization shall document:
  - the design and development stages;
  - the review(s) needed at each design and development stage;
  - the verification, validation, and design transfer activities that are appropriate at each design and development stage;
  - the responsibilities and authorities for design and development;
  - the methods to ensure traceability of design and development outputs to design and development inputs;
  - the resources needed, including necessary competence of personnel.
VERIFICATION PLAN
- Methods & acceptance criteria
- Statistical techniques with rationale for sample size

VALIDATION PLAN
- Methods & acceptance criteria
- Statistical techniques with rationale for sample size
- Conducted on representative product e.g. initial production units, batches or their equivalents.
- The rationale for the choice of product used for validation shall be recorded.
- Perform clinical evaluations or performance evaluations of the medical device in accordance with applicable regulatory requirements.
- If the intended use requires that the medical device be connected to, or have an interface with, other medical device(s), validation shall include confirmation that the requirements for the specified application or intended use have been met when so connected or interfaced.
- Validation shall be completed prior to release for use of the product to the customer.

TRANSFER PLAN
Document procedures for transfer of design and development outputs to manufacturing. Procedures shall ensure that design and development outputs are verified as suitable for manufacturing before becoming final production specifications and that production capability can meet product requirements.

CHANGE PLAN
- Document procedures to control design and development changes.
- Determine the significance of the change to function, performance, usability, safety and applicable regulatory requirements for the medical device and its intended use.
- Design and development changes shall be identified.
- Before implementation, the changes shall be: reviewed; verified; validated, as appropriate; and approved.
- Review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product in process or already delivered, inputs or outputs of risk management and product realization processes.
Design & Development: Findings

Planning:
- No or poor supporting management framework;
- No defined aims
- No documented definition of:
  - who plans, does, reports / approves;
  - competencies and understanding of medical design process;
- Sketchy outline Plan sometimes with Input, output, verification, validation headings
- Poor Document / Records Control;
- Plan does not embrace & integrate:
  - risk management;
  - manufacturing processes;
- No clear hold points / review / documentary evidence
- No updating of plan
- Assumption that design and development stages are purely sequential;
Requirement / Content:

- Intended Use
- Outputs of Risk Management
- Functionality & Performance
- Usability & Safety
- Regulatory / Standards
- Information from existing designs essential for D & D of device and processes
- Inputs shall be complete, unambiguous, able to be verified or validated, and not in conflict with one another
Requirement / Content:
- Provide information for purchasing, production and service provision;
- Contain or reference product acceptance criteria;
- Specify product characteristics that are essential for safe and proper use;
- In a form suitable for verification vst D&D Inputs
Experts in Global Quality Assurance and Regulatory Affairs for Medical Devices. Consulting, training and supporting your medical device development throughout the life cycle from proof of concept, design, clinical evaluation, manufacture, clearance to market and post market surveillance.

Call for a confidential no obligation discussion with our team.

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