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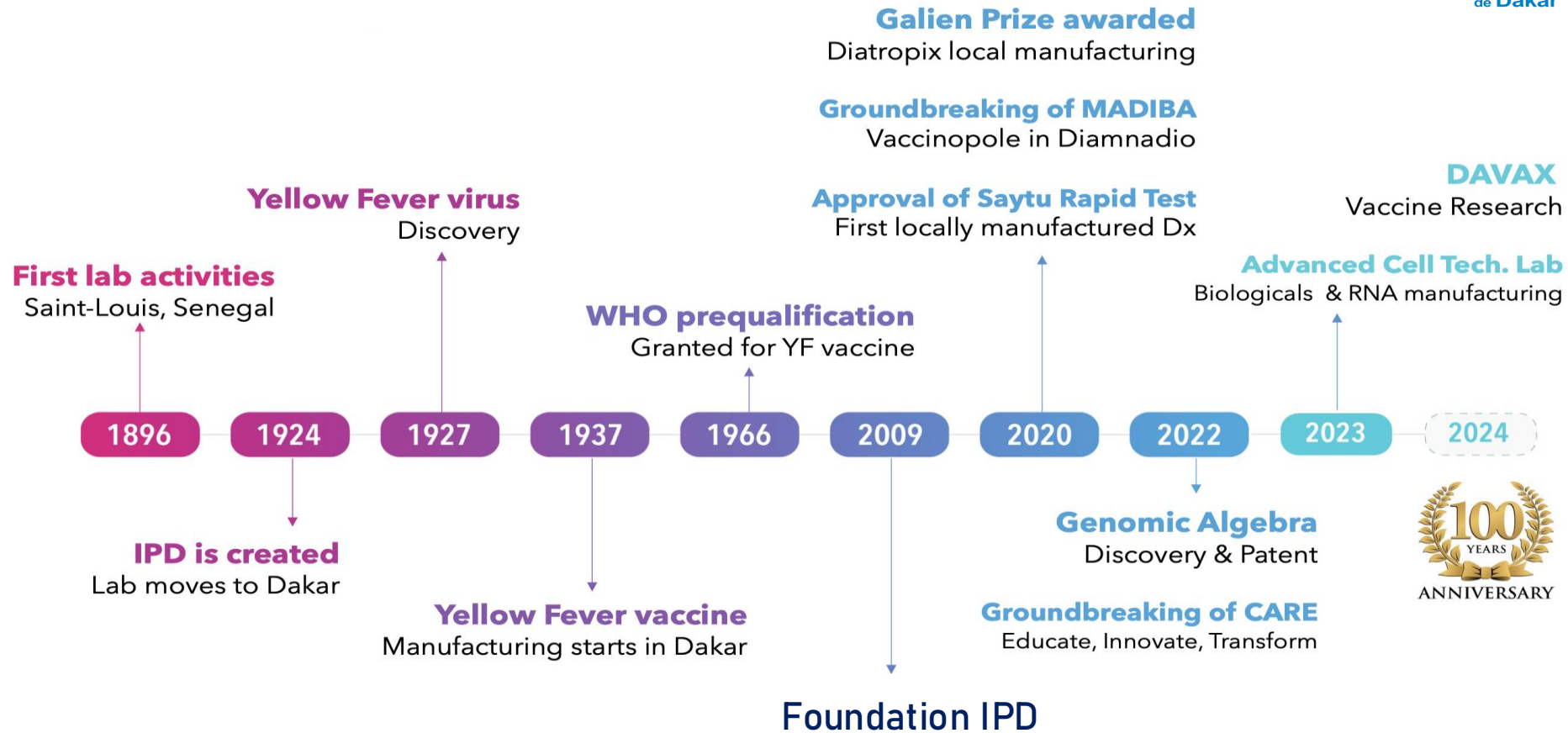
AFRICAN SOCIETY FOR LABORATORY MEDICINE

From the Lab to the Marketplace: ABCs of Diagnostic Product Development

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23 June 2026

A Century of Innovation at the Institut Pasteur de Dakar



Impact Figures

87

Years of vaccine production (over 390 millions doses)

12

Reference Laboratory for WHO, FAO, Africa CDC & ECOWAS

50

Sites of the Sentinel Syndromic Surveillance Network in West Africa

+40

African Countries supported in Epidemic Outbreaks

+100

Research articles published in 2024

+1,5 M

COVID-19 tests distributed

and several diagnostic tests in development (Measles, Yellow Fever, Meningitis, Ebola, HIV...).



Sovereignty-Driven Innovation

- Advancements in science and technology enable regional public health institutes in Africa like IPD to act as « First detector, First responder ».

DETECT

42 Senegal sites
10 regional sites

Daily data
Weekly samples
Reference labs

Mobile
laboratories to
decentralise tests

DISCOVER

Sequencing platform

Human, animal and
insect screening for
new viruses

Genomic and
immunological
assessment

DEVELOP

Bioprocessing and
R&D labs for
epidemics

Clinical trial platform
for regulatory
approval

Diagnostics and
mRNA vaccines

DELIVER

Responsive
manufacturing

Human capital
development for
biomanufacturing

Decentralised
production for
access and trust

DIATROPIX: promoting access to diagnostics

Visionary Partners



Business Model

DEMAND DRIVEN

African Union
Member States
procurement

IVD contract
manufacturing

NGO's, Charities,
& Donors
procurement



AFFORDABLE SUPPLY

MEMBERSHIP FEES
yearly subscription
covering fixed costs
(salaries, facility, etc)

MANUFACTURING FEES
on-demand
covering tests costs
(COGs, QA/QC)



Challenges

- Tests are **not available**
- Tests are available but **not satisfactory**
- Tests are available but **not affordable**

Opportunities

- Lateral Flow Assay
- Industrial partnerships

DIATROPIX: promoting access to diagnostics



R&D – tech transfer

ACT accelerator
ACCESS TO COVID-19 TOOLS



Manufacturing



COVID-19 Ag RDT



What are In Vitro Diagnostics (IVDs) ?

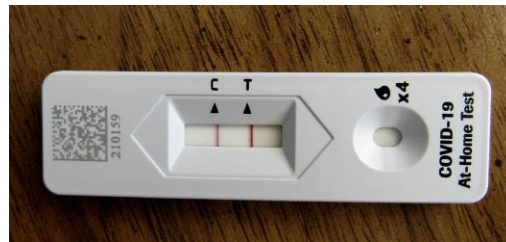
- **Definition:** Test kits, reagents, control materials, calibrators intended for use *in vitro* for the examination of specimens derived from the human body.
- **Purpose:** To provide information concerning a physiological or pathological state, a congenital abnormality, to monitor therapeutic measures, or to determine compatibility.



Glucose monitor



Pregnancy test



COVID-19 test



Extraction kits for PCR

The importance of IVD in Healthcare

- **Diseases Diagnosis:** Essential for early detection and accurate diagnosis of diseases (*eg. viral vs bacterial infection and AMR*).
- **Treatment Monitoring:** Guides patient management and therapy effectiveness (*eg. HIV viral load*).
- **Public Health:** Plays a vital role in disease surveillance and outbreak control (*eg. Ebola vs febrile illnesses*).
- **Personalized Medicine:** Enables tailored treatments based on individual genetic and molecular profiles (*eg. identifying relevant biomarkers*).

IVD Product Development Lifecycle management

MEDICAL DEVICES DEVELOPMENT PHASES



Risks Assessment

Design control according to ISO 13485:2016 or FDA 21CFR 820

ISO 13485:2016: An internationally recognized standard for quality management systems in the design and manufacture of medical devices. It outlines specific requirements that help organizations **ensure their medical devices meet both customer and regulatory demands for safety and efficacy.**

21 CFR Part 820 (QMSR in Feb 26) is a set of regulations from FDA that outlines the current good manufacturing practice (CGMP) requirements that medical device manufacturers in the United States must follow with regards to their quality system. These CGMP requirements **ensure medical device companies establish a QMS that enables the delivery of safe, effective, and compliant products.**

Phase 0: Planning



Objectives and Scope:

Defining project goals and expectations



Resources allocation:

Ensuring team capabilities, defining clear roles and responsibilities and allocating budget



Timeline:

Ensuring timely delivery



Risks Assessment & Mitigation:

Delays, budget overrun etc.

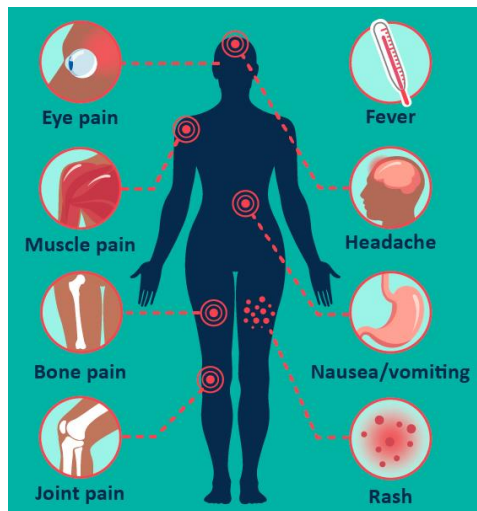
Project:

Dengue diagnostics

Risks should be assessed and mitigated throughout the entire product lifecycle.

Phase 1: Concept & Feasibility – Identifying the Need

- **Unmet Need Identification:** Pinpointing gaps in existing diagnostic solutions
- **Market Analysis:** Assessing market size, competitive landscape, and target user profiles.
- **Stakeholder Engagement:** Gathering insights from clinicians, patients, and regulatory experts.
- **Preliminary Business Case:** Evaluating commercial viability and strategic fit.

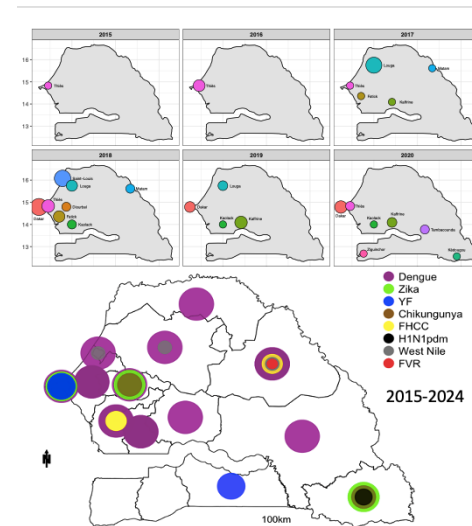


www.cdc.gov

Table 1 | Estimated burden of dengue in 2010, by continent

	Apparent	Inapparent
	Millions (credible interval)	Millions (credible interval)
Africa	15.7 (10.5–22.5)	48.4 (34.3–65.2)
Asia	66.8 (47.0–94.4)	204.4 (151.8–273.0)
Americas	13.3 (9.5–18.5)	40.5 (30.5–53.3)
Oceania	0.18 (0.11–0.28)	0.55 (0.35–0.82)
Global	96 (67.1–135.6)	293.9 (217.0–392.3)

Bhatt *et al.*, 2013



Surveillance in Senegal

Phase 1: Concept & Feasibility – Technology Assessment

- **Technology Scouting:** Exploring innovative scientific principles and platforms.
- **Proof of Concept (PoC) Studies:** Initial laboratory experiments to demonstrate technical feasibility (selection of analytes, reagents etc).
- **Risk Assessment:** Identifying potential technical, scientific, and operational challenges and mitigation plan (Failure Mode and Effects Analysis (FMEA), ISO 14971).
- **Intellectual Property (IP) Scan:** Assessing patent landscape and potential for novel IP.



Strip testing into NS1 buffer



FMEA



Risk management (ISO 14971)

Phase 2: Design & Development – Design Inputs

- Clearly defining the purpose, target population, and testing environment.
- Documenting what the users (clinicians, lab technicians, patients) need the device to do.
- Converting user needs into measurable requirements.
- Including regulatory, safety, and usability criteria.
- Choosing detection methods (colorimetric, fluorescence, PCR).
- Defining acceptable ranges for key metrics (LoD, run time, performance).
- Documenting in a Design Input Requirements file.
- Ensuring traceability to future validation steps (Design Traceability Matrix).

Phase 2: Design & Development – Assay Development

- **Component Selection:** Sourcing and evaluating raw materials, reagents, and components.
- **Iterative Prototyping:** Creating multiple versions of the device, learning from each iteration (optimizing sensitivity, specificity, and stability).

Phase 2: Design & Development – Design Outputs

Definition: Documents that show that the Design Inputs have been implemented.

- **Product specifications:** raw materials (BoM), components, sub-assemblies, packaging and labelling specifications
- **Instructions:** Design drawings, schematics, and manufacturing instructions
- **Risk management:** reports and validation documentation (per ISO 14971)

Phase 2: Design & Development – Examples

Users needs	Design inputs	Design outputs
The test must detect acute dengue cases with high accuracy to ensure clinical reliability	Sensitivity and specificity $\geq 98\%$ in whole blood and capillary samples	Validated antibody pair targeting biomarker NS1, integrated into strip with optimized capture line; performance verified through internal QC and clinical trial data
The sample collection must be minimally invasive and safe for patients	The device shall accept 20–50 μL capillary blood from a fingerstick, with no exposure risk to user	Pre-loaded lancet and integrated buffer/sample port system in sealed unit; validated for user safety and biosafety compliance (ISO 15190)
The device must function reliably in low-resource settings with limited electricity	The device must operate without mains power and store stably between 2–40°C for 12 months	Battery-operated device using lyophilized reagents with desiccant packaging; validated for stability at high temperature and humidity

Phase 3: Design Verification & Validation – Verification

- **Definition:** Confirmation by objective evidence that specified requirements have been fulfilled.
- **Test Methods:** Pilot lots manufacturing, functional testing, performance testing, reproducibility, repeatability, stability studies, stress testing.
- **Documentation:** Detailed test protocols, results, and deviation reports.
- **Traceability:** Ensuring every design output can be traced back to its corresponding input (Design Traceability Matrix).

Phase 3: Design Verification & Validation – Clinical Validation

Definition: Confirmation by objective evidence that the requirements for a specific intended use or application have been fulfilled.

- **Study Design:** Developing rigorous protocols (e.g., retrospective, prospective, comparative).
- **Ethical Approval:** Obtaining approval from Institutional Review Boards (IRBs) / Ethics Committees (ECs).
- **Patient Recruitment:** Identifying and enrolling suitable participants.
- **Data Collection & Analysis:** Meticulous collection and statistical analysis of clinical data.
- **Clinical Performance Report:** Documenting the study findings and conclusions.
- **User Acceptance Testing (UAT):** Involving end-users to confirm the device meets their needs.

Phase 4: Design Transfer – Manufacturing Processes

- **Process Validation:** Ensuring the manufacturing process consistently produces a product meeting specifications.
- **Design Master Record :** Final documentation handover (design drawings, QC methods, manufacturing instructions, packaging and labelling)
- **Good Manufacturing Practices (GMP):** Adherence to strict quality control during production.
- **Quality Control (QC):** Implementing in-process and final product testing.

*Any design changes must be controlled through a formal **change control process.***

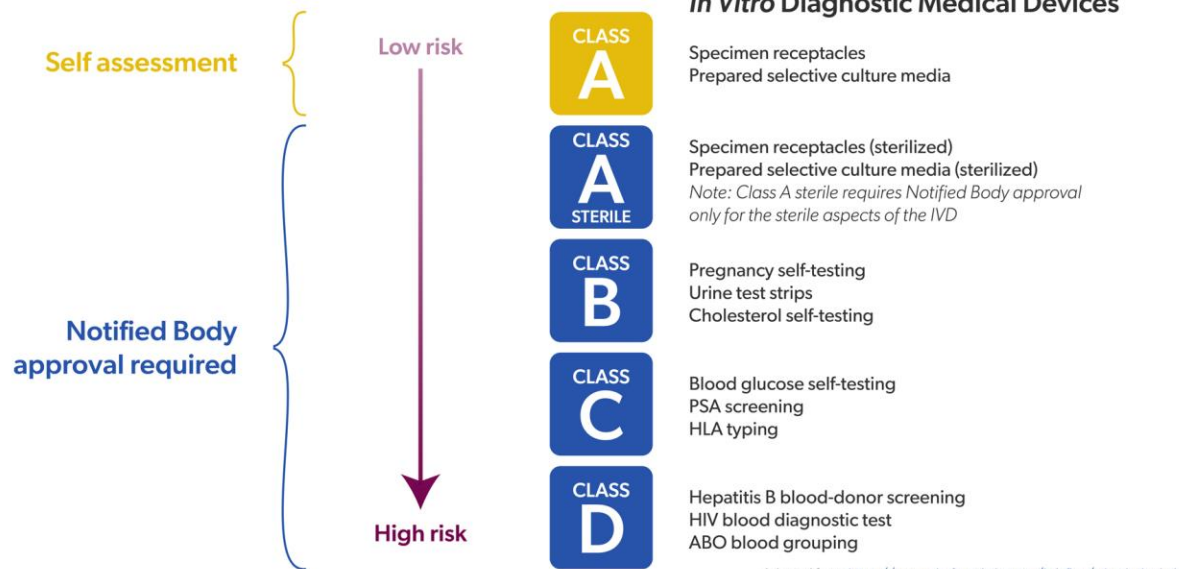
Phase 5: Market Access – Understanding Regulations

- **Key Regulatory Bodies:** SAHPRA (SA), FDA Ghana, PBB (Kenya), ARP (Senegal), FDA (US), CE Mark (EU), Health Canada, TGA (Australia), PMDA (Japan), NMPA (China) etc.
- **Classification:** Understanding the risk classification of the IVD device (e.g., Class I, II, III or A, B, C, D).
- **Quality Management Systems (QMS):** Adherence to standards like ISO 13485, QMRS.

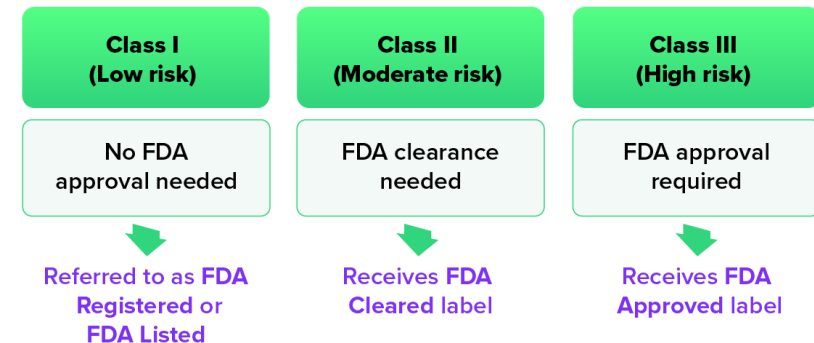
Phase 5: Market Access – Understanding Regulations

IVDR

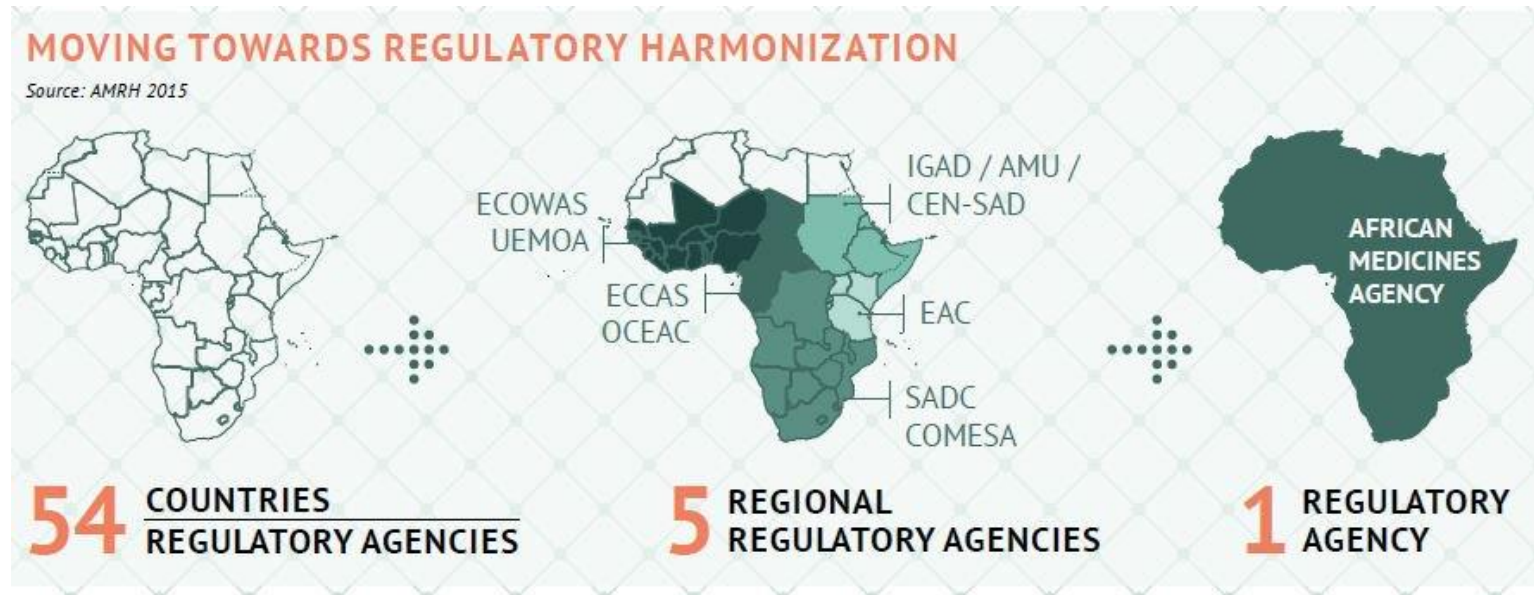
In Vitro Diagnostic Medical Devices



FDA



Phase 5: Market Access – Understanding Regulations



African Medicines Regulatory Harmonization

Phase 5: Market Access – Dossier Preparation

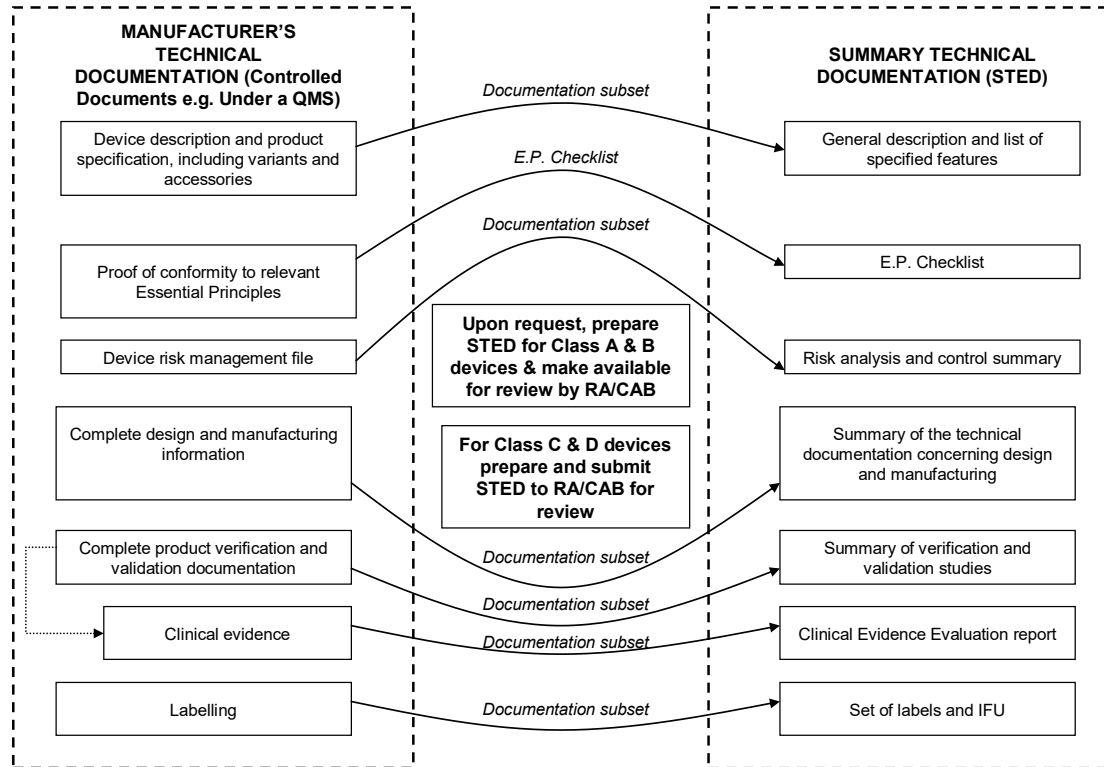


FIGURE 1: PREMARKET USE OF THE STED

Summary Technical Documentation (GHTF)

Important: Pre-submission Meetings: (engaging with regulatory authorities for guidance).

Phase 5: Market Access – Launch

- **Marketing & Sales Strategy:** Developing go-to-market plans (pricing, distribution channels, customers etc.).
- **Training & Support:** Providing comprehensive training for sales teams and end-users.
- **Customer Service:** Establishing channels for post-sales support and feedback.
- **Launch Event:** Officially introducing the product to the market.

Phase 5: Market Access – Go-To-Market Planning



Phase 5: Market Access – Post-Market Surveillance

- **Vigilance Reporting:** Monitoring and reporting adverse events and product malfunctions.
- **Complaint Handling:** Systematically managing and resolving customer complaints.
- **Post-Market Clinical Follow-up (PMCF):** Conducting studies to gather real-world performance data.
- **Continuous Improvement:** Incorporating feedback into product updates and next-generation designs.

Corrective Action Preventive Action (CAPA) will be used to identify, analyze, and resolve the root causes of nonconformities, complaints, or adverse events related to a product or process.

Design Control-Related Process: ISO 13485:2016 and FDA 21 CFR 820 (QMSR)

Topic	ISO 13485:2016	FDA 21 CFR 820
Design Control	7.3	820.3
Design Reviews	7.3.1	820.30 (e)
Design Planning	7.3.2	820.30 (a), 820.30 (b)
Design Change	7.3.9	820.30 (i), 820.70 (b)
Design Input	7.2.3	820.30 (c)
Design Output	7.3.4	820.30 (d)
Design Verification	7.3.6	820.30 (f)
Risk Analytics and Management	7.1, ISO 14971:2012	820.30 (g)
Design Validation	7.3.7	820.30 (g), 820.70 (l)
Design Transfer	7.3.8	820.30 (h)
Design History File	7.3.10	820.30 (j)
Device Master Record	-	820.181
MDR and Complaints	7.2.3, 8.2.2	803, 820.198
CAPA	8.5.2, 8.5.3	820.100
Postmarket Surveillance	8.2.1, ISO14971:2012	822



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Thank you

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