



## 17th TechNet Conference

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Immunization Programmes That Leave No One Behind

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# WHO PQS: First line of defense for the immunization supply chain

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# WHO Immunization Devices (IMD) Performance, Quality & Safety (PQS)



**The immunization cold chain's  
first line of defence**



Vaccines & Immunization Devices Assessment Team (VAX)  
Prequalification Unit (PQT)  
Regulation and Prequalification Department (RPQ)  
Access to Medicines and Health Products Division (MHP)

# Global impact



**14 million** lives saved 2000-2020<sup>1</sup>



**2 billion** doses annually<sup>2</sup>



**70** countries supplied<sup>3</sup>

# EPI impact – Deaths averted



**51,5 Million deaths averted  
by global vaccination by 2030**



# EPI impact - Coverage



## DTP-containing vaccine

1<sup>st</sup> dose  
30%

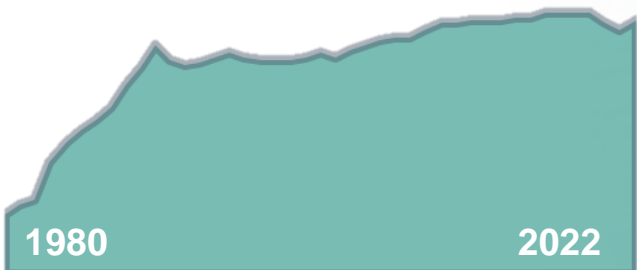
89%



3<sup>rd</sup> dose

20%

84%



## Measles-containing vaccine

1<sup>st</sup> dose

16%

83%



2<sup>nd</sup> dose

17%

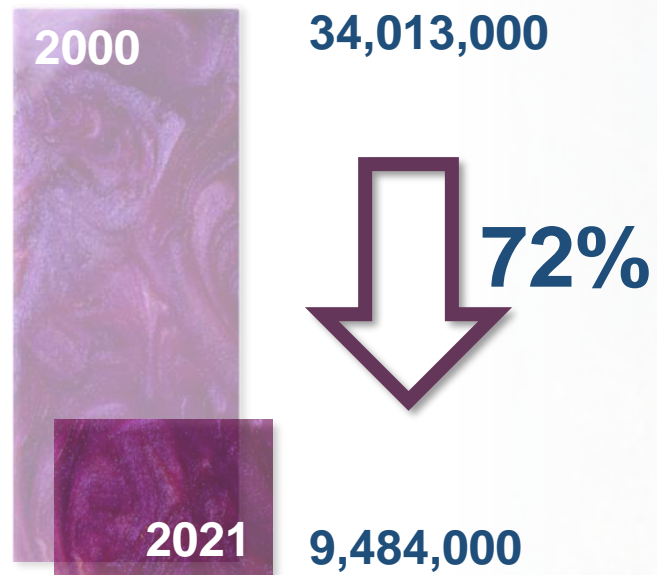
74%



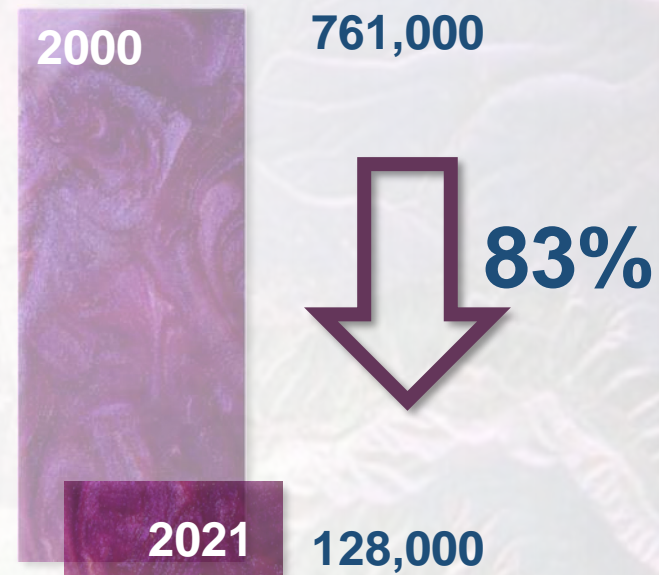
# EPI impact – Morbidity & mortality



## Est. Measles cases



## Est. Measles deaths



# Situating IMD PQS – WHO Mandate

**WHO is the UN specialized agency for health**

**WHO is the directing and coordinating authority on international health within the United Nations' system**



- **setting norms and standards** and promoting and monitoring their implementation
- articulating **ethical and evidence-based** policy
- **providing leadership** on matters critical to health

PQS – Performance, Quality & Safety

WHO – World Health Organisation

UN – United Nations

Reference: <https://www.un.org/en/about-us/un-system>

# Why WHO-IMD PQS?

PQS has a mandate to define equipment performance characteristics to meet known field conditions and requirements.

- **Country EPI Programmes:** need to understand and inform the performance characteristics of the products they are ordering.
- **Industry:** needs a fair basis for tendering existing products and for investing in product development.
- **Procurement agencies:** need to know that the products they are purchasing on behalf of their programmes are fit for purpose.







# IMD-PQS Categories



**E001: Cold rooms, freezer rooms & related equipment**



**E002: Refrigerated vehicles**



**E003: Refrigerators and freezers**



**E004: Cold boxes & vaccine carriers**



**E005: Coolant-packs**



**E006: Temperature monitoring devices**



**E007: Cold chain accessories**



**E008: Single-use injection devices**



**E010: Waste management equipment**



**E013: Therapeutic injection devices**



# WHO Immunization Devices (IMD) Prequalification



**88 MANUFACTURERS\***  
of PQS-prequalified products  
across all 6 WHO regions



WHO Immunization Devices (IMD), Performance, Quality and Safety programme (PQS) has prequalified products from 88 manufacturers (or resellers), across the 10 WHO IMD-PQS product categories, for procurement by United Nations (UN) agencies, across 29 countries and all 6 WHO Regions.

\* April 2023 to March 2024



<b>AFRO</b>	<b>4</b>	<b>4</b>
	Manufacturers	Categories
<b>AMRO /PAHO</b>	<b>10</b>	<b>5</b>
	Manufacturers	Categories

<b>EMRO</b>	<b>6</b>	<b>3</b>
	Manufacturers	Categories
<b>EURO</b>	<b>23</b>	<b>9</b>
	Manufacturers	Categories

<b>SEARO</b>	<b>22</b>	<b>8</b>
	Manufacturers	Categories
<b>WPRO</b>	<b>23</b>	<b>10</b>
	Manufacturers	Categories



# WHO Immunization Devices (IMD) Prequalification



**21 TEST LABORATORIES**  
accredited by WHO to test  
products for WHO IMD-PQS



WHO prequalification ensures the availability of quality, reliable products that help safeguard vaccine potency, as well as expand and extend their availability.

Laboratories that test products contribute to this mission by verifying that products submitted for prequalification meet stringent requirements and quality standards. WHO accredits only those laboratories that can demonstrate they conform to international standards of practice.



## North & South America

- BRAZIL TÜV Rheinland do Brasil Ltd
- CANADA Micom Laboratories INC.
- USA Tektronix Service Solutions  
UL LLC  
Next Breath LLC

## Europe

- DENMARK Danish Technological Institute  
ForceTechnology
- FRANCE CEMAFROID SAS
- GERMANY Nemko GmbH & Co. KG
- GREECE Labor SA
- ITALY UL International Italia S.r.l
- NETHERLANDS Re/Gent B.V
- SWITZERLAND METAS

## Asia Pacific

- CHINA Suzhou Institute of Metrology  
CHEARI
- INDIA Lisaline Lifescience Technologies PVT. Ltd  
UL India Private Limited  
Intertek India  
Techbio Solutions
- SINGAPORE TUV SUD PSB Pte Ltd
- UAE Dubai Central Laboratory Department

# WHO IMD-PQS:

## Vital at each stage of the supply chain

- PQS ensures the **availability and quality** of prequalified products to safeguard vaccines & other immunization supplies.
- PQS supports WHO's **disease elimination and eradication** efforts, as well as countries' **preparedness and resilience** for health emergencies.



# Current status



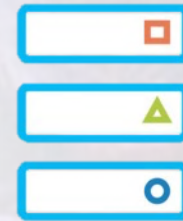
**> 100**

**PQS STANDARDS**



**443**

**PRODUCTS  
PREQUALIFIED**



**10**

**PRODUCT CATEGORIES**



*Which  
includes...*

**PRODUCT SPECIFICATIONS,  
VERIFICATION PROTOCOLS,  
MANUFACTURER GUIDES  
& MORE**



**88**

**MANUFACTURERS**



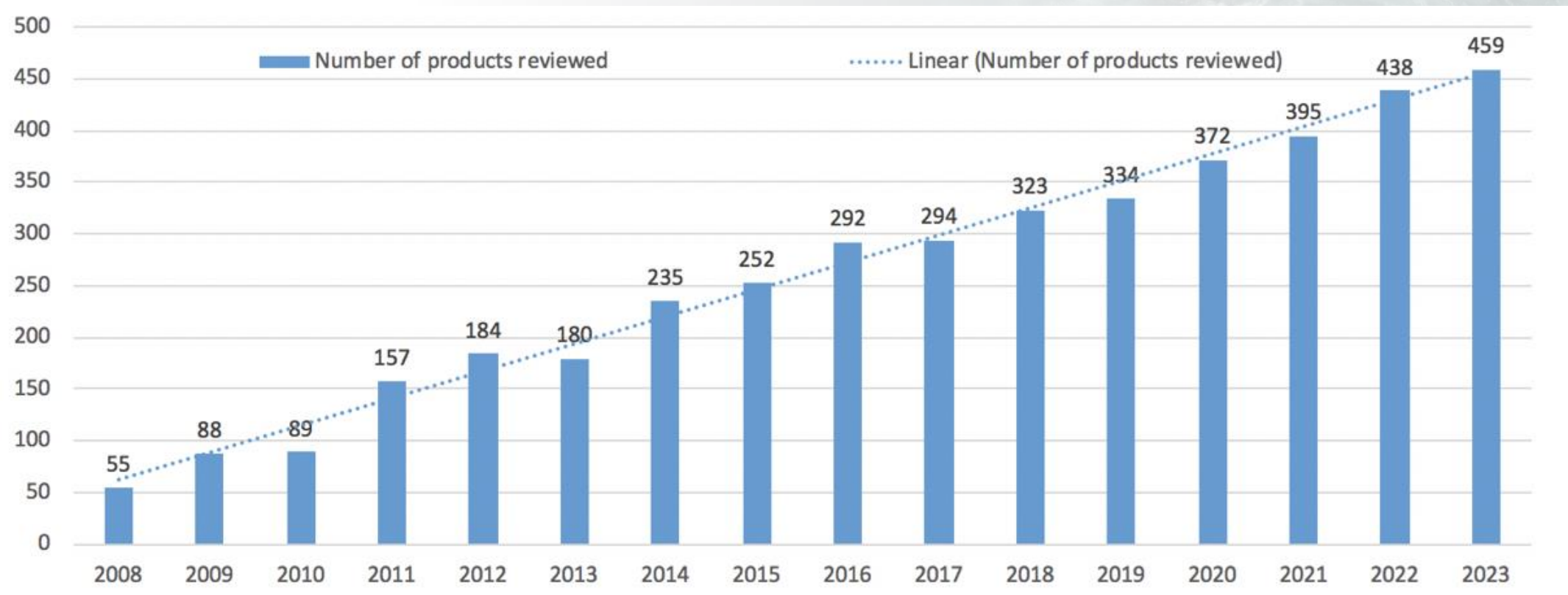
**6**

**ELECTRONIC MONITORING  
STANDARDS**

# Evolution of prequalified products

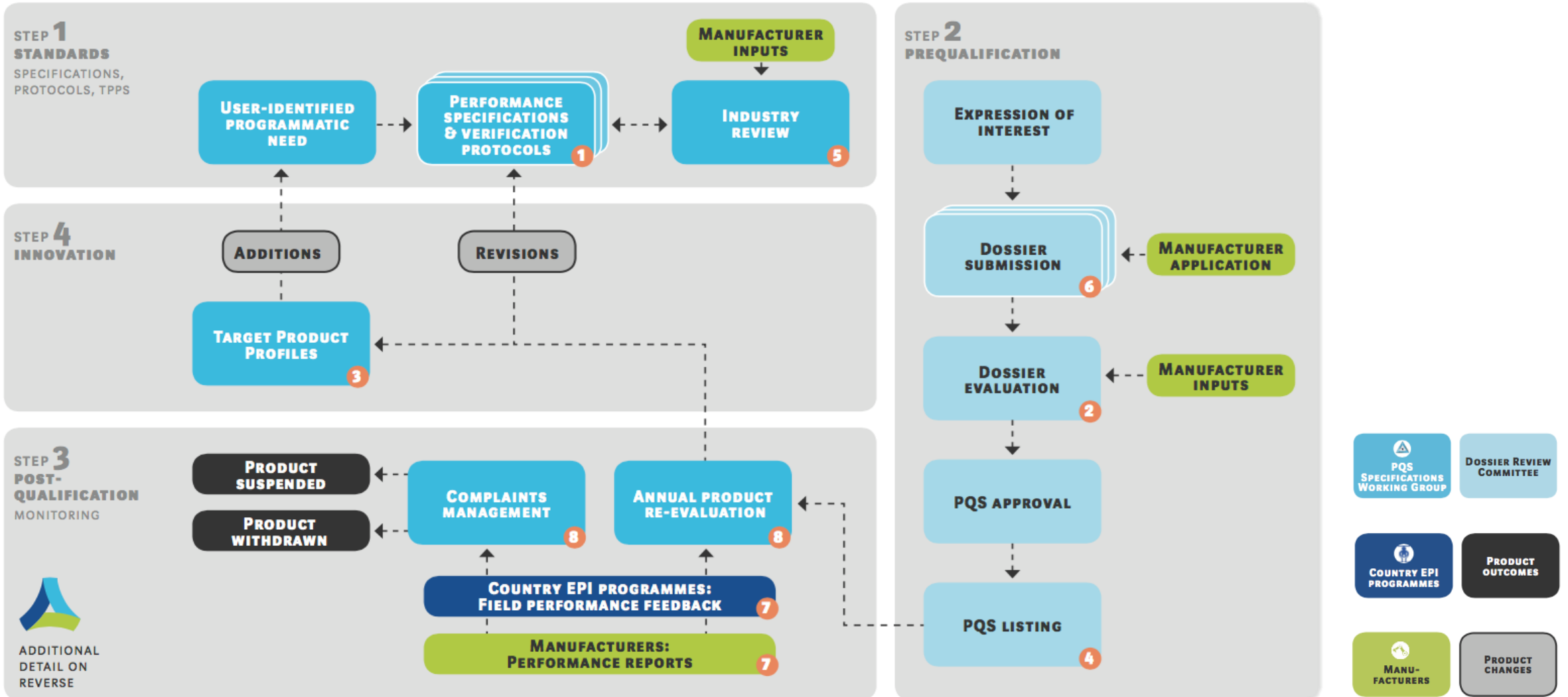


## Number of products reviewed each year\*



\* Going into each annual review. NOT number of prequalified products each year

# IMD PQS process





# IMD-PQS Standards



## PERFORMANCE SPECIFICATION



### PQS performance specification

WHO/PQS/E003/RF05.6  
Original: English  
Distribution: General

**TITLE: Refrigerator or combined refrigerator and water-pack freezer: Solar direct drive without battery storage**

Specification reference: E003/RF05.6  
Product verification protocol: E003/RF05-VP.5  
Issue date: 16 February 2012  
Date of last revision: 22 October 2020

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## VERIFICATION PROTOCOL



### PQS Type-examination protocol

WHO/PQS/E002/RV01-VP.3  
Original: English  
Distribution: General

**TITLE: Refrigerated vehicles – Type-examination protocol**

Verification protocol reference: WHO/PQS/E002/RV01-VP.3  
Specification reference: E002/RV01.3  
Issue date: 19 October 2020  
Date of previous revision: New document

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1. Scope	
This document describes the process for verifying the performance of refrigerated vehicles. It should be read in conjunction with the PQS performance specification <b>WHO/PQS/E002/1.2</b> for refrigerated vehicles which describes the performance requirements for all sizes of refrigerated vehicles suitable for transporting and/or storing vaccine. The performance specification also lists options and variations that the procurement agent or end user can select in addition to the standard specification.	

## TARGET PRODUCT PROFILE



### PQS Target Product Profile (TPP)

WHO/PQS/E003/TPP05.1  
Original: English  
Distribution: General

**TITLE: Humidity Control for Vaccine Refrigerators**

TPP Reference: E003/05.1  
Issue Date: 25 July 2020  
Date of last revision: New TPP

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#### 1. Need

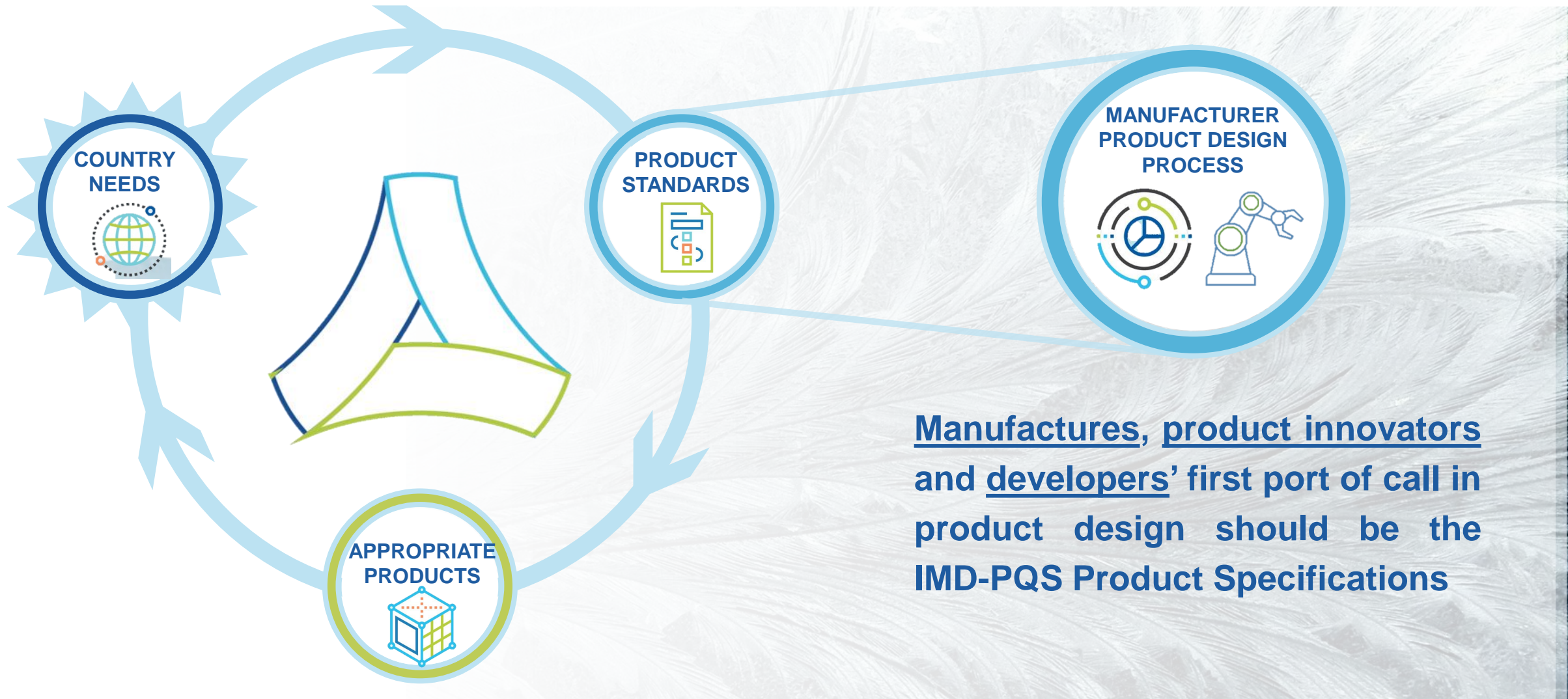
Field testing and reports have highlighted adverse refrigerator conditions that impact immunization activities, related to excess humidity and condensation present in ILR and SDD vaccine refrigerators. High relative humidity levels (RH%) contribute to mold growth on compartment surfaces, primary storage containers (e.g. vials) and secondary cartons, presenting possible health risks to health staff and patients. These sustained, elevated humidity levels are noted to lead to the formation of condensation on cold surfaces, leading to 1) waterlogging and damage to vaccine vial labels and secondary cartons and 2) pooling of condensate within and outside the compartment.

One potential approach to address some of the issues caused by condensation and high humidity is to change vial labeling and secondary container materials from paper to a moisture resistant material. This approach, however, would not reduce condensation or mold growth inside the refrigerator. Therefore, controlling humidity – and thereby condensation – directly is the preferred approach for vaccine refrigerators.

WHO PQS proposes to introduce requirements for maximum operating compartment relative humidity levels, as described in this target product profiles (TPP). A vaccine refrigerator achieving acceptable relative humidity levels will be recognized as having "humidity control" via its WHO PQS catalog data page. Such definitions and classification will be ultimately incorporated into a revised set of ILR and SDD TPPs



# IMD-PQS Specs respond to Country needs



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# THANK YOU!





**Thank You!**