

---

PERFORMANCE QUALITY SAFETY

---

## ***Equipping the Supply Chain***

# ***Update on the WHO PQS Prequalification of Equipment and Devices for Immunization***

**Denis MAIRE**

**WHO/HIS/EMP/PQT/**

**TechNet Conference, 11 - 15 May 2015**



**World Health  
Organization**

# Outline



Update on process



Prequalified products



Equipping the cold chain  
Supporting projects

# Scope of PQS

A three step cycle ...

Innovation: 3 + 2 step cycle ...

**Specifications working group**  
WHO GAVI UNICEF-SD PATH SELF CHAI

**Dossier Review Committee**

## 1. Standards & Innovation

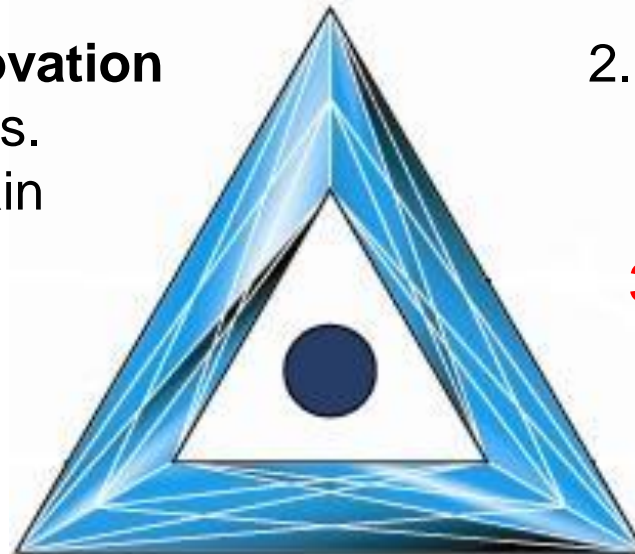
Identify requirements.  
Develop and maintain  
performance specs  
and verification  
protocols

**4. TPPs**  
**Timeline**

3. **Monitor** products post-  
market and inform new  
requirements

2. **Pre-qualify** products  
and accredit test  
laboratories

**3. Field validation**  
**Generic protocol**



# TPPs for Enhanced SDD Refrigerators

- TPP process to signal new needs and get inputs.
- Existing PQS specs can be upgraded or enhanced,
- New categories can be communicated and then specified.
- It can inform procurers and funding agencies on new proposed devices attributes

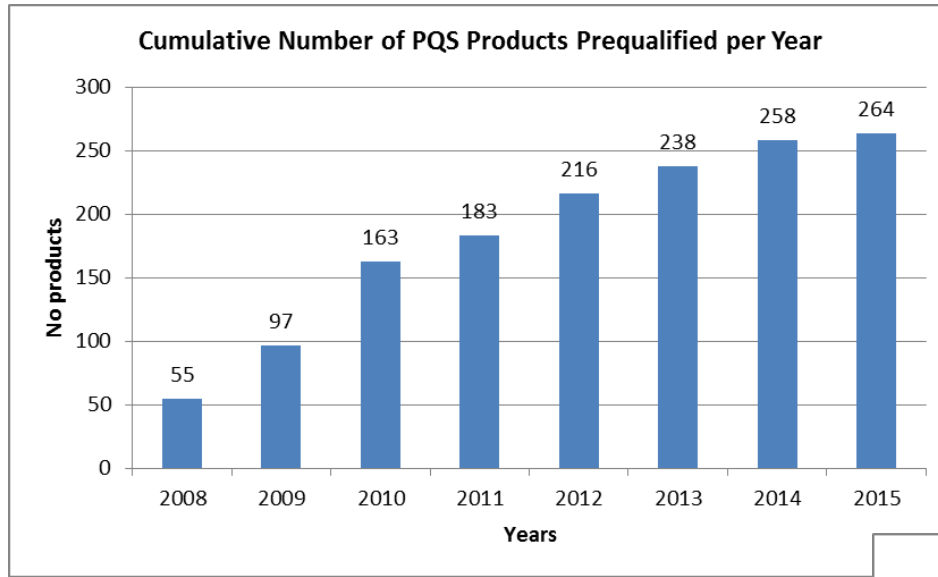


# Field Validation

- Only for new technologies
- Definition in protocol, but at discretion of PQS group
- Objective: get a minimum of experience before complete prequalification
- Min one month study
- Protocol to be adapted for each technology with PQS agreement.
- Implementation: facilitated by PQS and partners

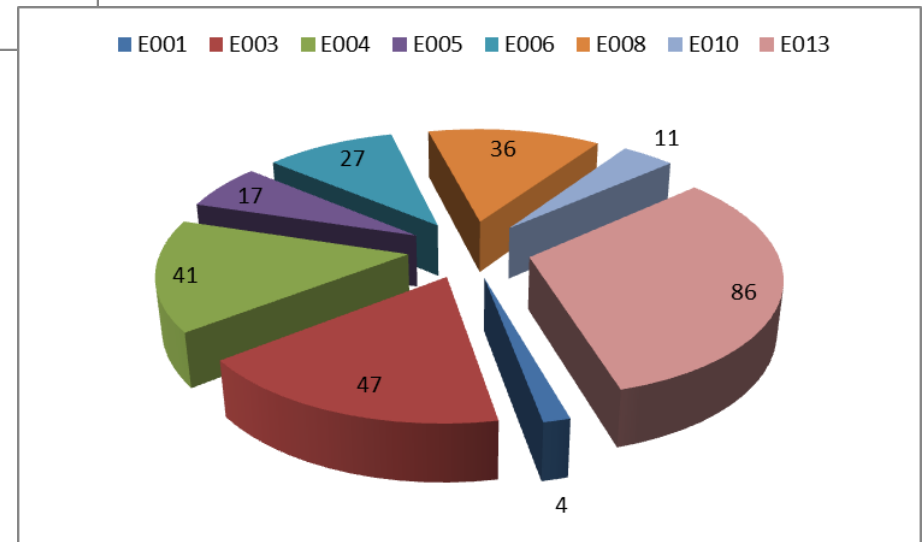


# Prequalified Products



**264 products prequalified  
From 54 manufacturers,  
50% from China and India  
Number of Products:  
x 5 since 2008**

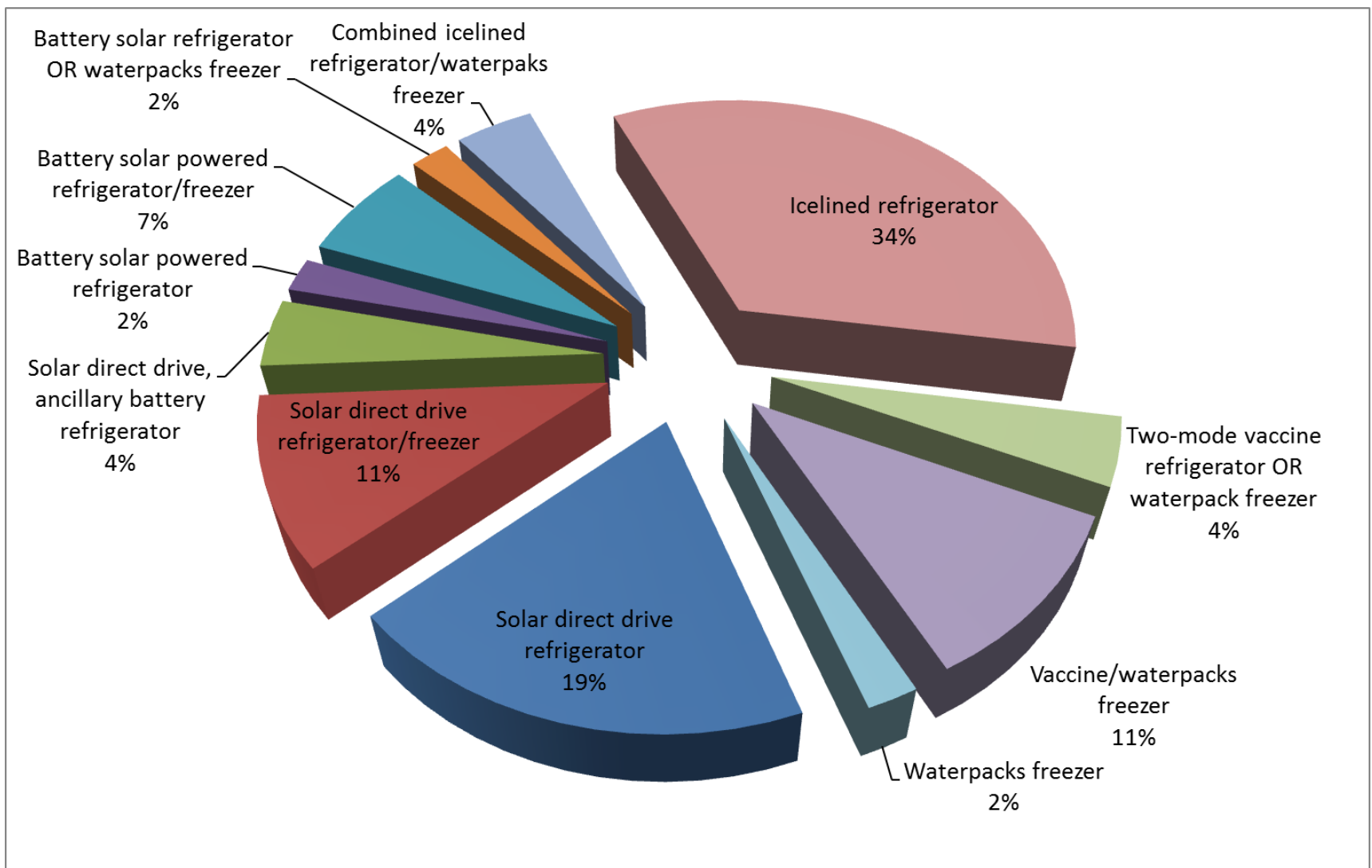
Repartition by category



- 32.5% RUPS syringes
- 20% refrigerators/freezers

# E003 Repartition by Sub-categories

- 47 products from 8 Manufacturers; **Solar 44.7%**



# Equipping the Supply Chain



## **PQS Partners' Supporting Projects**

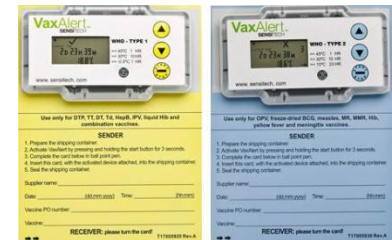
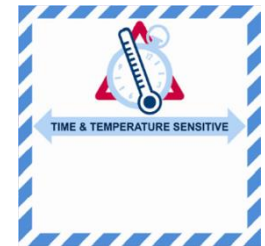
- **Interest of the BMGF and other funding agencies**
- **Supply chain initiative with CCE working group**
- **WHO/UNICEF hub – work in line with country programmes**



# Equipping the Supply Chain

## 1. International transport

International shipping guidelines to be revised through VPPAG incorporating the work on barcoding and on packaging harmonization



# Equipping the Supply Chain

## 2. In-country transport: large distribution

- Initiated the establishment of a list of refrigerated truck qualified suppliers (GAVI)
- Revision of the protocol on temperature studies for route validation started WHO/UNICEF Hub and multi-partners' effort



# Equipping the Supply Chain

## 3. In-country transport To provinces or large districts

- DRAFT Vaccine cold box freeze-prevention:  
WHO/PQS/E004/CB05.1
- Large capacity vaccine cold box:  
PQS performance specifications,  
WHO/PQS/E004/ CB02.1
- No device prequalified as yet



# Equipping the Supply Chain

## 4. In-country Transport: District & Health Facilities

- DRAFT Vaccine carrier freeze-prevention: WHO/PQS/E004/VC02.1
- No device prequalified as yet
- Various projects from UNICEF SD, CHAI and PATH are in progress
- Look at various options such as the use of gel-packs, protective sleeves and integrated protective layer.
- Will lead to a revision of specifications



# Improved Freeze-Safe Vaccine Carriers

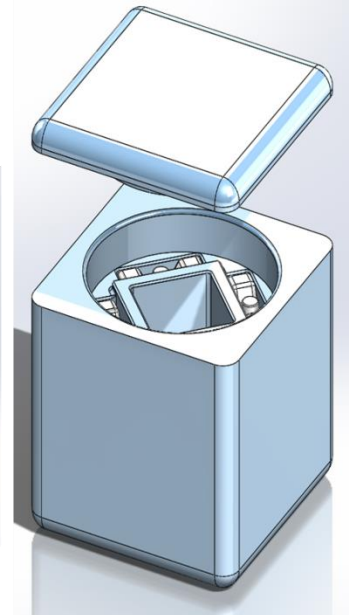
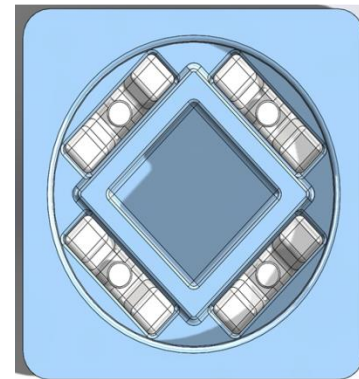
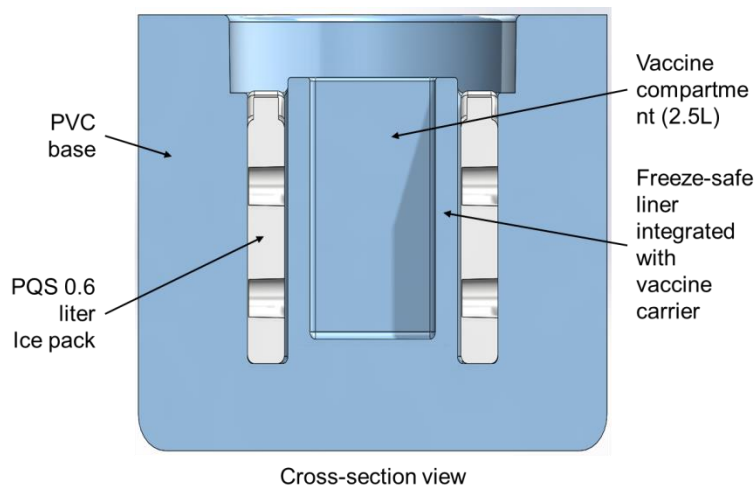
## **Technology solution in development by PATH**

- Redesigning existing vaccine carriers to be freeze safe
- Even when used with non-conditioned ice packs, the freeze-safe carriers will protect vaccines from temperatures below 0°C
- Advantages of freeze-safe designs could include longer holdover times than carriers that use cool water packs
- Reduced training burden.
- Exploring the potential for the redesigned carriers to maintain competitive costs to current carriers.

# Improved Freeze-Safe Vaccine Carriers

## Current status and results

- First lab results very promising
- PATH is now collaborating with equipment manufacturers to:
  - helping meet the latest WHO PQS freeze-protection specifications and
  - Further optimize the design of vaccine carriers that are low cost, durable, and freeze-safe.
  - process of transferring the technology to manufacturing partners to bring new freeze-safe vaccine carriers to market.



# Equipping the Supply Chain

## 1. National stores

E001 category:

- Specifications and protocols extended to large capacity cold rooms and freezer rooms
- UNICEF SD project on field evaluation
- WHO/IVB/EPI guideline on temperature mapping



# Equipping the Supply Chain

## 2. District Stores

- Use of ILRs and risk of vaccine freezing
- Use of inadequate AVR
- WHO/CHAI project
  - TPP and grading system
  - Conduct performance evaluation of selected refrigerators (Pennsylvania State University)
    - Propose (when relevant) any improvement to appliances
- Other CHAI project is looking at AVRs causes of failure to lead to revision of specifications





# Equipping the Supply Chain

## 3. Health facility Vaccine Storage

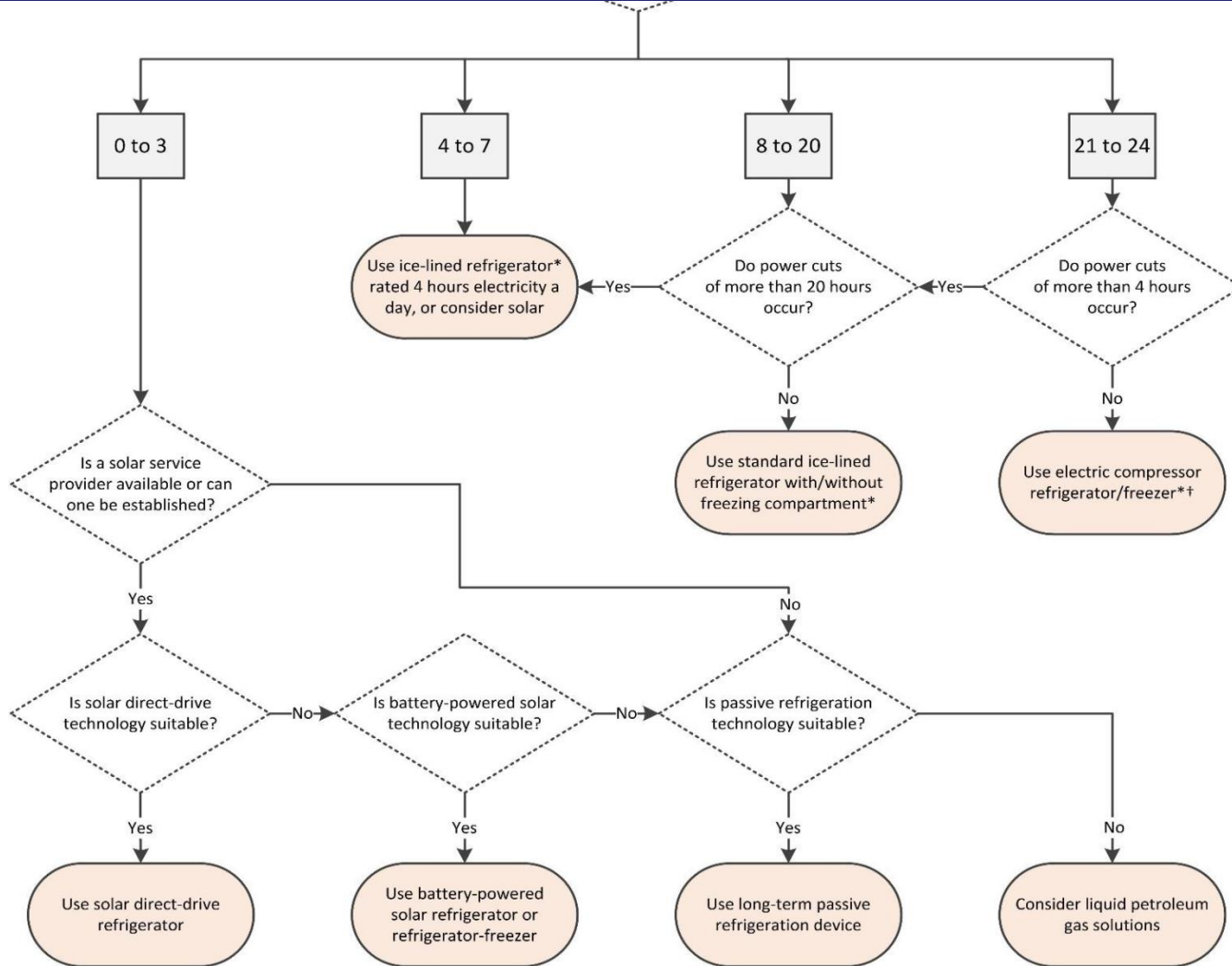
- Learning experience from project from SELF in Columbia & other countries on SDDs
- Enhanced equipment through TPPs – drafts published on SDD & solar system
- First draft on SDD freezer to be released
- Guidelines on solar systems introduction at finalization stage in support to VMHB
- PATH/SELF Solar energy harvesting project

**Add standalone freezing for SDD & Passive cooling**



# Selection of equipment

In average how many hours a day is power available?



\* With voltage regulator

† Do not use domestic refrigerators unless lab tested to PQS standards

## 4. Health Posts Vaccine Storage



- Arktek first long-term passive container prequalified
- Eventual solution for small health posts
- Need more field experience and field study underway by PATH in India
- Need recharge of conditioned waterpacks every month

This model not recommended for transport

# Equipping the Supply Chain

## 4. Temperature monitoring in the CC

- Part of the WHO/UNICEF hub agenda
- CHAI leading that work for PQS

She had only one vapour thermometer

NOW! 🙄



20-day electronic shipping indicators for int'l shipments



30-day electronic temperature logger



Freeze indicators



PRG data logger



## 4. Temperature monitoring in the CC

Remote vs locally centralized systems

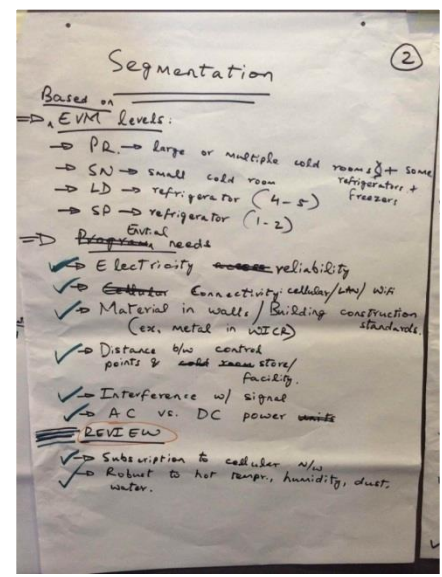
### Progress:

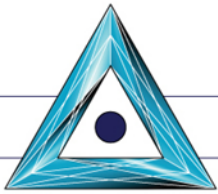
- **Providing countries and manufacturers with greater guidance**, e.g., segmentation for cold chain, hardware vs. software requirements.
- **Non-restrictive to any particular kind of technology**, i.e., encouraging innovation.
- **Increasing the speed and decreasing the burden** of PQS certification.



### UNICEF workshop in Zanzibar:

- PQS Working Group at the workshop adopted a **product design approach to identify usage conditions and product requirements**.
- A **segmentation approach** was proposed, with some requirements varying across segments.
- Requirements were **grouped into hardware and software** categories.





PERFORMANCE QUALITY SAFETY

# Thank You

*TO ALL OF THOSE SUPPORTING THE PQS WORK*

*COUNTRY PROGRAMMES*

*PARTNERS &*

*MANUFACTURERS*

*The first rule of any technology used in a business is that automation applied to an efficient operation will magnify the efficiency. The second is that automation applied to an inefficient operation will magnify the inefficiency.*

*Bill Gates*