WHO Prequalification: Built to Last in a Fast-Changing World

“PRESERVE THE CORE, STIMULATE PROGRESS”

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BUILT TO LAST
SUCCESSFUL HABITS OF VISIONARY COMPANIES

JIM COLLINS
(Bestselling author of GOOD TO GREAT)
JERRY I. PORRAS

MORE THAN ONE MILLION COPIES SOLD
When is an organization visionary?

• Core values (essential and enduring tenets) and sense of purpose (reason for existence; beyond just making money)
• Preserve the core **AND** stimulate progress
• Use big, audacious goals: bold commitments that stimulate progress + that are outside the comfort zone
• Doesn’t compromise standards for the sake of expediency
• Never think it has “done good enough”
• Self-induced change before the outside world imposes it
Let’s look at WHO prequalification …
Core ideology: core values + sense of purpose

• “This is who we are; this is what we stand for; this is what we’re all about”
• Core ideology exists not merely as words but as a vital shaping force; fundamental, rarely changes
• When you understand who you are rather than simply where you (might) be going
• Core values: your guiding principles
• Purpose: goes beyond what core values alone can do
WHO & PQT core values + sense of purpose (mission)

PQT’s core values:
- Services: Quality
- Technical principles: Evidence base; impartiality & confidentiality
- Added value: Expertise; equity
- Workplace: Ethics

PQT mission: to make quality priority health products available for those who need them

WHO core values & mission
Preserving PQ’s core but stimulating PQ progress…

PQ standards are never compromised but:

• performance always has to be as good (better than it has ever been)

What Collins & Porras call mechanisms of discontent help stimulate progress, e.g.: interaction with disease departments + procurers + manufacturers + donors + patient groups, pushing us to do more or differently or more effectively, to avoid complacency, e.g.

◦ API prequalification
◦ timelines to PQ
◦ alternative evaluation pathway for IVDs
◦ working on TFQ & G6PD at same time
◦ Changing from PSF to CTD for vaccines
No progress without audacious goals…

• Programmatic suitability for vaccines focusing on needs of LIC
• 2001: Start of PQ of ARVs: “we’ve got to do this, people are dying” (then director Dr Jonathan Quick, internal meeting)
• 2014: New fee system developed (goal = raise 50% of operating costs, more sustainable financing + potential to explore new but unfunded directions)
• 2015: Emergency use listing procedure
• 2017: Pilot prequalification of biotherapeutics for cancer
• 2019: Pilot prequalification of insulin
• 2016: now, for WHO: “triple billion” targets: 1 billion ➔ more universal health coverage; 1 billion more ➔ better protected from health emergencies; 1 billion more ➔ enjoy better health and well-being
Reminder!
We meet our goals in partnership

- Regulators who provide in-kind support
- WHO disease department who guide us on products
- Funders who fund activities
- Manufacturers who not only submit products but work with us; e.g. WHO model medicines dossier
Looking ahead...what are the challenges?

- Keeping pace: 1) new technology/new science 2) demand for PQ services 3) complexity of products/regulation
- Optimizing the PQ organization to deliver more value to stakeholders
- Finding the right people: competent experts available and committed to support PQ in new product areas: “With the right people we can get the work done AND address the issues as they come”, Matthias Stahl.
- Meeting/understanding demand/prioritizing given finite capacity
How can we best meet those challenges?
In partnership

- Manufacturers
- Regulators
- Donors
- Procurers

...working together to move essential healthcare products to vulnerable populations in need...
How can we best meet those challenges?

In partnership

• WHO-listed authorities will take on some of PQT’s work freeing it to work in other areas
• Enforce timelines for manufacture’s response to PQ questions
• Expand pool of experts and motivate them to dedicate time for PQ.
• Produce more guidance for applicants.
• Strengthen PMS for Immunization equipment, Cold Chain Equipment and Vector Control Products
• Pipeline scanning and parallel policy developing and determination of eligibility for Prequalification.
...but this meeting is a way of bringing us together to meet these challenges and TOGETHER we will!