



# Vaccine Production in Africa - Overview of establishing manufacturing capabilities for human vaccines

Kristopher Howard

[khoward@NRLsolutions.com](mailto:khoward@NRLsolutions.com)



## Speaker Background

### ■ Overview

- ❑ Nearly 15 years in the Vaccine/Pharma Industry
- ❑ Specialize in manufacturing facility design, build, startup and operation efficiency
- ❑ Lean Six Sigma Black Belt with over 10 years of global project experience

### ■ Vaccines work while with Merck and Co. Inc (MSD)

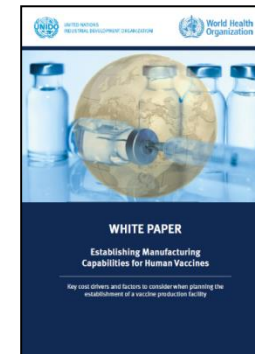
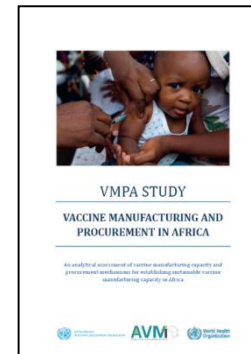
- ❑ Design, build and start-up of new Vaccines manufacturing facilities (ranging in size from \$15M-\$300M)
- ❑ Facility and manufacturing operations improvement projects
- ❑ Vaccine Licensing and Tech Transfer deals with Emerging Market manufacturing partners (Eastern Europe, Middle East and South America)

### ■ Last 5 years as independent consultant

- ❑ Largely focused on Sub-Saharan Africa
- ❑ Working for UNIDO as well as local and multinational firms
- ❑ Capacity building, training, project evaluation, Lean Six Sigma, Vaccines

## Overview

- White Paper Objective:
  - ❑ Basic introduction to the complex world of vaccine manufacturing
  - ❑ Primer for those looking to establish their first vaccine manufacturing facility
  - ❑ Target Audience: Governments, NGOs and firms interested in vaccine manufacturing
  
- Part of larger body of work jointly published in 2017-18 by UNIDO, WHO and AVMI
  - ❑ Vaccine Manufacturing and Procurement in Africa (VMPPA) study\* – 2017
  - ❑ Establishing Manufacturing Capabilities for Human Vaccines\* - 2017
  - ❑ Commercialising Vaccines: Case Study South Africa – 2018





## Topics for Discussion

- Vaccines in Africa
- A brief tour of the white paper
- Government's Role
- Key points for this symposium and beyond

# Vaccines Manufacturing: The African Context

- Imbalance between vaccine demand and local production
  - ❑ 40 African countries received some level of support from GAVI in 2016 (roughly half of all 2016 Gavi funding)
  - ❑ Africa represented 17% of the world's population but provides less than 1% of the vaccines it needs
  - ❑ Manufacturing taking place in only a few countries
- Challenges to local production specific, but not unique to Africa
  - ❑ Lack of critical mass of vaccine production hubs (personnel, services, know-how etc)
  - ❑ Relatively high capex, operating and infrastructure related costs
  - ❑ Limited number of global players creates partnership/competition paradox
- Growing number of opportunities exist
  - ❑ Increasing production quality standards across the continent
  - ❑ GAVI graduation of populous nations
  - ❑ Growing acceptance of value of local production (security of supply, preferential pricing, promotion of high tech sector, etc)

## Using the White Paper as a guide

- Overview of “**Establishing Manufacturing Capabilities for Human Vaccines**”
  - ❑ Provide overview of the technical and non-technical subjects relevant to vaccine manufacturing
  - ❑ Geared towards a non-technical audience
- Contents
  - ❑ How market dynamics shape feasibility of localized vaccine manufacturing
  - ❑ How Vaccines are made
  - ❑ Quick guide what to expect when planning a facility, including example facility costs and timelines
  - ❑ Outline of challenges faced by many vaccine manufacturers in developing world
  - ❑ List of next steps to take on the road to building a business case for local production
- Tips for a quick read
  - ❑ Section synopses at end of each section (in blue text)
  - ❑ Appendix 1: Deeper dive into facility examples
  - ❑ Appendix 2: Extended list of things to consider when evaluating a potential project
  - ❑ Appendix 3: Glossary of common terms



# Role of Government in promoting vaccine manufacture?

- Demonstrable, long term political support is vital
- Considerations, for example, could include:
  - ❑ Strong national regulatory authority and regulatory infrastructure
  - ❑ Policy coherence
  - ❑ Incentives
  - ❑ Direct (low cost?) Government investment in facility, alongside commercial capital
  - ❑ Other 'in kind' project support, e.g. provision of low cost land
  - ❑ HR capacity building – supporting required skills development
  - ❑ Other components of a supportive business environment

## Freetown and Beyond

- Don't be discouraged by the challenges
  - ❑ Accurate planning and business case construction requires a realistic view
  - ❑ Others have succeeded and all taken different paths
  - ❑ Developing Countries Vaccines Manufacturing Network (50 Companies in 17 Countries)
- Key Notes for this Meeting
  - ❑ Sustained political will and backing has been a hallmark of most successful past localizations
  - ❑ Emulation of other successful localized production strategies is important
  - ❑ Proper planning and use of networks like AVMI are vital keys to success
- UNIDO's continued support for Vaccines
  - ❑ Three documents that provide high level overview of global vaccines industry
  - ❑ Podcasts have been taped interviewing leaders of highly successful Developing Country Vaccine Manufacturers - Identifying and understanding success factors
  - ❑ Further collaborations with other key stakeholders....





## Feel Free to Contact Us!

### Kristopher Howard

Principal Author and Consultant

[khoward@NRLSolutions.com](mailto:khoward@NRLSolutions.com)

+1 (412) 613 2765

+44 (0) 20 7993 8252



[www.nrlsolutions.com](http://www.nrlsolutions.com)

### Martin Nicholson

Pharmaceutical Sector Expert

[M.Nicholson@UNIDO.org](mailto:M.Nicholson@UNIDO.org)



### Juergen Reinhardt

Senior Industrial Development Office

[J.Reinhardt@unido.org](mailto:J.Reinhardt@unido.org)

<https://www.unido.org/sites/default/files/files/2017-12/VMPA-Study-ebook.pdf>

<https://www.unido.org/sites/default/files/files/2017-12/Establishing-Manufacturing-Capabilities-for-Human-Vaccines-ebook.pdf>



# African Vaccine Manufacturing Initiative

Freetown, Sierra Leone

24 – 25 September 2018



## Our Generous Sponsors

