UNITED NATIONS
INDUSTRIAL DEVELOPMENT ORGANIZATION

SUSTAINABLE DEVELOPMENT GOAL 9
INDUSTRY, INNOVATION AND INFRASTRUCTURE

VACCINE MANUFACTURING IN DEVELOPING COUNTRIES

PERSPECTIVES ON APPROACHES TO TAKE, AND FACTORS TO CONSIDER, TOWARDS SUSTAINABLE MANUFACTURING CAPABILITY

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Outline

- Introduction to UNIDO
- Overview – UNIDO Global Pharmaceutical Project
- UNIDO's work in the vaccines arena:
  - VMPA Study – Vaccine Manufacturing and Procurement in Africa
  - White paper: Establishing Manufacturing Capabilities for Vaccines
- Key factors for the development of vaccine manufacturing facilities
- Role of Government in supporting the development of vaccine manufacturing
- 2018 UNIDO activities
- Conclusions

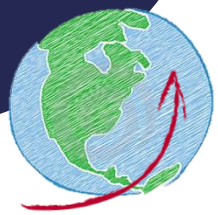
Inclusive and Sustainable Industrial Development

SHARED PROSPERITY

Inclusive growth with equal opportunities for all people, via partnerships with all relevant stakeholders

ECONOMIC COMPETITIVENESS

Industrial growth, increased trade, and technological progress, via modern industrial policies



SAFEGUARDING THE ENVIRONMENT

Environmentally sustainable growth, via cleaner industrial technologies and production methods

UNIDO functions

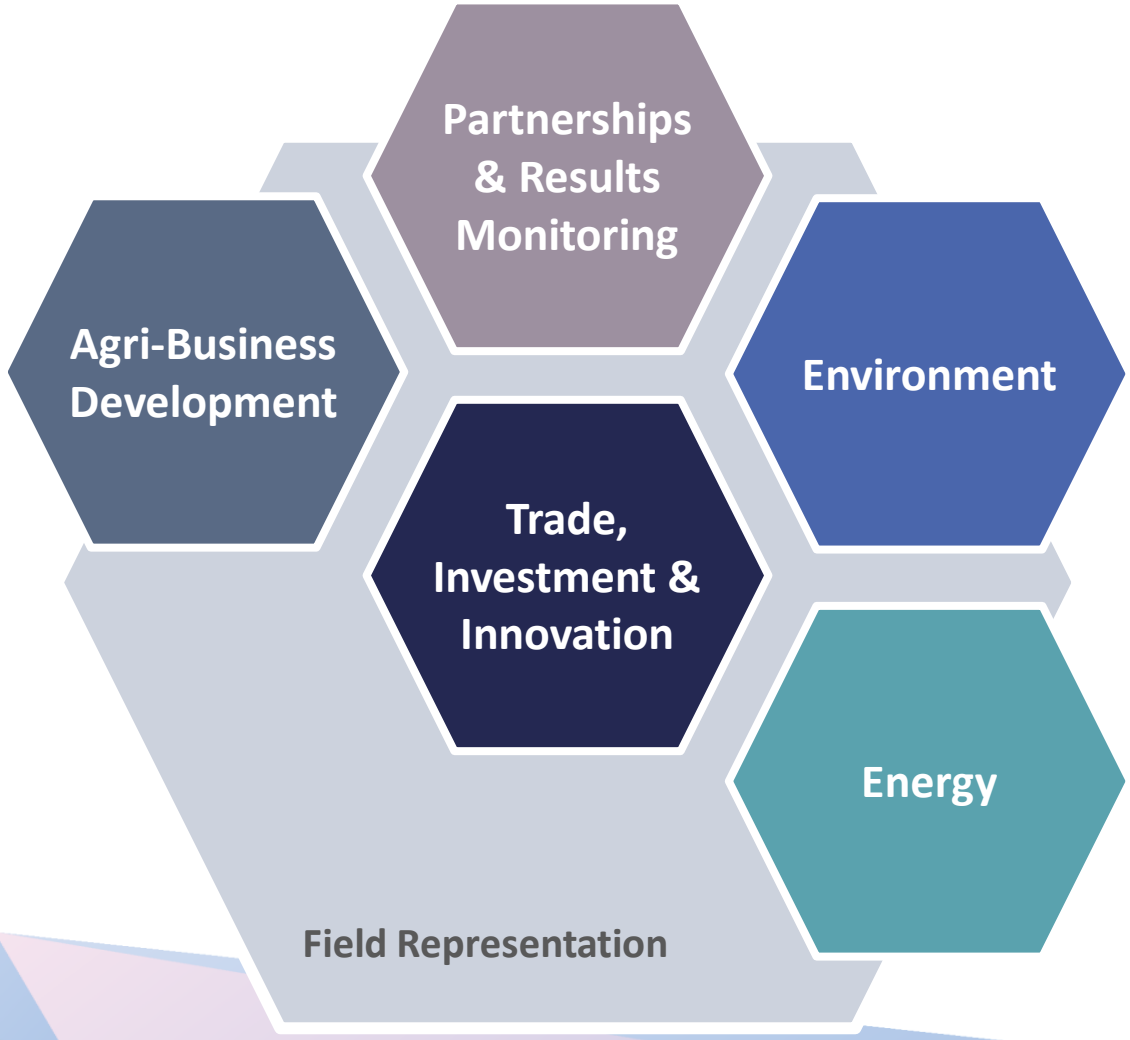
TECHNICAL COOPERATION

ANALYTICAL AND RESEARCH FUNCTIONS AND POLICY ADVISORY SERVICES

NORMATIVE FUNCTIONS AND STANDARDS AND QUALITY-RELATED ACTIVITIES

CONVENING AND PARTNERSHIPS FOR KNOWLEDGE TRANSFER, NETWORKING AND INDUSTRIAL COOPERATION

UNIDO areas of technical assistance



UNIDO's Global Pharmaceutical Project

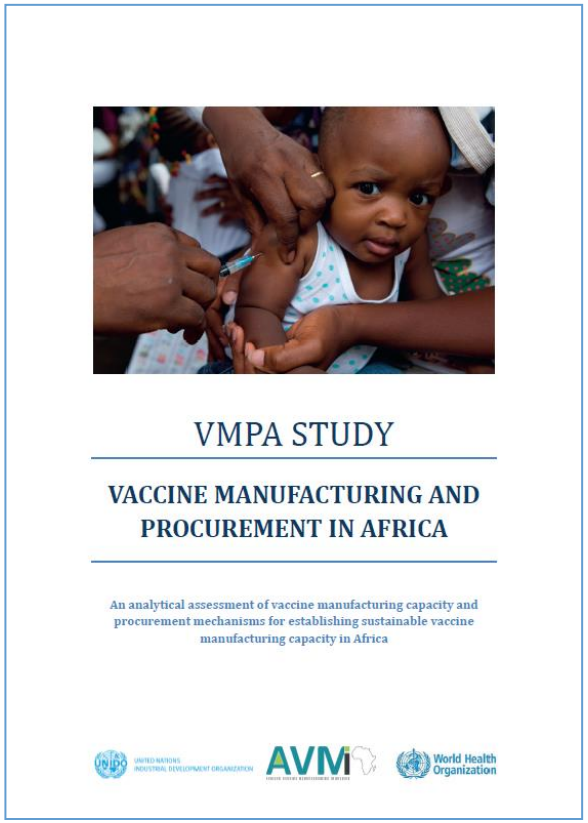
- "Strengthening the local production of essential medicines in developing countries"
- Active in Africa (majority of work conducted here), Asia and Latin America
- Basic core aim: increase production of quality assured medicines that are safe, efficacious, available and affordable
- Quality aspect: developing pharmaceutical manufacturing towards WHO standards of Good Manufacturing Practice
- Key outcomes - health and economic benefits
- Initially focused on generic medicine production
- Expanded into human vaccines in 2015

Federal Ministry
for Economic Cooperation
and Development

giz Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH

VMPA Study: Vaccine Manufacturing and Procurement in Africa

- Collaboration between UNIDO, WHO and AVMI
- Analysis of the case for vaccine manufacturing in Africa
  - Vaccine market dynamics
  - Vaccine procurement in Africa
  - Production feasibility
  - Finance



AVMI
AFRICAN VACCINE MANUFACTURING INITIATIVE

To promote the establishment of sustainable human vaccine manufacturing capacity in Africa

World Health Organization

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

Establishing Manufacturing Capabilities for Human Vaccines

- Introduction to the world of vaccine manufacturing
- Primer for entities looking to establish their first vaccine manufacturing facility
- Highlights key factors that need to be considered – initial steps in feasibility assessment prior to go/ no-go decision making process
- Discusses potential investment costs, timelines and other important factors that require consideration

World Health Organization

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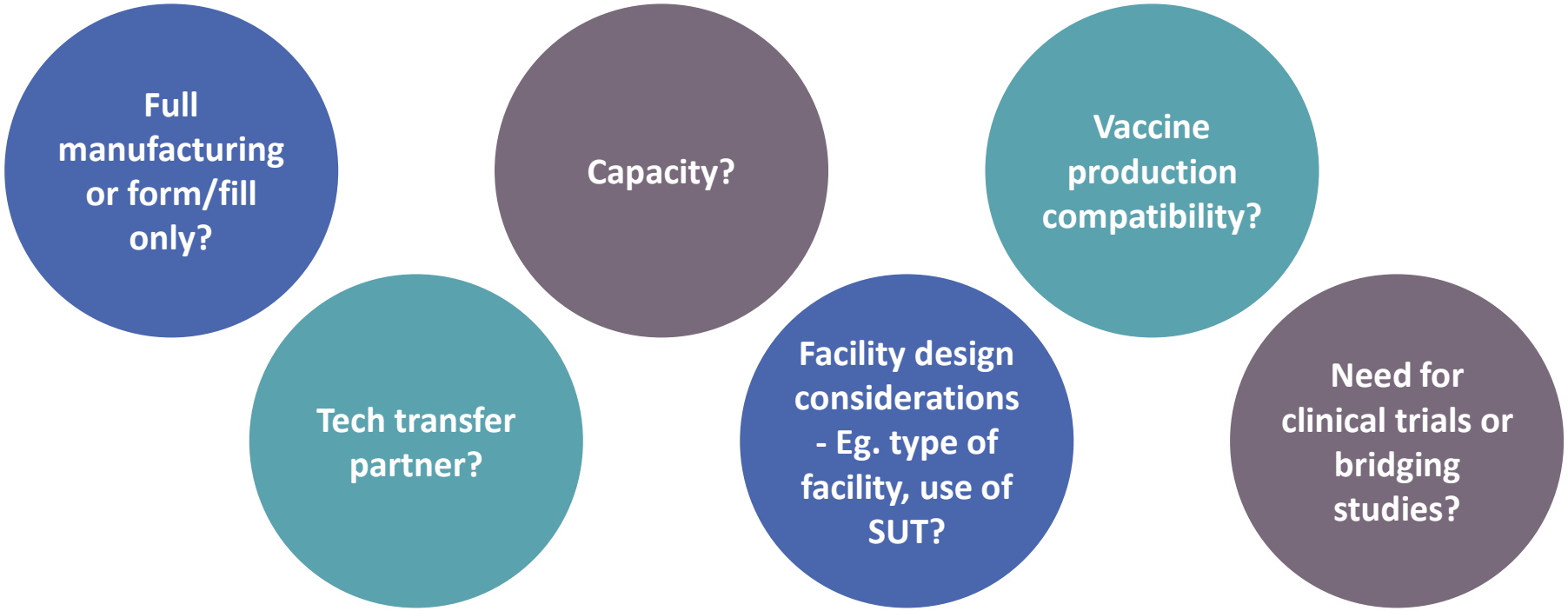
https://www.unido.org/sites/default/files/files/2017-12/Establishing-Manufacturing-Capabilities-for-Human-Vaccines-ebook.pdf

Vaccines versus generic medicines?

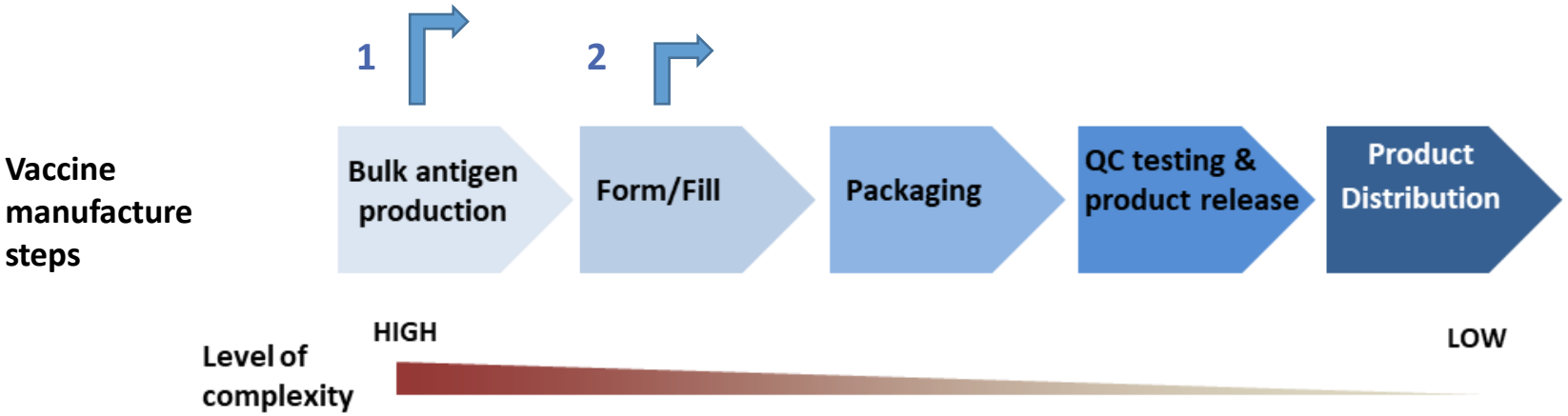
- Fundamental differences in designing, setting up and operating commercially sustainable facilities
- Vaccine facility set up **costs significantly more**, and **takes more time**, compared to a small molecule manufacturing operation (generics production)
- New build projects for vaccine facilities involve more complex technical AND business analyses when compared to setting up a generics facility

Developing manufacturing capability – key technical questions

- Many technical factors need to be considered and analysed during initial assessment



Full manufacture versus form/fill?



1. **Full manufacture**: more difficult from technical perspective but more value captured
2. **Form/fill only**: technically less challenging but captures less value; relies on partner to provide bulk material

- Tech transfer partnership may involve recipient initially performing only form/fill before developing bulk manufacture capability later during collaboration

Modern approaches offer expanded possibilities to reduce costs, time and complexity

Modern facility design can reduce factory set up costs and time

E.g. single use technology (SUT)

Courtesy of Merck KGaA, Germany

VS.

Courtesy of Cotter Brothers Corp., USA

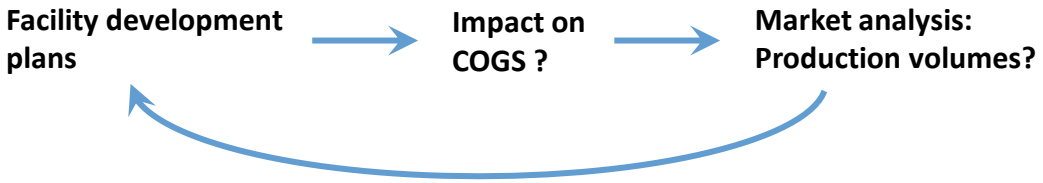
Modular design can reduce factory set up time and complexity

Courtesy of Key Plants AB, Sweden

Technical assessment, market case and business case

The technical assessment needs to be combined with a market assessment to generate the overall business case

Example: Importance of capacity utilisation and impact of investment on cost of goods



Key target: **Sustainable, commercially viable production**

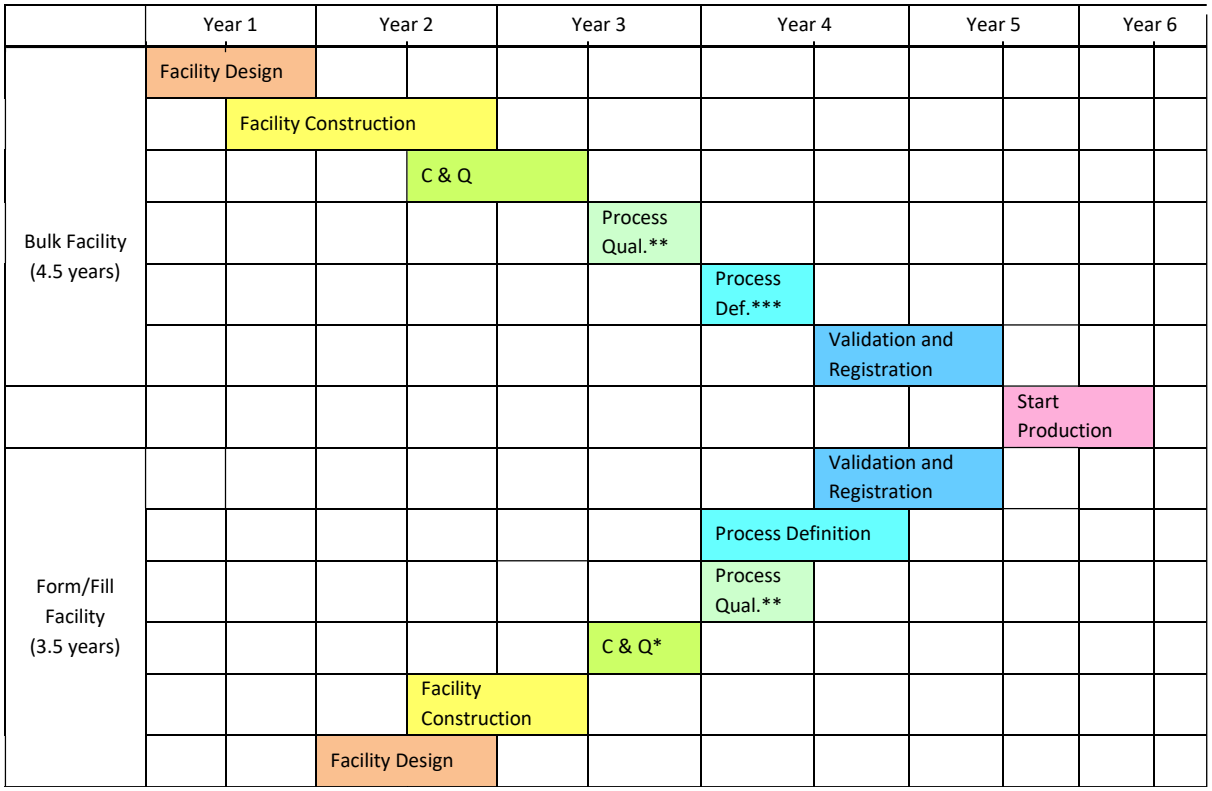
Financing the project?

- Vaccine facilities require a large capital investment
- Need a business case that:
  - Supports the repayment of upfront investment costs from profits
  - AND generates a long term sustainable commercial model
- Example scenario analysis: potential cost and timelines for a small vaccine facility*
  - Fully integrated vs. form/fill
  - Low (10m) vs. High (30m) dose/yr

Facility\Volume	Low (10m dose/year)	High (30m dose/year)
Fully integrated	COST: ~$30-65 Million TIME: 3.5 to 7 years **Facility Details:** • **Modular** facility • Capable of making 10 Million doses per year • 1-3 valent product • Average antigen fermentation efficiency • Single dose vials • Bulk production using mostly single use technology (SUT) • Form/fill with reusable stainless steel equipment • Manual visual inspection and packaging • Based on a theoretical facility	COST: ~$105 to 225 Million TIME: 7-10 years **Facility Details:** • **Stick built** facility • Capable of making 30 Million doses per year • 4 valent product • Bulk production using mostly Stainless steel • Form/fill with reusable stainless steel equipment • Based on real tech transfer using publically available information
Form-fill only	COST: ~$14-29 Million TIME: 2.5 to 5 years **Facility Details:** • Based on facility above, without bulk production • Staff and facility size has been reduced • Bulk antigen to be imported from technology transfer partner	COST: ~$46 to 98 Million TIME: 5-7 years **Facility Details:** • Estimated cost if above facility did not have bulk production • Bulk antigen to be imported from technology transfer partner

* Cost estimates excludes certain set up and other costs e.g. land, clinical trials, product registration, facility operating costs

Construction timelines - bulk vs. form/fill facilities?



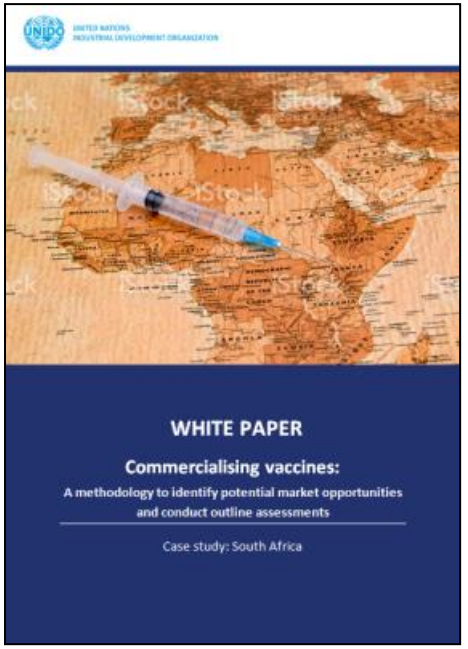
* Commissioning and Qualification
** Process Qualification
*** Process Definition

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

Upcoming UNIDO activities

- Further white paper to be published soon:
- Commercialising vaccines: A methodology to identify potential market opportunities and conduct outline assessments
  - Looks at how to start developing a business case
  - Complements first technically-focused white paper



- 2018 – interviews with leading industry figures from DCVMN companies
  - Identifying and understanding success factors
  - Paper and series of podcasts to be produced

Conclusions

- Despite the challenges, opportunities exist!

- Analysis of key factors and cost drivers is vital to build up the technical case; combination with the market assessment to build the overall business case
  - Consideration of 10+ year timeline and understanding of investment needs
  - Utilisation of modern technology and strategies to reduce investment costs, improve commercial viability and address technical challenges

- Importance of technology access and role of 'technology providers' to increase know how and provide technical capacity

- Role of Governments and regional initiatives to support manufacturing set up and operations

Thank you

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