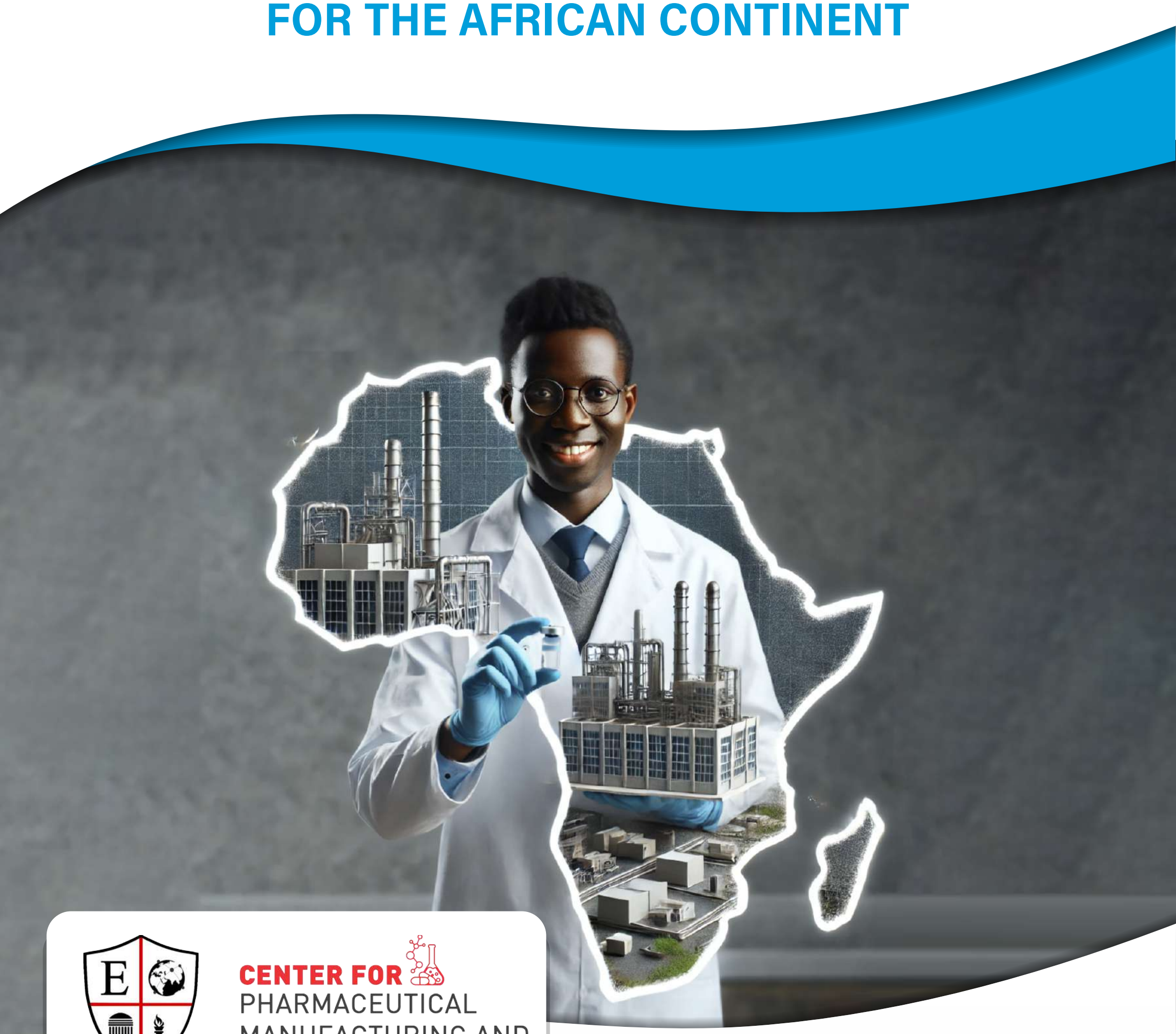
BIO-PHARMACEUTICAL MANUFACTURING SERVICES

FOR THE AFRICAN CONTINENT



CENTER FOR
PHARMACEUTICAL
MANUFACTURING AND
CAPACITY BUILDING

In partnership with industry and academia
from USA, EU, India, China and Africa

EMPOWER
SCHOOL OF HEALTH

New York | Geneva | Nairobi | Casablanca | New Delhi | Beijing

IMPORTANCE OF MANUFACTURING HEALTH PRODUCTS IN AFRICA

The COVID-19 pandemic exposed Africa's vulnerabilities in ensuring access to vital medicines, vaccines, and health technologies. In most nations of sub-Saharan Africa, imports comprise as much as 70 to 90 percent of the pharmaceuticals consumed. For vaccines, imports account for over 99 percent.

Given the current situation, The ***African Union's New Public Health Order*** aims to safeguard the health and economic security of the continent, and the first pillar of this order is to expand the manufacturing of vaccines, diagnostics and therapeutics.

To achieve this objective, African nations are prioritizing building infrastructure and systems for local production, including the engineering, financing, regulatory, trade, technology, and human resources needed to build an industry. In turn, African pharmaceutical industries are responding to this new demand with ambitious projects.

In response to the African Union's vision, and to support the African pharmaceutical sector, ***Empower's Manufacturing Center*** is partnering with government, industry, academia and the United Nations to accelerate this vision. Empower has partnered with world-class organizations in the US, Europe, India, China and Africa to accelerate African pharmaceutical industry growth.

OVERVIEW OF EMPOWER AND OUR SERVICES

The Empower Group has been working with government and industry in over 40 countries for more than a decade. ***Our new Centre for Pharmaceutical Manufacturing and Capacity Building*** focuses on supporting the vision of the African Union to transform the continent into a manufacturing hub for high quality pharmaceuticals and medical products.

Empower has expanded its team and developed new partnerships, bringing a wealth of experience in manufacturing projects across Africa, Middle East and Asia that includes establishing new facilities, upgrading existing plants and introducing new products that have been approved by the US FDA, EMA, and WHO-GMP.

The new Centre offers services ranging from ***full life-cycle project support***, including concept development, feasibility assessments, master planning, architectural design, detailed engineering, risk & hazard management, construction management, validation and commercial startup.

The new Centre also offers detailed engineering support which includes ***facility design, focusing on HVAC systems, building management systems (BMS), and the treatment, purification, filtration, and distribution of utility systems.*** We have experience in developing detailed piping and instrumentation diagrams for process and utility systems, alongside alternative plant layouts meeting regulatory requirements. We also provide men/material flow drawings and civil/structural engineering solutions. Additionally, our process engineering expertise ensures optimal equipment selection.

CENTRE FOR PHARMACEUTICAL MANUFACTURING AND CAPACITY BUILDING SERVICES

Consulting

- Feasibility studies and business plans
- Licensing new products and tech-transfer
- Procurement, sourcing, and supplies management
- Product optimization and/or development
- Portfolio management

Engineering & Design

- Project management
- Plant upgradation to meet new cGMP guidelines
- Process development and optimization
- Planning, design and detailed engineering
- Technical support/ After-sales-service

Validation & Qualification

- Qualification and validation master plans (QMP, VMP)
- Risk analyses (RA)
- GMP-audits and Regulatory compliance
- Quality control, laboratory setup and GLP

Large Turnkey Projects

- Design-Build-Operate-Transfer an end-to-end manufacturing plant
- Scaling up from pilot project to full-scale manufacturing
- Expanding or upgrading an existing manufacturing plant

Human Resource Skilling

- R&D
- Regulatory and QA
- Operations and Engineering Management
- Business and management
- Support functions (HR, IT/MIS, finance, legal, communication)

**refer to detailed section on 'Investing in human capital in Africa.'*

INVESTING IN HUMAN CAPITAL IN AFRICA

Educating and skilling the manufacturing workforce in pharmaceuticals, vaccines, devices and diagnostics

A critical requirement for expanding local production is to have a large pool of qualified and talented human resources. To do this, the manufacturing sector needs to work with many kinds of organizations from all over the world, including a) with universities to expand the pool of graduates b) with technical institutes for skilling and mentoring c) with industry for internships and on-the-job coaching, and d) with digital learning organizations for improving knowledge.

Digital learning can help fill part of the gap: flexible self-paced e-learning, supplemented with digital simulated training, can deliver cost-effective, standardized and customized training to a large number of people. Reviews of e-learning studies found that computer- and web-based e-learning methods are as effective for building knowledge and skills as traditional learning methods.

The five key areas for skilling and knowledge management that are needed in the workforce include: ***R&D, Regulatory and Quality Assurance, Operations and Engineering Management, Business Management and Support Functions.***

- *R&D:* Laboratory operations, clinical trial design and evaluation, new product development, new dosage form development, contract manufacturing, GMP and scale up
- *Regulatory and QA:* Regulatory compliance, product registration, GMP, GXP audit preparations, post-market surveillance, pharmacovigilance, quality control and GLP, computer and process validation
- *Operations & Engineering:* Supply planning, sourcing (raw materials, excipients, machinery, lab reagents), procurement, production, GMP, equipment and floor operations, safety and environmental management and continuous improvement
- *Business and Management:* Leadership and management (project management, performance management, portfolio management, market analysis), sales & marketing and risk management
- *Support functions:* Human resources, IT/MIS, finance, legal and communication

OUR TEAM

Professor Paul Lalvani
Founder and Executive Director,
Empower School of Health

H.E. Michele Sidibe
AU Envoy to the African Medicines Agency
Senior Advisor and Visionary,
Empower School of Health

Kaushik Desai
Pharmaceutical Manufacturing Expert
Senior Advisor,
Empower School of Health

Abdelkrim Smine, PhD
Former Director of Global Public Health, Africa, US Pharmacopeia (USP)
Senior Advisor and Faculty,
Empower School of Health

Bruce Lerner
Strategy Management Consultant, Public Health
Senior Advisor,
Empower School of Health

Sakhile Dube-Mwedzi
Coordinator, SADC MRH Programme,
Senior Advisor and Faculty,
Empower School of Health

Dr T S Rao, PhD
Former Senior Advisor,
Department of Biotechnology,
Govt. of India
Senior Advisor,
Empower School of Health

Dr Ray Yip
Former Head of Gates Foundation in China,
Senior Advisor,
Empower School of Health

Empower School of Health—
your Pharmaceutical Manufacturing Solutions partner

Get in touch with our specialists:

- **Prof. Paul Lalvani** (New York)**:** *paul.lalvani@empowerschoolofhealth.org*
- **Dr. Abdelkrim Smine** (Casablanca)**:** *senioradvisor2@empowerswiss.org, karimdqi@yahoo.com*
- **Mr. Kaushik Desai** (Mumbai)**:** *kaushik.desai@empowerswiss.org, kaushikdesai10@gmail.com*
- **Mr. Bruce Lerner** (Geneva)**:** *bruce.lerner@empowerswiss.org*
- **Dr. Nishant Sharma** (New Delhi)**:** *asstmgr1.bd@empowerschoolofhealth.org*

EMPOWER SCHOOL OF HEALTH

New York | Geneva | Nairobi | Casablanca | New Delhi | Beijing

For more information, please visit our website:
www.empowerswiss.org/en/manufacturing