Country needs and availability of resources for strengthening Healthcare Biotechnology facilities

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There are 6212 healthcare/diagnostic laboratories in Nepal.

Research culture is in early infant stage.

R & D to healthcare biotechnology product to Industry are invisible.

Animal/poultry healthcare biotechnology in government laboratory is on science but not progressive in R & D for new animal healthcare products.

Research institutes work on project basis only rather than a continuous process to launch research products of healthcare.
Current status of Healthcare Biotechnology institutes in Nepal

Government Laboratories

Central Veterinary Laboratory
Ayurved Research Center
Nepal Academy of Science and Technology (NAST)
National Public Health Laboratory (National Reference Laboratory)
Province Public Health Laboratory (#1-7)

Academic institutions

**Central Department of Biotechnology- Tribhuvan University**
Biotechnology Department – Kathmandu University
Center for Biotechnology – Agriculture and Forestry University

Private Research Laboratory

Hester Biosciences Nepal P. Ltd, Nala, Banepa
Shikhar Biotech, Lalitpur
Bio Vac Nepal P. Ltd, Nala, Banepa etc
Center for Molecular Dynamics (CMDN), Kathmandu
Center for Health and Disease Studies (CHDS), Kathmandu
Needs for healthcare biotechnology

- Establishment of research institution and industries for production.
- Advanced Instrumentation for upscaling of research output to industry
- Skilled human resources
- Public-Private-Partnership and AcademiInda-Industry collaboration
- Simple and doable projects like ELISA Kit Developments (HIV, Hepatitis, infectious diseases etc.) and its scale up for national need.
- Huge consumption of imported kits which are to be gradually replaced by national production.
- National budgetary allocation, bilateral and multilateral cooperation among countries and partnership with EDPs (External doner partners).
- International technology transfer
- Outcome based Long-Term research plan (at least 5 years)
- Easy availability of reagents
Priorities for healthcare biotechnology

- Upgrade the Biotechnology Department of Tribhuvan University as the **Center for Excellence**
- **Coordination and collaboration** with WHO, FAO and others
- **International technology transfer**
- **Long term projects** (at least 5 years)/Pilot Projects
- **Incubator Programs**
- Instrumentation and **human resources**.
Constraints

✓ Government commitment and investment is not prioritized for healthcare biotechnology products.

✓ Government and private laboratories are focused on the disease surveillance component.

✓ Negligible human healthcare production and animal healthcare having production category is continuing what it has in previous set up.

✓ Limited Government and private institutes though have funding resources but do not have national contribution in healthcare products.

✓ Country has yet not taken initiation for healthcare biotechnology products.
Favorables/Opportunities

- Covid-19 compelled the major government laboratories to improve the diagnostic facility with RT-PCR which can be exploited for other infectious diseases.

- Nepal has unique geography with all sorts of world’s climate within the travel of 200 km from South to North. So Nepal is a model country to do research for different environmental conditions fitting to respective part of the world.

- Availability of precious microorganisms to flora and fauna which can be exploited for healthcare biotechnology.

- Bunch of young generations of Nepali scientists have been on scene who have been trained in different parts of the world who can join the experienced researchers in Nepal.

- On March 11, a bill has been approved to carry out Phase-I to Phase-IV clinical trails of vaccines.
Required healthcare biotechnology areas

Nepal expects APCTT’s members support on the following aspects of the healthcare biotechnology. The enthusiast industry, academia and researchers will make availability of baseline requirements, and expects initial investment and technology transfer.

1. **Vaccine Production** – Establishment of a model vaccine company in the region with complete technology transfer from APCTT team as a preparedness for future need of healthcare biotechnology. Appropriate site and supportive human resources are available. Preferably initiation with poultry vaccine industry.

2. **Drug development** - Bioactive compound isolation, screening and drug development from medicinal plants against AMR pathogens using the huge biodiversity in a small land area coverage. Basic laboratory set up is available.

3. **Diagnostic kits production** - There are molecular to immunological researches in universities/ research institutes for diagnostic kits development which need a technical and initial investment to convert them to industrial healthcare products. For instance ELISA, PRC and RDT kits for diseases.
Projects (Specific proposals or requests)

- **ELISA kit and Vaccine candidate development for dengue** (an endemic disease).
  - **Phase I** - Dengue VLPs construct preparation using Bioinformatics (Completed)
  - **Phase II** - Construct synthesis and production of VLPs in cell line and assessment for its antigenicity (ongoing).
  - **Phase III** - Development of ELISA kits and trial on animal model for a Vaccine candidate.

- **Molecular and immunological analysis of infectious diseases circulating in Nepal and their application in diagnosis.**

- **Bacteriophage Bank enhancement for the use of the potential bacteriophages against MDR/AMR/XDR pathogens.**

- **Anti-snake venom production in collaboration with PPHL.**

- **Screening of medicinal plants for bioactive healthcare compounds**
Availability of resources for strengthening healthcare biotechnology facilities

National/Provincial Public Health Laboratory - Comparatively well facilitated

HPLC  Biochem Analyzer  Capillary electrophoresis  Real Time PCR

Biochemistry. Lab. Division  Polio/JE/Measels program  Endocrinology  Haematology  National Ref. AID/STD
Availability of resources for strengthening healthcare biotechnology facilities

Academic laboratory – Tribhuvan university

Nano drop                   PCR.                    Real Time PCR                   Gel doc               Fragment Analyzer                   Illumina MiSeq

Ultra Centrifuge.         Flow cytometry                    Lyophilizer          Agilent HPLC        MilliQ water system.   Power backup system
Availability of resources for strengthening healthcare biotechnology facilities

Academic laboratory – Tribhuvan university

- Fermentor
- Soxhlet and Rotaevaporator
- ELISA Plate Reader & Washer
- Automatic Nucleic acid extractor
- BSL-2 Hood
- cooling centrifuge
- -80°C Freezer
- Fluoroscent Microcope
- CDBT-TU Covid Lab
Existing examples of bilateral or multilateral collaborations which have resulted in successful transfer of technologies or establishment of healthcare biotechnology R&D infrastructure in the country.

**CDBT-TU**- NIH-U01 project on “Emerging infections: Surveillance, Epidemiology and Pathogenesis” - Comprises 5 regions of the world viz. USA, China, Hongkong, Nepal and Ethiopia. Skill transfer in

- Sequencing skill and bioinformatics.
- SARS Cov-2 Variant Identification that are circulating in Nepal
- Team is underway to find the etiology of the Viral FUO (Fever of Unknown Origin) noted in > 90% fever cases.

**IFS** grant to work on drug development from endolichen Fungi and actinomycetes

- Isolation of bioactive compounds
- Characterization of molecules

**Bio Vac** – It is a private institute funded by Dutch Private sector investment (PSI) grant as seed money to develop and manufacture poultry vaccines. It is a Nepalese company, and has developed thermostable formulation of Newcastle disease vaccine with Master seed from University of Queensland, Australia. Now the company is at the final process of marketing approval stage.
Model

Research Institute
With most advance instruments
Skilled human resources
(PhD/Post Doc)
For researches on healthcare products

Academic Institutes of Biotechnology
With updated advance instruments
Researchers
(Faculties/Post Doc/PhD/M.Sc.)
For researches on healthcare products

Budgetary Allocation
National/International/conditional grants

National Economy Increment

Healthcare Biotechnology Industry
With most industrial biotechnology equipment

Academia – Industry
Tie up for type production

Medical Biotechnology Laboratory
Implementation of Research Products

Academia Promotion
Seed Implementation funding

Health Care Laboratory
Advancement of Research Products

Academic Institutes of Biotechnology
With updated advance instruments
Researchers
(Faculties/Post Doc/PhD/M.Sc.)
For researches on healthcare products
Project Modality - Multiphase grant structure

Academia- Private association for initial Research and development inside university
Mandatory enroll criteria for early career and graduate student in the project

Healthcare based Product development

Phase I - Concept development for commercially viable product and prototyping, verification and validation.

Product development project hosted by academic lab (universities) included in proposal itself

Product testing and validation support by public health Lab and National labs

Optimization of production process of scaling up criteria- Assistance by Governing bodies.

Phase II- Practical scale up proposal and estimated with budget and part seed grant with part facilitated loan.
Marketing assistance to give product greater reach with provision to delicate 10% of profit being donated back to the program

Financial institute approves the proposal for investment.

Proposal assessed and seed grant approved.

Management and project implementation plan monitored by public health laboratory, regulatory body and academic body (council).

Logistical problem in health service sectors

Production inside the country

Possibility of exports

National Economy Increment

5 to 10 year program supporting till there are more than 50 companies and product in the market to sustain the program from 10% R&D funding given back by the companies.
1. For establishing healthcare biotechnology institutes
   • Needs [Medical Biotechnology course for M.Sc./PhD and Research Laboratories]
   • Priorities [Healthcare based PhD and Post Doc. Programs with projects]
   • Constraints [Funding resources]

2. Facilities regarding
   o human resource development
   o R&D focus
   o technical capacity
   o Investment
   o business models

In broad spectrum
   • Needs [Culture of research to be transferred]
   • Priorities [Higher academic courses]
   • Constraints [Expensive instrument and country policy]
THANK YOU