Setting up world-class Skilling Institute:

Quality & Manufacturing Excellence

June 2024
Agenda

1. Vision
2. Key Pillars
   a. Infrastructure & Facilities
   b. Program Offerings
   c. Faculty & Experts
   d. Partnerships
   e. Governance
3. Way Forward
Indian Pharma is at the cusp of transformation

Vision of the Sector

- **Market Size:** Grow to USD 120-130 Bn by 2030* from USD 57 Bn today
- **Quality as a Culture:** Demand for high levels of manufacturing and quality assurance / control
- **Strong Alignment with Government of India and US FDA** for skill upgradation

Industry Leader Insights

- **Hands-on Training:** Manufacturing, Quality, and Microbiology teams need training in aseptic & oral solid practices on actual machines
- **Faculty:** Qualified trainers / Industry SMEs / ex-FDA regulators
- **Future-ready Workforce:** Importance of SOPs and integrating digital formats into training

*Source: IPA Report 2020*
Industry leaders stepping up the plate
A world-class institute to build talent for the pharmaceutical industry and promotes a culture of manufacturing and quality excellence

- **1. Infrastructure & Facilities**
  - Set-up and launch in Ahmedabad, Multi-location Hub-Spoke in long-term

- **2. Program Offerings**
  - Focus areas: Manufacturing, Quality, Regulatory and Soft-skills

- **3. Target Audience**
  - Pharma Graduates, Operators, Line Supervisors, Technicians and Managers

- **4. Faculty and Experts**
  - Mix of full-time, visiting, and partner institute’s faculty

- **5. Ownership Model**
  - Section 8 company promoted by IPA member organizations

- **6. Governance & Org Design**
  - Renowned industry leaders of global reputation

- **7. Funding Commitment**
  - By leading Indian Pharma Companies

- **8. Partnership & Collaboration**
  - Offer world-class program in collaboration with PDA, NSF etc
Phase-Wise Growth Plan

Design Phase (0-18 months):
- Setting up the foundational building blocks of the institute
- *(Target Trainees: 1,000-2,000 / Year)*

Growth Phase (18-36 months):
- Expanding portfolio & develop institutional capabilities
- *(Target Trainees: 6,000 – 8,000 / Year)*

Scale Phase (36 months+):
- Scaling across multiple locations to achieve global recognition
- *(Target Trainees: 36,000 – 40,000 / Year)*
Infrastructure & Facility | Integrated campus as ‘Hub’ and specialized centers as ‘Spoke’

Develop a **hub at Ahmedabad** that is supported by **Spokes as specialized COEs**

**Short Term**: Launch a full-fledged campus in Sanathal Village as the Hub

**Long Term**: Operations in multiple locations (as CoE spokes) across major pharma clusters (Hyderabad, Baddi etc.)

COE#1: Aseptic Manufacturing (Spoke)

COE#2: Oral Solids (Spoke)

COE#3: Quality (Spoke)

COE#4: Leadership, Management & Soft Skills (Spoke)

Integrated Campus

Ahmedabad as Hub with Digital Underpin

Number of spokes may be increased in the future as per the requirement
Cultural-mindset shift | **Programs catering to diverse target audience & delivery models**

The following programs have been shortlisted based on the market needs, benchmarks, and discussions with the industry leaders comprising of quality, manufacturing, and HR heads.

<table>
<thead>
<tr>
<th>Proposed Programs</th>
<th>Pharma Graduates</th>
<th>Operator / Line Supervisors</th>
<th>Site Leaders / Senior Managers</th>
<th>Executive Management</th>
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</thead>
<tbody>
<tr>
<td>• Pharma Graduate Certification Program</td>
<td>• Manufacturing: Aseptic processing and sterilization</td>
<td>• All programs applicable for Operator/ Line Managers and</td>
<td>• Quality Culture</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Manufacturing: Oral Solids</td>
<td>❖ Documentation (GMP)</td>
<td>• Leadership &amp; Management</td>
<td></td>
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<tr>
<td></td>
<td>• Quality</td>
<td>❖ FDA 483 Inspection Readiness</td>
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<td></td>
<td>• Soft Skills (Behavioral/ Managerial)</td>
<td>❖ Simplifying SOPs</td>
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<td></td>
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<td>❖ Root Cause Analysis and Documentation</td>
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<table>
<thead>
<tr>
<th>Delivery Model and Duration</th>
<th>Pharma Graduates</th>
<th>Operator / Line Supervisors</th>
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<th>Executive Management</th>
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</thead>
<tbody>
<tr>
<td>• Hybrid</td>
<td>• 1-2 months</td>
<td>• On campus</td>
<td>• On-Campus</td>
<td>• On-Campus</td>
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<tr>
<td>• 1-2 weeks</td>
<td></td>
<td>• 1-2 weeks</td>
<td>• 1 week</td>
<td>• 1 week</td>
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**Thrust on quality-mindset and advanced digital technologies (like AI, AR/VR, Blockchain etc.)**

*Program Advisory councils will be formulated for specific program areas comprising of leading practitioners from across organizations to advice on the program design*
A multi-modal faculty engagement model leveraging global expertise

The ratio of Full-Time Faculty to Visiting Faculty is envisaged to be 75:25

In the initial years of operations, the core faculty will work closely with partner institutes and undertake a Train-The-Trainer model

- **PAGE Foundation Full-time Faculty**
  Full-time faculty to deliver the programs and learn from the partner institution experts

- **Experts from Partner Institutions**
  Leverage the faculty from partner institutions (PDA and ISPE) to deliver the trainings

- **Visiting Faculty**
  Visiting faculty will comprise of professionals from OEM, regulatory bodies, and other SMEs
SETTING-UP WORLD CLASS SKILLING INSTITUTE

Partnerships & Collaborations | Global Capability and Content

Potential Partners

Program Development

Program Delivery

Facility Planning

Subject Matter Experts support

International Repute & Credibility
Governance | A lean & agile model to promote specialization & enhance learning experience

**Representatives from industry leaders** and any other nominated industry experts, e.g. from regulatory agencies or OEMs

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**Foundation for PAGE** (Section 8 Company)

**Governing Council** (Principal body to provide leadership and strategic decisions)

**Global Advisory Council** (Advisory body to bring global insights and guidance)

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**Institute Head**

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**Program Chair – Aseptic***

- Advisors
- Faculty & Visiting Faculty** (e.g., Industry, Govt., Academia or Regulators)
- Machine experts

**Program Chair – Oral Solids***

- Advisors
- Faculty** & Visiting Faculty**

**Program Chair – Quality***

- Advisors
- Faculty** & Visiting Faculty**

**Digital & PD Support**

- Graduate Trainee program
- Student Affairs
- Learning Technology
- Program Administration
- Faculty development
- Career Services
- Exam & Certification

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**Training, Technology & Professional Development**

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**Program Chair – Oral Solids***

- Advisors
- Faculty** & Visiting Faculty**

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**Program Chair – Quality***

- Advisors
- Faculty** & Visiting Faculty**

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**Program Chair – Aseptic***

- Advisors
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**Roles supported by administrative staff working under guidance on Industry nominated expert**

- Representatives from industry leaders and any other nominated industry experts, e.g. from regulatory agencies or OEMs

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**May comprise eminent members of global repute in related areas**

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**Program Chair – Oral Solids***

- Advisors
- Faculty** & Visiting Faculty**

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**Program Chair – Quality***

- Advisors
- Faculty** & Visiting Faculty**

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**Program Chair – Aseptic***

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**Similar structure will be followed for additional training areas**

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**Retired Industry veterans, OEM Experts, Freelancer consultants, Industry SMEs from different Companies, Ex FDA, regulators.**
**Way Forward | India to be global benchmark in quality**

1. **Launch of the Campus:** December 2025

2. **Equipments** nearly INR 50 Cr committed by manufacturers:
   - Adam, Cadmach, Glatt, Iclean, IMA PG, Kevin/Kambart, Klenzoid, Labultima, Mille, Nishotech, NKP, Pharmalab, Saan, Shizmadzu / Perkin Elmer, SPAN, Technofour, Wraptech

3. **Training:** Pharma Graduates Program to begin in Jan 2025 and Program for Senior Executives to begin in July 2025

4. **Collaborative efforts by all stakeholders:** On the job trainings and participation support

5. **Governance:** High Commitment by Industry Captains
Contact Us

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