



The Blueprint of Global Compliance: Proven Impact & Customer Portfolios

Navigating every scale of operation and
global regulatory standard.

40+

Major Engagements

Trans-Nationals to
Specialized SMEs

7+

Global Markets

Including Australia, Europe,
Oman, and West Africa

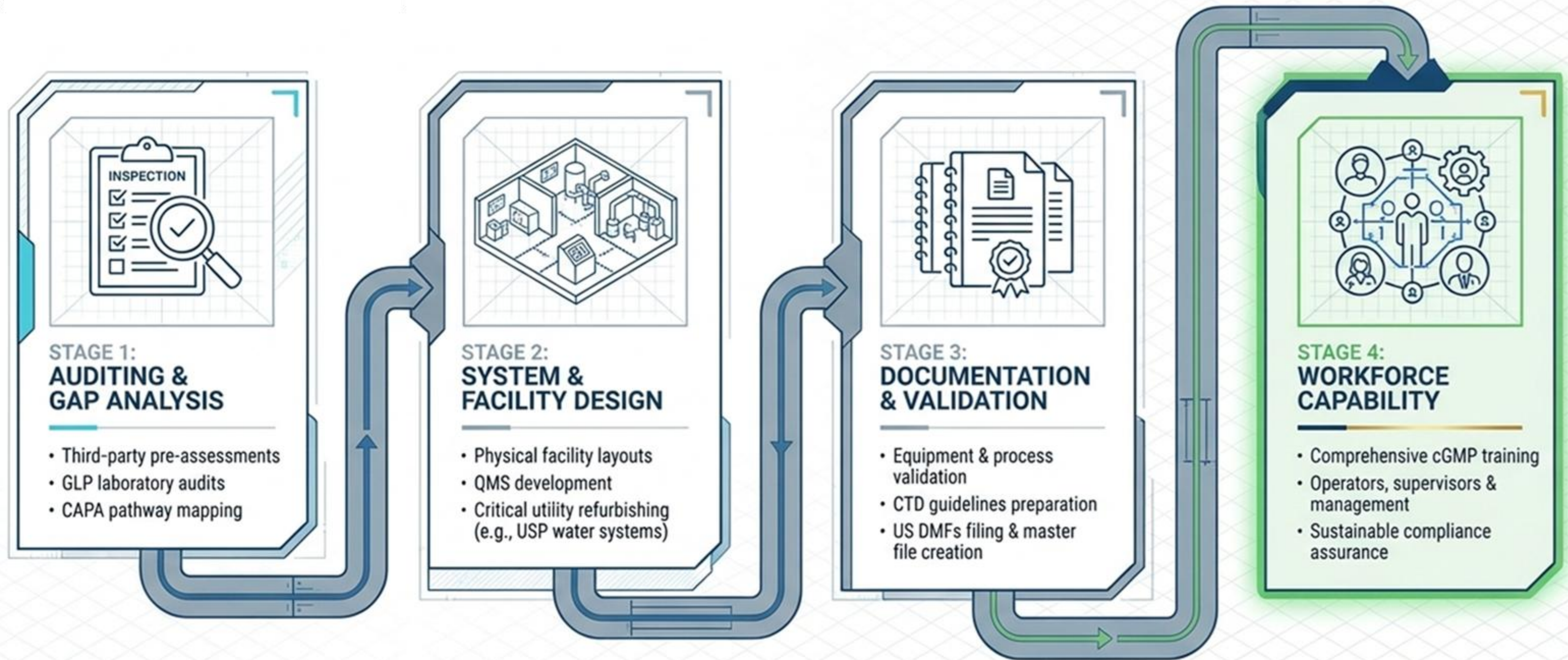
9+

Regulatory Standards Mastered

US FDA, WHO GMP, TGA,
EDQM, PMDA, PIC/S, HACCP,
AYUSH, GLP

Translating regulatory complexity into sustained operational
excellence across the entire pharmaceutical ecosystem.

WHAT WE DO



THE INTERVENTION FRAMEWORK

THE ULTIMATE METRIC: OUR REGULATORY SUCCESS



US FDA

- Krebs Bio
- Dr. Reddy's
- Teva Pharm India
- Srinu Pharmaceuticals



TGA (Australia)

- Maksons Pvt. Ltd
- Glochem Industries



WHO GMP

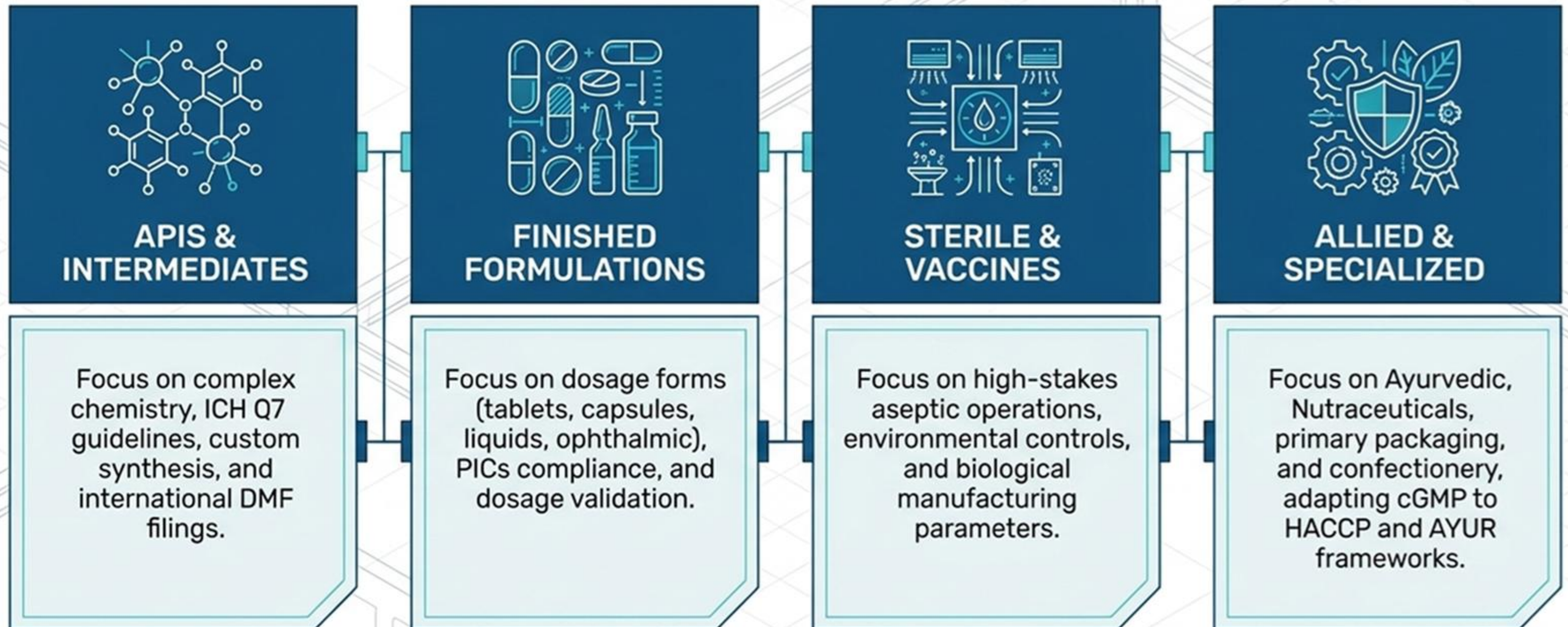
- Sprukfield LLC
- Dano Vaccines
- Sai Parenterals
- Elegant Chemicals



Specialized Agencies

- Nosch Labs (EDQM)
- Glochem (PMDA Japan)
- Priya Foods (HACCP)
- Imis Pharmaceuticals (AYUR)

BREADTH OF INDUSTRY VERTICALS



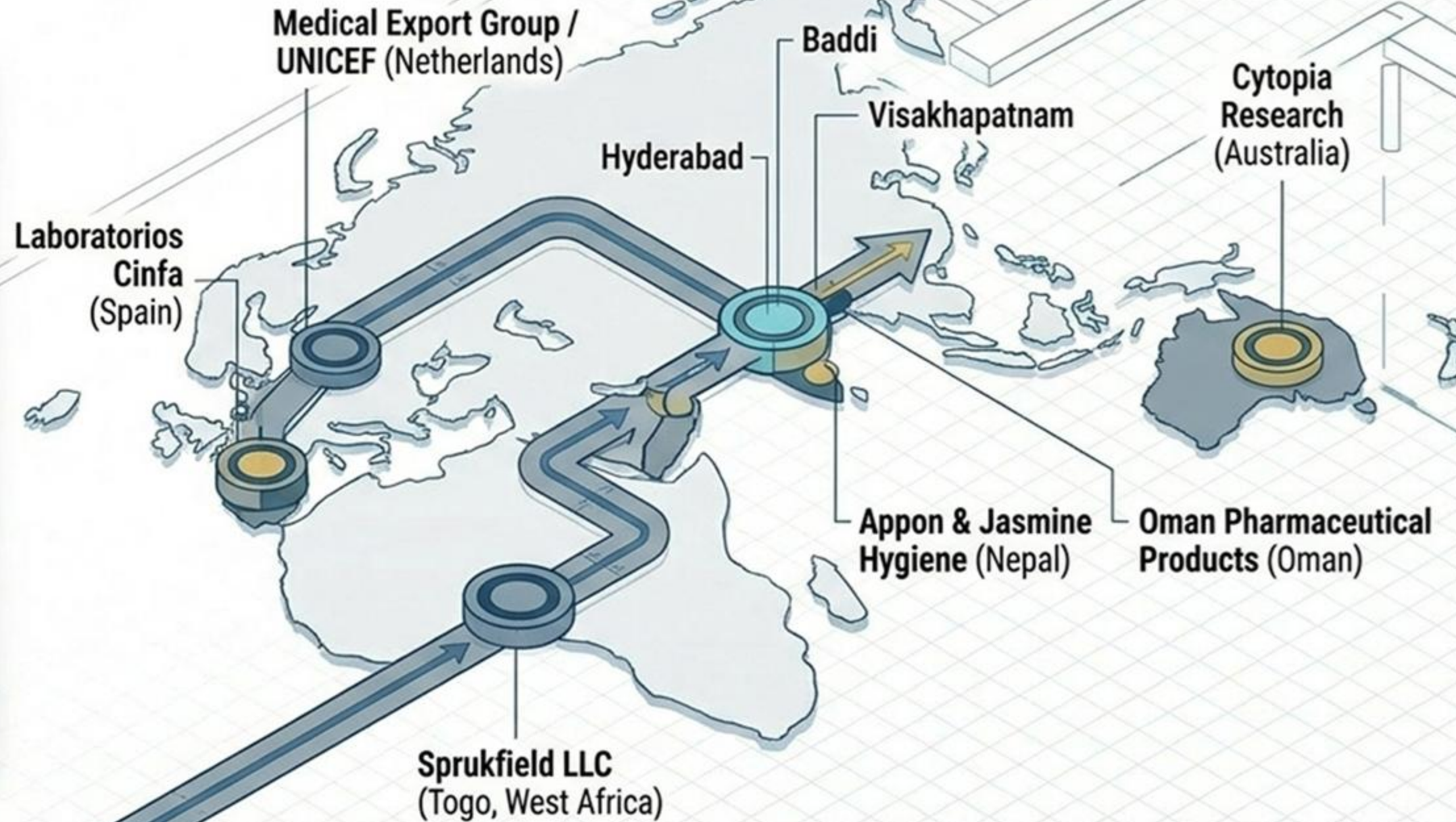
GLOBAL FOOTPRINT & OUR MARKET REACH

DOMESTIC & EXPORT HUBS

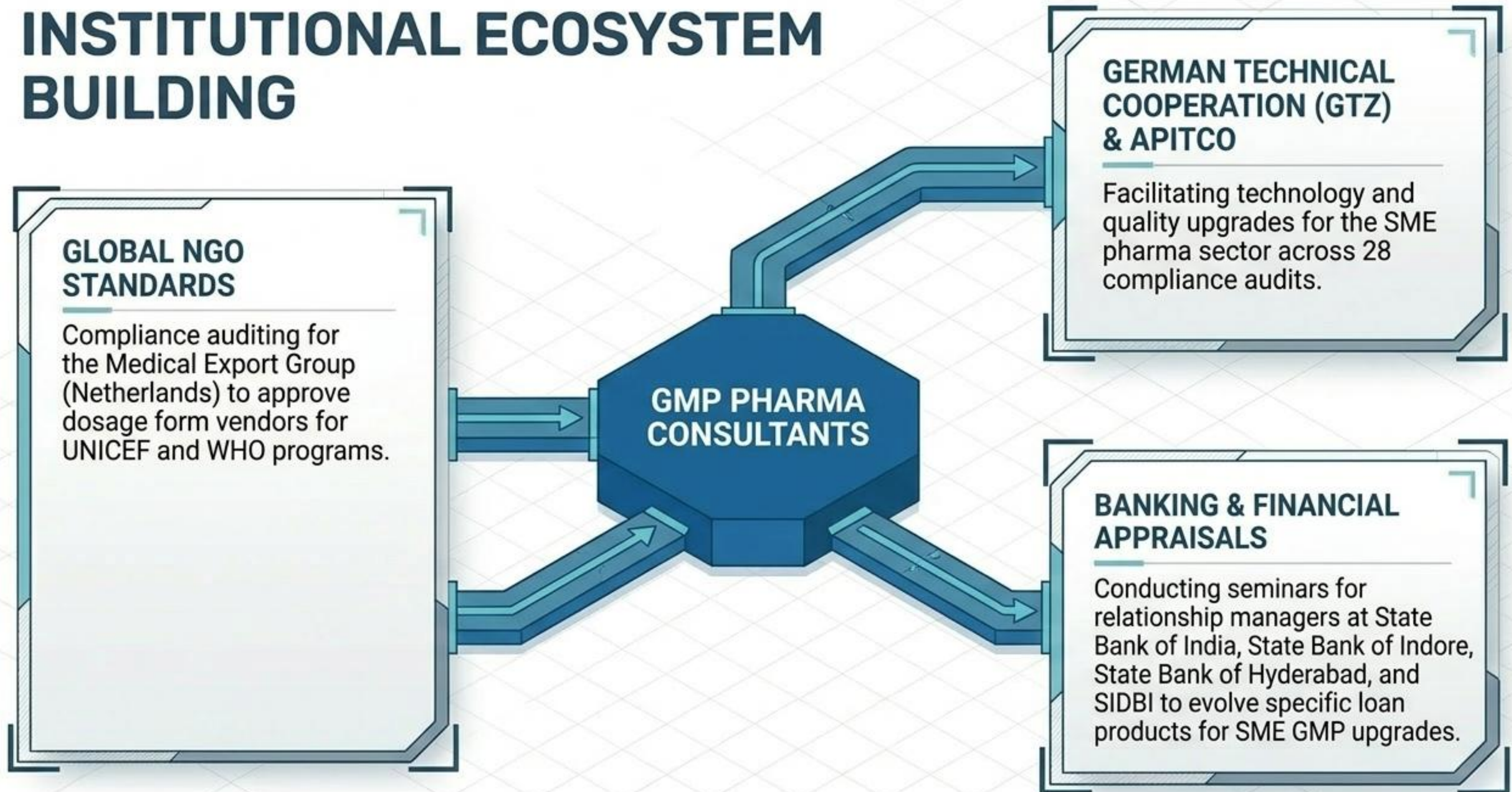
Highlighting deep roots across Indian pharma corridors (Hyderabad, Baddi, Visakhapatnam) scaling outward.

INTERNATIONAL AUDITS & INTERVENTIONS

- **Europe:** Laboratorios Cinfa (Spain), Medical Export Group / UNICEF (Netherlands)
- **Asia-Pacific:** Cytopia Research (Australia), Appon & Jasmine Hygiene (Nepal), Oman Pharmaceutical Products (Oman)
- **Africa:** Sprukfield LLC (Togo, West Africa)



INSTITUTIONAL ECOSYSTEM BUILDING



PORTFOLIO SHOWCASE: TRANS-NATIONALS & MAJOR PHARMA

DR. REDDY'S LABORATORIES

Trans-National API & Formulation

GMP intervention included advanced validation training, internal audit checklist evolution, and managing international labeling compliance under USFDA standards.

TEVA PHARM INDIA PVT. LTD

International API & Formulation

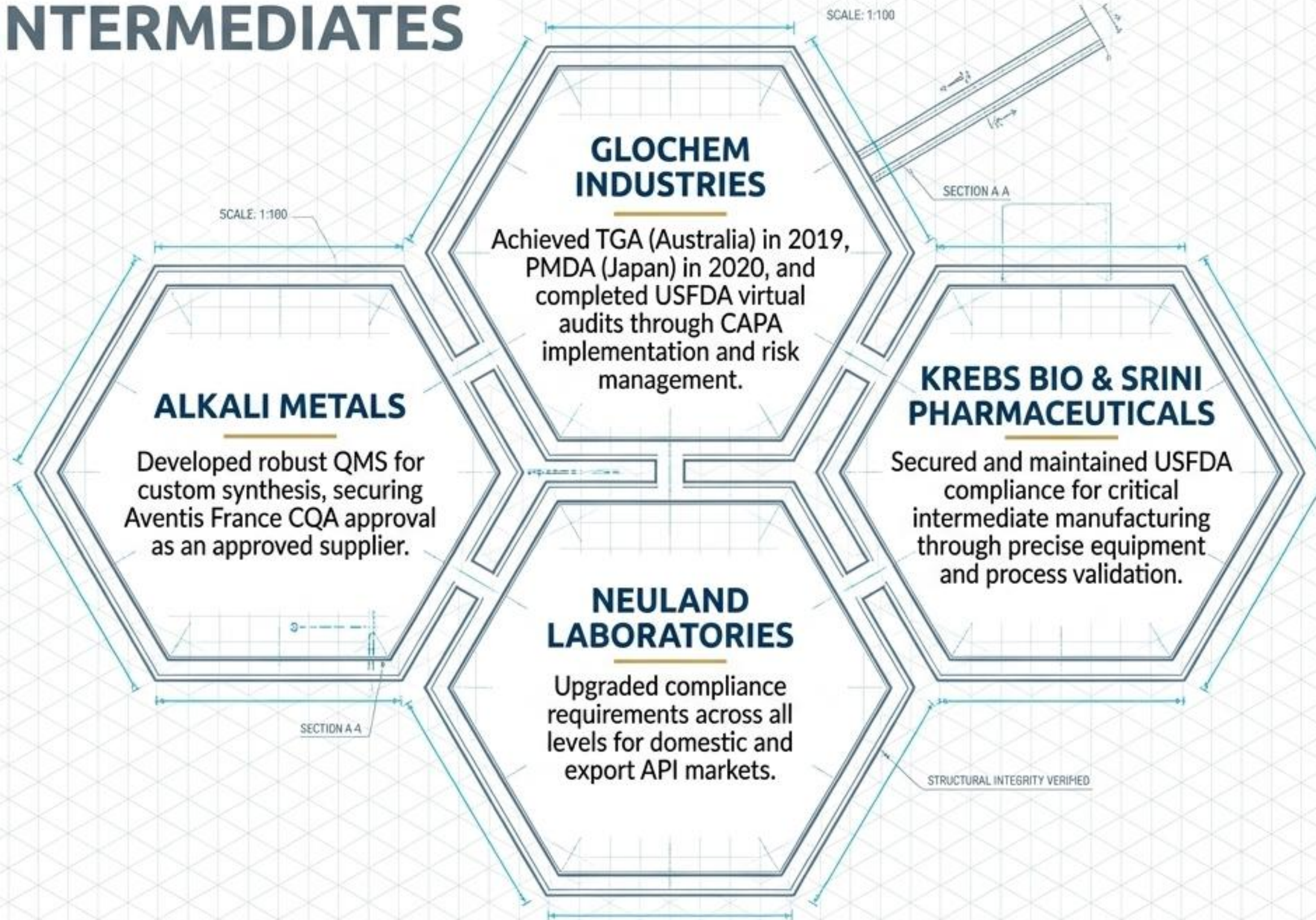
Conducted in-depth verification of quality control documentation (chromatograms, spectra, worksheets) at contract manufacturing premises for strict US FDA compliance.

NATCO GROUP

US FDA Approved Unit

Intensive training on cGMP (ICH Q7A) and CFR 210/211 across both API and formulation units, bridging the gap from operators to management.

PORTFOLIO SHOWCASE: APIs & INTERMEDIATES



PORTFOLIO SHOWCASE: FINISHED FORMULATIONS



— **ANGLO FRENCH DRUG INDUSTRIES:**

Upgraded cGMP awareness across supervisory and managerial staff for multi-dosage formats (capsules, tablets, dry syrup).



ESPI INDUSTRIES:

Secured facility and system approvals from corporate QA (including Wyeth, Pfizer, Dr. Reddy's) and WHO through rigorous auditing and validation.

— **CIPRO PHARMACEUTICALS:**

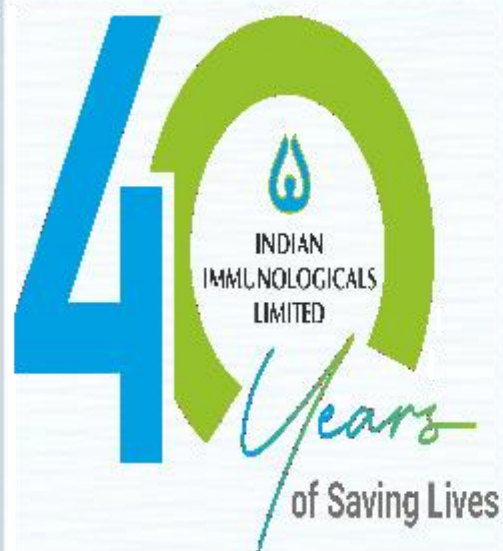
Conducted pre-assessment audits and suggested CAPA to successfully achieve TGA compliance.



ZIM LABORATORIES:

Implemented significant QMS improvements leading to EDQM approval for unregulated market exports.

PORTFOLIO SHOWCASE: STERILE OPERATIONS & VACCINES



INDIAN IMMUNOLOGICALS

Conducted comprehensive training on cGMP with special reference to sterile operations for human and animal vaccines across dual facilities.



SHANTA BIOTECHNICS

Engineered sterile operations compliance and validation techniques specifically for Hepatitis B vaccine manufacturing.



DANO VACCINES

Secured WHO GMP standards compliance through regular auditing and corrective action reporting.



COVALENT LABORATORIES

Piloted the facility through successful US FDA compliance for sterile and non-sterile APIs.

PORTFOLIO SHOWCASE: BEYOND TRADITIONAL PHARMA



Ayurvedic Compliance: Imis Pharmaceuticals & Venkateswara Ayurveda Nilayam. Navigated complex statutory frameworks to achieve rare cGMP approvals under specialized AYUR regulations.



Nutraceuticals: Sarvottam Care.
Designed QMS resulting in direct approvals from multinational corporations like Amway, P&G, and GSK Consumer Healthcare.



Food & Confectionery: Maksons Pvt. Ltd & Priya Foods.
Successfully adapted cGMP into HACCP frameworks, securing TGA compliance for P&G sugar-based contracts and HACCP for export-grade foods.

PORTFOLIO SHOWCASE: CRITICAL PACKAGING & ALLIED SYSTEMS



TRIVENI POLYMERS

Optimized systems for HDPE/PP containers, leading to massive customer growth and direct vendor acceptance by Dr. Reddy's, Lupin, and Aurobindo.



ARUNODAYA PRINTERS

Aligned self-adhesive labels and carton production with stringent pharma QMS requirements for major trans-nationals.



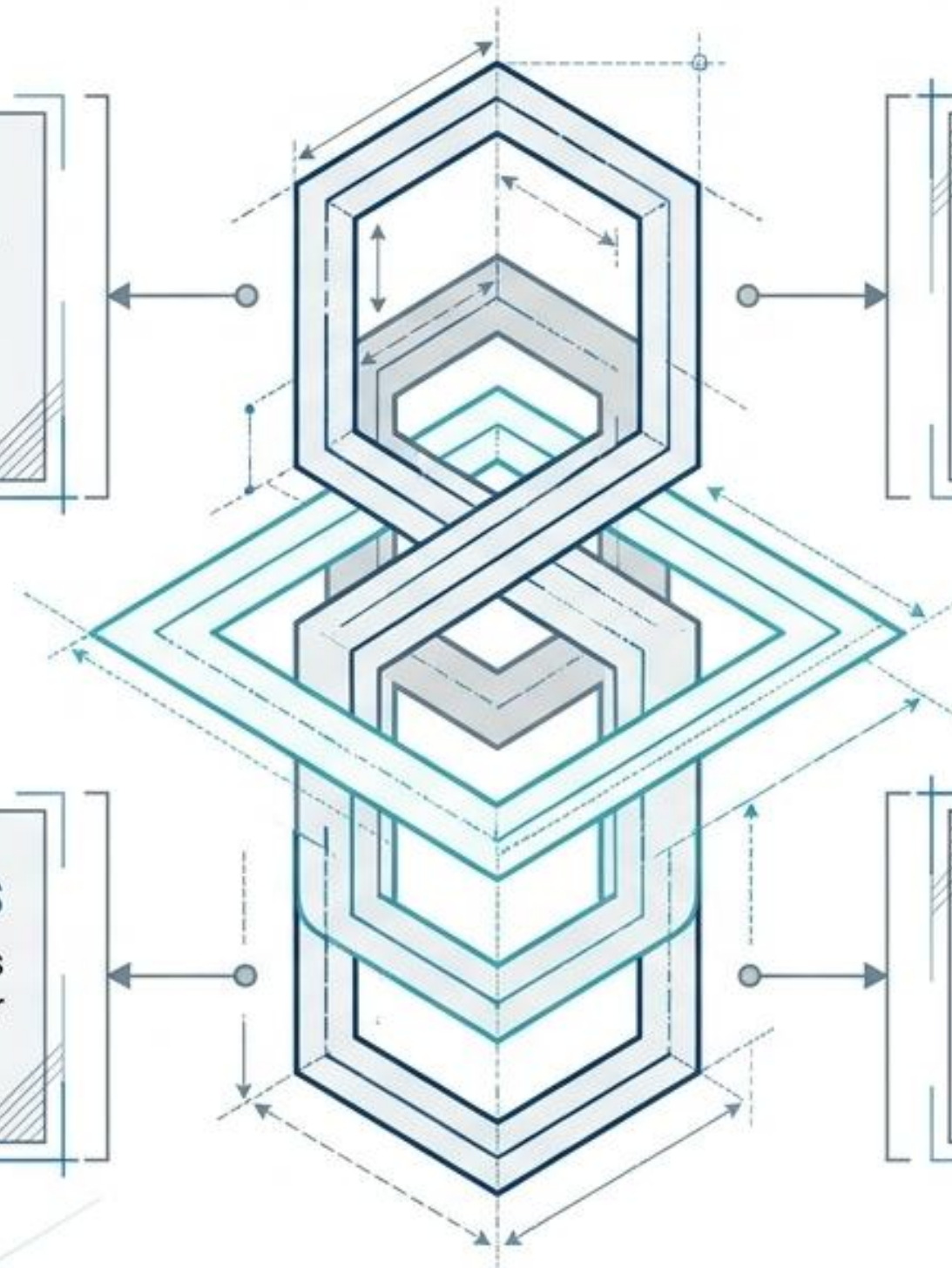
EXCEL PACK INDUSTRIES

Developed robust cGMP systems and supported US DMF filings for induction seal manufacturing.



WALNUT PACKAGING

Facilitated procedures that won direct system approvals from Cipla and Dr. Reddy's.



Capability Spotlight: Water Systems & Facility Design

Critical Water Systems

Auro Labs

Completely refurbished purified water systems to meet strict international Microbial, Endotoxin, and USP standards for ophthalmic preparations.

Physical Facility Design

Nexogenix Life Sciences & Jasmine Hygiene

Designed entire facility for HIV/Pregnancy diagnostic kits as per cGMP. Managed physical expansion and international compliance for consumer products.

Laboratory Upgrades

Gulf Oil Corp

Upgraded highly specialized laboratories for explosives and detonators to comply strictly with GLP requirements.

YOUR BLUEPRINT TO GLOBAL ACCEPTANCE.

From targeted gap analysis and critical utility design to workforce mastery and final regulatory triumph, we architect the systems that global agencies trust.



Secure your facility's regulatory future.
Contact GMP Pharma Consultants today.