For Kind Attention to
QA, RA, Clinical, Drug Safety & Engineering Team

INDIVIRTUS®

INDIVIRTUS HEALTHCARE SERVICES PVT. LTD.

- PHARMACOVIGILANCE
- BA/BE STUDIES & CLINICAL TRIALS
- GREENFIELD/ BROWNFIELD PROJECTS
- VALIDATION (CSV/ EQUIPMENT/ HVAC)
- CALIBRATION SERVICES (NABL ACCREDITED LAB)
- TECHNOLOGY TRANSFER (API & FP)
- GMP COMPLIANCE & TRAINING FOR REGULATORY APPROVALS
- ADE/PDE OEL/OEB & RISK ASSESSMENT OF IMPURITIES
- REGULATORY AFFAIRS

About Us:

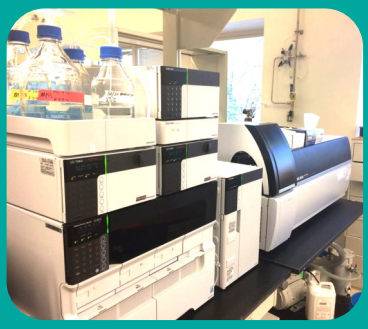
Indivirtus (**Indian company with virtuousness**, character, courage, transparency & truthfulness) is a group of companies offering **cost effective solutions wrapped with quality.**

INTRODUCING

Indivirtus Global CRO Pvt. Ltd.

Dedicated for Clinical Trials & BA/BE Studies

Indivirtus Global CRO is the 5th group company, under the umbrella of Indivirtus. The company will have focused approach in the field of Clinical Research i.e. **BA/BE Studies and Clinical Trials.**



BA/BE STUDIES & CLINICAL TRIAL MANAGEMENT

- Bioanalytical Service (Small Molecule PK Studies)
- BA/BE Studies in Healthy Volunteers & Patients
- Biostatistics and Statistical programming
- Management and Monitoring of Early Phase (Phase-I) & Late Phase (Phase II/III/IV/PMS) Clinical Trials
- Data Management and Electronic Data Capture (EDC)
- Medical Affairs & Writing

For any query, please contact

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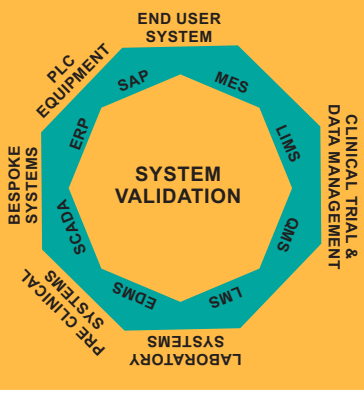
PHARMACOVIGILANCE

- Pharmacovigilance Database Setup
- Medical Information Call Centre (MICC)
- PSMF and SOPs Preparation
- ICSR Case Processing and ADR Reporting
- Literature Monitoring
- PSUR/ PBRER/ PADER
- Risk Management Plan
- Signal Management

GREENFIELD/ BROWNFIELD PROJECTS

Turnkey Pharmaceutical Project of

- Finished Dosage Forms
- Active Pharmaceutical Ingredients
- Intermediates



VALIDATION (CSV/Equipment/HVAC)

- Laboratory Systems (HPLC/GC/KF/UV/FTIR/POLARIMETER)
- Process Automation Systems (PLC/HMI/SCADA/IPC)
- Environment Monitoring Systems (EMS)
- Enterprise Applications (SAP/ERP/LIMS/DMS/QMS/LMS etc.)
- Temperature Mapping (SIP/ Autoclave/ Tunnel/ Cold Room/ Warehouse)
- HVAC (DOP/Air Velocity/NVPC/Filter Integrity)

CALIBRATION LAB (NABL ACCREDITED)

Thermal: Temperature & Relative Humidity (RH), IR Thermometers, Furnace, Oven etc.
Electro Technical: AC/DC Current, Voltage, Resistance, Inductance, Time, Frequency etc.
Mechanical: Dimension, Speed & Acoustics, Length etc.
Pressure/Vacuum: Pressure/Vacuum/Magnehelic Gauges, Transmitter, Safety Valves etc.
Mass & Volume: Weights, Weighing Balance, Pipettes, Burettes etc.
Others: pH Meters, ORP, Conductivity Meters, TDS, Flow Meter etc.

TECHNOLOGY TRANSFER

- R&D to GMP site transfer
- Formulation Development & Technology Transfer
- Know How Based Technology Transfer
- Analytical Method Development & Validations

TRAININGS ON

- Cleaning Validation
- GxP (GLP, GMP, GCP, GDP etc.)
- Revised Schedule M
- WHO TRS guidelines and Annexures
- Pharmaceutical Quality Systems like Data Integrity, Quality Culture, Human Error etc.
- Quality Management Systems

GMP APPROVALS FROM REGULATORY AUTHORITIES

EU-GMP | USFDA | WHO-GMP & PICS | TGA | Health Canada | GCC | ANVISA | COFEPRIS (Mexico)

- **Vender Assessment Audits for Plant & Product Approvals**
- **Assessment of**
  - Plant Layout Design, Equipment, Infrastructure, Process Flow, Flow of Man & Material, Raw Material and FG Store, Documentation
  - Validation, Calibration & Qualification
  - CAPA and Risk Management with Appropriate Mitigation and Contingency Plan

TOXICOLOGICAL RISK ASSESSMENT

- Toxicological Risk Assessment of Medical Devices
- ADE/PDE/OEL & OEB Calculation for Cleaning Validation
- Genotoxic (Mutagenic) Evaluation of impurities as per ICH Q3 A (R2), ICH Q3 B (R2), ICH Q3 C (R8) & ICH M7 guidelines.
- Training on Cleaning Validation
- Safety Assessment Report of Finished Formulations
- Preparation of MSDS/SDS

ICH M7 | MultiCASE | Derek nexus | Sarah nexus

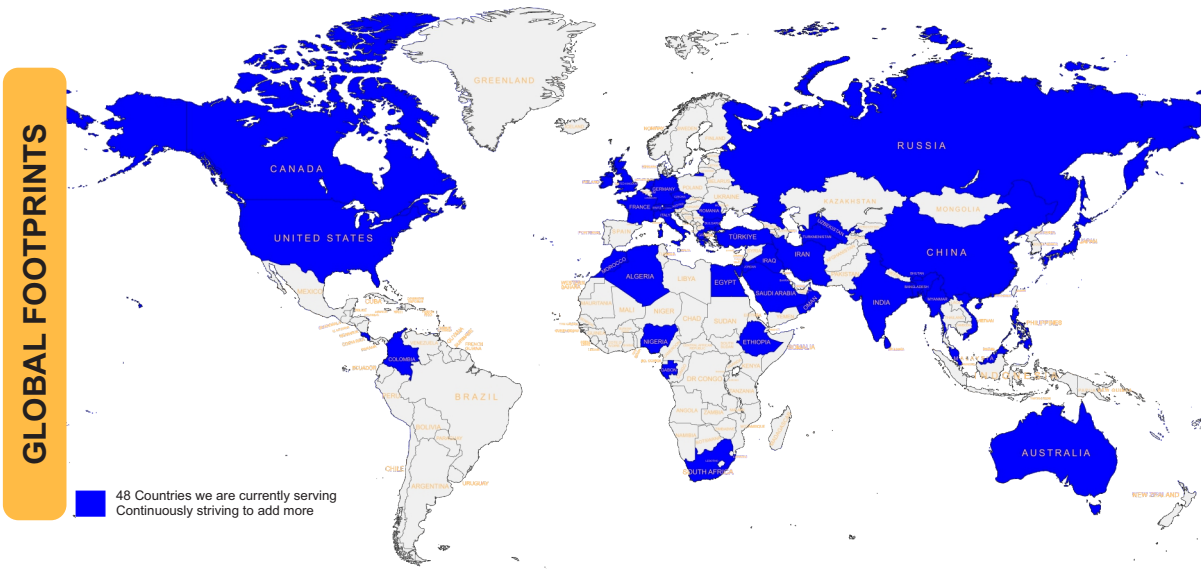
REGULATORY COMPLIANCE AND MEDICAL DEVICE REGISTRATION

- Preparation, Submission and Review of the CTD/ ACTD Dossiers
- Medical device (Class-A, B, C & D) Filing & Submission to CDSCO as per MDR-17 rule
- CEP/DMF Filing & Submission to EDQM/FDA/Health Canada.
- Clinical/Non-Clinical Overview and Bio Waiver Preparation
- Managing Regulatory Response & Remediation Activities
- M.A.H. representation, Qualified Person (Q.P.) & Batch Releasing & Testing Site for Europe Submission

OUR Unique Selling Proposition

- Team with Experience of Performing 1200+ BA/BE Studies
- Team with experience of conducting 100+ Phase III & 120+ Phase IV Trials
- End to End Pharmacovigilance Services
- Only company with a team of 6 Certified Toxicologists
- Experience of preparing 10000+ PDE/ADE & OEL Reports
- Experience of preparing 2000+ Genotox (Mutagenic & Risk Assessment Reports of Degradation/Nitrosamine/Elemental/Extractable Leachable Impurities
- Served 500+ clients in 48 countries
- Experienced & Certified Auditors to Conduct GMP and Vendor Audits
- Experienced Team to perform Technology Transfer
- Vast portfolio of products for Technology Transfer i.e. 650+ Products for Regulated Markets & 3000+ products for ROW markets

GLOBAL FOOTPRINTS



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