



INDIVIRTUS HEALTHCARE SERVICES PVT. LTD.



About Us:

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

OUR

Unique
Selling
Proposition

- End to End Pharmacovigilance Services
- Only company with a team of 6 Certified Toxicologists
- Experience of preparing 8000+ PDE/ADE & OEL Reports and 1500+ Genotox Evaluation Reports of Impurities
- Served 400+ clients in 41 countries
- Experienced auditors to conduct plant audits
- Team with experience of conducting 100+ Phase III & 120+ Phase IV Trials
- Experienced Team to perform Technology Transfer
- Available 600+ Products for Tech Transfer to WHO-GMP Plants and 150+ Products for Regulated Markets

For any query, please contact



Dr. Ashish Jain
+91-9131925456
director@indivirtus.com



Randeep Singh
+91-9888111109
director.bd@indivirtus.com

EXECUTION OF GREENFIELD/ BROWNFIELD PROJECTS

- Turnkey Greenfield/Brownfield Projects of APIs/Intermediates/ Finished Dosage Forms
- Vendor Assessment Audits to Plant Approvals



VALIDATION (CSV/Equipment/HVAC)

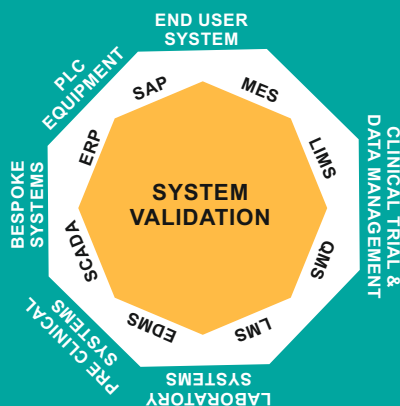
- Laboratory Systems (HPLC/GC/KF/UV/FTIR/POLARIMETER)
- Process Automation Systems (PLC/HMI/SCADA/IPC)
- Environment Monitoring Systems (EMS)
- Enterprise Applications (SAP/ERP/LIMS/DMS/QMS)
- Temperature Mapping (SIP/Autoclave/Tunnel/Cold Rooms)
- HVAC (DOP/Air Velocity/NVPC/Filter Integrity)

CALIBRATION

Mechanical: Volume, Density, Pressure, Vacuum, Sound, Pressure Gauges, Transmitter etc.

Thermal: Temperature & Relative Humidity (RH), Thermometers, Temperature Sensors etc.

Electrical: AC/DC Current, Voltage, Resistance, Capacitance, Time, Speed, Frequency etc.



TECHNOLOGY TRANSFER

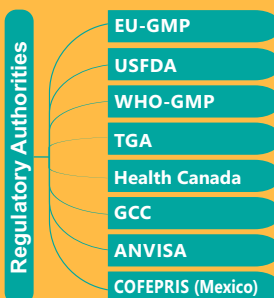
- Technology Transfer
 - Site Transfer
 - R&D to commercial site transfer
- Development of API by Fermentation Technology
- Analytical Method Development & Validations
- Stability and Photostability study as per ICH Guidelines



PLANT APPROVALS FROM REGULATORY AGENCIES

Assessment of

- Plant Layout, Infrastructure, Documents, Flow of Men & Materials, Raw Material Store, Process Flow
- Validation, Calibration & Qualification
- Manpower Adequacy & Capabilities
- CAPA, OOS and Risk Management with Appropriate Mitigation and Contingency Plan
- Managing Regulatory Response & Remediation activities (USFDA & EU)





REGULATORY COMPLIANCE AND MEDICAL DEVICE REGISTRATION

- Preparation and submission of the CTD, e-CTD & country specific dossier for Regulated, Semi-regulated & RoW market
- Medical device (Class-A, B, C & D) filing, submission & registration to CDSCO as per MDR-17 rule
- CEP filing & submission on EDQM portal and DMF filing to FDA
- Clinical & Non-Clinical Overviews and Bio Waiver Submissions

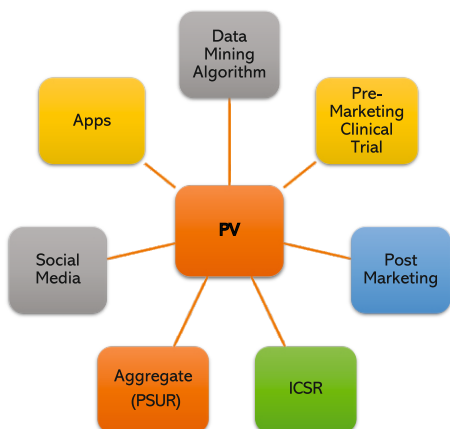
TOXICOLOGICAL RISK ASSESSMENT

- PDE/ADE & OEL Calculation for Cleaning Validation
- Genotoxicity and Mutagenicity Evaluation of Impurities as per ICH M7 Guidelines



CLINICAL TRIAL MANAGEMENT

- Phase III Clinical Trials
- Phase IV Clinical Trials
- Post Marketing Surveillance



PHARMACOVIGILANCE

- Pharmacovigilance System Set-up
- Medical Information Call Centre (MICC)
- PSMF and SOPs Management
- ICSR Case Processing and Reporting
- Literature Monitoring
- PSUR/PBRER/ PADER
- Risk Management Plan
- Signal Management

GLOBAL FOOTPRINTS



INDIA



USA



CANADA



UK



FRANCE



SWITZERLAND



NETHERLAND



RUSSIA



CHINA



AUSTRALIA



ITALY



GREECE



IRELAND



JAPAN



UAE



EGYPT



JORDAN



PHILIPPINES



PALESTINE



IRAN



TURKEY



ALGERIA



NIGERIA



SOUTH AFRICA



GABON



COSTA RICA



COLOMBIA



GERMANY



MYANMAR



VIETNAM



SINGAPORE



UZBEKISTAN



MALAYSIA



BANGLADESH



MOROCCO



ROMANIA



SRI LANKA



CAMBODIA



SAUDI ARABIA



OMAN



BULGARIA

GLOBAL OFFICES

UAE

502, Saleh Bin Lahej 341,
Al Barsha 1, Dubai
UAE, 345055
+971 5250 61253
support.uae@indivirtus.com

USA

21106 Sonoma,
San Antonio
Texas 78259
+1 (323) 522-5967
support.usa@indivirtus.com

INDIA- Head Office

521-522, Top Floor, Taj Plaza,
TDI City, Sector-118, Airport Road,
Mohali, Punjab, India 160059
+91 9131925456 | director@indivirtus.com
+91 9888111109 | randeep@indivirtus.com

EGYPT

5 El Nasr Street,
Sheraton Heliopolis El Nozha
Cairo, Egypt
+20 (106) 082-7300

UK

16 Bissley Drive,
Maidenhead, Berkshire
SL 6 3UZ
+44 20 3286 0405
support.uk@indivirtus.com

CANADA

unit 307, 14255 Boul Gouin O,
Pierrefonds, Montreal
Quebec H8Z3C2
+1 (647) 581-6157
support.ca@indivirtus.com

To find out more visit www.indivirtus.com

