Bilcare Research

Global Clinical Supplies

Bilcare Global Clinical Supplies, a division of Bilcare Ltd., is recognized as the leading providers of Clinical Trial Materials Services. With a world class cGMP compliant facility located in India providing cutting edge technology, Bilcare GCS has proven to be an able ally delivering end-to-end services for your global clinical supply needs. With strategic business partners located in the USA and the UK and a worldwide network of over 25 depots, our integrated offerings are aimed at establishing your critical success factor – speed-to-market.

With an experienced team, customer-first work ethic and exposure to a multitude of clinical trials across the entire spectrum of therapeutics, Bilcare GCS is ideally placed to solve complex clinical trial challenges and ensure your success.

Bilcare GCS Global Capabilities*:

Analytical & Formulation Development Services

- State-of-the-art Analytical Laboratory
- Analytical Method Development / Validation
- Stability Studies
- Impurity Profiling

Clinical Manufacturing

- Solids, Liquids, Creams, Injectables
- Blinding and Encapsulation
- Active & Placebo Manufacturing
- Phase I-IV Development and Preformulation
- Over-Encapsulation & Blinding

Packaging & Labeling

- Primary Packaging – Blister / Strip Packaging, High Speed Bottling, Tube / Vial Filling, Pouch Packaging, Child Resistant Packaging
- Secondary Packaging – Protocol Specific Pack Design and Development, Kit Assembly, Wallets, Blister Cards, Labeling at Refrigerated Temperature
- Label Design & Generation (Single / Multi Panel & Booklet Labels), Kit List Generation, Randomization, Text Translation Support, Country Specific Regulatory Review
- Innovative Packaging Solutions – Child Resistant Packs, Bilcare Optima, nonClonableID®

Storage, Distribution & Global Logistics

- Ambient (15-25 Deg C) / Refrigerated (2-8 Deg C) / Frozen (-20 Deg C) Storage
- Deep Freeze Storage (-70 Deg C)
- Controlled Drug Substance Storage & Distribution
- Vaccines, Injectables, Biologicals & Biosimilar Storage & Distribution
- Inventory Management through Validated SAP R3 ERP System

- Building Management System for 24/7 Temperature and Humidity Recording
- Transit Temperature Monitoring & Recording
- 24/7 Live Tracking through Customer Web Portal
- Global Storage & Distribution via Depot Partners Worldwide
- Strategic tie ups with Global Logistics Service Providers

Comparator Procurement & Ancillary Supplies

- Strategic Support in Developing, Planning & Effecting a Global Comparator Study
- Global Partnership with Manufacturers & Wholesalers to Maintain Confidentiality
- Local Regulatory Support Backed by a Global Supply Chain to Ensure Supplies Whenever, Wherever
- Ability to Source Large Volume of Drugs of Single Lot or Small Volumes in Multiple Batches as per Requirement
- Product Documents like Specifications, COA, MSDS Available on Request

IVRS / IWRS

- Multilingual Interactive Voice / Web response system
- Study Specific Customized Programming
- Accelerated Implementation (Within 4 Weeks)
- 24/7 Operation and Support
- Site Administration and Tracking
- Inventory / Shipment Management
- Forecasting and Simulation in the Planning Process
- Integrating Courier and Temperature Monitoring Data

Equipment Rentals

- Equipment Rentals with no Duration Commitment and 24/7 Support
- Onsite / Web Investigator Training
- 24/7 Online Technical Support & Resupply Requests
- Translation of User Manuals & Technical Documents in over 30 Languages
- Custom Clearance Support

Returns & Destruction

- Returns Handled per Customer Specific Protocols
- Destruction Handled using a Govt. Approved External Agency
- IXRS Controlled Drug Return & Destruction Process to Ensure Optimization

Regulatory Support

- Regulatory & Technical Support Throughout the Overall Drug Development Cycle – IND, Clinical Trials, Marketing Authorization Approvals
- Regulatory Support in Preparation & Approval of Label Text as per Country Specific Requirements
- Licensing Support for DCGI, ICMR, CDSCO, Local FDA, DGFT, CBN Approvals
- Import & Export Requirements for Shipping and Pre-Clearance of Shipments
- Global Network of Regulatory Experts with Local Knowledge

QP Services

- Auditory Services to Support QP Declarations
- QP Release Certificates
- Global Auditing of Third Party Manufacturing, Testing, Packaging and Labeling Facilities as Required in Support of QP Declarations for Import into the EU

Consulting

- Innovative Packaging Solutions
- Qualified Person (QP) Services
- Study Specific IXRS Services
- Licensing & Regulatory Support

*Services provided by Bilcare GCS and its strategic business partners

The data given are reference values and correspond to our current state of knowledge and services. No liability will be inferred for results that may be obtained in the application of our products / services.

Bilcare Research

Vision
Transforming health outcome - touching lives

Values
Speed | Innovation | Happiness

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