

## CMO Compass & Supply Chain Management



### Life science consulting (clinical trial material)

-  We provide critical GxP-based consulting services throughout the product lifecycle to help our clients successfully execute projects to bring products to market and maintain quality and compliance.
-  We offer an expansive suite of services to ensure quality, compliance, efficiency, and safety throughout the full lifecycle of a product.



CTM Qualified Person (for release)/MIA



Investigator brochure, IMPD, CTA and any technical writing



QMS GAP analysis, SOP development, QMS Maintenance



Setting up CTM supply strategy (distribution, shelf-life management, reconciliation and destruction) and project management



QA staffing and Inspections



Interactive response system (IVRS, IWRS) URS and qualification



Selecting and auditing services for CMO's (e.g. CTM packager and distributors)



Work via partners in distribution, label, import and comparator vendors (WDA covered by distributor)



Support in EU specific labelling guidelines

### Supply Chain Strategy



Supply chain management pertains to the activity of managing the movement of IMP/materials or goods throughout an organization while also maximizing customer value and maintaining a sustainable competitive advantage.

## CDMO & Logistics Partners

### Supply Chain Manager

- Support in EU specific labelling guidelines
- Setting up CTM supply strategy (distribution, shelf-life management, reconciliation and destruction) and project management
- Interactive response system (IVRS, IWRS), Material Requirements Planning (MRP), User Requirements Specification (URS) and qualification
- Work via partners in distribution, label, import and comparator vendors

### CMO Selection

- Our goal is to help you find and partner with the optimal Contract Manufacturing Organization (CMO)
- Through our methodology (CMO Compass®) we can identify and engage a CMO partner with the quality systems, technology, customer service, and cost structure that is critical to your success
- Our hands-on approach to GMP audits is our way of collaborating with you to develop risk-based remediation plans, enhancing the level of quality and building on your programs already in place
- Our standardised, ranked assessment provides you with an optimal partner based on:
  - Stage of development (clinical to commercial)
  - Your priorities
  - Specialty manufacturing capabilities such as processes for cell-based products, vaccines, transdermal, aerosols, etc.
  - Highest value in terms of speed, quality, and cost
  - Stage for effective quality audit, contract negotiation and tech transfer

### Distribution Partner

- Third party logistic (3PL) provider for partnership of storage, transport and distribution activities are being selected
- Own WDA at partner
- Physical importation activities at partner
- Optional labelling and translation capabilities
- Optional comparator vendors sourcing capabilities

## IMP Supply Project Management

### Engagement

ProPharma Group act as a liaison between the Sponsor and CMO or Suppliers to ensure continuous engagement and operational activities run smoothly & timely

### Product Life Cycle Management

Manage demand versus forecast of IMP  
Manufacturing Packaging, & Labelling activities  
Excess, Obsolete, Expired and Destruction

### Procurement

Preferential Pricing & Lead Times  
Liaise with vendors (Ancillaries & Comparative drugs)

### Logistics

Warehouse  
Distribution  
Import/Export

### Inventory Control

How much  
How often  
Risk Analysis/Risk Management

### Vendor Management

Integrated Partnerships  
KPI management  
Quality Standards

# Drug Supply Management

## Sponsor

- Study protocol
- Trial Management, data handling & record keeping
- CMO selection (DS & DP)
- Investigator selection
- Site & Country selection
- Financing



## ProPharma Group – Project Management

- Risk Management (Forecast & Demand)
  - Ensure the correct amount is scheduled, produced and delivered in time
- MOQ's, overage, Lead-times, Goods in Transit
- Supply to the sites and/or DTP
  - Either manual order placement or via IRT/IWRS system
- Depot & Site IMP management
  - Collaborate with CMO & Site Coordinators ensuring IMP compliance
  - Replenishment levels / Packaging & Labelling activities / Timelines
- IMP Processes & Procedures
  - SOP's and Wi's
- Reconciliation of patient supplies



## ProPharma Group - Warehouse/Distribution Management

- Storage
- Transport (Qualified Courier/Temp Controlled)
- Distribution tracking
- Import and Export
  - Compliance Documents / Requirements (USDA Statements, Customs Invoices & Cover Letter)
- Returns & Destruction
  - Deviations reporting, CAPA's, IMP compliance
- Reconciliation of patient supplies



Contact us to learn how our experienced team can help ensure successful outcomes throughout the product lifecycle

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