PharmSol

"Your Partner Of Choice For Global Pharma Compliance."

Corporate Presentation

PharmSol

Vision

"We aspire to be a partner of choice for global compliance & project management across the pharmaceutical value chain, adding value not only to pharma manufacturers and marketers, but to each member organization involved in the chain"

The Company

- **Entire spectrum of pharmaceutical services *under one umbrella*:**
  - ✓ *Product Development*
  - ✓ *Compliance*
  - ✓ *Regulatory Qualification*
  - ✓ *Project & Supply Chain Management*
  - ✓ *Providing innovative solutions to enhance Product Life Cycle*
- The compliance and regulatory support encompasses the entire value chain of pharmaceuticals right from product development to marketing & distribution of products
- **Direct presence** across Europe, Asia and Middle East
- Backed up by more than **30 years** of **industry experience** of its **promoters**

Our Group


PharmSol GmbH
Germany
PharmSol India Pvt. Ltd
India
PharmSol Ltd
Malta
PharmSol APAC Ltd
Hong Kong
PharmSol FZCO
PharmSol DMCC
PharmSol MPCC LLC
UAE
PharmSol (Zhuhai) Ltd
China

Our Group

Pharmaceutical Solutions FZCO, Dubai

- Corporate Headquarter

Pharmaceutical Solutions DMCC, Dubai

- Business Development,Commercial, Financial, HR & Admin

PharmSol MPCC LLC, Dubai

- Registration, Marketing & Distribution of Pharma & Allied Products in GCC & MENA

PharmSol GmbH, Bad Oldesloe, Germany

- EU Imports
- Storage
- Batch Release

PharmSol Europe Ltd, Malta

- EU Imports
- Batch Release

PharmSol India Pvt Ltd, Hyderabad, India

- Technical Talent Pool
- Compliance Management & Project Management

PharmSol (Zhuhai) Pharmaceutical Technology Co., Ltd, China

- Pharma Capability Enhancement
- Compliance & Regulatory

PharmSol APAC Limited, Hong Kong

- Generics Gateway to & from APAC

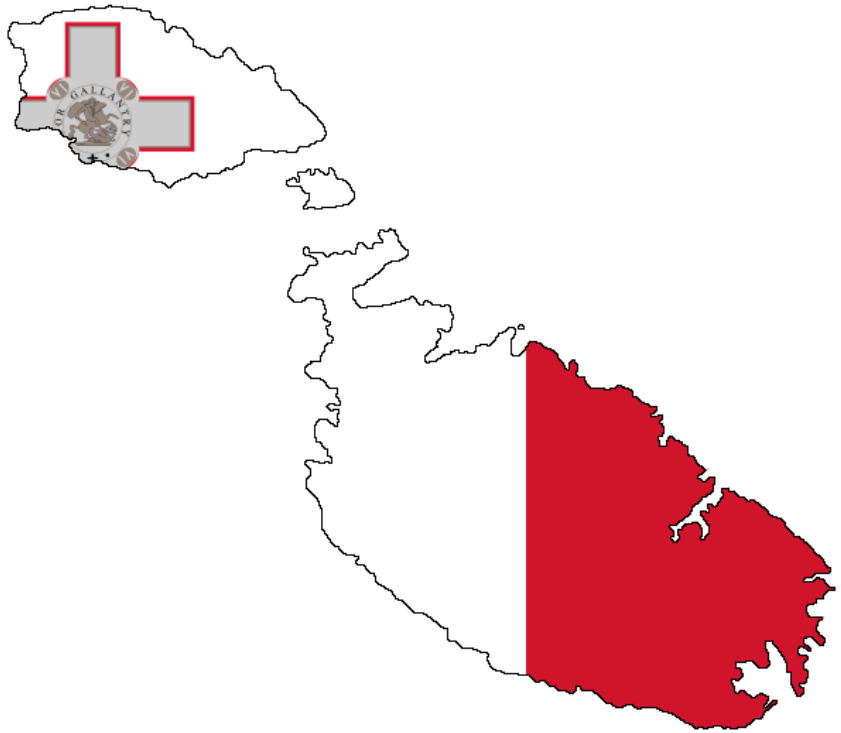
PharmSol GmbH, Germany

- ***EU GMP/GDP Compliant*** *from* ***Automated Warehouse***
- *Located in Bad Oldesloe 40 km Hamburg, Germany.*
- *600 – 3000 SKUs*
- *Storage Capacity:*
  - *2000 pallets cold store (2-8°C)*
  - *3000 pallets ambient store (15-25°C)*
  - *800 pallets ambient store (15-25°C)*
  - *50 pallets controlled drugs (15-25°C)*
- *GMP License*
- *Contract Manufacturing*
- *Primary & Secondary Packaging*
- *Capable of import, storage bonded and non bonded, releasing and distribution / re-export Finished Products as well as APIs*
- *Member at BPI and VCI*

Mitglied im BPI Bundesverband der Pharmazeutischen Industrie e.V.

Mitglied im VERBAND DER CHEMISCHEN INDUSTRIE e.V. VCI

PharmSol Europe Ltd Malta



- ***GMP/GDP Compliant Warehouse***
- *GMP License*
- *Batch Control / Bach Release Laboratory*
- *Secondary Packaging*
- Capable of import, release and distribution of Finished Products and APIs in Europe and for re-Export *with* ***added advantages of Commercial & IPR***

PharmSol HQ, UAE

- ***Pharmaceutical Solutions FZCO*** *is the* ***Headquarters*** *of the PharmSol Group.*
- *UAE also lists two additional group companies:*
  - ✓ *Pharmaceutical Solutions DMCC*
  - ✓ *PharmSol MPCC LLC*
- ***PharmSol MPCC LLC*** *plays the role of a* ***GCC Market Access Gateway*** *for companies across the Globe*

PharmSol India Pvt Ltd

- ***ISO 9001 : 2008 Certified***
- ***Technical Nerve Center*** *of PharmSol*
- *Supports all the activities of PharmSol in India, China, Europe and Middle East.*
- *Base for* ***Compliance Management and Project Management Team*** *of PharmSol Group*
- *Call Center for GDP*

cefic

APIC Active Pharmaceutical Ingredients Committee

BSI ISO 9001:2008

PharmSol APAC Ltd, HK & PharmSol (Zhuhai) Ltd, China

- *PharmSol APAC Ltd., Hong Kong, provides **a gateway to APAC Region** for Value added Pharmaceutical & Allied products and services.*

- ***PharmSol (Zhuhai) Pharmaceutical Technology Co., Ltd.** is being commissioned to provide the compliance and regulatory support to the manufacturers in China, enabling them to access the EU / US markets.*

PharmSol

Through the Years

2004
Founding of Pharmaceutical Solutions FZCO, Dubai

2005
Launch of the business model "Exclusive Sponsored Development On-Patent API's"

2007
Launch of "Contract Development of Formulations" and "Tech Transfer" services.
Inception of Third Party Audits in response to the mandate of EC Directive 2004/27/EC

2010
Founding of PharmSol Europe Limited, Malta

2011
Founding of Pharmaceutical Solutions DMCC, Dubai.
New office set-up in Dubai

2012
Founding of Shanghai Rep. Office.
Started exhibiting in CPhI China and CPhI Worldwide

2013
Founding of PharmSol GmbH, Germany

2014
Founding of PharmSol MPCC LLC, Dubai.
Founding of PharmSol APAC Ltd., Hong Kong.
Founding of PharmSol India Pvt. Ltd., India.
Landmark of 500 GMP Audits since 2007 crossed

2015
PharmSol GmbH becomes a member of BPI and VCI.
PharmSol India receives ISO 9001:2008 Certification.
Founding of PharmSol (Zhuhai) Pharmaceutical Technology Co., Ltd., China.

2016
Expansion of India Setup.
CEIV Certification by IATA

Success Record

- Conducted **over 500 audits** of various facilities across India, China, Korea, Taiwan, Europe and GCC/MENA.
- Effectively **launched several new business models** of collaboration between manufacturers from Asia and marketers from Europe.
- **25 APIs** have been **successfully developed,** 18 of which have already been commercialized.
- **12 FDFs** have been **successfully developed,** and PharmSol is currently involved in 8 FDF Developments.
- A total of **30 tech transfers** from Europe to India and vice versa have been done ‘til date and currently involved in 8 tech transfer projects.
- **40 (+) Analytical Methods have been Developed, Validated and Transferred** successfully to manufacturing / releasing sites.
- Built **strong bonds with over 30 major manufacturers** from Asia having credentials of US FDA and EU GMP approvals and the network is strongly growing.

Filling the gaps

Our Services

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Our Services

Compliance

- EU GMP Certifications
- GMP Audits (QP Audits)
- GDP, GLP, GCP Audits
- Facility Feasibility Audits
- Computer System Validations
- Data Integrity Solutions

Market Access & Supply Chain

- Dossier / ANDA Submissions
- Pharmacovigilance
- MA Holding
- EU Importation, Batch Control / Release
- GCC Product / Company Registration, Marketing & Distribution

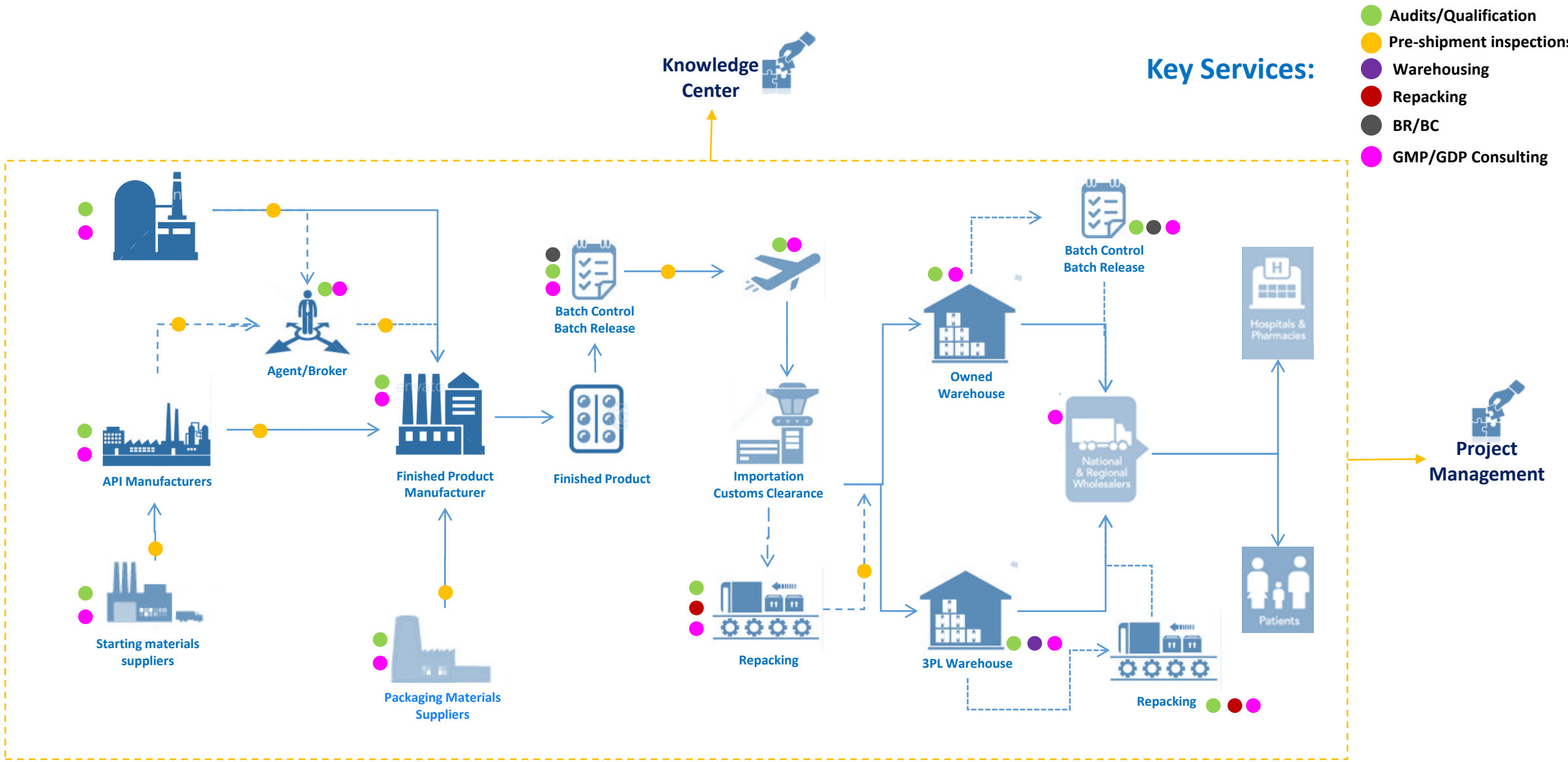
GDP

- Compliance Assessment
- Capability Enhancement
- Certification
- GDPNet Membership
- GDPvigilance™
- Support for CEIV Pharma Certification

Project Management

- Product Developments (API & FDF)
- Tech Transfers & Scale ups
- Facility Design & Upgradation
- QMS Set up
- Licensing In / Out

PharmSol Support Across the Value Chain



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Our Services

Compliance

PharmSol carries out **complete chain of audits** with which product safety & quality is assured to our clients across the globe, for Finished Products, APIs, KSMs and Intermediates:

- GxP Audits:
  - GMP Audit of API, FDF & KSM manufacturing facilities
  - GDP Audit of complete supply chain
  - GLP Audit – Audit of Development and Analytical Laboratory
  - GCP Audit – Audit of clinical studies CRO
- Facility Feasibility Audits – Prior to scale up or tech transfer of a product
- GAP Analysis Audit – Assess the compliance readiness of a facility
- CSV Audit – Computer Systems Validation Audit
- Data Integrity Audit
- GxP Compliance Training

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Compliance

- Third party GMP Audits of facilities manufacturing starting materials, APIs and Finished products
- All audits are conducted **in accordance with ICH Q7, EudraLex Volume 4 and PIC (s) guidance**
- Unabridged reports are shared with all the parties and guidance on compliance is offered instantly (CAPA assessment and response documents)
- **Certified EU GMP Auditors (CEFIC / APIC)**
- **Lead auditor is a member of European Compliance Academy (ECA)**
- Exclusive audits based on customer and authority needs
- Based on the Audit Report, the QP files the declarations as part of MAAs to various EU Authorities
- **Time and cost efficiency**

EUGMP Certification Assistance

PharmSol provides **end – to – end service for EUGMP Certifications**, which involve:

- Conducting GAP Analysis Audits
- Assistance in Facility Compliance based on the outcome of GAP Analysis Audit
- Conducting Preparatory / Mock Audit prior to Authority inspection
- Assistance in application and triggering of EUGMP Inspection from the Competent Authority
- Extension of Support by deputing PharmSol's team at Site during authority inspection
- Support in Post-inspection CAPA Closure for submission to the authority

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Our Services

Market Access & Supply Chain

*PharmSol has created a platform which provides a **comprehensive, integrated and seamless Market Access and Supply Chain Solution** with needed infrastructure for Finished Pharmaceuticals and on a **cost effective** basis.*

EU Market Access
Dossier / ANDA Preparation
QP Declarations
BE Study Design and CRO Selection
Regulatory Submissions & Follow Up
Pharmacovigilance Services
MA Holding
Creating EU Set ups
EU products importation
EU Batch Control / Batch Release
Manufacturing Expediting & pre-shipment inspections
Distribution

GCC Market Access
Local Agent for Foreign Manufacturer
Registration of Companies and Products
GCC Inspection Guidance
Pharmacovigilance Services
Import, Storage and Distribution
Facility Design and Upgradation
Product In-licensing
Tech Transfer
Compliance Management

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Our Services

Project Management

*PharmSol operates as **a single window service provider** to the Global clients, taking care of every aspect of the development*

- Strategic Product Development (API & FDF)
- Capability Assessment Service
- Capability Build up / Enhancement
- Analytical Development, Validation and Impurities
- Technology Transfer & Scale up
- Facility Design and Up-gradation
- Facility Commissioning and Validation
- Setting up QMS
- In Licensing & Out Licensing of products

Project Management

Technology Transfer Expertise

- PharmSol, with its technical teams based out of Europe, India & China, ensures that every key stages of tech transfer is monitored and delivered at a speed and to a precision.
- One of the key challenges of Tech Transfers is cultural differences across geographies, and PharmSol has been able to meet these challenges successfully and consistently.
- A total of **30 tech transfers** from Europe to India and vice versa have been done ‘til date and currently involved in 8 tech transfer projects

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Project Management

Facility Designing Assistance

PharmSol provides support in following areas:

- On Site / Off Site Facility Assessment in accordance with GMP – GEP guidelines
- Facility Conceptual Design
- Basic as well as Detailed Engineering
- New Facility Commissioning Support
- QMS Setup
- Product Mix Selection
- Turn Key Solutions

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Our Services

GDP

Good Distribution Practice (GDP) is that part of quality assurance which ensures that products are **consistently** stored, transported and handled under **suitable condition** as required by the marketing authorization or product specifications.

The **new guidelines** have set new complex requirements for the pharma companies and the logistic industry.

In order to provide such assurance, companies will require more than just a set of quality manuals, it **requires a comprehensive systems to "give assurance".**

This may include appropriate procedures, suitably qualified personnel, correct processes / facilities / equipment as well as **clear** and **timely documentation**, to **credibly demonstrate** the **consistency** of **quality assurance**.

GDP COMPLIANCE REQUIREMENT

- Quality Management Plan
- Assign a responsible person to ensure GDP compliance
- Risk Management Plans
- Detailed & complex documentation
- Monitor across all steps for temperature, cleanliness and security
- Qualification of suppliers and customers – as well as brokers (MA holder)
- Adequately equipped facilities throughout the supply chain
- Properly trained & certified personnel
- Qualified vehicles
- Data available for inspection when needed
- Suppliers/Contractors audits
- Currently on FPs and APIs, but soon on excipients (EXCiPACT) & critical packaging materials
- …and many more & more compliance issues to be closely monitored

Huge Complexity; Investment Requirement; Operational Costs Increase; Risk Of Non Compliance

GDP COMPLIANCE CHALLENGES

- Regulatory confusion and non-compliance due to many different guidelines
- Lack of pharmaceutical knowledge (or expertise) to handle:
  - product specific issues
  - risk assessment
  - corrective action
  - real time reporting
- Not enough data at all milestones and lack of information/knowledge sharing
- Geographically specific licensing procedures, import controls and reporting requirements for controlled substances
- Inconsistent Infrastructure

A Plethora Of Certification Schemes Available As A Great Start….

… and more

CERTIFICATES ALONE ARE NOT SUFFICIENT…

- Each pharmaceutical product has its own quality requirements on the top of the GDP requirements.
- Certificates are still far from guaranteed compliance of every shipment as the chain has currently different standards per country (over 60 national GDP standards).
- Until a specific service quality and reliability level has been reached, it takes time.
- Dealing with such a broad range of products and different transport conditions does not allow full standardization. Unfortunately the exception is the rule and suitable qualified Human interaction is needed.
- An exhaustive reporting system is needed to track journey of cargo

GDPv™

"A future proof, fully validated, integrated GDP Compliance platform"

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GDP Vigilance

GDP SERVICES

- GDP compliance readiness assessment and GAP analysis
- Enhancement and build up of capabilities and systems' development
- **GDP Compliance Audit and Certification**
- Membership to our GDP Network (**GDPv.net**)
- **100% deviation monitoring & reporting** on product flow from the manufacturer to the end user, minimizing risk for the QP
- **24 x 7 QA Monitoring Centre** and real time tracking of the products movement
- **Dedicated Help Line** for compliance support to contracted clients

CEIV Pharma Certification Guidance & Assistance

- PharmSol's **10 auditors** have been **certified as Independent Validators** for **CEIV Pharma and Temperature-Controlled Cargo Operations** by the IATA

- PharmSol provides assistance in designing and implementation of QMS

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GDP Vigilance

COMPLIANCE CONTROL OF SUPPLY CHAIN

GDPvigilance®

Monitoring and documenting the entire journey of pharmaceutical cargo right from the manufacturer's warehouse through all transit points, such as ports, airports, short term warehouses etc.; to the end user's warehouse.

Each input is **secured by biometric control** and data is continuously collated and analyzed at the **24x7 call center**.

At the point of final discharge, a **QP** has **access** to the **full journey data** and a final report which allows him/her to decide whether to release the product to the market.

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GDP Vigilance

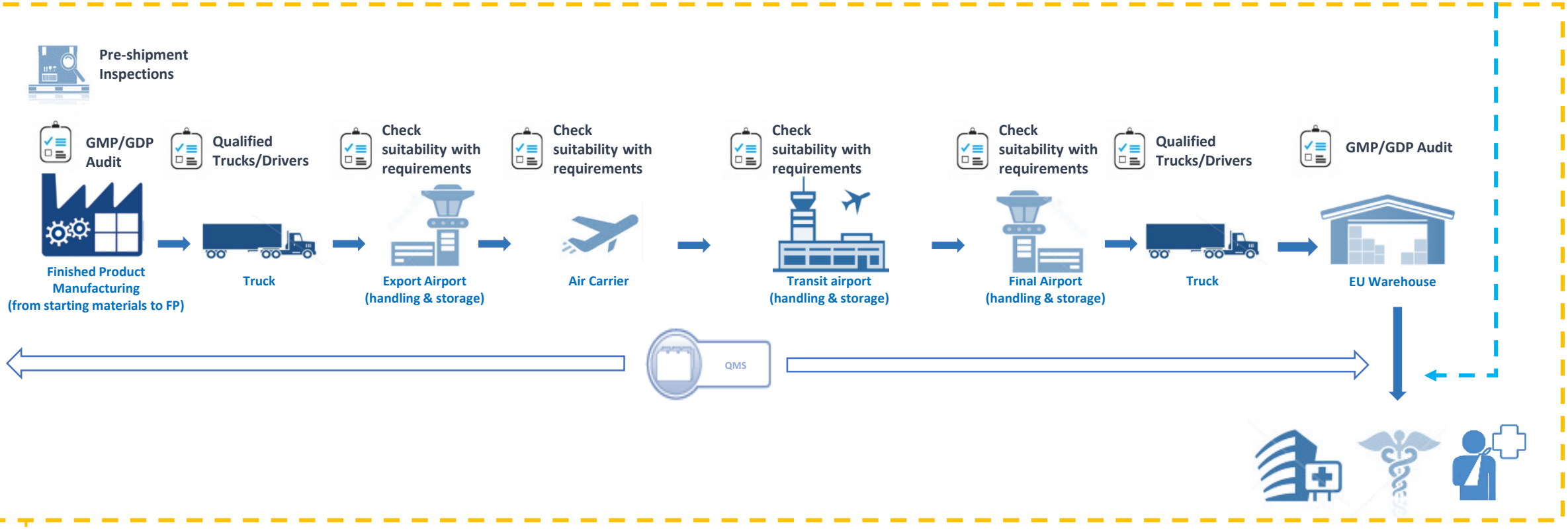
GDPvigilance.NET®

Data are centrally collected and secured with biometric controls

The full report is delivered to the QP/RP who now has everything at one place, readily available to make the product final release

QP/RP

Data flow: Audit Reports, CAPAs, Records, Deviations, Corrected actions, Inspections, Qualifications, etc



24/7 fully dedicated call center – Knowledge Center with experts on Pharmaceuticals

GDP Vigilance – *Providing The Missing Link*

Currently Available

GDPvigilance.NET®

Batch Records
(Mfg Site)

Analytical Records
(BC site)

Pre-shipment Inspections

QA monitoring of the full journey from pick up to final destination

GDP Compliance report Deviations & CAPA report on GDP issues

A future proof, integrated information & decision making platform that enables QPs and RPs to quickly & effectively perform their Batch Release duties

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Thank You!