1. Who we are ...
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EALTH is comprised of leading European logistics and transport companies which have dedicated operations for warehousing, handling, commissioning, and/or shipping of pharmaceutical & healthcare products. Each member company is represented by their respective logistics professionals who are both experienced and respective of the unique requirements for the pharmaceutical industry. An antitrust declaration is necessary for membership.

EALTH is listed in the Transparency Register of the European Union, n° 257135610488-90

EALTH is registered as stakeholder for EMA, EU DG Pharmaceuticals and Medical Devices Units

EALTH is Affiliate Member with reciprocity of ALICE and ELA
We are pre-wholesalers, service providers, distribution networks, and dedicated transport specialists. Our activities cover the entire Healthcare supply chain.
Our Objectives

- **To provide logistics & transport companies** which are dedicated to and have stake in the professional high-quality distribution of the pharmaceutical & healthcare products **a voice to communicate to the E.U. and international institutions alongside other established stakeholders.**

- **Differentiate our members as professional** logistic and transport services providers in accordance with local and international laws, guidelines and established industry procedures.

- **To identify areas for improvement and propose solutions**, define guidelines and help enact certifications through relevant European and national bodies.

- **Work to improve the interest of patient safety and ensure product quality.**

- **Contribute** to support Countries wishing to **enter EU considering Pharma Supply Chain guidelines compliance.**
Membership Requirements

Be a company which has dedicated operations for warehousing, handling, commissioning, and/or shipping of pharmaceutical & healthcare products operating as a service provider.

EALTH members do not trade in the goods being handled, stored and/or transported.

- pre-wholesalers with pharmaceutical licenses*
- dedicated transport specialists.

* means wholesaling, secondary packaging, importation, ...
Global Regulatory approach

- **ICH 8, 9 and 10 guidelines** and revised chapter 7 of GMP have formalized a global framework for Quality Assurance of Pharma processes. **WHO** is supporting the ICH guidelines. **FDA and EMA** are exchanging same points of view sharing the same agenda.

- **Medical devices** are also concerned by the same topics (ISO 13485 and 14971).

- **This global common view** of managing the Quality Assurance in Healthcare built for GMP lead the operations concerned by GDP.

- The **inspectors** have also now their common view on GDP through **PIC/S**
Global Regulatory approach

Pharma compliance in healthcare and particularly in transportation is not emerging now, it’s a **global approach all around the world** supported and defined by **relevant bodies**

- ICH 2009
- WHO 2010
- US FDA 2010
- EU GMP 2012
- EU GDP 2013
- CDSCO* GDP 2013
- NA-DFC** GDP 2013
- PIC/S PE 011-1 ...

* Central Drugs Standard Control Organization/India
** National Agency of Drug and Food Control/Indonesia
At this stage we need to explore actors of wholesaling/distribution activities

- **Distributor**
  - Owns the product
  - Represents the brand/manufacturer in the territory

- **Wholesaler**
  - Owns the product
  - Distributes to dispensing points

- **Prewholesaler**
  - **Doesn’t own** the product
  - Acts in the name and on behalf

- **Manufacturer**
  - Owns the product
  - Distributes himself or through a Prewholesaler
Key drivers

Relations are clearly defined in GMP/GDP between Manufacturer and Prewholesaler

- Pharmaceutical status on both side (QP/RP) subject to authorization

- Contract Giver (PQS control and review activities, competence assessment, providing necessary information and knowledge, monitoring and reviewing performance, ..)

- Contract Acceptor (adequate premises/equipment/competent personnel, subcontracting approved, changes approved, authorities inspections, ..)

- Audits to assess subcontractor

- Matrix of responsibilities
Key drivers

Contract Giver can **benefit** from a Prewholesaler

- Mutualization
- Optimisation
- Expertise
- Activity Based Costing invoicing
- Additional services
Pharmaceutical logistics schemes in EU

**Abroad**
- Manufacturer

**Country**
- Marketing authorization holder (MAH)
  - Contract giver

**Pharmaceutical contract**
- PLSP (Pharmaceutical logistics service provider)
  - Contract acceptor

**Responsibilities under QP/RP control:**
- Pharmacovigilance
- Medical information
- Batch release
- Importation
- Subcontractor management
- ...

**Licenses:**
- Manufacturing
- Wholesaling
- Importation

**Responsibilities under QP control:**
- To guarantee compliance with GDP / GMP
- To guarantee the good realization of orders coming from MAH

**Factory**
- Move of the products

**Pharmaceutical logistics service provider (PLSP) – Contract acceptor**
- Bonded (customs) warehouse
- Quarantine warehouse
- Distribution warehouse
- Secondary packaging workplace

**Licenses:**
- Depositary wholesaling
- Manufacturing limited to secondary packaging

**Move to PLSP**

**Ownership flows**
- Patients
- Hospital
- Wholesaler
- Pharmacy

**Physical flows**
- Hospital pharmacy
- Wholesaler platform
- Community pharmacy

**Patients**
Pharmacy summit of Ukraine – 2015

getting in touch

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