



World Health Organization



Quality Safety and Standards

GL/VQ

Global Learning Opportunities for Vaccine Quality



MENTORING SERIES
3-8 June 2013, TURKEY



Pharmaceutical cold chain management on wheels

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Pharmaceutical cold chain management on wheels
in association with

"The end is nothing, the road is all"

INTRODUCTION

Members of the pharmaceutical supply chain have various global requirements to meet during the storage, transport and handling of time and temperature sensitive products. Changing product portfolios, requirements for good storage and distribution practices, regulatory expectations, quality management, and risk assessment factors bring many challenges to pharmaceutical cold chain management.

WHO and PDA's purpose in sponsoring this unique course is to provide key players of the pharmaceutical cold chain an opportunity to gain insights into complete cold chain operation and oversight from product manufacture (or arrival in a country) to the product's administration to the patient. This is done by bringing together a group of participants from the national regulatory authorities and pharmaceutical, biopharmaceutical, vaccine industry involved in the supply, packaging, distribution, logistics and cold chain management areas as well as industry members of immunization related equipment and device manufacturers.

The World Health Organization QSS team provides a "prequalification of vaccines" service to UN procurement agencies. This ensures that vaccines used in immunization services are safe and effective and that tender specifications meet the specific needs of individual country programmes. Validation of the packaging and the shipping of vaccines are part of this prequalification process.

WHO also publishes guidelines on the international packaging and shipping of vaccines that form part of the contractual agreement between vaccine manufacturers and UN procurement agencies, when vaccine contracts are awarded.

COURSE OBJECTIVES

Pharmaceutical Cold Chain Management on Wheels (PCCMoW) is a learning event for learners to develop their knowledge and skills enabling them to critically evaluate a pharmaceutical cold chain system and improve their associated supervisory skills. The

course encourages participants to make direct observations at the storage, warehousing, distribution and health care facilities that they visit as they physically travel with mentors by bus down the length of the cold chain. This approach is designed to show participants how the theoretical background of pharmaceutical cold chain management is applied in a variety of storage, distribution, and health care facilities. It is a practical application of experiential learning theory.

By the end of the 6-day event, the participants will be able to:

- Identify the major operational components in a pharmaceutical cold chain
- Identify deficiencies in given situations using the “good distribution practice” (GDP) guidelines
- Illustrate the inputs, activities, and outputs of each operational component of a pharmaceutical cold chain
- Develop a quality agreement that is appropriate to a given situation
- Given a cold storage facility, assess and control the risks to pharma, biopharma, and vaccine products consistent with GDP and “good storage practice” (GSP) guidelines
- Given a mode of transportation, assess and control the risks to pharma, biopharma, and vaccine products consistent with GDP
- Given a mode of distribution in the “last mile”, assess and control the risks to pharma, biopharma, and vaccine products consistent with GDP
- Given a situation, select the appropriate methods and materials for packaging and shipping cold chain products to minimize risk
- Given a situation, select the appropriate methods and materials to monitor temperature and/or humidity for cold chain products to obtain necessary data for making decisions
- Given a specific temperature monitoring strategy, assess and control the risks to pharma, biopharma, and vaccine products consistent with GDP/GSP
- Examine and assess documents and records that support a cold-chain process consistent with GDP/GSP
- Identify work practices that contribute or reduce risks to a cold-chain worker’s health and safety
- Conduct the shake test to identify whether a given freeze-sensitive vaccine has been affected by freezing

TARGET AUDIENCE

The maximum number of participants for each course is set at 15.

Primary target audience

Representatives from the government sector including military services involved in pharmaceutical cold chain in the areas of: regulation, inspection, planning and monitoring.

Representatives from the pharmaceutical/ biopharmaceutical/ vaccine industry in the areas of: Supply, packaging, distribution, logistics and cold chain management. Manufacturers who already supply WHO prequalified products are encouraged to participate.

Representatives from the equipment and device manufacturing industry in the areas of: Active cooling, passive cooling, temperature monitoring, and track and trace. Manufacturers who already supply WHO PQS prequalified products, or who wish to enter this market, are encouraged to participate.

Secondary target audience

Representatives from the pharmaceutical/ biopharmaceutical/ vaccine industry in the areas of: R&D, quality, regulatory, and manufacturing.

Representatives from WHO, UNICEF and other partner organizations: Technical officers responsible for pharmaceutical cold chain management activities at regional level, intercountry logisticians, health officers, EPI officers, and immunization advisers whose involvement in pharmaceutical cold chain is confirmed by their organizations.

Representatives from logistics providers.

Members of the faculty of institutions of higher education in health professions.

Independent consultants.

APPLICATIONS, SELECTION PROCESS and COURSE FEE

Representatives of the above mentioned primary and secondary target audiences should apply directly to the GLO/VQ secretariat with the attached GLO/VQ application form.

Applicants should send their applications along with their CVs to the following addresses: Dr Ümit Kartoğlu kartogluu@who.int and Ms Sinéad Jones jonessi@who.int by email or +41227914384 by fax.

Deadline for application is **31 March 2013**. Following this date, all applications will be evaluated by the WHO GLO/VQ secretariat and acceptance letters will be sent the following week.

Course fee is established as USD 5,500 (five thousand and five hundred) including accommodation and meals throughout the course. Accepted participants will receive detailed information regarding the bank transfer for the course fee. **Course fee is waived for public sector NRA/NCL representatives and WHO staff.**

When the course fee is waived, participants are expected to cover their air travel and accommodation, lunch and dinner expenses throughout the course (through institutions, country or regional office funds). There will be no extra charges for the bus, tea/coffee breaks, gala dinner and any other extracurricular activities. An Information Bulletin will be circulated in April.

METHODOLOGY

Four major methods that will be used during this learning opportunity: illustrated lectures, guided observations, group discussions and individual and group assignments.

Illustrated lectures will be interspersed throughout the course, designed to illustrate the theoretical and practical issues surrounding each day's activities.

Guided observation exercises will take place at the facilities that are visited during the course of the tour. Course participants will use checklists to ensure that they observe critical system elements in a real (as opposed to a classroom) environment. There will also be opportunities to interview and interact with local staff.

Group discussions will take place in restaurants, cafes and in the open air whilst travelling between facilities along the route.

Individual and group **assignments** will take place throughout the course.

All mentors/facilitators will be available throughout the programme for coaching, consulting, information sharing and problem solving. Participants are encouraged to network with the course mentors as well as with their fellow participants.

MENTORS/FACILITATORS

Three international content experts/mentors/learning professionals will facilitate the event. All mentors are WHO certified facilitators. Tıp Kurumu (Turkey) is responsible for all logistics of the course.

Dr Ümit Kartoğlu (WHO) - Course Director



Global Learning Opportunities for Vaccine Quality coordinator. Twenty eight years of experience in adult learning and management of time and temperature sensitive pharmaceutical products, and has had developed various learning tools and courses. Received 2010 IQPC Cool Chain Europe Excellence Award and 2011 Ludwig Rajchman Public Health Award. Named as one of the "Temperature Controlled Logistics Leaders for 2012" by the IQPC's Temperature Control Logistics & Quality Network, an international industry peer group recognizing 15 of the most influential and inspiring thought leaders in global pharmaceutical supply chain.

James Vesper (USA), Learning Professional



James Vesper designs and develops instructional courses and workshops for the pharmaceutical and medical device industries. Founder and president of the firm LearningPlus Inc., and has had more than 30 years of experience in the pharmaceutical industry and written 5 books on GMP and technical topics.

Kevin O'Donnell (USA), Author, Educator & Industry Consultant



Chair of the LATA Time & Temperature Task Force, Committee Member – USP Expert Committee on Packaging, Storage & Distribution and member of faculty for the PDA Training Research Institute. Over 30 years of experience in design, development, qualification and implementation of temperature controlled distribution packaging. Named as one of the "Temperature Controlled Logistics Leaders for 2012" by the IQPC's Temperature Control Logistics & Quality Network, an international industry peer group recognizing 15 of the most influential and inspiring thought leaders in global pharmaceutical supply chain.

Dr Hakan Gönendik (Turkey), Training support, tour guide and administration



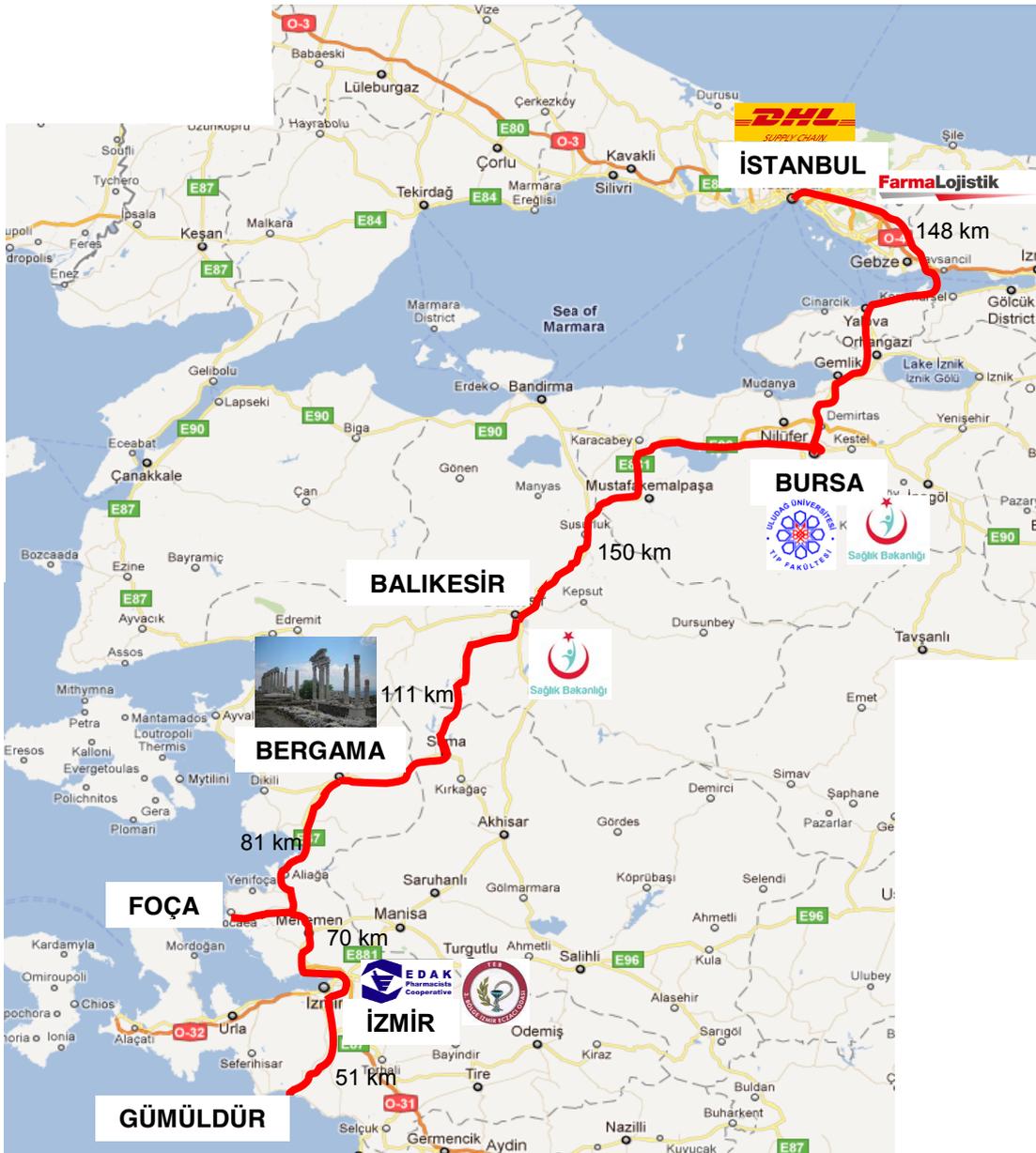
WHO accredited training centre (Tıp Kurumu) liaison person.

ROUTE

2013 course will take place in İstanbul, Bursa, Balıkesir and İzmir (total of 611 km). Before each facility visit participants will receive an information package on the facility to familiarize themselves. Following a facility tour and presentation, participants will be split into smaller groups to study on a particular subject. Initially, participants will be assigned randomly to these groups and then on a rotational basis:

- lay out and volume requirements
- temperature monitoring
- temperature controlled truck distribution
- packaging and dispatch
- stock management / standard operating procedures

There are no set or typical classroom arrangements. All group discussions take place in rest areas, restaurants and cafes - usually in semi-open or open areas.

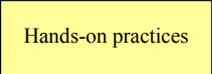
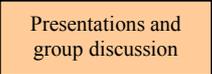
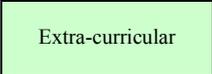


COURSE PROGRAMME*

MONDAY 3 June	TUESDAY 4 June	WEDNESDAY 5 June	THURSDAY 6 June	FRIDAY 7 June	SATURDAY 8 June
					
Opening and warm up	Check-out Warm up	Check-out Warm up	Check-out Warm up	Check-out Warm up	Warm up
Expectations and objectives	Farmalojistik warehouse	Provincial Health Directorate Vaccine Storage facility	Primary Health Centre visits	EDAK Pharmacists Cooperative warehouse	Presentations and group discussion
Introduction					
LUNCH	LUNCH	LUNCH	LUNCH	LUNCH	LUNCH
Warm up	Warm up	Warm up	Warm up	Warm up	Warm up
DHL Excel Supply Chain Cold Storage and Distribution	Depart for Bursa (148 km)	Uludağ University visit	Depart for Foça/İzmir (192 km)	Retail pharmacy visit	Boat tour
		Depart for Balıkesir (150 km)	Bergama ruins (3 rd Century BC) 	Depart for Gümüşlük (51 km)	Free time
Presentations, group discussion, evaluation of the day and dinner	Presentations, group discussion, evaluation of the day, dinner in Cumalıkızık Village, Bursa	Presentations and group discussion	Presentations and group discussion	Check-in hotel in Gümüşlük	Evaluation of the course and closing
	Check-in hotel in Bursa	Check-in hotel in Balıkesir	Check-in hotel in Foça/İzmir	Preparations for presentations	Photography contest
		Dinner and evaluation of the day	Dinner and evaluation of the day	Dinner and evaluation of the day	Evaluation of the day and dinner

* All participants must arrive in İstanbul on Sunday before the course and can depart starting on Sunday morning following the gala dinner.

Legend

 Hands-on practices	 Presentations and group discussion	 Extra-curricular
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FACILITIES TO BE VISITED

- DHL Supply Chain - Cold storage and distribution – İstanbul (Monday afternoon)
- Farmalojistik warehouse facilities – İstanbul (Tuesday morning)
- Provincial vaccine storage and distribution facilities – Bursa (Wednesday morning)
- Uludağ University Hospital Pharma Store – Bursa (Wednesday afternoon)
- Family Health Centre (4 groups) - Balıkesir (Thursday morning)
- EDAK Pharmacists Cooperative warehouse facilities – İzmir (Friday morning)
- Retail pharmacy (4 groups) – İzmir (Friday afternoon)

LOGISTICS

Tip Kurumu (an accredited WHO learning centre) is responsible for logistics of the course. Their responsibility includes arrangement of hotels, group check-in and check-out at hotels, rental bus, arrangement of social activities and provision of all necessary equipment and stationery materials.

FOLLOW UP

All course graduates will become member of the WHO GLO EZCollab Pharmaceutical Cold Chain Management community (<http://ezcollab.who.int/glovq/pccmow/>) where discussions and support services will continue.