

Extensio et Progressio **TIP KURUMU**

MENTORING SERIES

Pharmaceutical Secure Supply Chain Management on Wheels
İzmir, Aydın, Kaş, Antalya, 25-30 September 2023
 in association with

selçuk ecza deposu a.ş. **TEB** **Yıldırım Beyazıt University** **Yaşam Hastanesi LIFE HOSPITAL** **savsu TECHNOLOGIES** **SENSITECH**
ZEBRA **berlinger feel safe** **GDP-UCI** **mediline Isothermal Solutions** **SERVA INSTITUTE OF INDIA**

THE END IS NOTHING, THE ROAD IS ALL

IQPC
 International Quality & Productivity Centre
2010 Europe Cool Chain Excellence Award

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, security, and quality risk management bring many challenges to pharmaceutical safe supply chain management.

This learning event is brought to you by its creators, Extensio et Progressio (Switzerland) and Tip Kurumu (Türkiye). The purpose in offering this unique learning event is to provide key players of the pharmaceutical supply chain an opportunity to gain insights into complete supply chain operations and oversight from product manufacture (or arrival in a country) to the product's administration to the patient via experiential learning approach. 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.

COURSE OBJECTIVES

Pharmaceutical Secure Supply Chain Management on Wheels (PSSCMoW) is an experiential learning event for learners to develop their knowledge and skills enabling them to critically evaluate a pharmaceutical supply 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 supply chain. This approach is designed to show participants how the theoretical background of pharmaceutical supply 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 supply 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 supply 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 avoid/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 quality 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 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.

METHODOLOGY

Two major methods that will be used during this learning opportunity: guided observations and group discussions.

Expert views will be interspersed throughout the learning event, 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. Event 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.

All mentors 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.

Tıp Kurumu (Türkiye) is responsible for all logistics of the course.



Ümit Kartoğlu, MD, DrPH (Switzerland) - Course Director

Co-founder and CEO of Extensio et Progressio. Previously Global Learning Opportunities coordinator at WHO Headquarters. Thirty-nine 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 and 2013

Ludwig Rajchman Public Health Award. Author of the "Pharmaceutical and Vaccine Quality Illustrated", "Quality Risk Management Mental Modelling", "Go authentic: Activities that support learning", and "The Book of VVM: Yesterday, today, and tomorrow".



Kelly Moore, MD, MPH (USA) – President and CEO, immunize.org

Leader in national and global vaccine policy and immunization program implementation. Previously a state immunization program manager and member of the U.S. Advisory Committee on Immunization Practices (ACIP). Received the 2012 AIM Natalie J. Smith, MD award for excellence in immunization program management. She

has been an advisor to the World Health Organization (WHO) since 2016 in several roles, including as chair of the Immunization Practices Advisory Committee (IPAC), as a member of the Committee on Programmatic Suitability for Vaccine Prequalification (PSPQ), and on the steering committee of the Vaccine Innovation Prioritization Strategy (VIPS) project led by Gavi.



Alan Kennedy (UK), Executive Director, GDP-UCI

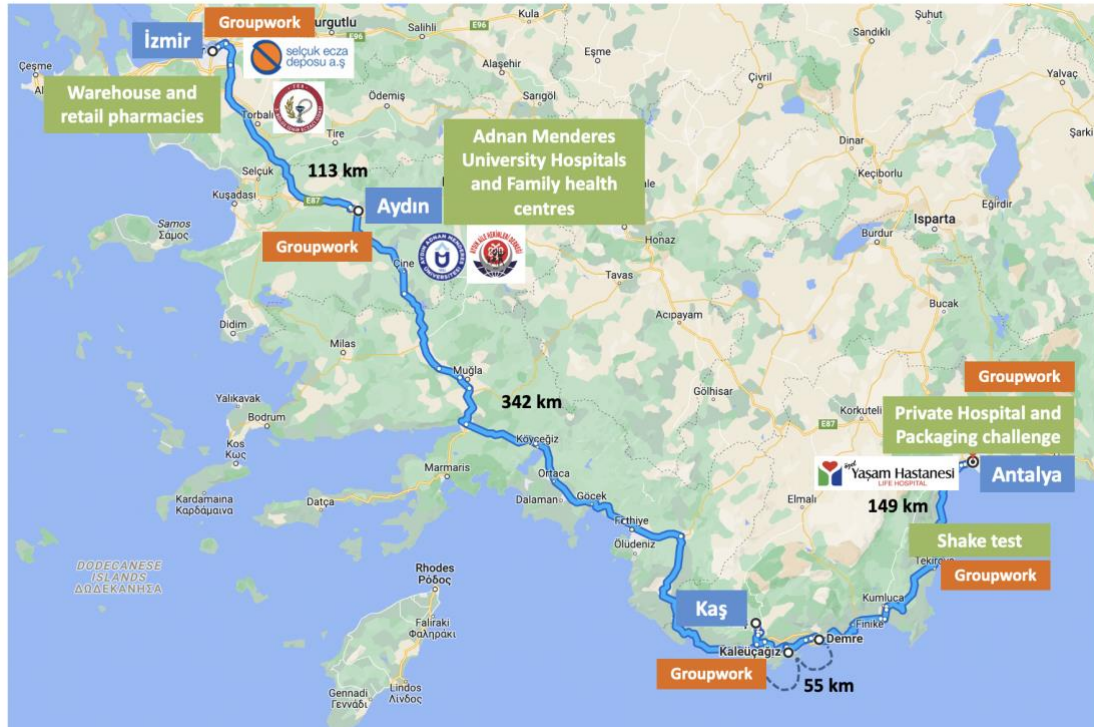
Alan Kennedy is a specialist in supply chain dynamics who, with his extensive cross-sector experience, is focused on bringing best-collaboration practice to pharma-logistics. Alan is a registered UN/CEFACT expert and has served as the Executive Director of Poseidon, the independent pharmaceutical logistics network. He is the founder of the GDP Universal Compliance initiative (GDP-UCI) which is a cross-industry program aimed at improving and reforming GDP compliance for medicines and vaccines.

ROUTE

2023 course will take place in İzmir, Aydın, Kaş and Antalya (total of 633 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. 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.

FACILITIES TO BE VISITED

- Selçuk Pharma Store (warehouse) facilities – İzmir
- Retail pharmacies - İzmir
- Adnan Menderes University Hospital – Aydın
- Family Health Centres – Aydın
- Özel Yaşam Hastanesi (hospital) – Antalya







AUTHENTIC TASKS

2023 course offers two additional authentic tasks in addition to risk assessments to be conducted in each facility that is visited. Temperature controlled packaging challenge is introduced on Day 1. Five different packaging technologies randomly assigned to groups with a challenge of packing vaccines to survive 2-8°C for 72 hours. Redundant temperature monitoring devices are also included in the package to study various aspects of these devices.




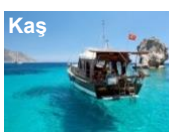

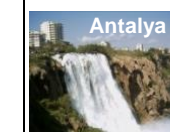

In addition, shake test to distinguish freeze damaged vaccines is offered on the 5th day. Each participant receives three vials of a freeze-sensitive vaccine (one of them being the negative frozen control) to conduct the shake test to differentiate the vials that are affected by freezing.



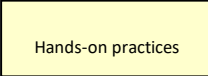
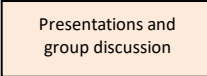
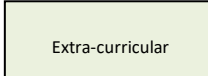
GROUP WORK LOCATIONS

Location	Presentations and discussion on	
İzmir Monday, 25 September	Selçuk Pharma Store (Warehouse)	
Aydın Tuesday, 26 September	Retail pharmacies and Family Health Centres	
Üçağız, Kekova Thursday, 28 September	Adnan Menderes University Hospitals	
Havuzbaşı Thursday, 28 September	Packaging challenge (box opening) and shake test	
Antalya Friday, 29 September	Özel Yaşam Hastanesi (Hospital)	

COURSE PROGRAMME*

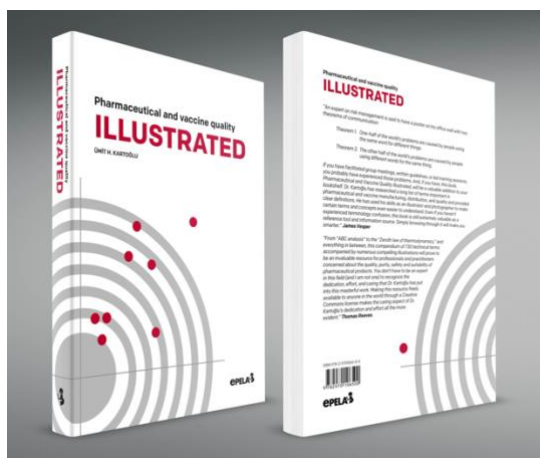
MONDAY 25 September	TUESDAY 26 September	WEDNESDAY 27 September	THURSDAY 28 September	FRIDAY 29 September	SATURDAY 30 September
					
Opening and icebreaker	Check-out Warm up	Check-out Warm up	Check-out Warm up	Warm up	Warm up
Expectations and objectives	Retail pharmacies visit	Adnan Menderes University Hospitals visit	Depart to Üçağız (33 km)	Özel Yaşam Hastanesi (Hospital) visit	Presentations (packaging challenge) and group discussion
Introduction			Presentations (AMU) and discussion (Üçağız)		
LUNCH	LUNCH	LUNCH	LUNCH	LUNCH	LUNCH
Warm up	Warm up	Warm up	Warm up	Warm up	Warm up
SELÇUK Pharma Store Warehouse visit	Depart for Aydın (113 km)	Depart for Kaş (342 km)	 Kekova sunken city (5th Century BC)	Group work (Özel Yaşam Hastanesi), presentations and discussion	Presentations (packaging challenge), group discussion and scavengers hunt
	Family Health Centres visit		Depart for Kale (Demre) with boat (weather permitting)		
					Depart for Havuzbaşı (73 km)
Group work (warehouse), presentations, group discussion, evaluation of the day and dinner	Check-in hotel in Aydın	Group work (Adnan Menderes University Hospitals)	Packaging challenge (box opening) and shake test	Preparations for presentations on packaging challenge (for tomorrow)	Free time and Gala dinner
	Group work (family health centres), presentations, group discussion, evaluation of the day and dinner		Check-in hotel in Kaş		
			Dinner and evaluation of the day	Depart for Antalya (71 km)	
			Check-in hotel in Antalya	Evaluation of the day and dinner	

* All participants must arrive in Izmir latest on Sunday, 24 September. Departure is from Antalya, and participants can depart starting on Sunday, 30 September morning.

Legend	 Hands-on practices	 Presentations and group discussion	 Extra-curricular

BOOKS BY UMIT KARTOGLU

Everyone taking the course receives hard cover copies of all three books written by Dr. Umit Kartoglu. The books are also available in PDF and ePUB3 formats for free download.

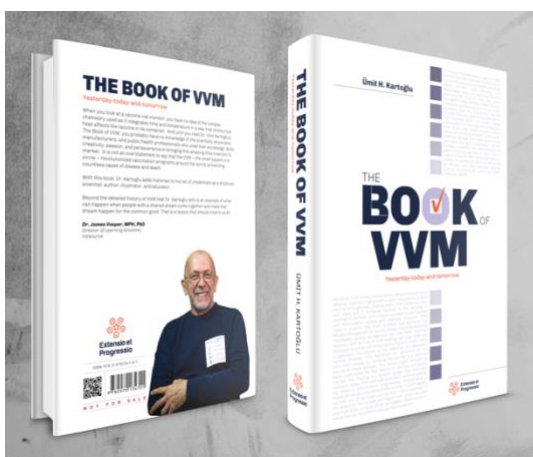


Pharmaceutical and vaccine quality illustrated

<http://epela.net/illustrated/>

Hard cover, 16.5 x 24 cm, 310 pages. 730 terms defined with tables, flow charts, decision tables, illustrations, sketches, and photographs.

Limited edition (only 500 copies printed of the book in hard cover), all numbered and signed by the author.



The Book of VVM: Yesterday-today-and-tomorrow

<http://kartoglu.ch/vvm/>

A to Z of VVM. A celebration of all the efforts of individuals, organizations, agencies, donors, and manufacturers involved in the development, scaling, applying, advocating for, enforcing, helping health workers to excel in their practice, and using it. Limited edition (1,000 copies only) in hard cover, 16.5 x 24 cm, 424 pages.



2019 Platinum Winner

LOGISTICS



Hakan Gönendik, MD (Türkiye), Course management and tour guide

Tip Kurumu liaison person. Previously technical officer at the Ministry of Health. Also worked as family health physician and as an occupational health provider. Active in photography, mountaineering and cave exploration.

Tip Kurumu is responsible for logistics of the learning event. 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.

CARTOONIST ON THE BUS



Muhammet Şengöz

Director
Graphics Design Department
Faculty of Fine Arts, Design and Architecture
Topkapı University
İstanbul/ Türkiye

PHOTOGRAPHER ON THE BUS



Gençer Yurttaş

Narphotos Photography Agency
İstanbul/ Türkiye

HOW TO APPLY?

Application deadline: 31st May 2023.

Participants should apply using an online application form at <https://bit.ly/3mhEk6T>





**Pharmaceutical Secure Supply Chain Management on Wheels
Application Form**

All applicants by submitting their application declare that they/their organization will cover the travel (flight) costs outside of this course and the CHF 5,500.00 course fee (inclusive of all hotels and meals throughout the course).

Maximum number of participants to be accepted is 15. If applicant fits into participant profile, “first apply - first accepted” principle is applied.

Accepted participants will receive an acceptance letter and information on how to transfer the course fee.

“Information Bulletin” and “List of Participants” will be shared with all accepted participants at a later stage before the course.

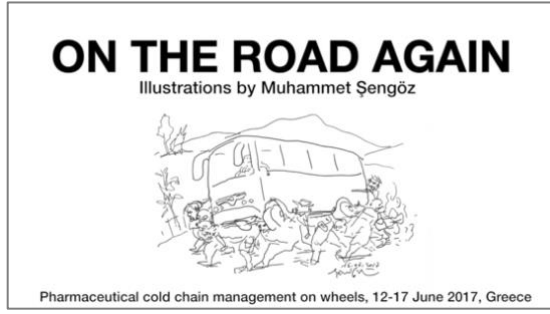
The bus is ready to hit the road again!

Listen to what participants have said...



REFLECTIONS: Pharmaceutical cold chain management on wheels, Greece 2017

<https://www.youtube.com/watch?v=FytBRCAR5pk>



Pharmaceutical cold chain management on wheels, 12-17 June 2017, Greece

<https://www.youtube.com/watch?v=IPSlowejM4o>



<https://www.youtube.com/watch?v=orGyQloZwPw&t=17s>



<https://www.youtube.com/watch?v=L3KWxIAoPk4&t=181s>

Read the philosophy behind the course

Original Research

A Case Study in Experiential Learning: Pharmaceutical Cold Chain Management on Wheels

James Vessey, MPH; Ümit Kartıoğlu, MD, DPH; Barış Bostan, PhD; Thomas Reeves, PhD

Introduction: People who handle and regulate temperature-sensitive pharmaceutical products require the broad edge and skills to extract from product nature itself. People, skills, and efforts throughout that chain. People learn through such knowledge and skills through "experiential learning" that involves working with other learners and experts.

Methods: The World Health Organization developed a voluntary experiential learning event for participants on the road with experience in low-temperature sensitive products for handling, storage, and distribution throughout the length of the pharmaceutical supply chain. The experiential learning event involved participants in real, clinically relevant, disease and report on the various components of the cold chain process. An emphasis was placed on team members working together to learn from one another and to address other expert learners who were available to guide the learning, share their experiences, and respond to questions.

Results: The learning event, Pharmaceutical Cold Chain Management on Wheels, has been conducted since early 2008 in Turkey with participants from the global pharmaceutical industry, health care providers, national regulatory authorities, and academic leaders. Over 1000 participants have attended the course, which has been conducted in 10 different countries and 100 different regions.

Discussion: Reflecting the critical nature derived from experiential and social learning theories, the factors contributed to the success of this unique experiential learning event. These factors may also have relevance in other experiential learning settings and, possibly, for experiential learning events.

Key Words: experiential learning, social learning, pharmaceutical cold chain, handling of pharmaceutical products

Introduction

Cold Chain Description

Many pharmaceutical products are temperature sensitive and must be stored and transported at controlled temperatures—for instance, 2 to 8 degrees Celsius.¹

Discussion: The value proposition

Exposure to temperatures outside the recommended range can result in damage to the product and cause safety issues for all stakeholders.

A "cold chain" is the integrated system of equipment, facilities, procedures, records, and activities used to handle, store, transport, distribute, and receive temperature-sensitive products.^{2,3} The challenge is that, as a physical chain, it is not linear in nature or energy in the real world. People are a critical element of a cold chain. They must correctly execute procedures and take appropriate actions in the event of a problem. Beyond the people directly involved in the cold chain are those who design and develop equipment and services used to handle pharmaceutical products. Experts and good teachers have the appropriate knowledge and skills to perform their jobs, as well as a vision of how the whole handling operation can be maintained and enhanced.

Conclusion

Research in food products, published in a limited design form, has been used to demonstrate the value of experiential learning in the handling and distribution of pharmaceutical products. The experiential learning event, Pharmaceutical Cold Chain Management on Wheels, was designed to provide a similar experience for participants in the pharmaceutical industry. The event was held in Turkey, and the results of the event are presented in this paper.

References

1. Vessey J, Kartıoğlu Ü, Bostan B, Reeves T. Pharmaceutical Cold Chain Management on Wheels: A Case Study in Experiential Learning. *Journal of Continuing Education in the Health Professions*. 2019;29(2):100-105.

<https://bit.ly/3zNJ33c>

APPLY NOW!