

Improve the quality of healthcare across Asia?



As an integrated solutions provider?

Challenge accepted

HKLA Vaccine Logistics Seminar 19-Feb-2021
Standards of Vaccine Storage and Last Mile Delivery

Our promise

WE ARE



RESPONSIVE



INSIGHTFUL



COLLABORATIVE



INNOVATIVE



PROVEN



DCH

AURIGA

Challenge accepted

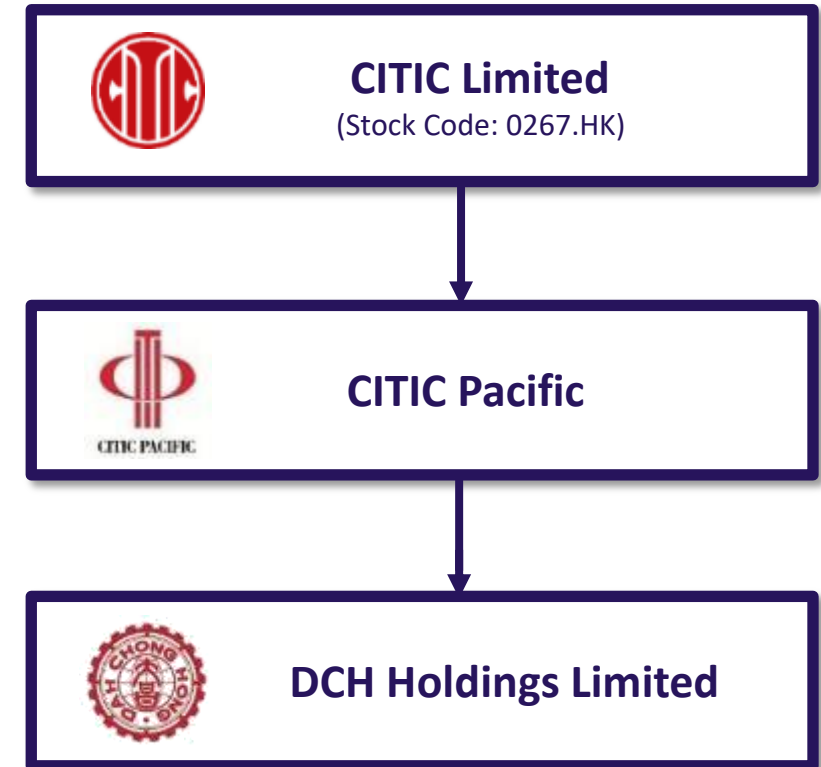
AURIGA History

With more than 50 years of history, Auriga has developed an extensive network of operations, long term relationships and teams of industry experts in each market we serve



Company History

- DCH AURIGA joined Dah Chong Hong in July 2016 as LF Asia
- Dah Chong Hong is a fully owned subsidiary of CITIC Limited
- DCH operates an extensive distribution and logistics network in the motor, food, healthcare, electronics and beauty segments
- DCH has more than 17,000 employees with operations in mainland China, Hong Kong, Macao, Taiwan, Japan, Singapore, Myanmar, Thailand, Malaysia, Indonesia, the Philippines and Brunei



Our name means



Auriga is taken from a constellation known as the “charioteer” to symbolize our commitment to guiding partners through the complexities of dynamic markets.

Our logo represents not only the five stars of the constellation, but is designed to be a symbol of motion and connectivity.

Together, they represent our spirit of stewardship and culture of responsive and insightful collaboration.

Our Locations

Geographical Reach



Our business model

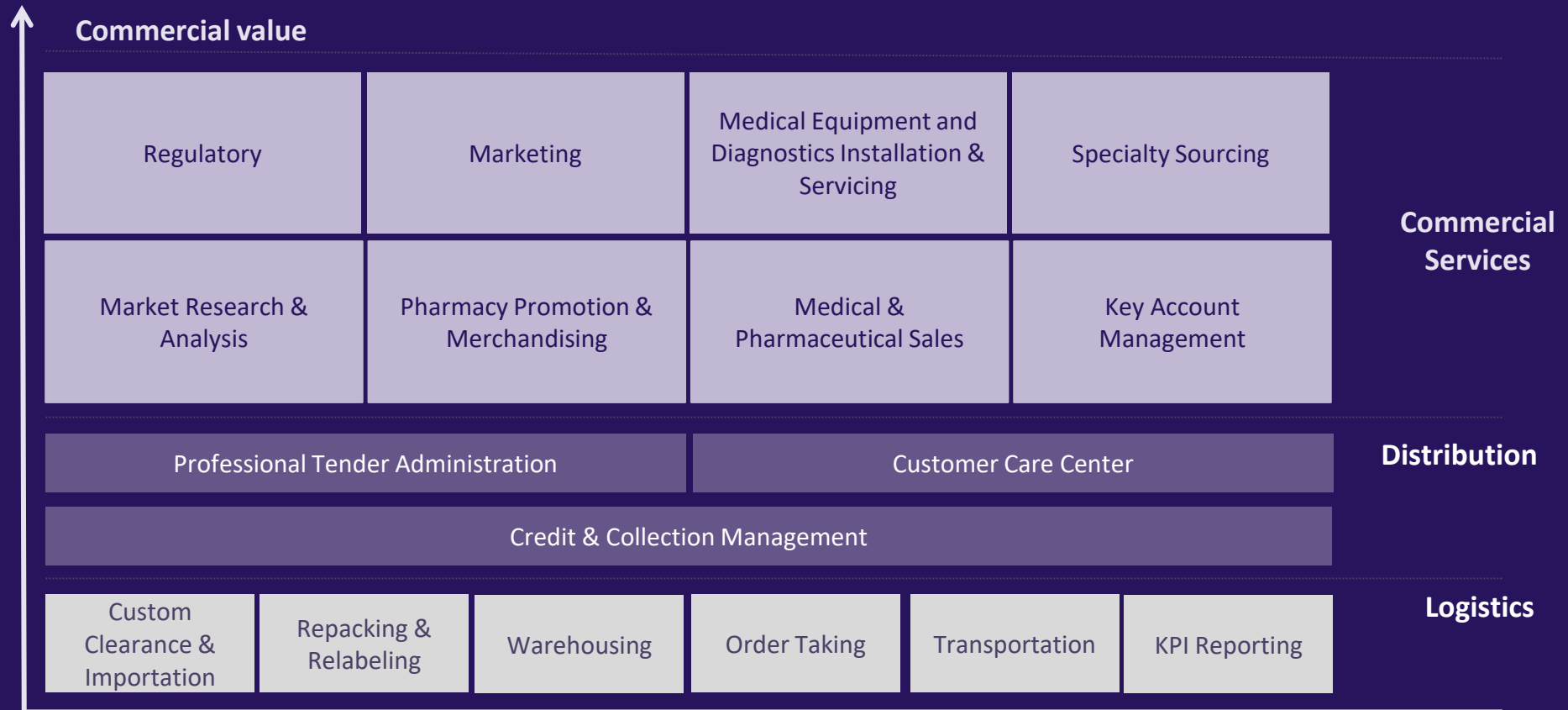


Auriga partners with world leading healthcare companies to help them expand their business in the region.

We offer integrated solutions ranging from supply chain services to market management to simplify the complexity of market entry and management.

Our extensive network extends across the healthcare industry to help bring products to the right stakeholders.

Commercial services



DCH AURIGA – Wyler Distribution Center



- The only warehouse in HK fully dedicated for Healthcare business and **fully owned** by group of company
- All floors are managed and ran by DCH AURIGA
- Total capacity 400,000 sq ft
- 11 multi-storey building in GMP/GDP standard
- Dedicated outbound docks and cargo lifts
- **27 owned trucks** for local distribution
- More than 500 staffs for both operations and commercial



Preparation of storage and delivery solution

To provide a quality logistics solution for vaccines, a great deal of information related to the product itself is required



Stability Data

- The impact of different temperature conditions over different periods of time is crucial for developing a coherent and robust logistics solution
- Data interchange between the logistics provider and the manufacturer is required

Temperature Ranges		≤ 2 hours	≤ 3 hours	≤ 6 hours	≤ 60 hours	≤ 5 days	≤ 6 months	≥ 6 months
$-90^{\circ}\text{C} \leq x \leq -60^{\circ}\text{C}$	Static storage							
	Transportation							
$-60^{\circ}\text{C} < x \leq -35^{\circ}\text{C}$	Static storage							
	Transportation							
$-35^{\circ}\text{C} < x \leq -15^{\circ}\text{C}$	Static storage							
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$-15^{\circ}\text{C} < x \leq 0^{\circ}\text{C}$	Static storage							
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$0^{\circ}\text{C} < x < 2^{\circ}\text{C}$	Static storage							
	Transportation							
$2^{\circ}\text{C} \leq x \leq 8^{\circ}\text{C}^{+}$	Static storage							
	Transportation							
$8^{\circ}\text{C} < x \leq 25^{\circ}\text{C}^{+}$	Static storage							
	Transportation							
$> 25^{\circ}\text{C}$	Static storage							
	Transportation							

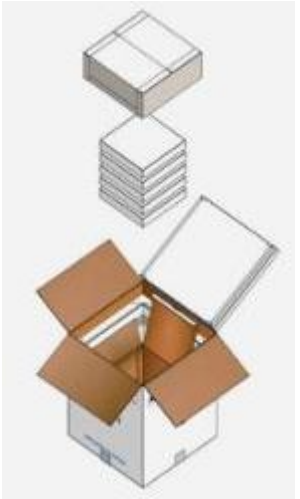
Product Information

Understanding how the vaccine is to be administered will help the logistics provider to work out the processes necessary to be able to deliver the vaccine in the very best condition. Example:

- Thawing – for vaccines stored in very low temperature they must undergo a specific period of thawing in a specific condition before they can be applied. The thawing process itself will impact the shelf life of the vaccine.
- Dilution – some vaccines require dilution before being applied such as with a saline solution. Any logistics solution must also ensure such saline solutions are also available otherwise the vaccine cannot be applied.
- Syringes – clearly availability of syringes is critical for the application of any vaccine



Packing format



The receiving solution will depend on the packing format. The volume of vaccine within each shipping unit from the manufacturer must be understood together with the size and weight of each shipping unit

- Ensure the storage solution can fit the physical size and weight of the product (especially if refrigerators are being utilized as the storage solution)
- If the packing unit is being shipped in a thermal box, must understand the size and weight of the thermal box



If using dry ice to maintain ultra-low temperature, operators must be equipped with necessary protective equipment such as gloves and visors

Re-Packaging

- The delivery solution will depend on the volume in the registered packaging formats
- The original packaging from the manufacturer may be changed to suit the market where the product is to be consumed only if the packing is legally registered
- Licensed GMP Secondary Redressing areas are critical for providing any repacking value-added services



Labeling & Inserts

Registered labels and inserts may be required to apply to the packaging for indicating:

- Product description
- Directions of use
- Storage conditions
- Product shelf life and expiry date

Licensed GMP Secondary Redressing areas are critical for providing labeling value-added services

Enablers

Robust and well-tested and validated IT system and Quality Management System are the key enablers to providing the quality controls necessary for a vaccine logistics operation



Operations Flow

The proper handling of vaccines needs to be understood from the manufacturer all the way to patient to ensure that the storage and delivery solution maintains the product in best condition

Quality Management System for Operation



ISO 9001

Proves the ability to consistently provide high-quality services to achieve principals, customers and regulatory requirements

- QMS ensure product quality from good receiving, storage, pick & pack to delivery
- Well established procedures for handling product complaint, deviation, CAPA, risk assessment, vendor assessment, etc.
- QMS kept verified and improved by more than 30 audits per year, conducted by DoH, SGS, HKQAA and all healthcare principals
- QMS supported by top management and followed in regular Management Review Meeting
- ISO 9001 certified by HKQAA



ISO 13485

Demonstrates our comprehensive medical device capabilities

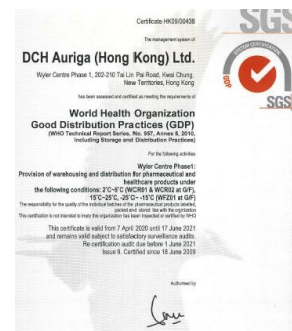
- ISO 13485: ver2016** for Medical Device QMS by SGS (Hong Kong's first distributor accredited by SGS for this latest version high standard ISO)
- Extensive experience in Quality Management System (QMS) and meeting Pharma & Medical Device Regulations Requirement



GMP/GSDP

The GMP/DSDP certification certified our best practice of distribution process

- Possess DoH issued Pharma Wholesale and Repackaging Licence
- Professional Quality Assurance (QA) and Regulatory Affairs (RA) team lead by registered pharmacists
- Good Distribution Practice & Good Manufacturing Practice according to WHO & EU guideline by SGS



Inbound Standards

Envirotainer can maintain required temperature conditions during transfer from manufacturer to logistics provider DC



- Particularly effective for larger 2-8C shipments
- Envirotainers are normally the property of the shipper and need to be unloaded and returned within a short turnaround time

Thermal Containers are a validated and reliable medium for transporting of cold chain products from manufacturer



- Particularly effective for transporting ultra-low temperature products using dry ice
- It should be noted that shipments containing dry ice can become a risk on long haul flights since dry ice will evaporate to leave CO2

Operations Standards - Inbound

Shipment arrival

Early flight details
confirmation



Parking near cargo terminal



Pick up at airport

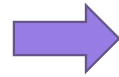


Transfer to DC



- In some cases, the logistics provider may also be required provide for additional dry ice to replenish to thermal containers at airport*

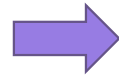
Operations Standards - Receiving



Put-away to cold room



Unloading



Unpacking & Put-away
to refrigerator

- Standard time for unloading

- Datalogger information records temperature throughout journey and must be downloaded to verify no temperature excursion has occurred.
- Put-away to cold room / refrigerator must be timed with video evidence.

- Standard time for cold room / refrigerator door opening
- Standard time from opening thermal container to put-away to refrigerator
- Standard time that refrigerator must remain closed before can be opened again

Operations Standards - Storage

Standard storage features for Cold Chain Operations for Vaccines

- Temperature mapping validation, identification of hot and cold spots, regular recording of temperatures
- Temperature alarm system e.g. for 2-8C cold room, alarm will normally be set to go off for below 3C or above 7C
- Alert system to PIC's in the event of temperature excursion (24/7 Security to alert PIC's, max time for PIC's to be onsite if alerted, regular drill test)
- Preventive maintenance program for cold room compressors including holding stock of regular spare parts
- Back up generator with automatic start within 30 seconds in the event of power outage with regular drill test, SOP for fuel refilling, regular preventive maintenance program
- 24/7 security with access control to cold room area including CCTV footage covering all angles in area, GMP redressing area and validated temperature monitoring control box



Real Time Cold Chain
Temperature Monitoring



Ultra-Low Temperature Refrigerators



Back up Generator

Last Mile Delivery

Validated transport with experienced transport delivery operators

Operations Standards – Outbound

- Cold box validation – temperature data mapping
- Product thawing – time and condition
- Redressing:
 - Licensed GMP 2-8C redressing area
 - Re-packing to registered pack sizes
 - Labelling according to approved label size & design
 - Labelling jobs by Batch Processing Record (BPR)
 - Quality Control checking
 - Line clearance
 - Completion of BPR documentation
- Time tracking for all process steps



Validated cold box for goods delivery 2-8C



Goods shipped with temp data logger to ensure product quality

Operations Standards – Outbound

- Cold box preparation
 - Precooling according to Standard Operating Procedure
 - Application of pre-cooled ice packs according to registered packing configuration
- Pick/Pack/Check according to Standard Operating Procedures using 2 separate staff for picking and checking
- Packing to cold box
 - Application of datalogger to payload
 - Verification of cold box temperature
- Cold box security and time & temperature logging
- Pick/Pack/Check of saline/syringe accompanying orders
- Handover of all orders to transport
- Verification of truck condition and temperature
- Loading to truck, application of lock / elock to truck



Operations – Last Mile Delivery



Security during transport

- eLock security – real time alert and logging then eLock is applied to the truck and each time it is opened
- GPS tracking of vehicle, used in conjunction with eLock to verify door opening at expected location



- Vaccines kept at 2C to 8C within passive cold box with temperature datalogger monitoring, while cold box transported within validated truck cabinet of 15C to 25C.
- Cold box taken to injection point:
 - Dry runs to each location done in advance
 - Preferred route documented
 - Truck parking location identified and reserved
 - Confirmation of truck location via GPS on opening the elock
- Contingency & communication plans & procedures in event of accident or delay

Operations – Last Mile Delivery

- Handover of vaccines to customer
 - Open in front of the receiver
 - Receiver checks the accompanying datalogger to confirm the temperature within 2C to 8C
 - Open cold box and remove vaccine package
 - Verify datalogger on vaccine package to confirm no temperature excursion during trip
 - Vaccine product handed over to receiver
 - Receiver to put-away to 2-8C refrigerator
 - Receiver signs temperature on arrival on the order as proof of delivery with signature and chop
- On return to the Distribution Centre, all orders will have chops/signatures verified before confirming in system



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Thank You