

Experience. Our Precision.

STRATEGIES FOR SUCCESSFUL LANE QUALIFICATION & VALIDATION

CAMPBELL BLAGG,
DIRECTOR, LOGISTICS FEASIBILITY
& IMPLEMENTATION

25 FEBRUARY 2025



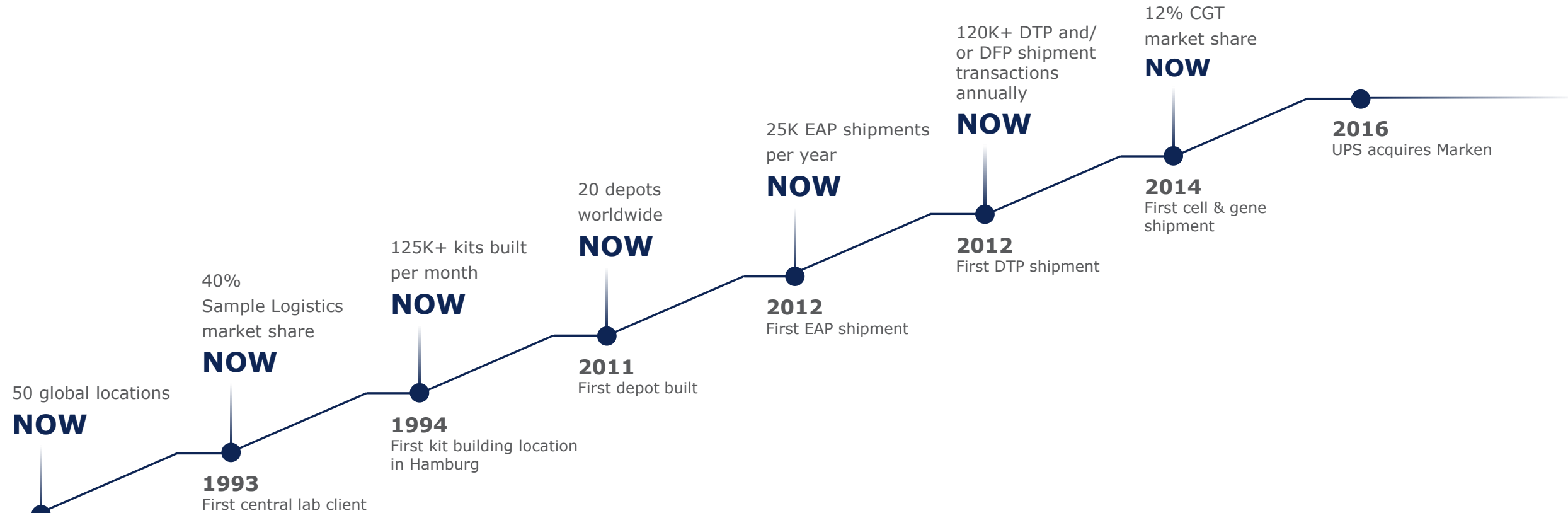
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MARKEN'S HISTORY

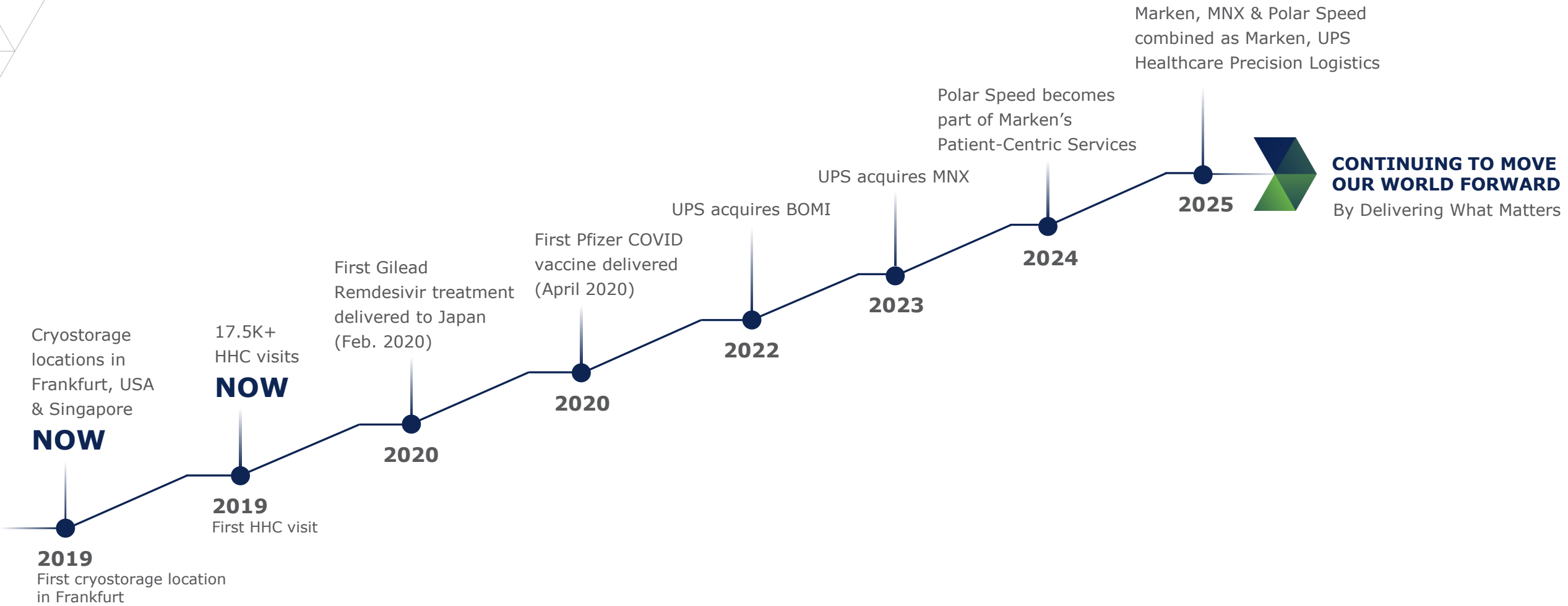
1980 - PRESENT





MARKEN'S HISTORY

1980 - PRESENT

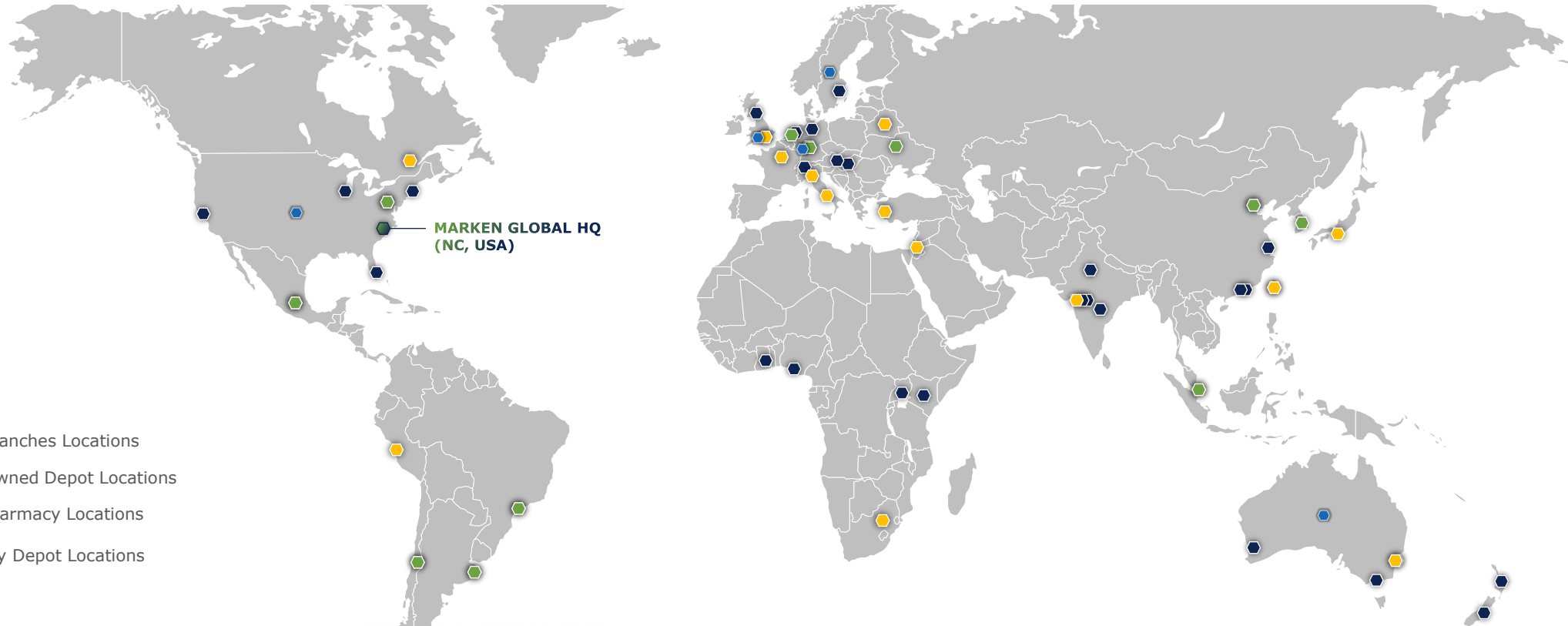


**CONTINUING TO MOVE
OUR WORLD FORWARD**
By Delivering What Matters



MARKEN GLOBAL REACH

STRATEGICALLY LOCATED GLOBAL FOOTPRINT GMP DEPOT, PHARMACIES & BRANCHES



- Marken Branches Locations
- Marken-Owned Depot Locations
- Central Pharmacy Locations
- Third-Party Depot Locations

AMERICAS (11)

Boston, USA	Miami, USA
Buenos Aires, Argentina	New York, USA
Chicago, USA	Research Triangle Park, USA
Los Angeles, USA	Santiago, Chile
Pennsylvania, USA	São Paulo, Brazil
Mexico City, Mexico	

EUROPE & AFRICA (19)

Amsterdam, Netherlands	Hamburg, Germany	Stockholm, Sweden
Brussels, Belgium	Johannesburg, South Africa	Uganda, Africa
Chiswick, UK	Kiev, Ukraine	Vienna, Austria
Edinburgh, UK	Kenya, Africa	Zurich, Switzerland
Feltham, UK	Lagos, Nigeria	
Frankfurt, Germany	Milan, Italy	
Ghana, Africa	Paris, France	
Gyor, Hungary		

ASIA PACIFIC (20)

Ahmedabad, India	Hyderabad, India	Singapore
Auckland, New Zealand	Melbourne, Australia	Sydney, Australia
Bangalore, India	Mumbai, India	Taoyuan, Taiwan
Beijing, China	New Delhi, India	Tokyo, Japan
Christchurch, New Zealand	Perth, Australia	
Gimpo, South Korea	Pune, India	
Guangzhou, China	Seoul, South Korea	
Hong Kong, China	Shanghai, China	



LANE QUALIFICATION & VALIDATION

INITIAL QUESTIONS



CONSIDERATIONS

What are the tolerances & specifics of the product?

How is the product impacted by time & temperature?

What are your expected turnaround times per lane?



REGULATORY, QUALITY & LEGAL

What are the regulatory requirements for the protocol?

Are there different regulatory requirements in each country of distribution?

What are the documentation requirements for export & import?



PRODUCT, SPONSOR & PROTOCOL REQUIREMENTS

Are there standards procedures that the sponsor requires?

What evidence must be provided to comply?



REVIEW DOCUMENTS

- Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use (Text with EEA relevance) (2013/C 343/01)
- ISO 9001



LANE MAPPING & RISK ASSESSMENT



TRANSPORTATION PARTNERS



ADDITIONAL CONSIDERATIONS

- Product of shipment value
- Incoterms
- Customs
- "Green light" approvals
- Shipper & consignee requirements
- Pre-known barriers such as public holidays



QUALIFIED PACKAGING SOLUTIONS UNDER ONE ROOF

MARKEN QUALIFIED SOLUTIONS

- **MARKEN MONARCH:** REF & CRT (multi-use)
- **CREDO:** Series 4, 22, 20M – 4L to Xtreme full pallet (multi-use)
- **CREDO DRY ICE:** 4L – 56L (4 sizes, multi-use)
- **CREDO CARGO:** Series 4, 22, 20M - pallet shipper (multi-use)
- **COOLGUARD ADVANCE:** Series 4, 22 – 12L and 28L (single-use)
- **MARKEN SMART BOX:** 4 temp ranges including D-I, 4L and 11L
- **BIOSYSTEM / BIOTHERM:** dry ice shippers (single-use)
- **NANOCOOL:** 2-8°C (single-use)
- **VA-Q-TEC:** 5 pallet sizes, 5 temperature ranges including D-I
- **ACTIVE SOLUTIONS:** Envirotainer e1, e2, Releye CSafe RKN / RAP
- **TOWER COLD CHAIN:** On-demand leased pallets for dry ice
- **MVE IATA:** Cryogenic dry-vapor solution (multi-use)
- **BIOLIFE DV-10:** Cryogenic dry-vapor solution (multi-use)





TIVE SOLO 5G

REAL-TIME TRACKING & VISIBILITY

WORLD'S FIRST SINGLE & MULTI-USE TRACKER

PHARMA CRITERIA

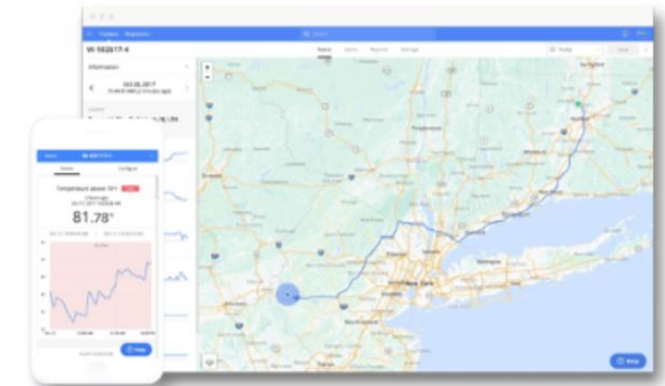
- 21 CFR part 11 compliance 3-point calibration to a NIST STD
- GAMP-5 controlled validation of hardware & software
- Increased measurement intervals & ping
- Best-in-class global coverage in 186+ countries & approval for use on 170+ air carriers

VISIBILITY AS A SERVICE PROVIDING 24/7 LIVE MONITORING

- Client-specific dashboarding for multiple shipment viewing
- Custom URL link for customers
- APIs available to integrate or operate independently
- Multi-sensor Solo trackers report real-time shipment location & a **wide variety of conditions** – including temperature, light, humidity & shock
- **Eliminate return logistics** – can be used as a single-use tracker

MARKET LEADING INNOVATION

Industry's most intuitive application



SOLO 5G SINGLE-USE TRACKER (LITHIUM)



SOLO 5G TRACKER WITH DRY ICE PROBE



TEMPERATURE BEACON





LANE MAPPING

KEY VALUE DRIVERS



1. LANE MAPPING

- Identifies most efficient transit times
- Contingency transit options



2. RISK ASSESSMENT

- Calculation of risks for each specific lane
- Easily understandable factors for consideration



3. SOLUTION SUMMARY

- Each new project will receive a solution summary highlighting all necessary considerations



4. IMPLEMENTATION

- Specialized project plan
- Test model
- Training for sites, staff & clients

IMPLEMENTATION MAJOR STEPS

- Dedicated implementation manager for set-up & to ensure the first shipments execute as planned
- MSA / QTA sign-off
- Account set-up
- Maestro training, booking template creation & starter pack creation
- COP creation – if required
- Lane review, mapping & risk assessment
- Internal project training

PROVIDING RELIABLE SOLUTIONS IN AN EVER-CHANGING WORLD

Develop best-in-class solutions to ensure successful implementation by proving clear visibility on capabilities vs client's requirement

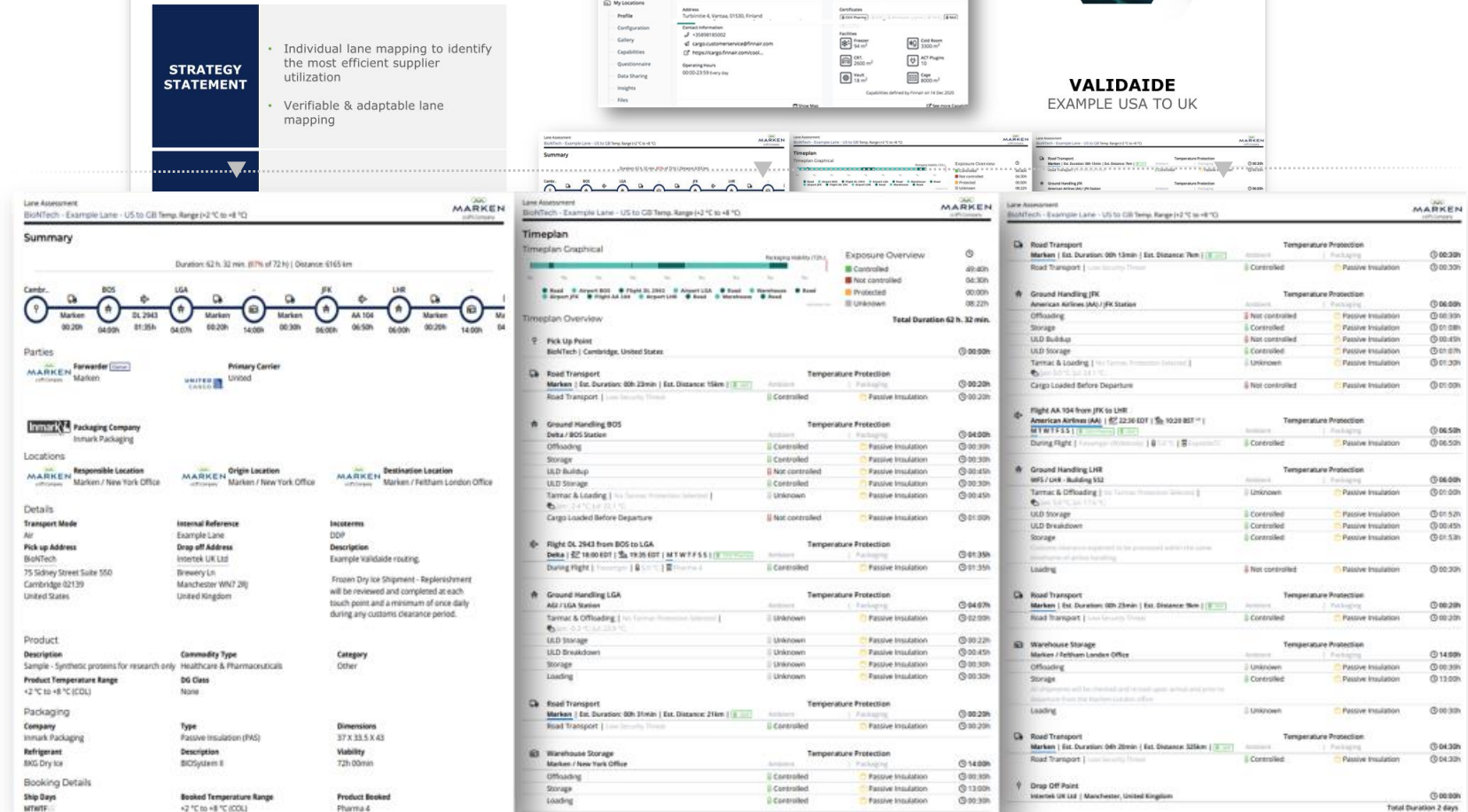


- Individual lane mapping
- Verifiable & adaptable lane mapping

- Quarterly lane reviews
- Monthly TAT review

- Validaide lane mapping
- Manual verification review
- Marken database of lane capabilities

LANE MAPPING FEATURES



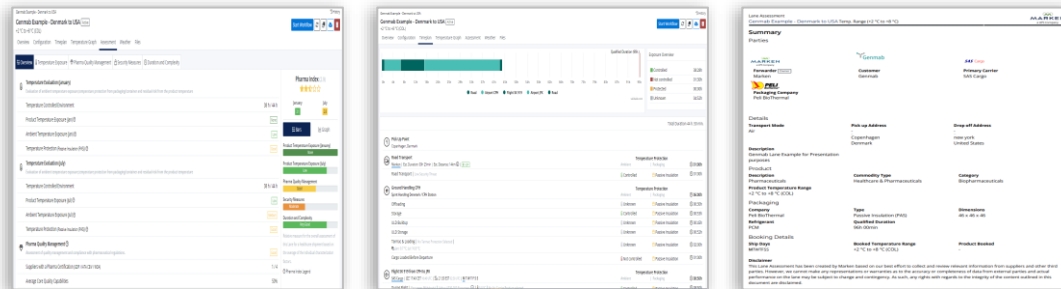


SHIPPING VERIFICATION & CONTINGENCY PLANNING

LANE ASSESSMENT							
Request date				Shipping Location			
Estimated completion date				Delivery Location			
Customer							
Product							
Service Level		Door to Door					
Packaging Type		RAP Envirotainer					
LIVE SHIPMENT (Main)	TRANSPORT TYPE	ROUTING	FLIGHT	FREQUENCY	DEPARTURE	ARRIVAL	TAT
	Road			Daily			
	Flight			Daily			
LIVE SHIPMENT (Backup)	TRANSPORT TYPE	ROUTING	FLIGHT	FREQUENCY	DEPARTURE	ARRIVAL	TAT
	Flight			Daily			
	Flight			Daily			
LIVE SHIPMENT DETAILED ANALYSIS (MAIN OPTION)							
STEP	Est. Duration (h)	Temp. controlled storage possibility	Low/High temp. exposure risk	Remarks/ Risk Mitigation			
Collection / Loading from shipper	1	YES	Low	Temperature controlled facility			
Transit from shipper to departure airport	1	YES	Low	TCV movement in Active container			
Tender to airline & Storage Prior to departure	13	YES	Low	Active Container			
Flight LEG 1	10	N/A	Low	Active Container			
Unloading and storage at destination airport	24	YES	Low	Active Container			
Customs clearance	1	YES	Low	Active Container			
Recovery from destination airport	1	YES	Low	Active Container			
Transit from destination airport to consignee	4	YES	Low	TCV movement in Active container			
Unloading at consignee	1	YES	Low	Active Container			
TOTAL TRANSIT TIME		61					
ADDITIONAL LANE CONSIDERATIONS							
1	Envirotainer RAP to be utilised as packaging.						
2	Customs Clearance indicate as 24hrs. Ultimate transit time will vary based on customs release.						

LANE MAPPING SOLUTIONS

- Define transport mode & routing for each lane including back up contingencies
- Multiple options for documenting such as client template lane map files or utilizing tools such as Validaide, Smart CAE, etc.
- Airline performance
 - Based on local airlines & airport capabilities
- Customs clearance time & required documents
- Overall Turn Around Time (TAT) | DOOR-TO-DOOR
- Identify if TAT is within defined time & packaging validation
- Alternate routing contingencies





CONTINGENCIES

UNFORESEEN CIRCUMSTANCES

MARKEN ACCELERATES SUPPLY CHAIN OPERATIONS DURING POLAR VORTEX

CHALLENGE

A strong winter storm hit the northeast U.S. causing dangerous sub-zero temperatures and some of the coldest weather the Chicago area had seen in decades. The result was a powerful polar vortex, which brought a sweep of Arctic air and record-breaking temperatures. At the peak of the storm, Chicago recorded temperatures of -23°F (or -30°C).

Struggling against blizzard-like conditions and plunging temperatures,



MARKEN'S RAPID RESPONSE TO CROWDSTRIKE CRISIS ENSURES VITAL THERAPY DISTRIBUTION TO PATIENTS

MITIGATING MASSIVE AIRLINE DISRUPTION TO EXPEDITE LIFESAVING TREATMENTS WORLDWIDE

Described as the "largest IT crisis in history"¹, the CrowdStrike outage on July 19, 2024, caused widespread crashes of operating systems, disrupting many industries and companies around the world. Triggered by a faulty update to the company's security software, the incident had a global impact on commercial supply chain cancellations threatening time-sensitive healthcare distribution.

MARKEN SUCCESSFULLY IMPORTS NOVEL IMMUNOTHERAPY TO CANCER PATIENTS IN UKRAINE DURING TIME OF WAR

GOAL

To deliver clinical study treatments from a sponsor's Clinical Manufacturing Organization (CMO) in Europe direct to sites in Central and Western Ukraine so that patients could continue their cancer immunotherapy.

CHALLENGE

Being a war zone, air transport and routine logistics operations have been gravely affected in and out of Ukraine. While most roads are open, the importation of clinical drugs can present complex regulatory hurdles to overcome.

- **PREPARE FOR THE CHANGE**
- **LEVERAGE YOUR LOGISTIC PARTNER'S EXPERIENCE & NETWORK**
- **BUILD CONTINGENCY INTO YOUR STANDARD PROCEDURES**



LANE QUALIFICATION & VALIDATION

SUMMARY





THANK YOU

FOR MORE INFORMATION:



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