

**Experience. Our Precision.**

# **STRATEGIES FOR SUCCESSFUL LANE QUALIFICATION & VALIDATION**

CAMPBELL BLAGG,  
DIRECTOR, LOGISTICS FEASIBILITY  
& IMPLEMENTATION

25 FEBRUARY 2025



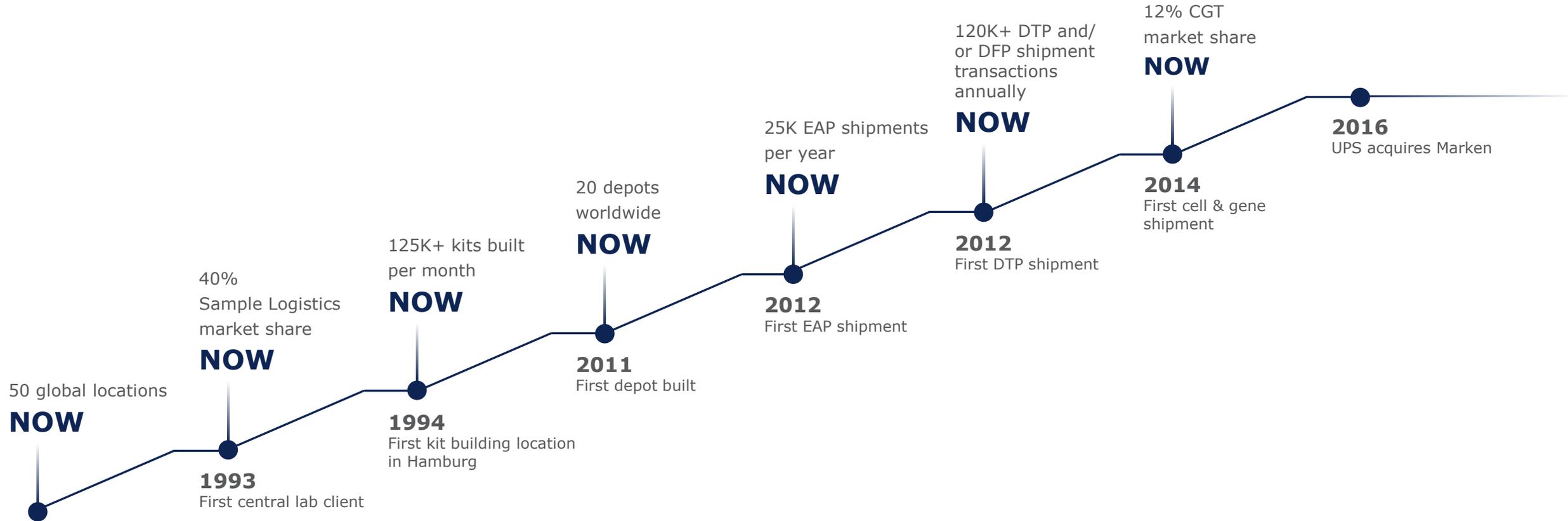
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# MARKEN'S HISTORY

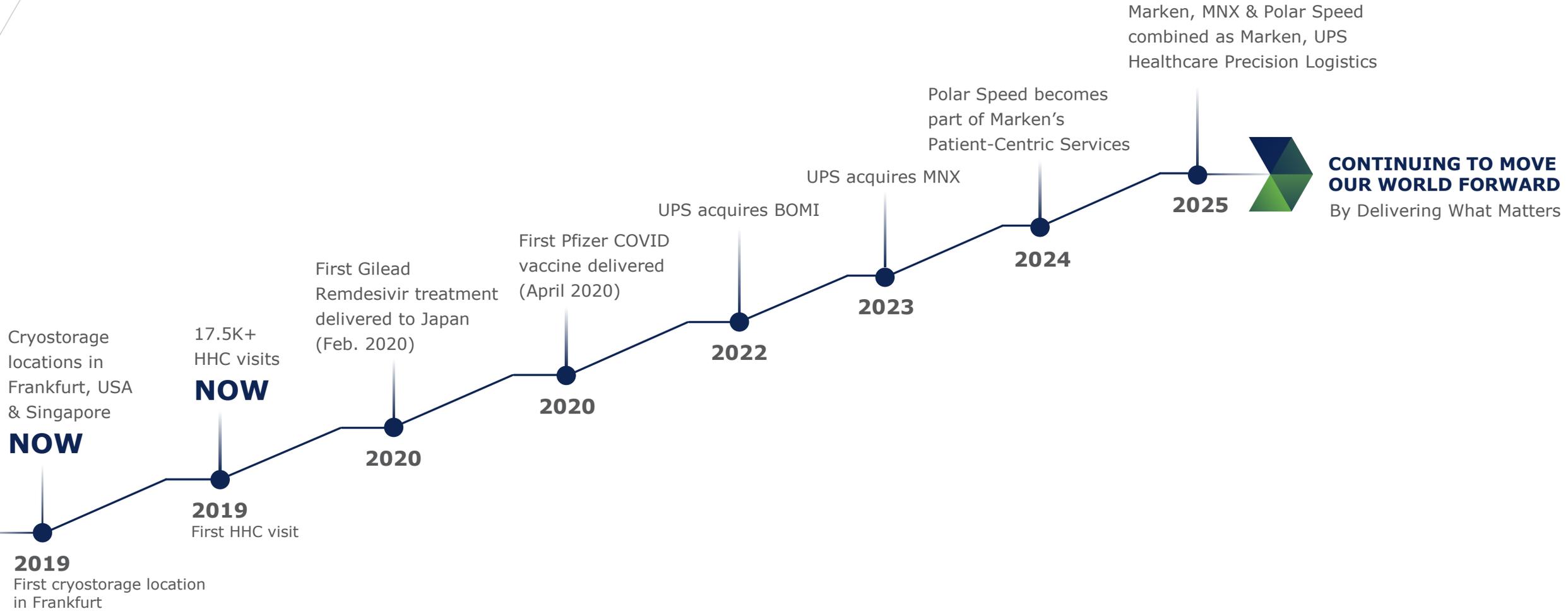
## 1980 - PRESENT





# MARKEN'S HISTORY

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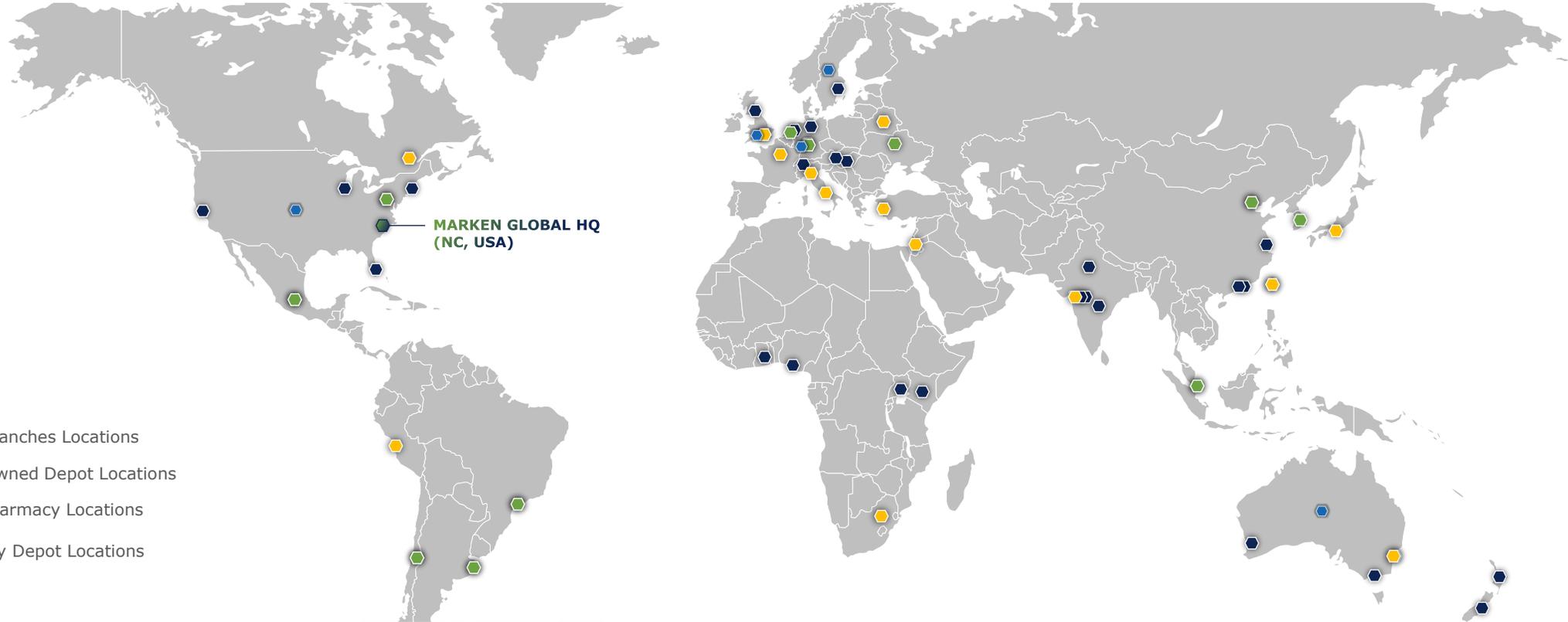


**CONTINUING TO MOVE OUR WORLD FORWARD**  
By Delivering What Matters



# MARKEN GLOBAL REACH

## STRATEGICALLY LOCATED GLOBAL FOOTPRINT GMP DEPOT, PHARMACIES & BRANCHES



MARKEN GLOBAL HQ  
(NC, USA)

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

### AMERICAS (11)

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

### EUROPE & AFRICA (19)

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

### ASIA PACIFIC (20)

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



# 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

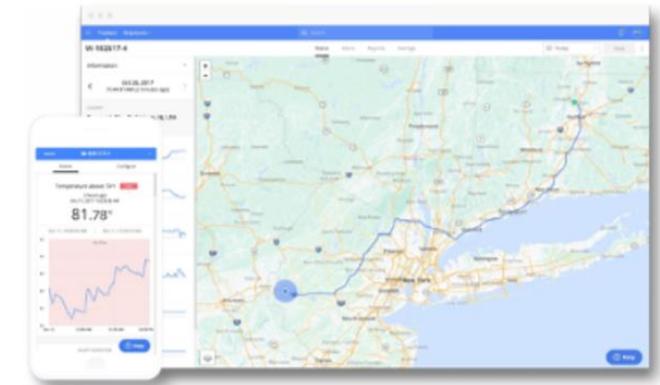
- 21 CFR part 11 compliance 3-point calibration to a NIST STD
- GAMP-5 controlled validation of hardware & software
- Increased measurement intervals & ping
- Best-in-class global coverage in 186+ countries & approval for use on 170+ air carriers

#### 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



# LANE MAPPING FEATURES

## STRATEGY STATEMENT

- Individual lane mapping
- Verifiable & adaptable lane mapping

## STANDARDS IN PLACE

- Quarterly lane reviews
- Monthly TAT review

## TOOLS

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

## LANE MAPPING FEATURES

**STRATEGY STATEMENT**

- Individual lane mapping to identify the most efficient supplier utilization
- Verifiable & adaptable lane mapping

HEL COOL Terminal (HEL)  
Services and Commodities: [Icons]  
Location Information:  
Address: [Address]  
Profile: [Profile]  
Configuration: [Configuration]  
Capacity: [Capacity]



Line Assessment: BioNTech - Example Lane - US to GB Temp. Range (+2 °C to +8 °C)

**Summary**  
Duration: 62 h, 32 min (87% of 72 h) | Distance: 6165 km

**Parties**  
Forwarder: Marken  
Primary Carrier: UNIBED

**Locations**  
Responsible Location: Marken / New York Office  
Origin Location: Marken / New York Office  
Destination Location: Marken / Feltham London Office

**Details**  
Transport Mode: Air  
Pick up Address: BioNTech, 75 Sidney Street Suite 550, Cambridge CB21 3JF, United States  
Internal Reference: Example Lane  
Drop off Address: Intertek UK Ltd, Brewery Ln, Manchester W17 2JF, United Kingdom  
Product: Sample - Synthetic proteins for research only  
Commodity Type: Healthcare & Pharmaceuticals  
Product Temperature Range: +2 °C to +8 °C (COL)  
Packaging: Inmark Packaging, Refrigerant: BXG Dry Ice

**Intercoms**  
DDP  
Example Validaide routing  
Frozen Dry Ice Shipment - Replenishment will be reviewed and completed at each touch point and a minimum of once daily during any customs clearance period.

**Category**  
Other

**Dimensions**  
37 X 33.5 X 43  
Viability: 72h 00min

**Product Booked**  
Pharma 4

Line Assessment: BioNTech - Example Lane - US to GB Temp. Range (+2 °C to +8 °C)

**Timeplan**  
Timeplan Graphical: [Graph showing temperature and packaging stability over time]

**Exposure Overview**  
Controlled: 49:40h  
Not controlled: 04:30h  
Protected: 00:00h  
Unknown: 00:22h

**Timeplan Overview**  
Total Duration: 62 h, 32 min

**Pick Up Point**  
BioNTech | Cambridge, United States | 00:00h

**Road Transport**  
Marken | Est. Duration: 00h 23min | Est. Distance: 15km | 00:20h  
Temperature Protection: Controlled, Passive Insulation

**Ground Handling BOS**  
Delta / BOS Station | 04:30h  
Offloading: Controlled, Passive Insulation  
Storage: Not controlled, Passive Insulation  
ULD Buildup: Not controlled, Passive Insulation  
ULD Storage: Controlled, Passive Insulation  
Tarmac & Loading: Unknown, Passive Insulation  
Cargo Loaded Before Departure: Not controlled, Passive Insulation

**Flight DL 2943 from BOS to LGA**  
Delta | Est. 18:00 EDT | MTWTFSS | 01:35h  
During Flight: Controlled, Passive Insulation

**Ground Handling LGA**  
Add / LGA Station | 04:07h  
Tarmac & Offloading: Unknown, Passive Insulation  
ULD Storage: Unknown, Passive Insulation  
ULD Breakdown: Unknown, Passive Insulation  
Storage: Unknown, Passive Insulation  
Loading: Unknown, Passive Insulation

**Road Transport**  
Marken | Est. Duration: 00h 21min | Est. Distance: 21km | 00:20h  
Temperature Protection: Controlled, Passive Insulation

**Warehouse Storage**  
Marken / New York Office | 14:00h  
Offloading: Controlled, Passive Insulation  
Storage: Controlled, Passive Insulation  
Loading: Controlled, Passive Insulation

Line Assessment: BioNTech - Example Lane - US to GB Temp. Range (+2 °C to +8 °C)

**Road Transport**  
Marken | Est. Duration: 00h 13min | Est. Distance: 7km | 00:20h  
Temperature Protection: Controlled, Passive Insulation

**Ground Handling JFK**  
American Airlines (AA) / JFK Station | 06:00h  
Offloading: Not controlled, Passive Insulation  
Storage: Not controlled, Passive Insulation  
ULD Buildup: Not controlled, Passive Insulation  
ULD Storage: Controlled, Passive Insulation  
Tarmac & Loading: Unknown, Passive Insulation  
Cargo Loaded Before Departure: Not controlled, Passive Insulation

**Flight AA 154 from JFK to LHR**  
American Airlines (AA) | Est. 12:30 EDT | MTWTFSS | 06:50h  
During Flight: Controlled, Passive Insulation

**Ground Handling LHR**  
WFS / LHR - Building 552 | 06:00h  
Tarmac & Offloading: Unknown, Passive Insulation  
ULD Storage: Controlled, Passive Insulation  
ULD Breakdown: Controlled, Passive Insulation  
Storage: Controlled, Passive Insulation

**Road Transport**  
Marken | Est. Duration: 00h 23min | Est. Distance: 9km | 00:20h  
Temperature Protection: Controlled, Passive Insulation

**Warehouse Storage**  
Marken / Feltham London Office | 14:00h  
Offloading: Unknown, Passive Insulation  
Storage: Controlled, Passive Insulation

**Road Transport**  
Marken | Est. Duration: 04h 20min | Est. Distance: 326km | 04:30h  
Temperature Protection: Controlled, Passive Insulation

**Drop Off Point**  
Intertek UK Ltd | Manchester, United Kingdom | 00:00h

Total Duration: 2 days

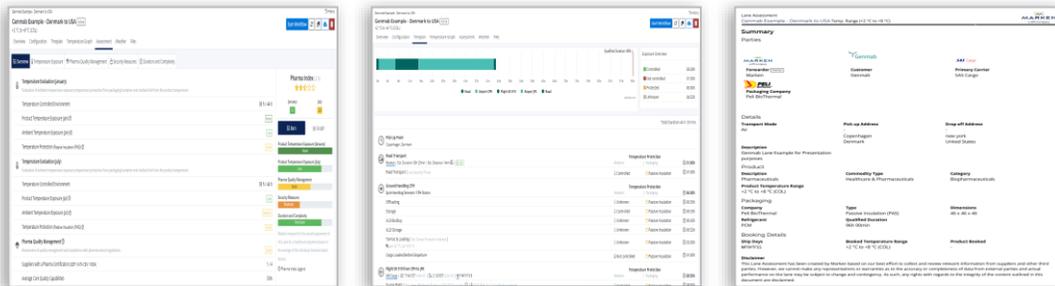


# SHIPPING VERIFICATION & CONTINGENCY PLANNING

LANE ASSESSMENT							
Request date				Shipping Location			
Estimated completion date				Delivery Location			
Customer				MARKEN a UPS Company			
Product				Delivery Location			
Service Level		Door to Door					
Packaging Type		RAP Envirotrainer					
LIVE SHIPMENT (Main)	TRANSPORT TYPE	ROUTING	FLIGHT	FREQUENCY	DEPARTURE	ARRIVAL	TAT
	Road Flight			Daily Daily			
LIVE SHIPMENT (Backup)	TRANSPORT TYPE	ROUTING	FLIGHT	FREQUENCY	DEPARTURE	ARRIVAL	TAT
	Flight Flight Flight			Daily Daily 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			
<b>TOTAL TRANSIT TIME</b>	<b>61</b>						
ADDITIONAL LANE CONSIDERATIONS							
1	Envirotrainer 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"<sup>1</sup>, 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 cascading effect on global IT systems and commercial supply chain cancellations threatening timely 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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