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# Digital Pharma Lane Risk Assessment
## Improving Compliance and Reducing Transport Risk

**MYTIGATE**

## IMPROVE COMPLIANCE AND SHOWCASE YOUR CAPABILITIES TO THE WORLD

Mytigate is a state-of-the-art, fully digital platform that ensures that forwarders & integrators comply with the Guidelines on Good Distribution Practice by

· Providing a digital lane risk assessment,
· Continuous monitoring of lane quality and
· Presenting the proper documentation for regulatory authorities

# INTRODUCTION TO MYTIGATE

Since the introduction of the EU GDP Guidelines in 2013, pharma companies and their forwarders & integrators are required to assure quality throughout their supply chain and to conduct a risk-based selection process for their transport partners. Until now, however, many have been unable to meet these requirements.
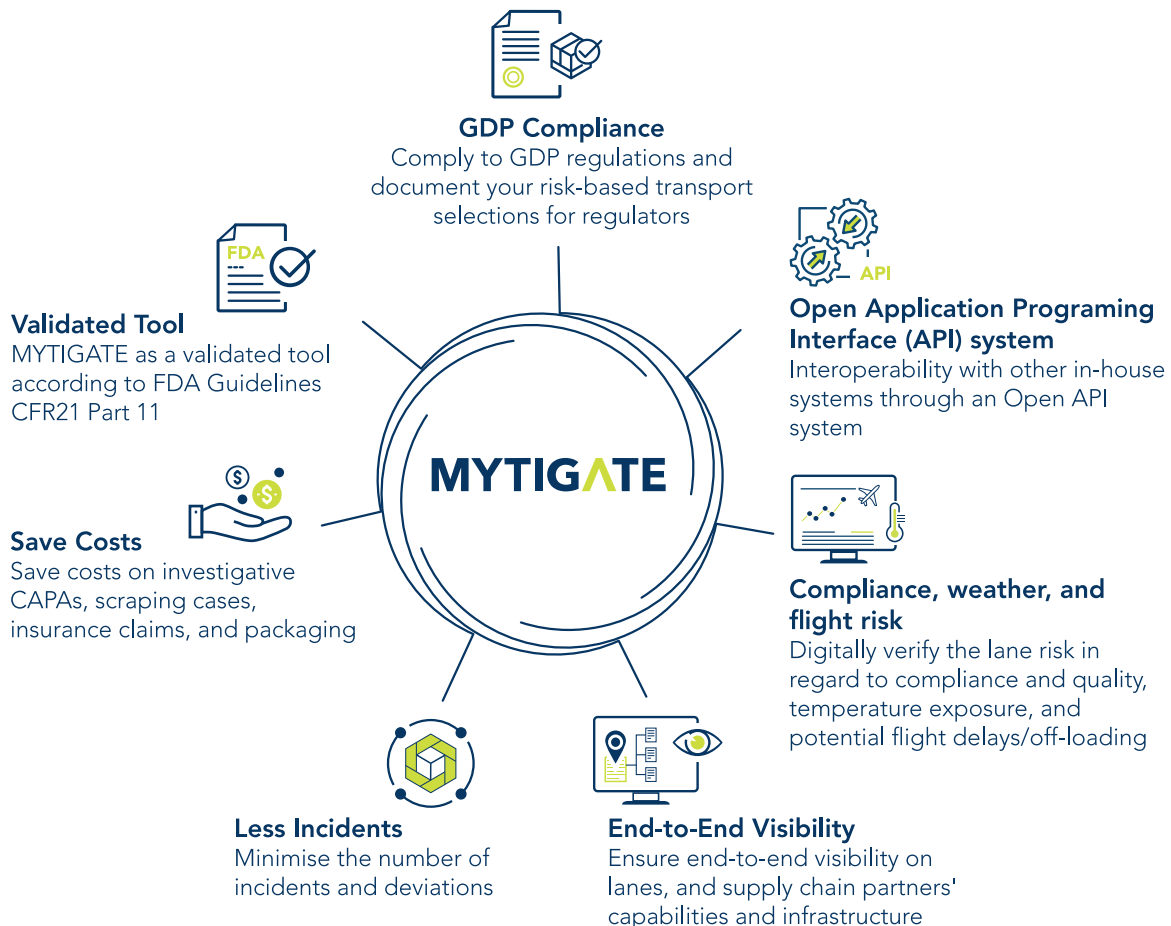
Mytigate - being an innovative, web-based service - offers a new solution that will help you to be compliant, and to select lanes using those supply chain partners that offer the highest quality and lowest risk.

Risks are continuously calculated, starting from the design phase of the lane through to the operating phase. The calculation of these risks is based on state-of-the-art, scientific-mathematical risk modelling using information from transport partners  (self-assessment of capabilities, and certificates), weather database providers and pharma companies (operational deviations, root cause data, and temperature logger data).

By these means, Mytigate aims to be a must-have risk management standard within the pharma industry and to be the driver for innovation in the transport and supply chain industries. Through analysis of this data, predictive analytics can be applied to identify the trends.
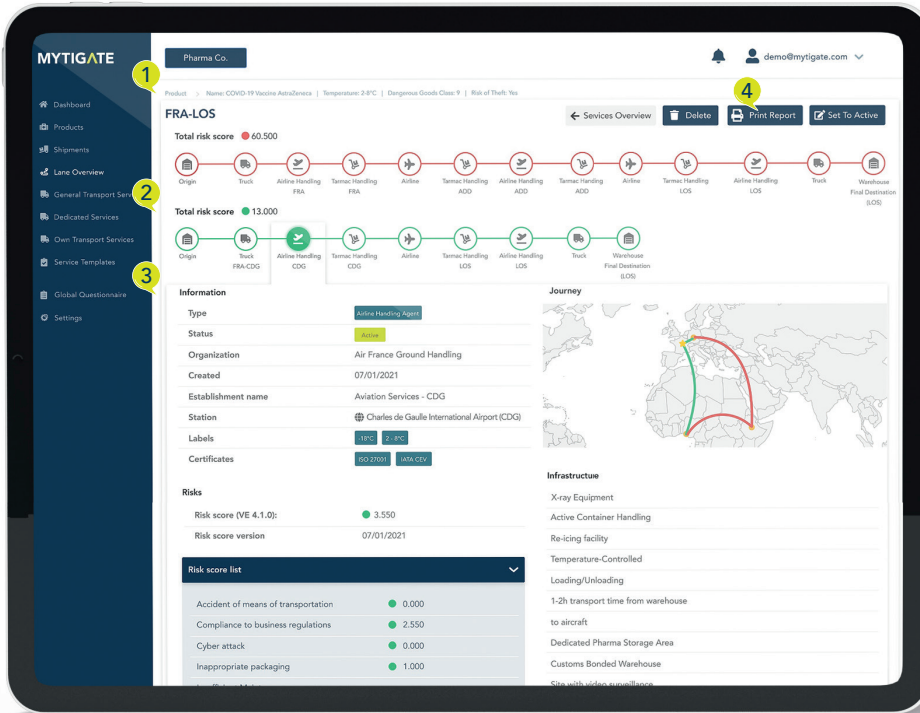
The Mytigate risk management platform is a Software-as-a Service (SaaS) that was co-created with the pharma industry, working hand in hand with global forwarders to plan, monitor and improve the quality of pharma shipments in a legally compliant and safe manner.

# THE ADVANTAGES OF MYTIGATE

**GDP Compliance**
Comply to GDP regulations and document your risk-based transport selections for regulators

**Open Application Programing Interface (API) system**
Interoperability with other in-house systems through an Open API system

**Validated Tool**
MYTIGATE as a validated tool according to FDA Guidelines CFR21 Part 11

**Save Costs**
Save costs on investigative CAPAs, scraping cases, insurance claims, and packaging

**MYTIGATE**

**Compliance, weather, and flight risk**
Digitally verify the lane risk in regard to compliance and quality, temperature exposure, and potential flight delays/off-loading

**Less Incidents**
Minimise the number of incidents and deviations

**End-to-End Visibility**
Ensure end-to-end visibility on lanes, and supply chain partners' capabilities and infrastructure
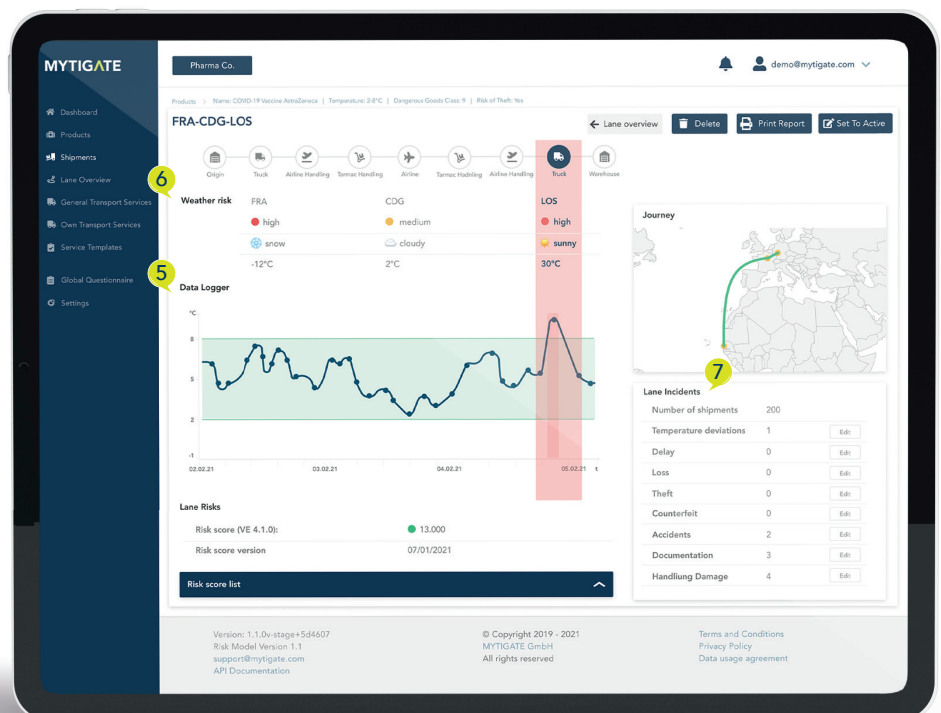
# KEY FEATURES

## Lane Planning



1. **Product Requirements**
Specification of product handling and transportation conditions

2. **Lane Design**
Digitise your lane management process from risk assessment to qualification and validation

3. **Partner Profiles**
Evaluation and selection of major transport companies including airlines, handling agents, warehouses, and other logistics suppliers based on their pharma-specific handling capabilities

4. **Reporting**
Issue reports to regulators and document your risk-based lane assessment

## Lane Quality Control

5. **Temperature Data Logger**
Continuously monitor the quality of transport on the selected routes by linking your own performance data (e.g. temperature logger data) to the shipments

6. **Weather- and Temperature-Related Risks**
Consideration of amount of time the shipments are exposed to external temperatures

7. **Lane Incidents**
Monitoring of lane performance and other quality data. e.g. temperature incidents, delays, damage, and documentation problems
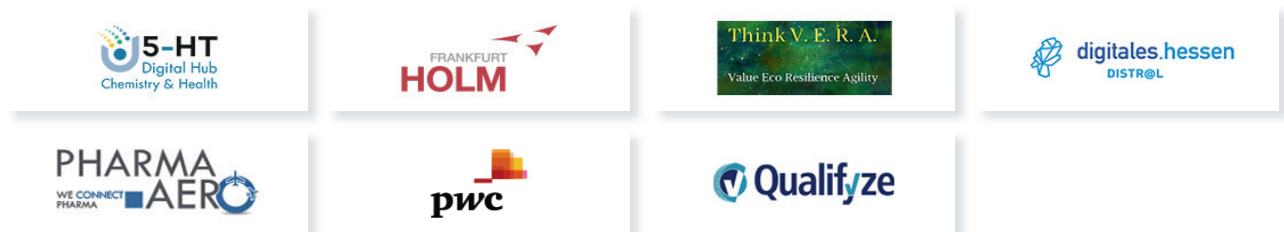
# DEVELOPMENT PARTNERS

The Mytigate tool was developed by three universities: Frankfurt University of Applied Sciences, Fulda University of Applied Sciences and RheinMain University of Applied Sciences. They worked hand in hand with industry partners from the pharmaceutical industry as well as the logistics and supply chain industry:



# BUSINESS PARTNERS

# CONTACT US

We look forward to your inquiries and are happy to offer you a free demonstration of the tool.

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**Prof. Dr. Yvonne Ziegler**
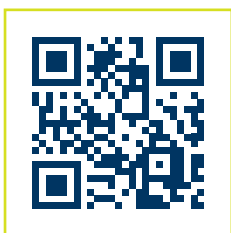Founder & CEO
Yvonne.Ziegler@mytigate.com

**Sarra Rachdi**
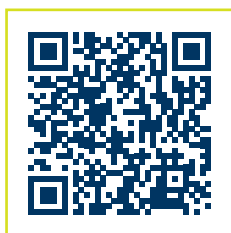Sales Manager
Sarra.Rachdi@mytigate.com

# ABOUT US

Mytigate GmbH is based in the Rhine-Main area, yet by embracing a fully digital work environment, our international team spans multiple countries and different time zones. Our office is located in the House of Logistics and Mobility (HOLM) in Frankfurt, Germany. Mytigate commenced operations in April 2020 in order to operationalise the results of the research project „Pharma Supply Chain Risk Management". This project started in 2017 and was funded by the LOEWE3 innovation fund of the state of Hesse in Germany and managed by Frankfurt University of Applied Sciences.

Working hand in hand with industry leaders and academic institutes, our vision is to become the quality and sustainability standard for both the pharma and the forwarder industry. To achieve this vision, we bring together the scientific collaborative efforts of the different parties involved, connecting academic and research knowledge with the industry.

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