IATA AirPharma Conference

29 – 31 October 2019, Amsterdam, Netherlands
IATA AirPharma Conference

29 – 31 October 2019, Amsterdam, Netherlands
Opening Day 1

Andrea Gruber
Head of Special Cargo
IATA
IATA Competition Law Compliance

Do not discuss:

- Pricing, including fares, service charges, commissions, etc.
- Bids on contracts or allocation of customers
- Geographic/Product market allocations and marketing plans, including
  - Expanding or withdrawing from markets
  - Group boycotts
  - Your commercial relations with agents, airlines or other third parties

Any discussion aimed at influencing the independent business decisions of your competitors

You will be asked to leave the meeting, and the meeting may be terminated, if the above-mentioned discussions occur.

Remember: All discussions count, even informal ones outside the meeting room!
Thank you to all our sponsors!
Welcome Address & Chairman Opening Remarks

Maarten van As
Managing Director
Air Cargo Netherlands (ACN)
AIR CARGO NETHERLANDS IN 52 SECONDS
AIR CARGO NETHERLANDS IS THE CHAIN WIDE INDUSTRY ASSOCIATION FOR THE AIR CARGO SECTOR IN THE NETHERLANDS.
BRINGING TOGETHER THE PARTIES IN THE AIR CARGO SECTOR ALLOWS STEPS TO BE TAKEN IN A UNIQUE WAY.
DEFENDING THE INTERESTS OF AIR CARGO INDUSTRY

INNOVATING TO INCREASE COMPETITIVENESS OF OUR AIR CARGO COMMUNITY

FACILITATOR

INNOVATOR

LOBBYIST

MEETING PLACE NETWORK

OUTLOOK, RESEARCH, KNOWLEDGE PARTNER VISION

REPRESENTING INTERESTS
WE BELIEVE THAT
A STRONG AIR CARGO COMMUNITY IS AN IMPORTANT ASSET
Pharma Gateway Amsterdam is an alliance between 23 logistics companies centered around Amsterdam Airport Schiphol to ensure a certified closed chain for your pharmaceutical air cargo shipments.
A POWERFUL JOINT EFFORT TO IMPROVE THE QUALITY OF PHARMACEUTICAL SUPPLY CHAIN
IATA AIRPHARMA CONFERENCE

THESE DAYS ARE ABOUT

GETTING TO KNOW EACH OTHER
SHARING EXPERIENCES
RECOGNIZING TRENDS
LEARNING TOGETHER
Keynote Speech

Dr. Marco J. van de Velde
Head of Department
Farmatec
Challenges of transporting cannabis as a legal medicinal drug

Marco van de Velde (PhD)
Head Office of Medicinal Cannabis (OMC)
Ministry of Health, Welfare and Sport
The Netherlands

October 29th 2019
Multiple sclerosis: chronic disease with high impact on quality of life
Therapeutic Indications

• Chronic pain / neuropathic pain;

• Spasticity: multiple sclerosis, spinal cord injury, etc;

• Gilles de la Tourette syndrome;

• Glaucoma;

• Anti-emetic: chemotherapy, radiotherapy, etc;

• Epilepsy.
History of cannabis as a ‘therapeutic agent’

- Already 2000 BC: China, India;
- 1900-1930: >20 products in U.S.;
- >1937 prohibited; list of forbidden drugs;
Single convention on narcotic drugs and psychotropic substances (1961/1971) U.N.

Aims of the convention/treaty:

• To limit the possession, use, trade in, distribution, import, export, manufacture and production of drugs exclusively to medical and scientific purposes;

• To combat drug trafficking through international cooperation to deter and discourage drug traffickers;

• Establish a national agency.
Reasons for a new policy on medicinal cannabis

*From 1993 onward:*

- Increasing pressure from society against prohibition of medicinal use;

*Health Council advised (1996):*

- Insufficient evidence of efficacy;
- Clinical trials done with ill-defined products.

*Existing practice of illegal medical use*

- No quality control;
- No medical coaching of patients;
- Patients at the mercy of illicit trade.
### Microbiology: *illegal* cannabis coffee shop

(Source: A. Hazekamp et al; University of Leiden, the Netherlands)

<table>
<thead>
<tr>
<th>Cannabis sample</th>
<th>aerobic bacteria (cfu/gram)</th>
<th>aerobic fungi (cfu/gram)</th>
<th>Identified pathogens</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bedrocan ²</td>
<td>&lt;10</td>
<td>&lt;100</td>
<td></td>
</tr>
<tr>
<td>Bedrobinol ²</td>
<td>&lt;10</td>
<td>&lt;100</td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>&lt;10</td>
<td>480000</td>
<td></td>
</tr>
<tr>
<td>B</td>
<td>4500</td>
<td>900</td>
<td></td>
</tr>
<tr>
<td>C</td>
<td>&lt;10</td>
<td>1000</td>
<td></td>
</tr>
<tr>
<td>D</td>
<td>70</td>
<td>120</td>
<td></td>
</tr>
<tr>
<td>E</td>
<td>13000</td>
<td>6500</td>
<td></td>
</tr>
<tr>
<td>F</td>
<td>80000</td>
<td>4800</td>
<td></td>
</tr>
<tr>
<td>G</td>
<td>180</td>
<td>350</td>
<td></td>
</tr>
<tr>
<td>H</td>
<td>27000</td>
<td>1300</td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>350</td>
<td>4200</td>
<td></td>
</tr>
<tr>
<td>J</td>
<td>23000</td>
<td>91000</td>
<td></td>
</tr>
<tr>
<td>K</td>
<td>5900</td>
<td>3600</td>
<td></td>
</tr>
</tbody>
</table>

1) : CFU = colony forming units
2) : limit: total aerobic bacteria and fungi <100 cfu

E. coli
Penicillium
Cladosporium
Aspergillus
Illegal cannabis

• Heavily contaminated with fungi
  – Up to 600,000 colony forming units/gram
    (source: Hazekamp);

• 50% of samples contaminated with pesticides
  (source: Rikilt, The Netherlands);

• Heavy metals;

• No constant content (st dev: 15%).
Foundation of OMC

• In 1998 the Dutch government decided to establish an agency as regulator for medicinal cannabis according to art. 28 of Single Convention (U.N.);

• Foundation of the Office of Medicinal Cannabis (OMC) (1 March 2000);

• Office of Medicinal Cannabis empowered as national agency (1 January 2001);
National legislation

Amendment to the Opium Act (2002-2003)

With respect to hemp, hashish and hemp oil Our Minister e.g. the OMC is, to the exclusion of others, authorized:

- to import or export from the Netherlands;
- to sell and deliver it;
- to have it available, with the exception of stocks maintained by those who have a license to cultivate, work up and convert.

Amendment to the Royal Decree (2002)

Royal Decree on prescribable and dispensable controlled substances.
Main responsibilities of the OMC

- Ensure constant quality of medicinal cannabis produced which meets **pharmaceutical standards**;

- Establish an effective procedure for distribution;

- Prevent leakage to the criminal circuit (tracking procedure / recordkeeping);

- Ensure availability of medicinal cannabis.
Production and distribution model – supply chain

Office of Medicinal Cannabis (OMC)

- growers
- packager
- logistics service provider
- laboratory
- distribution
- invoicing
- collection
- Dutch pharmacy
Contracted third parties:

- **Cultivation** (Bedrocan BV)

- **Quality control** (Proxy - Eurofins)

- **Packaging and distribution (national)** (Fagron BV)

- **Pharmacy/Research/Product development**
Growers

• GAP- and GMP certified

• License to grow cannabis
  – according to Opium Act
  – supervised by Health Inspectorate
  – permitted by OMC

• Contract to supply cannabis
  – with Minister of Health
  – supervised by OMC
## Certificate of Analysis

<table>
<thead>
<tr>
<th>Test</th>
<th>Test method</th>
<th>Specification</th>
<th>Result</th>
<th>Comply</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Monograph</td>
<td>Brown green clustered flowers of 1.5 to 3 cm with a characteristic smell</td>
<td>Conform</td>
<td>Yes</td>
</tr>
<tr>
<td>Identity by microscopy</td>
<td>Monograph</td>
<td>Mainly gland hair visible</td>
<td>Conform</td>
<td>Yes</td>
</tr>
<tr>
<td>Identity by TLC</td>
<td>Monograph</td>
<td>Must comply</td>
<td>Conform</td>
<td>Yes</td>
</tr>
<tr>
<td>Foreign material</td>
<td>Monograph</td>
<td>Stalks, internodes and other vestiges are absent</td>
<td>Conform</td>
<td>Yes</td>
</tr>
<tr>
<td>Fineness</td>
<td>Monograph</td>
<td>No leaves shooting out more than 20% of the length of the flowers. Stalks are cut away directly under the bottom flowers of the inflorescence</td>
<td>Conform</td>
<td>Yes</td>
</tr>
<tr>
<td>Microbiological purity</td>
<td>Monograph</td>
<td>Not applicable</td>
<td>2.4 x 10^5 cfu/mg N/A</td>
<td></td>
</tr>
<tr>
<td>TACN</td>
<td>Monograph</td>
<td>8.0 x 10^4 cfu/mg N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TYPN</td>
<td>Monograph</td>
<td>3.0 x 10^5 cfu/mg N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pseudomonas aeruginosa</td>
<td>Monograph</td>
<td>Absent ** N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Simple bacillus aerogenes</td>
<td>Monograph</td>
<td>Absent N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tolerant gram neg bacteria</td>
<td>Monograph</td>
<td>&lt; 0.000 mg N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Loss on drying</td>
<td>Monograph</td>
<td>≤ 10.0%</td>
<td>9.8 %</td>
<td>Yes</td>
</tr>
<tr>
<td>Assay (UPLC)</td>
<td>Monograph</td>
<td>Fingerprint must be similar</td>
<td>Conform</td>
<td>Yes</td>
</tr>
<tr>
<td>Related substances (UPLC)</td>
<td>Monograph</td>
<td>Conform</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Absence of aflatoxins</td>
<td>Monograph</td>
<td>Aflatoxin R1: Not applicable</td>
<td>&lt; 1.0 μg/kg N/A</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Monograph</td>
<td>Aflatoxin R2: Not applicable</td>
<td>&lt; 0.2 μg/kg N/A</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Monograph</td>
<td>Aflatoxin G1: Not applicable</td>
<td>&lt; 0.5 μg/kg N/A</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Monograph</td>
<td>Aflatoxin G2: Not applicable</td>
<td>&lt; 0.5 μg/kg N/A</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Monograph</td>
<td>Sums R1, R2, G1 and G2 ≤ 4 μg/kg</td>
<td>&lt; 2.2 μg/kg Yes</td>
<td></td>
</tr>
<tr>
<td>Absence of penicilates</td>
<td>Monograph</td>
<td>Ph.Eur (correct of) 2.8.15 *</td>
<td>Conform</td>
<td>Yes</td>
</tr>
<tr>
<td>Absence of heavy metals</td>
<td>Monograph</td>
<td>Lead ≤ 20.0 ppm</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Monograph</td>
<td>Molybdenum ≤ 0.5 ppm</td>
<td>&lt; 0.5 ppm Yes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Monograph</td>
<td>Calcium ≤ 6.5 ppm</td>
<td>&lt; 6.5 ppm Yes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Monograph</td>
<td>Arsenic: Indicative</td>
<td>&lt; 2 ppm N/A</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Monograph</td>
<td>Nickel: Indicative</td>
<td>2.1 ppm N/A</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Monograph</td>
<td>Zinc: Indicative</td>
<td>42.7 ppm N/A</td>
<td></td>
</tr>
</tbody>
</table>

**Remark:**

*) The following components are not being analyzed on the current method:

- Dibenzo[a,h]anthracene
- Perylene
- Methylnaphthalene

**) Probable genus identification: Pseudomonas putida determined.

**Q-statement:**

This study met the criteria for a valid test and was performed in compliance with the Good Control Laboratory Practice as defined in the Guide to Good Manufacturing Practice for Medicinal Products in the European Community. The reported results adequately reflect the raw data of the study.

**Conclusion:**

The results do comply with the specifications.

This certificate is approved by Manager QA on 17 January 2017
Logistics – packaging and distribution (national)

• External partner with experience in packaging, labelling and distribution of pharmaceutical products to Dutch pharmacies;

• Quality standards and certification: GMP and GDP-certified, FDA audited / approved;

• Recordkeeping procedure for tracking medicinal cannabis to the patient.
Clean rooms
Medicinal cannabis complies with pharmaceutical quality guidelines

• Standardized product with constant content (dronabinol, cannabidiol and other)
  – Within ranges of regulatory authorities

• Very low concentration of degradation compounds (e.g. CBN)

• Free of contamination
  – Micro-organisms
  – Pesticides
  – Heavy metals
Products - varieties

- Cannabis flos, variety Bedrocan: 22% THC, <1% CBD
- Cannabis flos, variety Bedrobinol: 13,5% THC, <1% CBD
- Cannabis flos, variety Bedica granulated: 14% THC, <1% CBD
- Cannabis flos, variety Bediol, granulated: 6,3% THC, 8% CBD
- Cannabis flos, variety Bedrolite granulated: <1% THC, 8% CBD

Note: all varieties are also available in ‘placebo’
Cannabis flos, variety Bedrocan
- Approx. 19% dronabinol,
- <1% cannabidiol,
- Other cannabinoids very low

Cannabis flos, variety Bedrobinol
- Approx. 12% dronabinol,
- <1% cannabidiol,
- Other cannabinoids very low

Cannabis flos, variety Bediol, granulated
- Approx. 6% dronabinol and 7.5% cannabidiol,
- Other cannabinoids very low

Bedrocan dried flowers
Bediol granulated
Cannabis filos graminae
BEDIOL

Cannabis sativa dried human flowers, granules
Batch no. : [REDACTED]
Content: THC approx. 9 %; CBD approx. 0 %
Netto weight: 100 grams
Pharmaceutical characteristics:

- Pharmaceutical raw material;
- Standardised herbal medicinal product;
- Not registered as a medicine;
- Opium Act.
Export of Medicinal Cannabis (or derivatives)

• Import license (original copies in duplo) issued by authorities of importing country;

• Export license issued by authorities of the Netherlands;

• Transported volume reported to the UN (INCB);

• Contract with the OMC.
Dutch policy rules concerning export (additional)

- Country of import is member of UN and supports international treaty on narcotics and psychotropic substances;

- Cannabis may only be used for treatment of patients, for scientific research or product development;
Im Namen der Regierung der Bundesrepublik Deutschland genehmigt das Bundesinstitut für Arzneimittel und Medizinprodukte aufgrund des Betäubungsmittelgesetzes und der internationalen Übereinkommen über Suchtstoffe und psychotroppe Stoffe hiermit die folgende Einführung:

On behalf of the Government of the Federal Republic of Germany, the Federal Institute for Drugs and Medical Devices, in the meaning of the national legislation on narcotic drugs and the international Conventions on Narcotic Drugs and Psychotropic Substances, hereby authorizes the following import:

Betreff:
Erleichterung

Empfänger:
Bureau voor Medicinale Cannabis
Kloveniersburgwal 50
NL-1017 XP Den Haag

Menge und Bezeichnung der Stoffe oder Zubereitungen:

- 12.000 x 1 g Cannabis (Bedrocan)
- 7.500 x 1 g Cannabis (Bedrocan)
- 1.000 x 1 g Cannabis (Bedrocan)
- 1.500 x 1 g Cannabis (Bedrocan)

Menge und Bezeichnung der enthaltenen Suchtstoffe oder psychotropen Stoffes:

- 25 kg Cannabis

Die Unterweisung der Einführerendenden in den nachgeordneten Lagern erhältlich genehmigt:

- Verwendung in Lagern oder Freihallenlager verboten!
- Shipping to a bonded warehouse or into a free port prohibited

Sonderbedingungen:

- Tielosendungen verboten!
- Partial shipments prohibited

Verfallsdatum: 30.09.2019

Exploitation date: 30.09.2019

Bundesinstitut für Arzneimittel und Medizinprodukte

A. Klein, TB
<table>
<thead>
<tr>
<th>Patient use</th>
<th>Product development</th>
<th>Scientific research</th>
</tr>
</thead>
<tbody>
<tr>
<td>Italy</td>
<td>Germany</td>
<td>United Kingdom</td>
</tr>
<tr>
<td>Germany</td>
<td></td>
<td>Switzerland</td>
</tr>
<tr>
<td>Norway</td>
<td>Israël</td>
<td>Israël</td>
</tr>
<tr>
<td>Sweden</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Denmark</td>
<td></td>
<td>Australia</td>
</tr>
<tr>
<td>Finland</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Poland</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Canada</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
# Packages

<table>
<thead>
<tr>
<th>Package sizes (lxlxb)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>120 x 80 x 100</td>
<td></td>
</tr>
<tr>
<td>62 x 43 x 67</td>
<td></td>
</tr>
<tr>
<td>53 x 43 x 34</td>
<td></td>
</tr>
<tr>
<td>37 x 28 x 24</td>
<td></td>
</tr>
</tbody>
</table>
Partnership

- A logistics company operating worldwide;
- Experience in transport of pharmaceutical products;
- Adhere to G(ood)D(istribution)P(ractices) guidelines;
- Maintenance of product quality, safety and efficacy during shipment;
- Temperature-controlled if needed;
- Pickup on time, flown as booked, delivered on time, and accompanied with relevant documentation.
Experiences of the OMC with export/air freight

- Damage of image;
- Part of the protocol;
- ‘Fear of cold water’;
- Lack of knowledge about legislation:

*Fully controlled in conformity with international treaties and under the auspices of national authorities*
Cases

1. Airline was not allowed to transport; other airline only with transit via Bucharest. Transit authorization needed and special permit from authorities;

2. Damage of (outer) package;
Cases

3. Airline will not treat the goods as pharmaceutical products but as valuables: temperature-controlled transport not possible;

4. Temperature-controlled transport: datalogger only present in one of three boxes and/or recordings show strong temperature deviations;

5. Exchange of customer addresses;

In general:

- Contact and collaboration with logistic companies is positive;

- Objective of the OMC is to further optimize the whole supply chain in cooperation with the logistic partner(s).
Thank you for your attention.
Networking break 10:30 – 11:00

Kindly sponsored by;

Viking Packing Specialist

40th Anniversary 1979-2019

IATA Airpharma Conference
Amsterdam, Netherlands
29-31 October 2019
Know your Customer Speed Dating
Meet the Pharma Shippers
Meet the Pharmaceutical Experts

- **Steef van Amersfoort**, SC integrated Planning and Logistics
- **Gavish Hurgobin**, Manager - Logistics, Supply Chain
- **Julian Wann**, Global Category Leader - Procurement Freight & Logistics
- **Christopher Stein**, Transport Expert
- **Ine Kemper**, Logistics Specialist/Security Advisor
- **Eddy Weygaerts**, Transportation Manager
- **Roman Mijnhart**, Sr. Director Global Supply Chain Quality
“Know your Customer Speed Dating”

GE Healthcare
SANOFI GENZYME
AbbVie
AstraZeneca
Pfizer
aspen GLOBAL
MSD
Bayer

8 Tables
8 Sessions
10 minutes each
“Know your Customer Speed Dating”

1. Round Table Introduction

2. Potential topics of discussion

➢ Regulatory Environment:
  – Compliance and application of the existing Regulations, how well are these understood, interpreted locally or regionally?
  – What is to be expected in the industry?

➢ Operations / Visibility
  – Are roles and responsibilities in the supply chain clearly defined and understood? How can this be enhanced?
  – Are the shipper’s operational challenges shared with the airlines?
  – Are the complexity of the airport processes, starting from the booking, well known from the shipper’s community?

➢ Investments
  – Improved packaging can affect the processes, how is this communicated with the stakeholder of the supply chain?
  – Are the investments done by the air freight industry meeting the shippers’ expectations?

➢ Certification/Audits
  – How to simplify/reduce the number of audits and how could shippers accept audit requirements performed by other companies?
  – How can the shipper’s community be more supportive to the air freight industry?
Networking Lunch 12:30 – 14:00

Kindly sponsored by;

iSHARE
Industry Partnership
The Manufacturer's perspective

Gavish Hurgobin
Manager Logistics Supply Chain
Aspen Global Incorporate
Industry Partnership
The Freight Forwarders perspective

Nina Heinz
Global Head of Network & Quality
DHL Global Forwarding
INDUSTRY PARTNERSHIP

Freight Forwarder Perspective

Nina Heinz
Global Head of Network & Quality

Amsterdam, October 2019

FORWARD-THINKING, INTELLIGENT HEALTHCARE

#DHLWECARE
Industry trends

Business is going digital & large amounts of data are being produced within supply chains

<table>
<thead>
<tr>
<th>2017</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>1  Temperature Control/Cold Chain</td>
<td>2  Temperature Control/Cold Chain</td>
</tr>
<tr>
<td>2  Cost Efficiency</td>
<td>3  Cost Efficiency</td>
</tr>
<tr>
<td>3  Digitalization of SC / Data Analytics</td>
<td>4  Digitalization of SC / Data Analytics</td>
</tr>
<tr>
<td>4  Network Optimization/ DC Consolidation</td>
<td>5  Network Optimization/ DC Consolidation</td>
</tr>
<tr>
<td>5  Transport Mode Optimization/A2O</td>
<td>6  Transport Mode Optimization/A2O</td>
</tr>
<tr>
<td>6  New Technologies in Supply Chain</td>
<td>7  New Technologies in Supply Chain</td>
</tr>
<tr>
<td>7  Serialization</td>
<td>8  Serialization</td>
</tr>
<tr>
<td>8  Supply Chain Transformation via LLP</td>
<td>9  Regulation/ Compliance</td>
</tr>
<tr>
<td>9  Direct-to-Pharmacy, Hospital and Lab</td>
<td>10  Supply Chain Transformation via LLP</td>
</tr>
<tr>
<td>10 Regulation/ Compliance</td>
<td>11 Supply Chain Resilience</td>
</tr>
</tbody>
</table>

Source: 2018 post conference surveys, LSH Sector Strategy Team; 1) Ranking based on occurrences of customer answers only; 2) Question asked to participants: We would like to understand the key hot topics (key opportunities & challenges) for your organization in the next 1-3 years. Please choose up to 6 topics.
Voice of the customer

Customers are seeking to transform data into actionable insights to support continuous improvement & risk reduction

“How quickly can you **visualize risk** across our key trade lanes?”

“When do you provide **lane risk assessments** to allow us to make an informed decision?”

“How robust are your **risk management activities**?”

“Can you give us further **consultation** beyond your trade lane risk assessment?”

“Can you provide risk assessments throughout our **entire network**?”
GDP Regulatory Requirements

Worldwide regulation of distribution requires quality risk management principles to supply chain management of pharmaceutical product

<table>
<thead>
<tr>
<th>WHO¹)</th>
</tr>
</thead>
<tbody>
<tr>
<td>The relevant sections of these guidelines should also be considered for implementation by, among others, governments, regulatory bodies,</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>EU GDP²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.5. Quality risk management</td>
</tr>
<tr>
<td>Quality risk management is a systematic process for the assessment, control, communication and review of risks to the quality of medicinal products. It can be applied both proactively and retrospectively.</td>
</tr>
<tr>
<td>Quality risk management should ensure that the evaluation of the risk to quality is based on scientific knowledge, experience with the process and ultimately links to the protection of the patient. The level of effort, formality and documentation of the process should be commensurate with the level of risk. Examples of the processes and applications of quality risk management can be found in guideline Q9 of the International Conference on Harmonisation (ICH).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>USP³)</th>
</tr>
</thead>
<tbody>
<tr>
<td>15. Risk Management System</td>
</tr>
<tr>
<td>Risk Management System strategies should ensure that each organization’s best interests are served by adhering to proper practices, controls, and procedures, including but not limited to the following: the nature of the drug product; distribution requirements on the readable container labeling; exposure to adverse environmental conditions; number of stages/receipts in the supply chain; manufacturer’s written instructions; contractors; and drugs at risk from freezing (vaccines, insulin, and biological products) or elevated temperatures (freezing-based suspensions, vaccines, insulin, and biological products).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PIC/S⁴)</th>
</tr>
</thead>
<tbody>
<tr>
<td>15. Quality Risk Management</td>
</tr>
<tr>
<td>1.5.1 Quality risk management is a systematic process for the assessment, control, communication and review of risks to the quality of medicinal products. It can be applied both proactively and retrospectively.</td>
</tr>
<tr>
<td>1.5.2 Quality risk management should ensure that the evaluation of the risk to quality is based on scientific knowledge, experience with the process and ultimately links to the protection of the patient. The level of effort, formality and documentation of the process should be commensurate with the level of risk. Examples of the processes and applications of quality risk management can be found in guideline Q9 of the International Conference on Harmonisation (ICH).</td>
</tr>
</tbody>
</table>

Do you have a strategy in place for mitigating risk?

Life sciences companies need to mitigate risk aggressively due to increasing regulatory enforcement and cost pressure

<table>
<thead>
<tr>
<th>Customer Needs</th>
<th>Description</th>
</tr>
</thead>
</table>
| **Regulatory Compliance**               | - LSHC companies required to ensure regulatory compliance from EU GDP, USP, China FDA, etc  
- EU GDP regulation enforcement increase (audits doubled since 2013)  
- Increase in supply chain regulation published worldwide since 2010
- Ensure patient safety through regulatory compliance |
| **Total Cost Management**               | - Mitigate product delay (and product loss), especially for biotech products and increasingly demanded biologic drugs  
- Identify best carriers, packaging, and service levels for optimal cost |
| **Network Reliability**                 | - Decrease overall distribution risk (e.g., temperature deviation)  
- Establish optimized new routes for expanding market reach, especially in developing markets  
- Create reliable product supply and leaner inventory |

Source: DHL Consulting; Cold Chain IQ; 1) Voice of customer collected from interviews with LifeConEx Business Development Team; 2) Temperature-controlled supply chain regulations from Brazil, China, Singapore, and the World Health Organization published after 2010
Growth of big data

Big data is growing exponentially, providing an opportunity to use it for powerful analytics

Key Insights

1) Volume: Data increases by a factor of 50 between 2010 and 2020

2) Variety: High variety of data types due to increase in unstructured data, (e.g., images, video footage, blog entries)

3) Velocity: Connected devices (e.g., packaging sensors, cars) continuously generate data streams

Source: 1) Big Data in Logistics, DHL in cooperation with Detecon Consulting, December 2013
The biggest challenge in any organization’s analytics journey is transforming insights into outcomes from end-to-end, this is how the value of analytics is ultimately extracted.
Data analytics use cases

Life sciences customers needs are different through the general life cycle of a product; identify areas to focus on through data analytics

<table>
<thead>
<tr>
<th>Product Life Cycle</th>
<th>Customer Pain Points</th>
<th>Customer Use Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Launch</td>
<td>Resource-intensive trade lane verification process</td>
<td>New trade lane qualification and validation</td>
</tr>
<tr>
<td>Launch Phase</td>
<td>Ensuring market availability ASAP</td>
<td>Prioritizing trade lanes</td>
</tr>
<tr>
<td>Patent Phase</td>
<td>Properly balancing shipment costs and risks</td>
<td>Provide benchmarking capabilities</td>
</tr>
<tr>
<td>Off-Patent</td>
<td>Reducing costs</td>
<td>Evaluate optimization opportunities to reduce costs</td>
</tr>
</tbody>
</table>

- Identify highest-risk lanes for new packaging validation
- Identify high-risk carriers to support lower cost options
- Evaluate potential scenarios based on service level changes, by season, alternate transport modes
- Evaluate companies’ performance/risk during M&A
Food for thought on how to make use of data

- Packaging performance
e.g. active vs. passive vs. thermal blanket

- Ambient temperature data
e.g. captured by forwarder external data logger

- Temperature overlays
e.g. forwarder logistics milestone vs. external ambient temp vs. your internal data logger data

- Risk probability vs. severity vs. detectability
e.g. Failure Mode Effects Analysis

- Infrastructure analysis
e.g. temp. controlled historical performance vs capabilities present for storage/handling at each port
Data Analytics: What can it do for you?

Enabling our customers to simplify complex data to make faster and smarter decisions

- **Web-based tool** as single platform to access data on demand
- Segment shipment data into meaningful **visualization**
- Ability **to identify problems and trends**
- Include **own reference data to measure KPIs**, manage vendors and report on exceptions
- Build **customized dashboards**
- Easily **share information** across organization
Why is collaboration key for successful data analytics?
Why is collaboration key for successful data analytics?

1. Setting up the best team
2. Empowerment of People
3. Establishing Trust
4. Mindset Change
5. Driving digitalization & innovation
6. Bringing on board the right players
“Processed data is information. Processed information is knowledge. Processed knowledge is wisdom.”

Ankala V. Subbarao
Our common goal: Patient safety
THANK YOU

Nina Heinz
Global Head of Network & Quality
Temperature Management Solutions
DHL Global Forwarding
Mobile: +33.6.0875.2286
nina.heinz@dhl.com
Networking break 15:30 – 16:00

Kindly sponsored by;
Another day in the life of Pharma Shipper

Steef van Amersfoort
SC Integrated Planning & Logistics
AbbVie
The Innovation journey

Gary Roche
Global Operating Officer
GEFCO Freight Forwarding

Omar van Geest
Logistic Development Director
GEFCO
GEFCO

**Life Sciences & Healthcare**
Pharmaceuticals and medical devices

**Humanitarian relief**
Crisis situations, war and natural disaster

**Body care**
Demand driven products

**Automotive**
Component supply, spare parts logistics

**2-wheelerers**
Component supply, spare parts logistics

**Heavy Equipment**
Industrial project cargo

**Aerospace & Defense**
Satellites / aircraft parts

**Energy**
Electrical, Oil & Gas

**Retail**
Demand driven products

**Hi-Tech & Media**
Demand driven products

**KEY FACTS & FIGURES**

70 YEARS EXPERIENCE

47 COUNTRIES

5 CONTINENTS

130 AIR AND SEA LOCATIONS

+15,000 EMPLOYEES
SCHIPHOL CENTRE OF EXCELLENCE

- CLOSE PROXIMITY TO SCHIPHOL AIRPORT
- OVER 10,000SQM
- GDP CERTIFIED
- TEMPERATURE CONTROL: 2-8ºC & 15-25ºC
- SECURITY SCREENING
- RF SCANNING
- SERIALIZATION CAPABLE
- WHOLESALE DEALER LICENCE (MINISTRY OF HEALTH IGZ)
- IATA CEIV
- TAPA-A
- ISO 9001:2015
- AEO
Operational Excellence

Efficiency without Compromising on Compliance

Visibility of Products

Cost optimized Solutions
Supply chain optimisation:

Putting customer experience at the heart of innovation for GEFCO

Building a culture of innovation

Delivering innovation to LS&H market challenges

Solution driven to meet customer needs
INNOVATION IS PART OF OUR DNA

- Flexible and knowledgeable pool of people
  - Grow together
- Explore
- Innovate
- Open our space
- Become innovation enablers
OUT OF THIS WORLD SOLUTIONS
CUSTOMER EXPERIENCE AT THE HEART OF INNOVATION FOR GEFCO

Smart Speaker Track & Trace
CUSTOMER EXPERIENCE AT THE HEART OF INNOVATION FOR GEFCO

Augmented Reality
AUGMENTED REALITY AT GEFCO

THE STORY SO FAR...

**Why AR tech?**
- Complex, traditional pick and pack process
- Increased demand for quality
- Performance improvement

**Proof of Concept**
- Prove AR is beneficial to GEFCO business and will contribute to business excellence
- Project POC launched with Innovation factory
- Partnership with artishock.com

**TRIAL**

INCREASE THE QUALITY OF COLD CHAIN PACKING PROCESS FOR CLINICAL TRIALS
THANK YOU!

ANY QUESTIONS?

GARY ROCHE AND OMAR VAN GEEST
Chairman Closing Remarks

Maarten van As
Managing Director
Air Cargo Netherlands (ACN)
Thank you to all our sponsors!
Thank you to our sponsor!

PayCargo®
Welcome Reception 18:00 – 19:30
Exhibition Hall area

Kindly sponsored by
PayCargo®