2nd Medical Valley Inhalation Symposium
The future of inhalation

16 October 2013
09.00–17.00
Medicon Village, Lund, Sweden

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120 delegates from:

- Austria
- Denmark
- France
- Germany
- Hungary
- The Netherlands
- Sweden
- Switzerland
- UK
- USA
Session 1
Future Opportunities of Inhalation
Chairman Karin von Wachenfeldt

09.00–09.30 Welcome
Orest Lastow, MVIC

09.30–10.00 How capsule based DPI systems meet the demand of patients and markets
Frédérique Bordes-Picard, Capsugel

10.00–10.40 Coffee
Session 2
Inhaled biomolecules
Chairman Karin von Wachenfeldt

10.40–11.00 Inhalation of biomolecules
Per Wollmer, Lund University

11.00–11.20 MannKind Technologies: Expanding the pulmonary route for drug delivery Chad Smutney, MannKind

11.20–12.00 Panel discussion – future of inhaled insulin
Moderator, Wollmer, Smutney

12.00–13.30 Lunch
Session 3
IP and regulatory
Chairman Orest Lastow

13.30–14.00 Patents and dry powder inhalation
Jan Trofast, Ligatum

14.00–14.20 Registration of Medicines – with emphasis on inhalation
Elisabeth Joelsson, Joelsson Regulatory Consulting
Session 4
Device and manufacturing aspects
Chairman Orest Lastow

14.20–14.40 pMDI’s – Past, Present and Future?
Philip Cocks, 3M

14.40–15.00 Precision DPI Filling
Marco Laackmann, Harro Höfliger

15.00–15.20 Establishing AstraZeneca Inhalation Product Development on the West Coast
Gunilla Petersson, AstraZeneca

15.20–16.00 Coffee
Session 5
Clinical aspects
Chairman Orest Lastow

16.00–16.20 Inhalation from a patient and clinical perspective
Lars-Göran Carlsson

16.20–16.40 Nasal administration is not dead, it just smells funny
Stefan Ulvenlund, CR Competence

16.40–17.00 The use of industrial design to improve compliance
Jonas Svennberg, Zenit Design

17.00 Closing remarks and end of symposium

18.00 Dinner
2nd Medical Valley Inhalation Symposium
The future of inhalation

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09.00–17.00
Medicon Village, Lund, Sweden

inhalationsymposium.com
How capsule based DPI systems meet the demand of patients and markets?

Inhalation Symposium, Lund (SE)
October 16, 2013
<table>
<thead>
<tr>
<th>Table of content</th>
</tr>
</thead>
<tbody>
<tr>
<td>The challenges and opportunities</td>
</tr>
<tr>
<td>The “unmet” market</td>
</tr>
<tr>
<td>The “unmet” patient needs</td>
</tr>
<tr>
<td>The manufacturing opportunity</td>
</tr>
<tr>
<td>Case studies</td>
</tr>
<tr>
<td>Conclusions</td>
</tr>
</tbody>
</table>
The challenges & opportunities
The key challenges: **Market Re-distribution**

- **European Crisis (PIIGS)** (e.g. Greece € 1.9 billion)
- **Fiscal Cliff** (USA) (drug spending $ 98 billion)
- **Emerging markets** (BRIC) ($121 China vs $892 USA on drugs)

The total market will grow from ~$ 1 trillion to $ 1.2 trillion by 2016, but will have to cover a much more and more demanding patients.
The key challenges: **Market Re-distribution**

Source: IMS Market Prognosis, May 2012; Economic Intelligence Unit, Jan 2012
The key challenges: Aging population in developed countries

Demographic development in Germany: 1956 – 2006 - 2050
The key opportunities: **improving current drug therapies**

In the USA there is a USD 500 bio opportunity for optimizing drug therapy

The major driver is patient adherence

Source: IMS Institute for Healthcare Informatics (2012)
The key opportunities: improving current drug therapies

“Increasing the effectiveness of adherence interventions may have a far greater impact on the health of the population than any improvement in specific medical treatments”

Haynes RB. Interventions for helping patients to follow prescriptions for medications. Cochrane Database of Systematic Reviews, 2001, Issue 1

5 years survival rate of self-reported adherence / non-adherence in patients with stable Coronary Heart Disease

The key opportunities: manufacturing efficiency

“The US pharmaceutical industry could be wasting more than $50bn (€39bn) per year in manufacturing costs due to inefficient processes.” (Macher and Nickerson 2006)

“Manufacturing defects in fact account for almost three-quarters of all drug recalls.” (Dean, Bruttin and van Dyck, April 2005 (Source: U.S. Food and Drug Administration Enforcement Reports, 2000 –2004).
The “unmet” market
COPD remains undiagnosed even in the mature markets (data from USA 2000)

“If you consider the GOLD classification, the Stage II [moderate] and Stage I [mild]... more than 70% maybe are under-diagnosed. When we arrive at Stage III [severe], Stage IV [very severe], it would be around 50%.”

EU key opinion leader

Prevalence of COPD among adults aged 18 and over, by age group and sex: United States, annual average 2007–2009

Akinbami & Liu, CDC Brief N°63, June 2011
Chronic Obstructive Pulmonary Disease (COPD)

Fast growing segment in BRIC countries…

Datamonitor: Forcast insight Asthma/COPD (2010)

…because of high percentage of smokers in the society.

In China

Smokers: 57.4 % ♂ and 2.6 % ♀
Prevalence: 16.7 % (in people aged 50 years and older)
The “unmet” patient needs
Patient associations with asthma / COPD

Patient survey revealed reveals the strong anxiety related to the disease, particularly the fear of crises that can eventually lead to death.
Patients disease burden (COPD/asthma)

1. The disease itself

Impact on quality of life

- Reduced physical activities.
- Triggering of crises in highly emotional situations.
- Problems carrying out daily activities.

Fear of crises

- Strong irritation caused by the uncontrollable and urgent aspect of crises
- Need to keep one’s treatment close at hand
Avoidance of social life

- Because of the fear of crises, they avoid certain activities. Some asthmatics feel they live a marginal social life.
- Patients are embarrassed by taking medication in public.
- Patients do not want to be considered as ill people by others.
Patients disease burden (COPD/asthma)

3 The treatment

Treatment rituals

• Patients often have several treatments:
  • A basic treatment generally in the form of a dry powder inhaler
  • A crisis treatment in spray form
• The inhaler is the visible STIGMA of this disease.
Key attributes in the acceptance of an inhaler delivery system

Primary criteria of most importance are:

- **Easy to use**
  - Avoid additional stress when there is a crisis
  - Do not complicate treatment
  - A simple treatment that does not make the disease overly important

- **Discreet**
  - Be discreet during administration in order to avoid attracting the attention of others
  - No bright colors in order to avoid making it attractive to children
  - It has to fit easily in the palm of the hand

- **Easy to carry**
  - It has to fit in a pants pocket
  - Designed to be able to fit in a small carrying case with everything

- **Evaluation of remaining doses**
  - Be able to count the number of remaining doses
  - Be able to anticipate the next doctor’s visit to renew the prescription
Key attributes in the acceptance of an inhaler delivery system

Secondary criteria of less importance are:

- **Easy loading**: Be able to load a dose in the device easily, hygienically and quickly.
- **Hygiene**: Be able to lock and keep clean the parts of the system in contact with the mouth and the inhalation chamber.
- **Doses and device sold separately**: For reasons of cost and avoiding waste.
Affordability (Millennium Development Goal (MDG) 8, Target 8.E)

Annual healthcare spending in Pharmerging markets is below USD 100


“The majority of medicine purchases are made *out of pocket* in low- and middle income countries, making affordability of medicines a key determinant of access.”
The manufacturing opportunity
Cost structure of pharmaceutical manufacturing per unit operation

- GMP space
- Number of surrounded equipment
- Energy
- Solvent/water/detergence
- HVAC
- Validation/qualification
- QA/QC/QbD
- Operators/planning
- Cleaning/waste
- Maintenance
- Yield losses
- Inventory/JIT implication
- Depreciation
- Equipment effectiveness (utilization time)
- Safety stocks
Cost structure of pharmaceutical manufacturing per unit operation

- GMP space
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- HVAC
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- QA/QC/QbD
- Operators/planning
- Cleaning/waste
- Maintenance
- Yield losses
- Inventory/JIT implication
- Depreciation
- Equipment effectiveness (utilization time)
- Safety stocks

Overheads! Shared across all products equally

St. Gallen report 2006
COGS key considerations

• The **performance of the finished product** and the fine particle fraction delivered to the lung
• Amount of **capital investment** for the manufacturing operation
• The level of utilizing **standard operation** processes and **OEE** achieved in manufacturing
• The **number of components** for the product and primary packaging (blister, container, capsule)
• The **number of unit operations and complexity** to manufacture the product
• The **number of the high precision pieces**, assembly and finishing of the device
• Level of technology **ownership**
• Technology **flexibility** in terms of products and capacity for quick market response and low **operational capital**
Manufacturing of blister based DPI

Line concept for manufacture of blister–based DPIs

Blister manufacturing (1)
Blister strip buffer (2)
Blister coiling and
Inhaler assembly (3)
Manufacturing of capsule based DPI

**Capsule Filling**

Capsule filling (1)

Fill weight check (2)
COGS key considerations

KISS principle: Keep It Simple and Safe
COGS key considerations

KISS principle: Keep It Simple and Safe
Case studies
Capsule-based Dry Powder inhaler (DPI)

Dry Powder Inhaler (DPI) consists of

1. Device
2. Powder container (capsule)
3. Interactive powder mixture (API, powder blend, porous particles)
Case study

Brand and patient recognition
Shrestha R, Shakya R (2009) COMPARISON OF BRONCHODILATOR EFFECT OF SALBUTAMOL DELIVERED VIA MDI AND DPI IN COPD PATIENTS

A study performed 2007-2008 in Nepal.

Overall evidence suggests that although both MDI & DPI improve the lung function of COPD patients to similar extent, DPI is cheaper and more preferred and can be easily handled by the patients which can result in reduction of non-compliance.

Source: SAARC J. TUBER. LUNG DIS. HIV/AIDS 2009 VI (2) 22-30
Case study

Advair Diskus vs Rotahaler

• GSK is testing a capsule-based inhaler, in exploring a cheaper version of its best-selling asthma therapy for emerging markets or to compete with generic versions.

• Glaxo completed a 60-patient, mid-stage trial in June 2011 comparing its Advair Diskus dry-powder inhaler against the capsule-based version of the drug-device combination.

• A single-dose, capsule-based inhaler is less complex and less expensive than the Advair Diskus, and may be aimed at customers in emerging market

GSK corporate communication Feb 9, 2012
Conclusions
Conclusions

• The traditional market landscape for pharmaceutical products is changing, with regard to
  ✓ regional coverage
  ✓ pricing
  ✓ expectations
  ✓ demographics

• “Patient centricity” will be key in moving from “drug” to “therapeutic outcome”

• Product and process design will have a major impact on final COGS and manufacturing efficiency level
Conclusion

There is no ideal device, but a very good understanding on how to develop and improve pulmonary drug delivery

device – capsule – formulation

• Lung deposition has been markedly improved from older capsule based inhalers (Rotahaler 6.2%) to the newer ones (Aerolizer 13-28%, Flowcaps 44%)

• The performance of new generation capsule based inhalers is at the same level as multidose devices (Turbuhaler 15-31%, Easyhaler 25-35%)
Many thanks to
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Pharmaceutical Business Development Manager
phone: +33 6 8385 9896
e-mail: frederique.bordes-picard@capsugel.com
Inhalation of biomolecules

Per Wollmer

Dept. of Clinical Sciences, Malmö
Lund University
Prime biomolecule: insulin

25.8 million children and adults in the United States — 8.3% of the population — have diabetes (2011).

Due to the progressive nature of type 2 diabetes, insulin therapy is eventually indicated for many patients with type 2 diabetes.

American Diabetes Association
The need for injections is perceived as an important barrier to the initiation of insulin treatment.
Psychological Insulin Resistance in Type 2 Diabetes Patients

Petrak et al., *Diabetes Technol Ther* 2013; 15: 703
Psychological Insulin Resistance in Type 2 Diabetes Patients

- Positive insulin-related outcome expectation 7.33/10
- Fear of hypoglycemia 6.17/10
- Stigmatization by insulin injections 4.21/10
- Expected hardship from insulin therapy 4.13/10
- Fear of injection 3.13/10

Petrak et al., *Diabetes Technol Ther* 2013; 15: 703
Port of entry: the lungs

Rationale: The lung offers an absorption area of 100 m$^2$
Aerosol particle deposition in the normal lung

Adapted from Byron J Pharm Sci 1986
Inhaled insulin

Four large projects:

Pfizer – Exubera
Novo Nordisk – AERx
Eli Lilly – AIR
Mannkind – Afrezza
Absorption of inhaled insulin: diabetes type I

Brunner et al. Diabetologia 2001; 44: 305
Absorption of inhaled insulin: differences between systems

Afrezza contains the excipient fumaryl diketopiperazine
• Pulmonary absorption of insulin is faster than s.c. absorption.

• Pulmonary absorption of insulin is incomplete; only approx. 15% of the insulin deposited in the lungs is absorbed.
Inhaled insulin compared s.c. insulin: HbA1c

<table>
<thead>
<tr>
<th>Study, Year (Reference)</th>
<th>Study Duration, wk</th>
<th>Weighted Mean Difference (95% CI), %</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type 1 diabetes</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skyler et al., 2001 (15)</td>
<td>12</td>
<td>0.15 (−0.20 to 0.50)</td>
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<tr>
<td>Garg et al., 2006 (25)</td>
<td>12</td>
<td>−0.10 (−0.29 to 0.09)</td>
</tr>
<tr>
<td>Quattrin et al., 2004 (20)</td>
<td>24</td>
<td>0.14 (−0.04 to 0.32)</td>
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<tr>
<td>Skyler et al., 2005 (23)</td>
<td>24</td>
<td>−0.11 (−0.30 to 0.08)</td>
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<tr>
<td>Heise et al., 2005 (12)</td>
<td>24</td>
<td>0.00 (−0.38 to 0.38)</td>
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<tr>
<td>Exubera study 1027, 2005 (9)</td>
<td>24</td>
<td>0.07 (−0.07 to 0.21)</td>
</tr>
<tr>
<td>Exubera study 1022, 2005 (9)</td>
<td>104</td>
<td>0.25 (0.13 to 0.37)</td>
</tr>
<tr>
<td><strong>Type 2 diabetes</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cappelleri et al., 2002 (16)</td>
<td>12</td>
<td>0.17 (−0.23 to 0.57)</td>
</tr>
<tr>
<td>Hermansen et al., 2004 (18)</td>
<td>12</td>
<td>0.08 (−0.21 to 0.37)</td>
</tr>
<tr>
<td>Hollander et al., 2004 (19)</td>
<td>24</td>
<td>−0.07 (−0.31 to 0.17)</td>
</tr>
<tr>
<td>Exubera study 1029, 2005 (9)</td>
<td>104</td>
<td>0.09 (−0.05 to 0.23)</td>
</tr>
<tr>
<td><strong>All studies</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.08 (0.03 to 0.14)</td>
</tr>
<tr>
<td>Study duration: 12 wk</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>0.01 (−0.13 to 0.14)</td>
</tr>
<tr>
<td>Study duration: 24 wk</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.03 (−0.06 to 0.11)</td>
</tr>
<tr>
<td>Study duration: 104 wk</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>0.18 (0.09 to 0.27)</td>
</tr>
<tr>
<td>Type 1 diabetes</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.09 (0.03 to 0.16)</td>
</tr>
<tr>
<td>Type 2 diabetes</td>
<td></td>
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</tr>
<tr>
<td></td>
<td></td>
<td>0.06 (−0.04 to 0.17)</td>
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Inhaled insulin compared to oral agents in type 2 diabetes: HbA1c

<table>
<thead>
<tr>
<th>Study, Year (Reference)</th>
<th>Study Duration, wk</th>
<th>Weighted Mean Difference (95% CI), %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weiss et al., 2003 (17)</td>
<td>12</td>
<td>−2.20 (−2.70 to −1.70)</td>
</tr>
<tr>
<td>Rosenstock et al., 2005A (22)</td>
<td>12</td>
<td>−1.20 (−1.43 to −0.97)</td>
</tr>
<tr>
<td>Rosenstock et al., 2005B (22)</td>
<td>12</td>
<td>−1.67 (−1.90 to −1.44)</td>
</tr>
<tr>
<td>DeFronzo et al., 2005 (21)</td>
<td>12</td>
<td>−0.89 (−1.23 to −0.55)</td>
</tr>
<tr>
<td>Barnett et al., 2006 (24)</td>
<td>24</td>
<td>−0.20 (−0.38 to −0.02)</td>
</tr>
<tr>
<td>Exubera study 1002, 2005 (9)</td>
<td>24</td>
<td>−0.20 (−0.41 to 0.01)</td>
</tr>
</tbody>
</table>

All studies: $I^2 = 68.9\%$

Study duration: 12 wk: $I^2 = 39.3\%$

Study duration: 24 wk: $I^2 = 0\%$

• Inhaled insulin works, both in T1D and T2D.
Inhaled insulin: special circumstances
Absorption of insulin from the lungs of smokers

Absorption of insulin from the lungs during exercise

Exercise increases the rate of absorption but not bioavailability

• Reduced bioavailability in asthmatics

Bioavailability improves after bronchodilatation in subjects with reversible obstruction

COPD

- Absorption variable – increased or decreased cf. control subjects
- Reasons not clear
Inhaled insulin: is it safe?
- No acute effects on lung function in asthmatics

Pulmonary function declines mainly during the initial treatment and then remains stable

Raskin et al., *Diabetes Obes Metab* 2012; 14: 163.
In the Exubera phase III trials: more cases of lung cancer in the inhaled insulin groups than in controls.

Monitoring of subjects on inhaled insulin will be necessary.
Inhaled insulin

Four large projects:

- Pfizer – Exubera
  - Launched 2006, withdrawn 2007

- Novo Nordisk – AERx
  - Closed in phase III

- Eli Lilly – AIR
  - Closed in phase III

- MannKind – Afrezza
  - NDA submitted 2009, resubmitted October 2013
Where did it go wrong?

- Needle fear overestimated?
- Change in treatment paradigm - shrinking market
- Cost issues
- Difficult to convince endocrinologists
- First product to market awkward to use and poorly marketed
The fate of Afrezza will probably be very important for the future of inhaled biomolecules.

so

if you are interested in inhaled pharmaceuticals, wish MannKind luck.
MannKind Oral Inhalation Technologies: Expanding Pulmonary Route for Drug Delivery

MVIC Symposium
October 16, 2013
Overview of MannKind Technologies

- Innovative technologies that enable drug delivery by oral inhalation
- Designed to achieve clinical benefit
- Patient-friendly breath-powered inhalers
- Integration of advanced formulation science with practical device designs
- Provide sensible and simple self-administered medicines.
- Tailored to API properties and therapeutic indication
MNKD Oral Inhalation Technologies

Introduction

Powder

Device

Development Tools
Technospheres® Technology
Dry Powder Formulations
Technospheres® Particles: What Are They?

Microparticles formed from FDKP (fumaryl diketopiperazine)

Chemical structure of FDKP

- Crystalline particle
- Amorphous particle

Graph showing solubility as a function of pH
FDKP – Ideal Excipient

- **FDKP is the ideal excipient for inhalation drug delivery**
  - Compatible with wide range of API
    - MW 500 to 150,000 Da
    - Drug content 0.5 to 90% by weight
  - Reproducible, well-controlled particle formation
    - Particle size fixed prior to API introduction
    - No sizing, milling or blending required
  - No metabolism
    - Excreted unchanged in urine
  - Full toxicology package available
    - Chronic toxicology in 2 species
    - Carcinogenicity in 2 species
    - Reproductive toxicology
    - Safety pharmacology
    - Genetic toxicology
Making a Crystalline Technosphere Powder

1. Drug Solution
2. Technosphere® Suspension
3. MIX
4. Adjust pH
5. Pellet into liquid nitrogen
6. Lyophilize

Crystalline particles
Making an Amorphous Technosphere Powder

- Drug Solution
- FDKP Solution
- MIX
- Spray Dry

Amorphous particles
Technosphere® Inhalation Powder

pH < 6
as TI Inhalation Powder

pH > 6
in the lungs
Technosphere® Technology
Characteristic PK Profile

Adapted from Amer Coll of Phys J, from Kipnis, DM, Ann Int Med, 69(5), 1968 (with permission)
Improved Post Prandial Glucose Control with TI (MKC-TI-03B)

* ANOVA transformation, $P = 0.0073$
Device Technology
Dry Powder Delivery

Attributes
- Breath powered, high resistance
- Simple, easy-to-use, discreet
- Pre-metered drug
- Low cost and manufacturable
- Application across therapies

Re-usable Dreamboat™ Family

Single Use Cricket™ Family
DreamBoat™ Inhaler System

Highlights
- 5 part plastic inhaler
- Cartridge opened by inhaler
- Ease of use for patients ≥ 4 yrs of age
- Efficient flow mechanics

Highly Manufacturable
Low part count with top-down assembly

Simple Use and Operation
Open, load, close, inhale
Cricket™ Inhaler System

Highlights
- 2 part plastic inhaler
- Inhaler opened with push button
- Ease of use for patients ≥ 4 yrs of age
- Efficient flow mechanics

Highly Manufacturable
Low part count with top-down assembly

Simple Use and Operation
Push, inhale
Delivery Performance

Standard Testing – Predictive Impaction

- DreamBoat™ with Technosphere® powder
  - Aerodynamic particle size assessment
    - 4 kPa pressure (22 LPM)
    - High fine particle fractions and excellent emptying

### Aerodynamic Performance – NGI

<table>
<thead>
<tr>
<th>Dreamboat Inhaler</th>
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<tbody>
<tr>
<td>Powder</td>
</tr>
<tr>
<td>Fill Mass (mg)*</td>
</tr>
<tr>
<td>Drug Content (µg)*</td>
</tr>
<tr>
<td>% Empty from Cartridge</td>
</tr>
<tr>
<td>Delivered Dose (µg)</td>
</tr>
<tr>
<td>FPF** (≤ 5.0 µm)</td>
</tr>
</tbody>
</table>

* Based on nominal content
** FPF is ratio of fine particle dose to delivered dose
Development Tools
Development Tools

Non-standard Testing - BluHale, Anatomical Models, and MIDAS
- Bring Patient Factors into the lab
  - Anatomy, physiology, and delivery performance
    - Flexible test conditions (pulse, pressure, volume, etc)
  - Typical “mass to filter” values of 70% for MKC combinations
Development Tools

*Working to improve pre-clinical DPI test models*

- **Current insufflation technique is challenging (small rodent)**
  - Discharging of 1-3 mg dry powder with 2-3 mL of air
  - Air volume and timing (discharges) limitations

- **Automated discharge in-sync with animal breathing patterns**
  - Reduced air volume, multi-pulse approach (timed with breathing pattern)
  - 500 µL needed per pulse, 5-10 pulses needed for 1-3 mg

---

1. **Actuator**
   - Strap mounted accelerometers monitor animal breathing.

2. **Insufflator Module**
   - Breathing signal is analyzed. When inhalation is detected, the actuator is discharges the powder. Multiple low volume pulses occur at defined points in the inhalation.

3. **Powder discharge device**
   - Rodent delivery cannula

---

**Powder discharge is actuated**
Clinical and Nonclinical Examples
## GLP-1 Technosphere® Study Summary

<table>
<thead>
<tr>
<th>Pharmacology</th>
<th>Significant Adverse</th>
</tr>
</thead>
<tbody>
<tr>
<td>✅ insulin secretion</td>
<td>✗ reduced well-being</td>
</tr>
<tr>
<td>✅ ↓ fasting &amp; PP glucose</td>
<td>✗ profuse sweating</td>
</tr>
<tr>
<td>✅ ↑ heart rate</td>
<td>✗ nausea</td>
</tr>
<tr>
<td>✅ ↑ blood pressure</td>
<td>✗ vomiting</td>
</tr>
<tr>
<td>✅ delayed gastric emptying</td>
<td></td>
</tr>
<tr>
<td>✅ ↓ food intake/satiety</td>
<td></td>
</tr>
</tbody>
</table>
Opioid Efficacy in Mice

- Pain relief comparable to morphine without opioid side effects
  - Respiratory depression
  - Locomotion
  - Addiction
- Extremely rapid onset of pain relief
- Inhaled using breath-powered, disposable inhaler
MannKind Technologies Summary

- **Dry powder formulations**
  - Can be used for wide range of APIs
  - Simple, reproducible particle formation and performance
  - Ideal excipient for inhalation drug delivery
  - Excellent bioavailability and rapid kinetics

- **Inhalation devices**
  - Customized for patient needs and medical indications
  - Simple, easy to use, discreet inhalers
  - Applicable to wide range of therapies and formulations
  - Low COGs

- **Advanced development techniques**
  - Translational medicine approach, bench to bedside
  - Patient-focused development
Introduction to MannKind Oral Inhalation Technologies

MVIC Symposium
October 16, 2013
2nd Medical Valley Inhalation Symposium
The future of inhalation

16 October 2013
09.00–17.00
Medicon Village, Lund, Sweden

inhalationsymposium.com