



Connecting People, Science and Regulation

Development and Usability of Disposable Autoinjectors

Advantages of Platform Products for Pharma Customers

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Development and Manufacture of Self-Injection Devices

- **Ypsomed is a leading medical technology company in the field of self-injection solutions** and products for the treatment of diabetes
- **Ypsomed has 30 years of experience in the development and manufacture of injection pens, infusion systems and pen needles**
- Ypsomed is headquartered in Burgdorf, Switzerland, and employs approx. **1,100 people**
- Sales in the 2014/15 financial year: CHF 306.6 million
- **Vision: Ypsomed solutions make self-care simpler and easier**





Contents

- Market development of disposable autoinjectors
- Usability developments of disposable autoinjectors
- Pharma needs and platform advantages
- Technology aspects in platform development
- Automation considerations and quality control





Market Development of Disposable Devices - 1

1980s

Launch of first reusable pens



NovoPen (Novo Nordisk)



OptiPen® I (Hoechst)



KabiPen (Kabi)

1990s

Launch of first disposable pens



Novolet (Novo Nordisk)



OptiSet (Hoechst)

2000s

Next generation disposable pens
First disposable autoinjectors



SoloSTAR (Sanofi)



Humira (AbbVie)



Enbrel (Amgen)

2010s

Approx. 3-5 disposable pens
Approx. 15 disposable autoinjectors



FlexTouch (Novo)

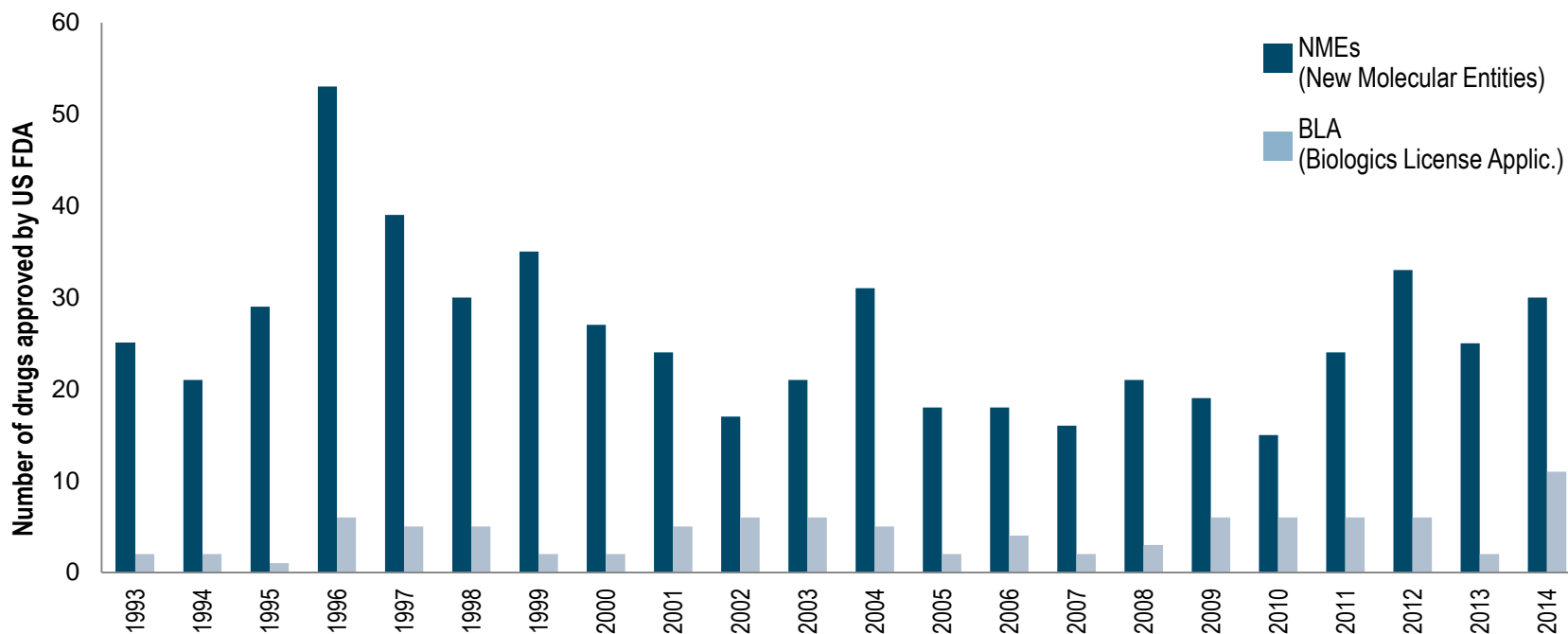


Repatha (Amgen)



Market Development of Disposable Devices - 2

- Patent expiration Many new therapies in phase 3 in the areas of diabetes, autoimmune asthma, cancer, cardiovascular etc.
- of important (blockbuster) injected products
- Global injectable market keeps growing – up to \$225 billion by 2020





Disposable Autoinjector Landscape



SHL DAI



SHL Amber „push-click“ AI



Ypsomed YpsoMate



Lilly's Trulicity AI



SHL Biogen Plegridy

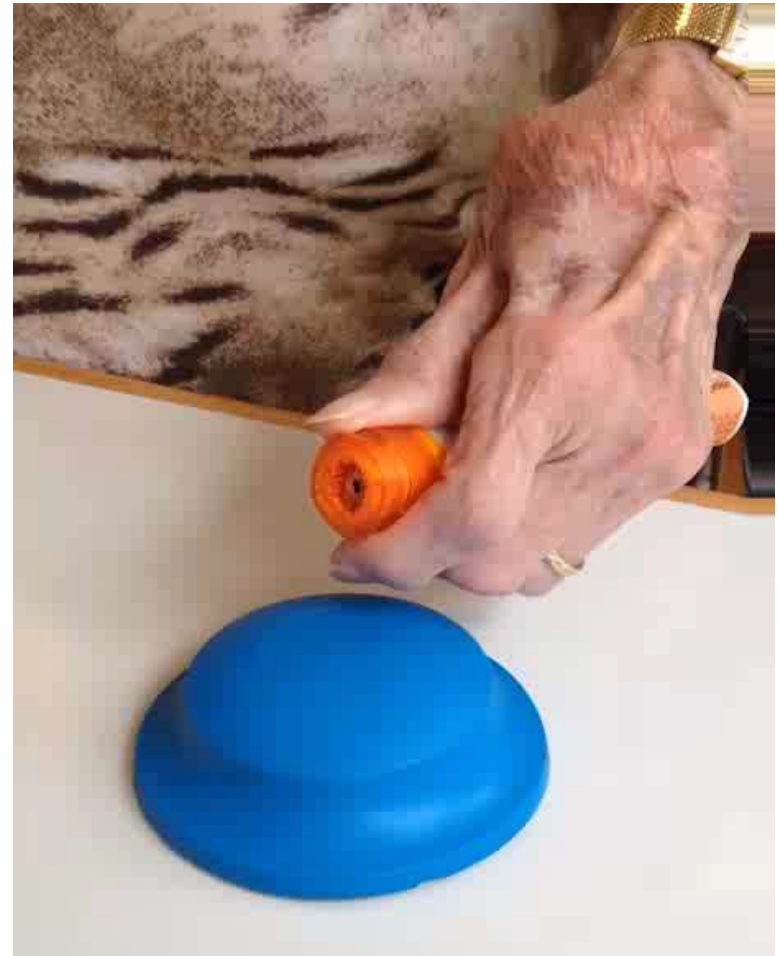


Bespak Syrina



Formative User Studies

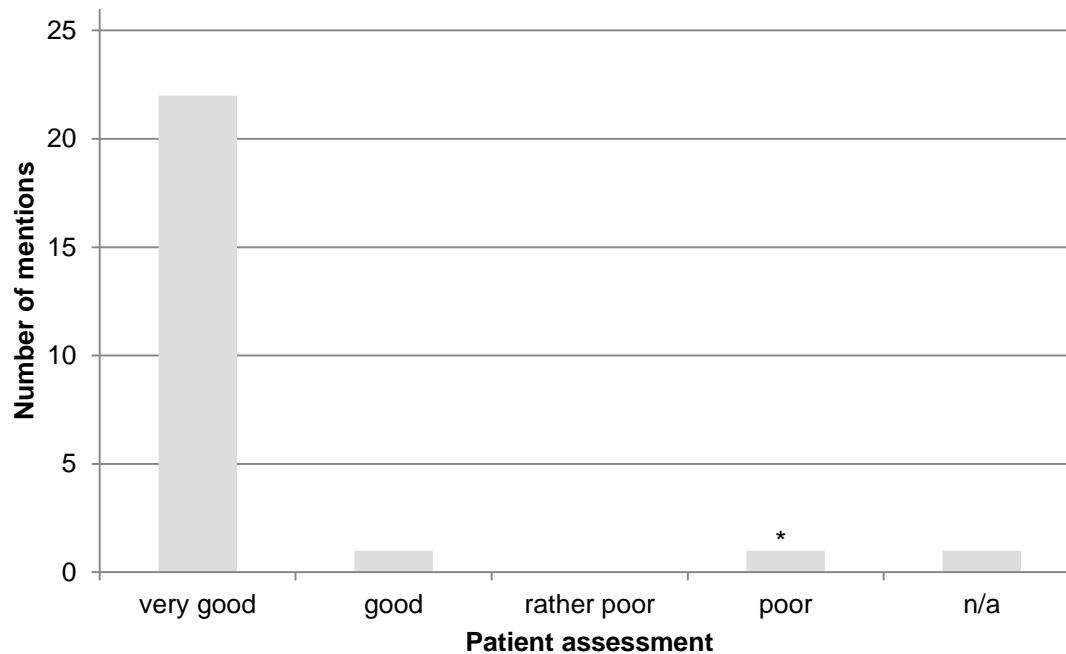
- YpsoMate has been tested in various formative and summative human factor studies during customer projects
 - Feedback is important
 - Audible start and end of injection signals
- Large viewing window
- Broad formative handling studies published in peer-reviewed journals, findings
 - Discrete and compact design desired
 - Fewer operation steps preferred, 2-step handling principle preferred to 3-step operation





User Feedback – Triggering the Injection

- “Better than my Humira pen: Only push, no need to press a button in parallel.”
- “Simple to use”
- “I do not like to see the needle”

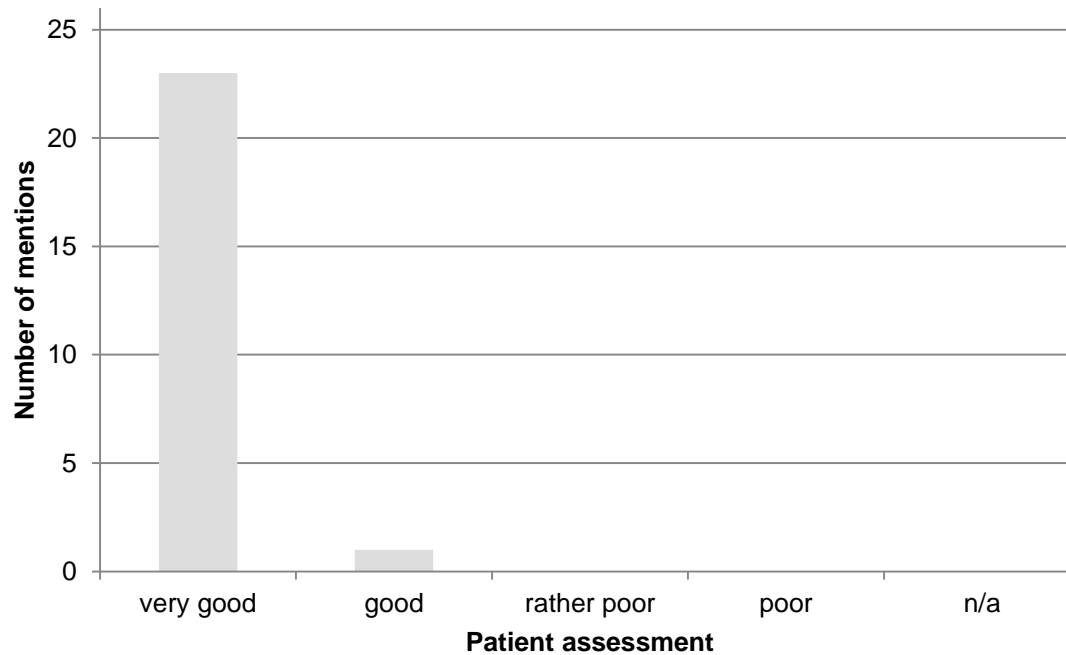


* Felt pain in the wrist when using the device. Was rather critical throughout the evaluation.



User Feedback – Gripping the Housing

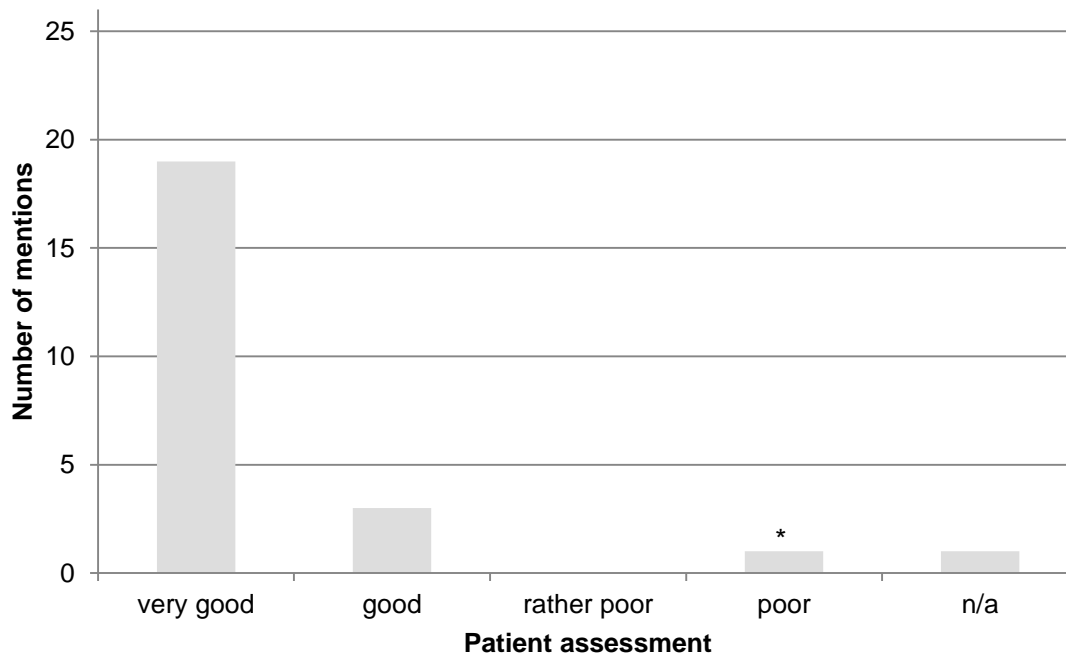
- “Good shape – not completely round”
- “Diameter is OK for RA patients”





User Feedback – Overall Impression

- “I like not to see the needle”
- “I would use it”
- “Don’t like to waste that much plastic – it should not be bigger”



* Felt pain in the wrist when using the device. Was rather critical throughout the evaluation.



User Feedback – Customer Studies

Please provide three words to describe the device you used today:

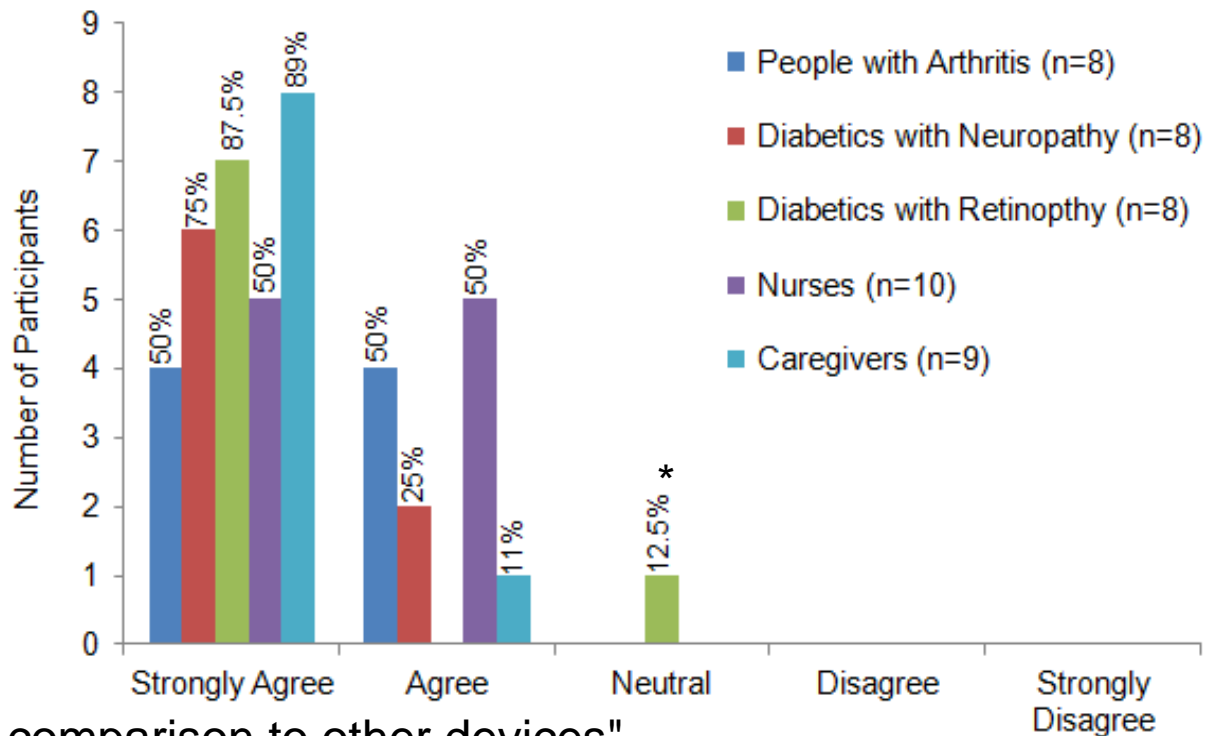


I am not a big fan of the activation button..... to me no button is ingenious

I felt very confident....it was very easy fewer steps made it better



User Feedback – I felt confident when using YpsoMate

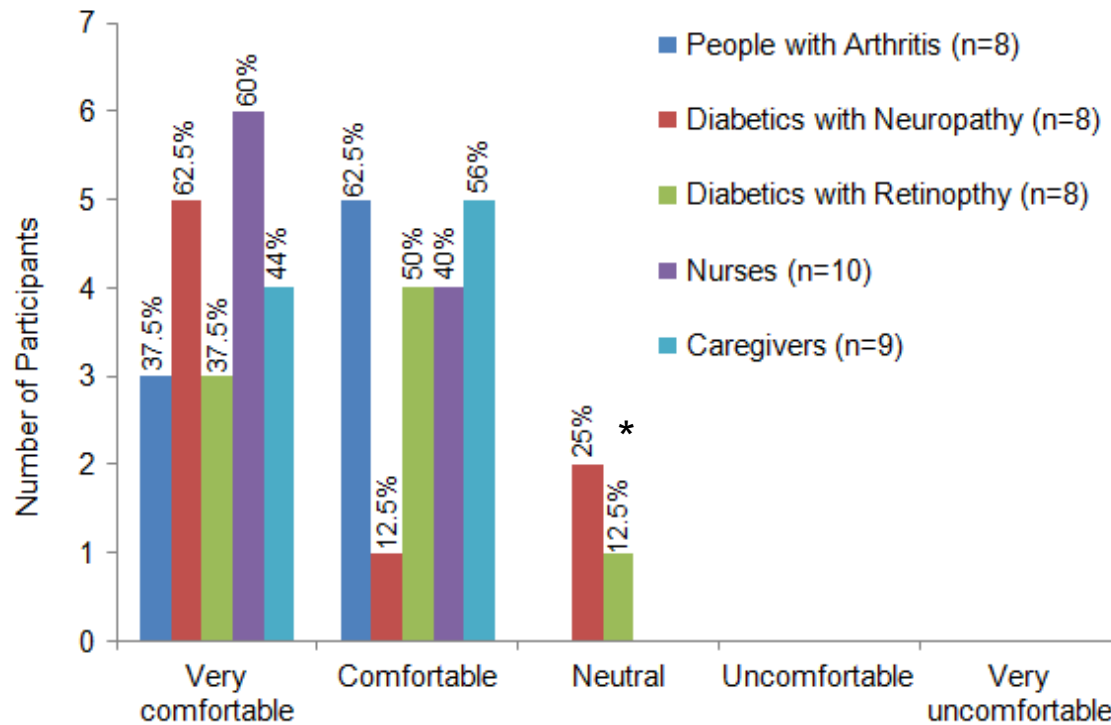


"Simple in comparison to other devices"
"Easy to use"

* Was uncertain about using the device.



User Feedback – How would you rate your hand comfort when injecting?



"Good grip (steady and easy to control)"
"Device is comfortable to hold"

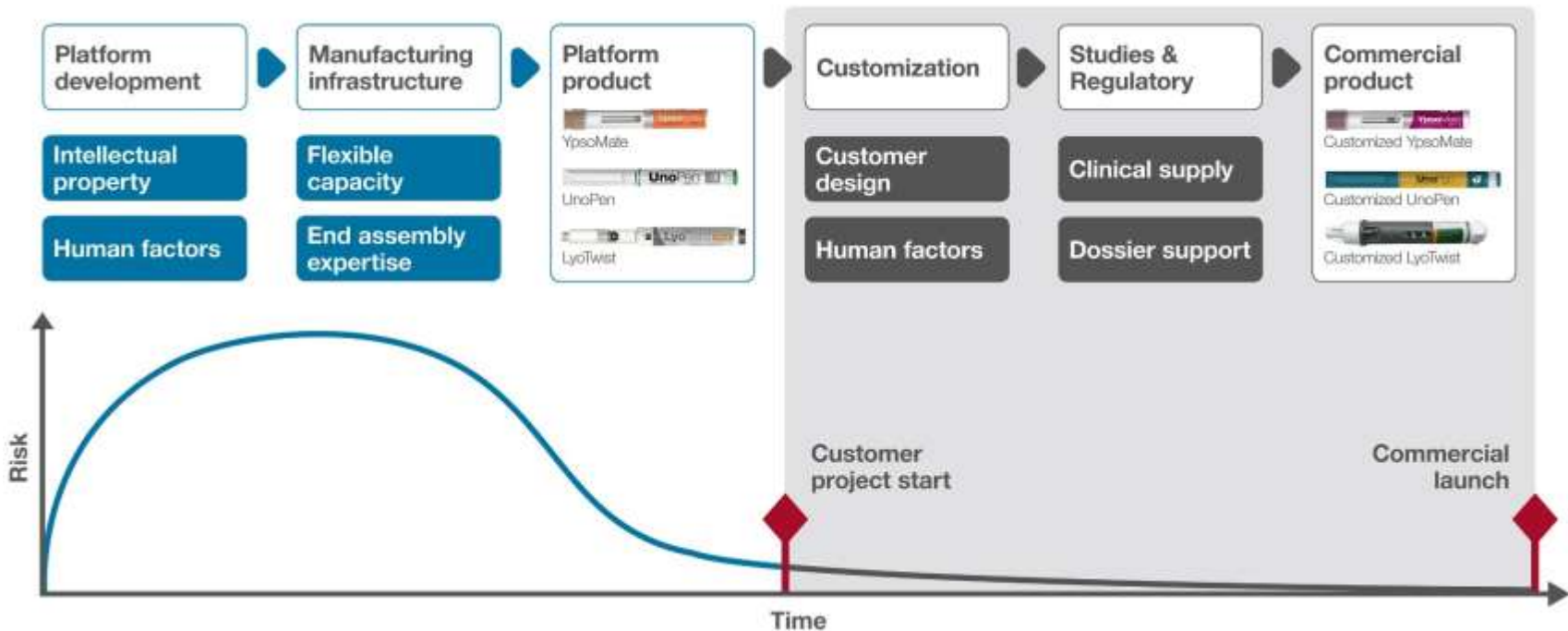
* Was uncertain about using the device.



Pharma's View on Quality

- **State-of-the-art** device, based on **proven** technology
- Available **quickly** (time-to-clinic and time-to-market) and at **low risk**
- **No changes** of the device between **clinic and market**
- **Flexibility** to use for different **drug entities**
- **Clear differentiation** from competition
- **Product differentiation** based on **sound usability**
- Designed for **large-scale manufacturing**, **automated manufacturing capacity** available

Device Platform Development Aspects



Development of new platform products decoupled from customer projects. Risk moved in-house to cover platform development and installation of manufacturing infrastructure



ODM View of Customised Product Approach

- **Provide innovation** by developing new features **without time-pressure**
- **Reduce project risks** by basing customer projects on **proven technology**
- **Shorter and more reliable** commercial **project timeline**
- **Prototype devices** available for **handling studies**
- **Devices available quickly** for clinical trials
- **Reduced project costs** and **sharing of manufacturing** equipment
- **Established patent** position
- **Flexibility** due to **modularity**



Automation Strategy – Disposable Devices are Complex

- Single cavity moulds are only used during innovation phase
- Typically 2-cavity base moulds only used for customer specific parts
- Fully automated manufacturing infrastructure available for clinical quantities





Automation Strategy – Manufacturing

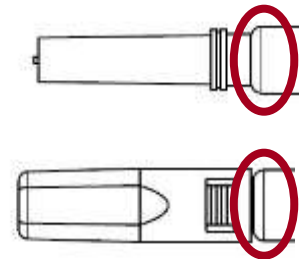
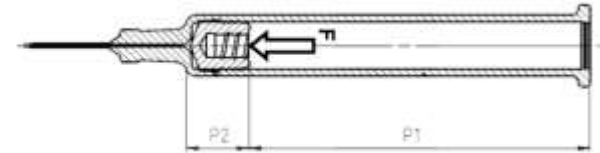
- Immediate scale-up from 2-cavity to 8-/16-/32-cavity tools for most industrial-scale components
- Fully automated assembly equipment flexible to accommodate different versions and customer capacities
- No scale-up issues



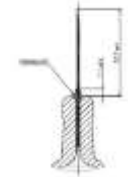


Customisation Aspects

- Adaptation to primary container, drug volume, viscosity, air bubble
- Definition of needle insertion depth
- Adaptation to needle shield type
- Clever platform solutions are compatible with existing standard primary packaging containers



 <p>Special flange design to resist impact of plunger rod</p>	 <p>RMS designed to suit the decapping process</p>	 <p>Higher dimensional tolerances</p>
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Unique and cost-efficient designs

- Customers require clear differentiation from their competitors, yet want to use the benefits of platform products
- Maintain the full automated infrastructure for different device designs:
 - Free-form areas as part of the industrialised platform
 - Outer shells offer highest flexibility and may include soft-touch components



YpsoMate® in platform shape



YpsoMate® with modified free-form areas



YpsoMate® Design offering full flexibility of shape



Quality Control

- Implementing proper quality control in fully automatic systems is a challenge but leads to a new level of safety and confidence
- Automatic performance control of assembly stations in real time
- Camera controls
- In-line functional checks
- Seamless interface with SAP system, all parts entering the machine are traceable in the finished product





Shared Equipment Approach

- Sharing equipment was reserved to fill & finish CMOs, but has now reached ODM companies
- Access to manufacturing capacity at only a fraction of cost
- No investment in equipment that may become redundant
- Flexible capacity that perfectly suits changing market demands
- Clear differentiation from competitors through various design options





Fully Automated Autoinjector Manufacturing Line





End Assembly Expertise

- Understanding the end-assembly process is the starting point of the concept development process
- Final assembly takes place at contract filling, customer and packaging specialist sites
- Partnering with equipment suppliers needs to cover the full range of clinical and industrial quantities





Summary

- **Usability is key to all successful products → disposable pen and autoinjectors are mature, but many innovations still to be made**
- **Platforms speed up** time-to-clinic and time-to-market at lower risk
- **Automated manufacturing** needs to be an **integral part of the innovation cycle** to facilitate easy scale-up
- Demand for **specific and exclusive** self-injection devices is **compatible with easy to access proven technology**
- Pharma partners appreciate **flexible access to the latest manufacturing infrastructure** at a **fraction of the associated cost** for installing their own equipment



Thank you for your attention

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