



# Injection device platform technologies

*The adoption of platform technologies by pharma customers*

*PDA Europe*

*UPS, DDS Global Technical, Regulatory & Quality Challenges*

*Vienna, 10. October 2017*

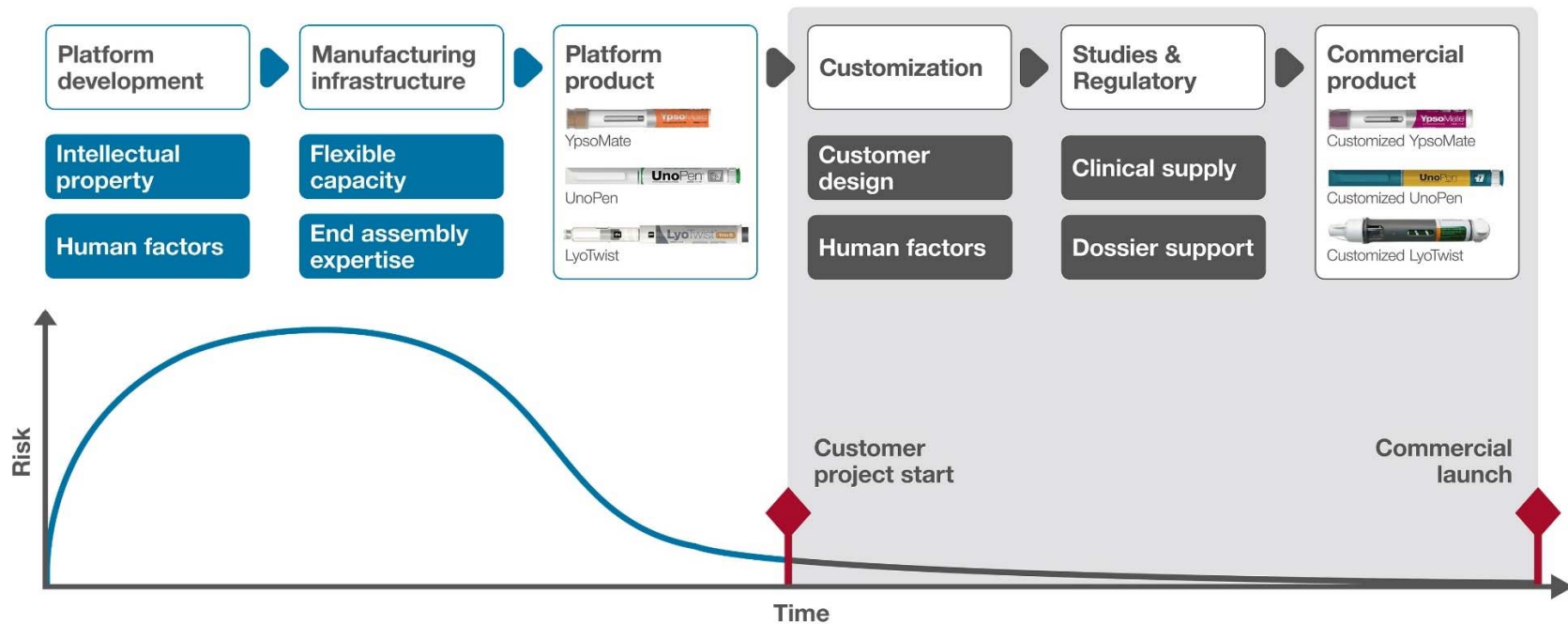
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*Ypsomed*

- General approach to platform technologies
- Manufacturing and scale-up
- Quality and regulatory aspects



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



## Why develop / select a platform?

- **Innovate** by developing new features **without time-pressure**
- **Reduce project risks** by basing customer projects on **proven technology**
- **Shorter and more reliable** commercial project timelines
- **Prototype devices available** immediately for handling studies
- **Clinical devices available quickly**
- **Reduce project costs** and **share manufacturing equipment**
- **Known and established patent position**





## Pharma's view

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

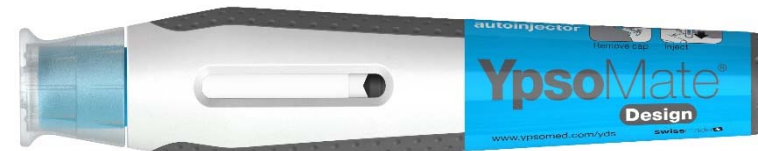
- Customers require clear differentiation from their competitors, yet want to use the benefits of platform products
- The aim is to maintain the full automated infrastructure for different device designs:
  - Free-form areas as part of the industrialised platform
  - Outer shells offer highest flexibility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



**YpsoMate in platform shape**

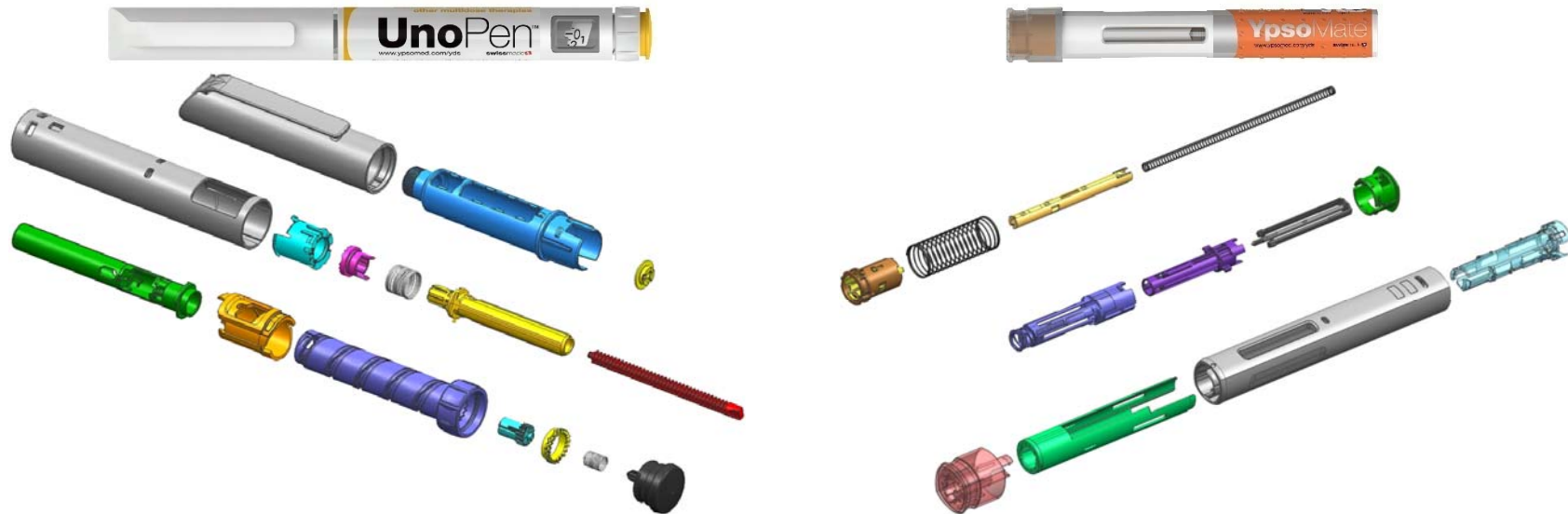


**YpsoMate with modified free-form areas**



**YpsoMate Design offering full flexibility of shape**

- Pens and autoinjectors 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



- 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
- Reliability of supply





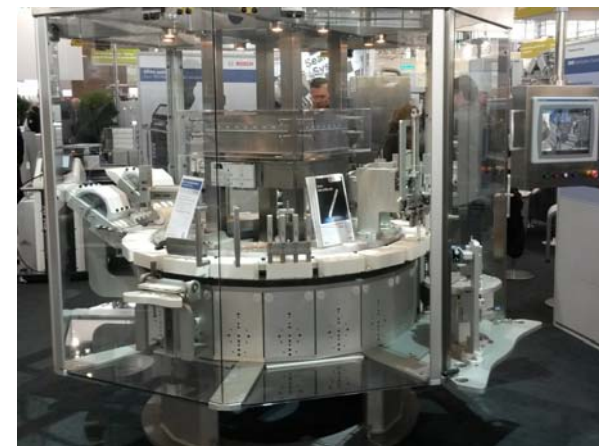
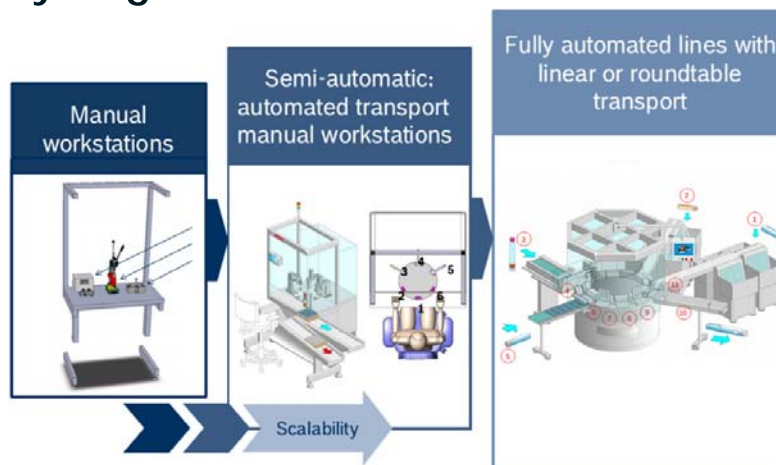
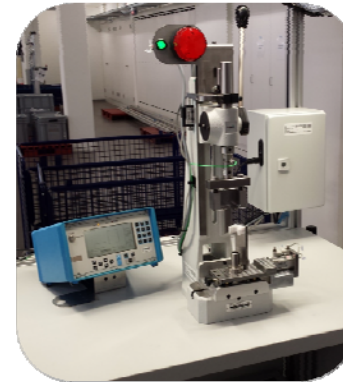
- **Sharing equipment** was reserved to fill & finish CMOs, but has now reached ODM companies
- Access to **manufacturing capacity** at only a fraction of the cost
- No investment in **equipment** that may become redundant
- **Flexible capacity** that suits changing market demands
- Clear **differentiation**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

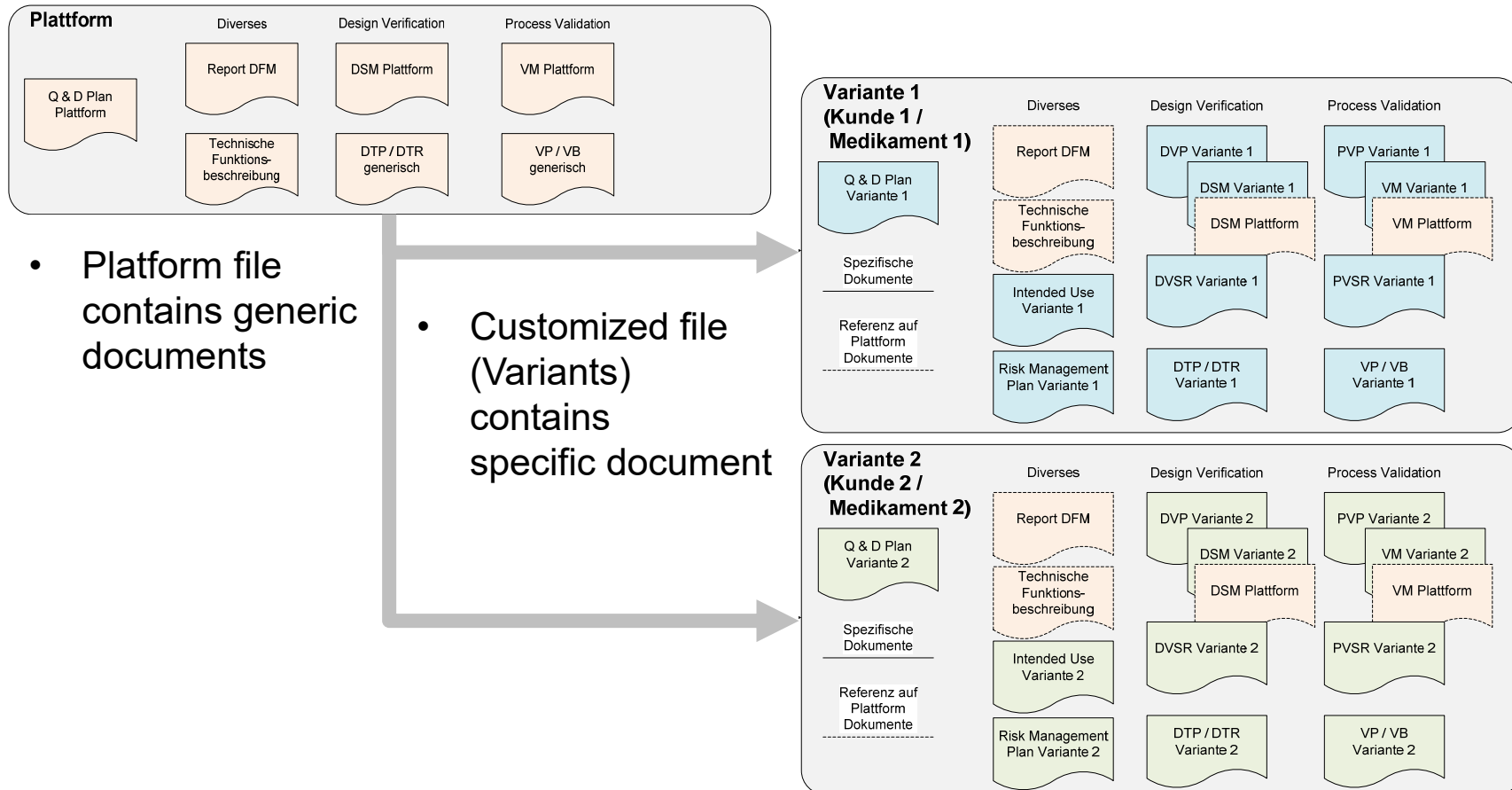


- Implementing proper **quality control** in fully automatic systems is a challenge but leads to a **new level of safety** and confidence
- Automatic **performance control** of each assembly station in real time
- **Camera** controls of colours and parts
- **In-line functional checks** of all assembled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



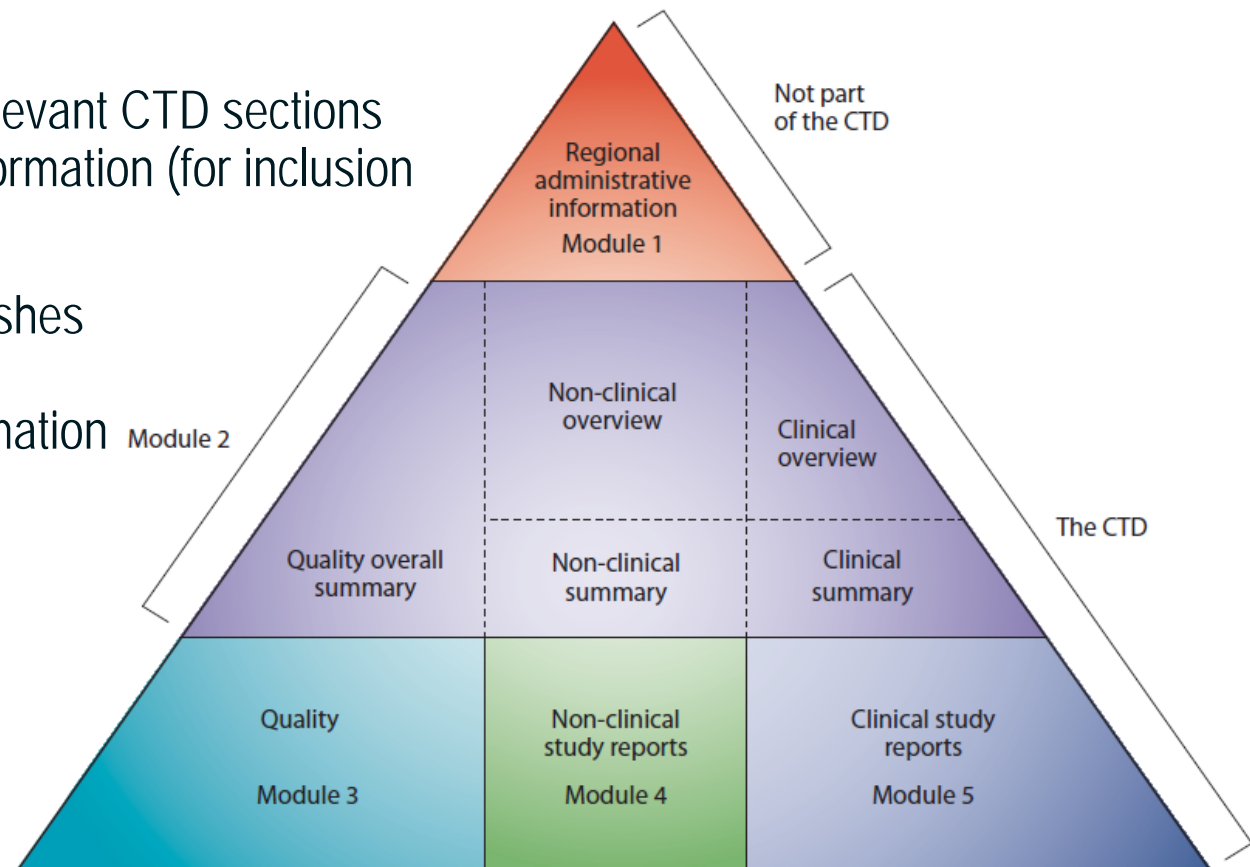
- Range of manual, semi-automated and fully automated workstations available from reputable manufacturers
- Pharma customers, contract fillers and packers building up internal expertise → leveraging platform synergies





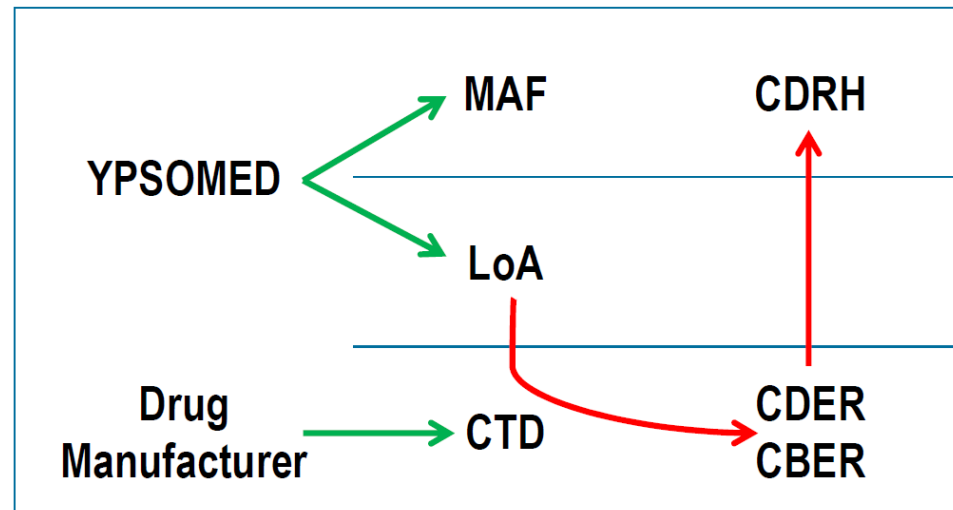
## CTD approach (ICH)

- Device mfr. provides relevant CTD sections with device relevant information (for inclusion in 3.2.P, 3.2.R)
- Pharma customer publishes and submits CTD containing device information



## Master File Approach (MAF, primarily US)

- Device mfr. submits a Master File with device information
- Letter of Authorization issued for customer submission
- Pharma customer submits CTD with Letter of Authorization
- FDA reviews MAF for device-relevant information





## Summary

- **Maturing technologies** allow the development and industrialisation of **platform devices** for pens, autoinjectors and wearable injectors
- Demand for **specific and exclusive self-injection devices** is compatible with easy to access **proven platform devices**
- **Pharma customers** appreciate flexible access to the **latest manufacturing infrastructure**
- **Synergies** related to equipment, manufacturing processes, manufacturing capacities and documentation **result in more flexibility and reduced risks all at a lower cost**



Thank you for your attention...  
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