



# Lifecycle Management for Drug Delivery Devices

*What is driving the industry?*

*PDA Europe*

*Workshop Innovative Drug Delivery Systems*

*Vienna | 6 November 2017*

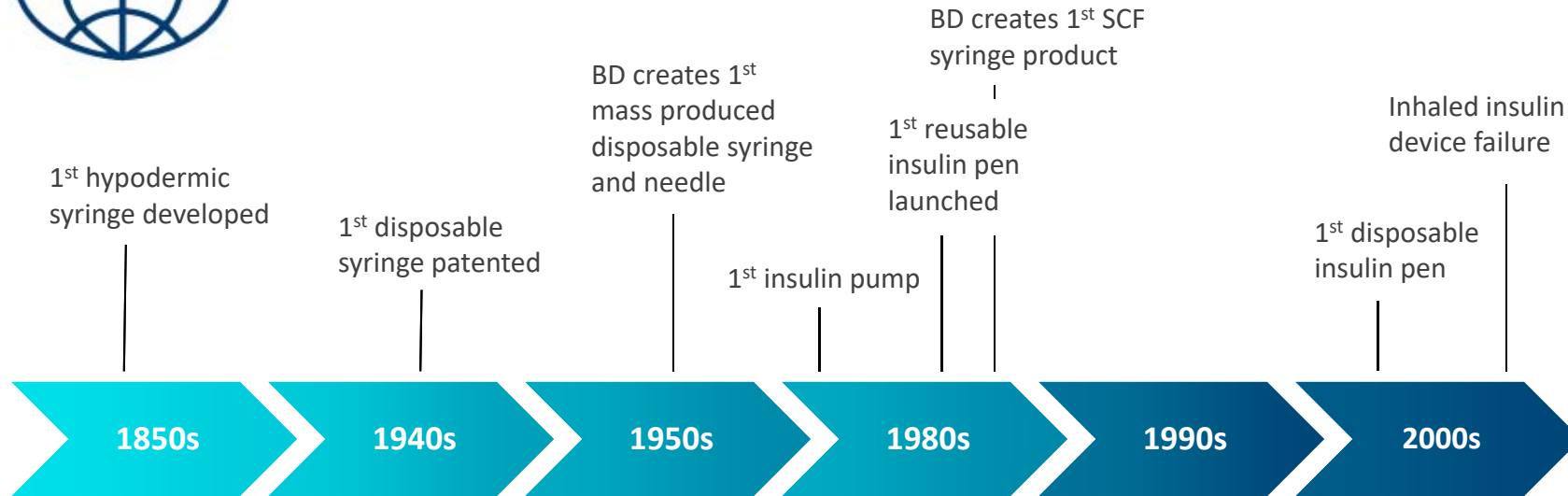
*Dr: Thomas Schönknecht*

*SHL Group*





# Pharmaceutical Drug Delivery Has Evolved Substantially



Syringe

rDNA Product Commercialization

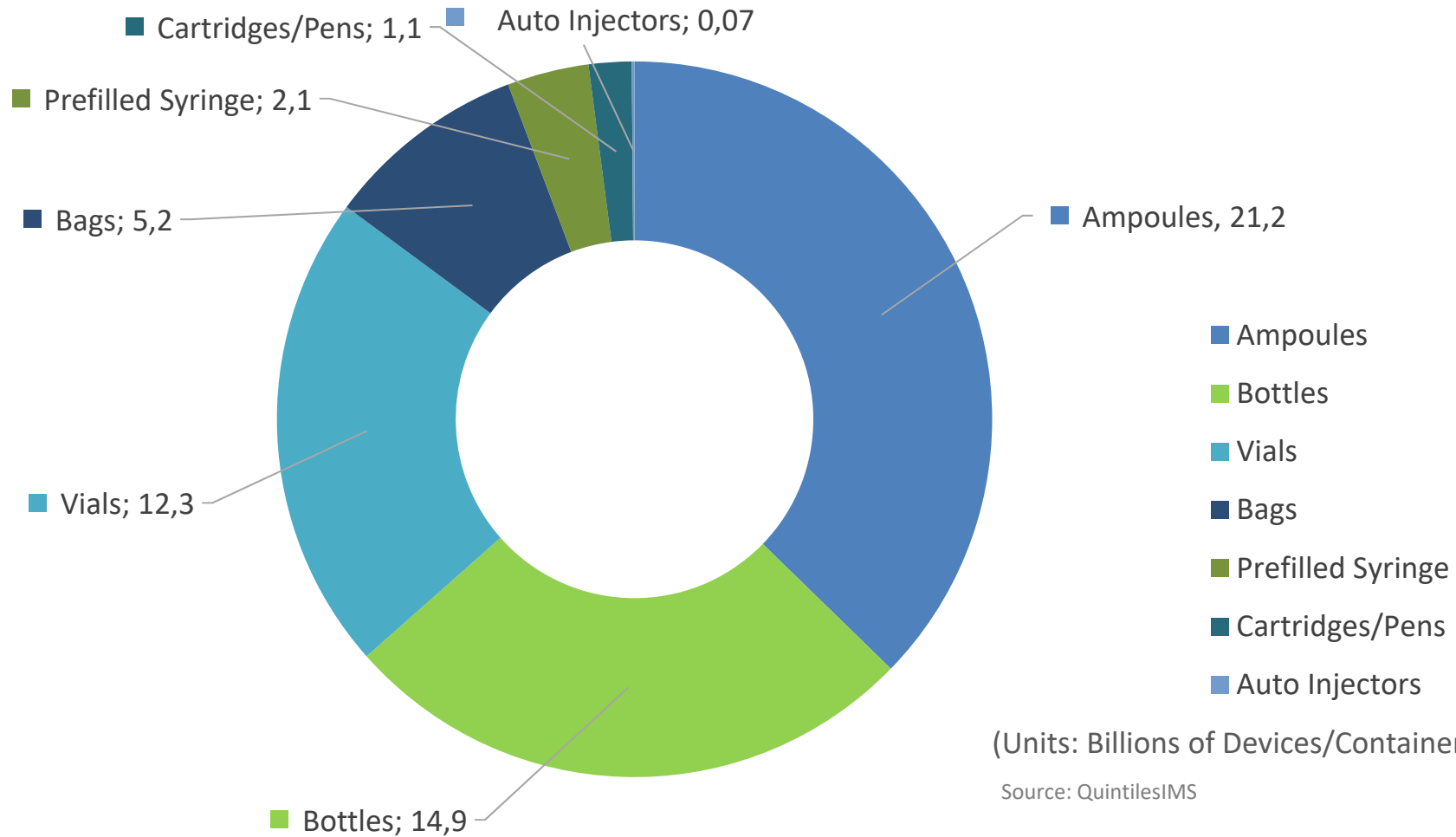
Devices

- hGh Pen
- Hep Pen
- hGh NF
- MS Als
- Anti-TNF Als



Source: Amgen

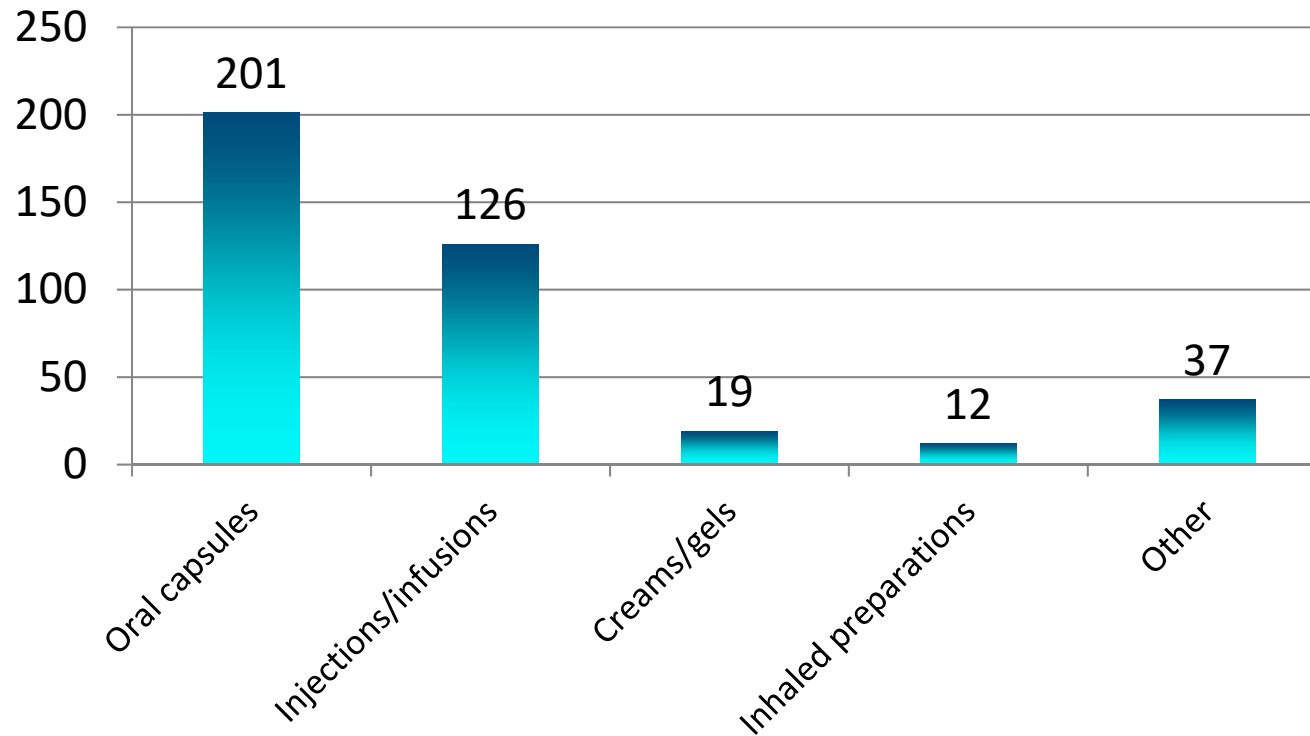






# Growth in the Number of Drugs Approved for Self-Injection

New drug approvals by FDA  
Jan 2010 - April 2017

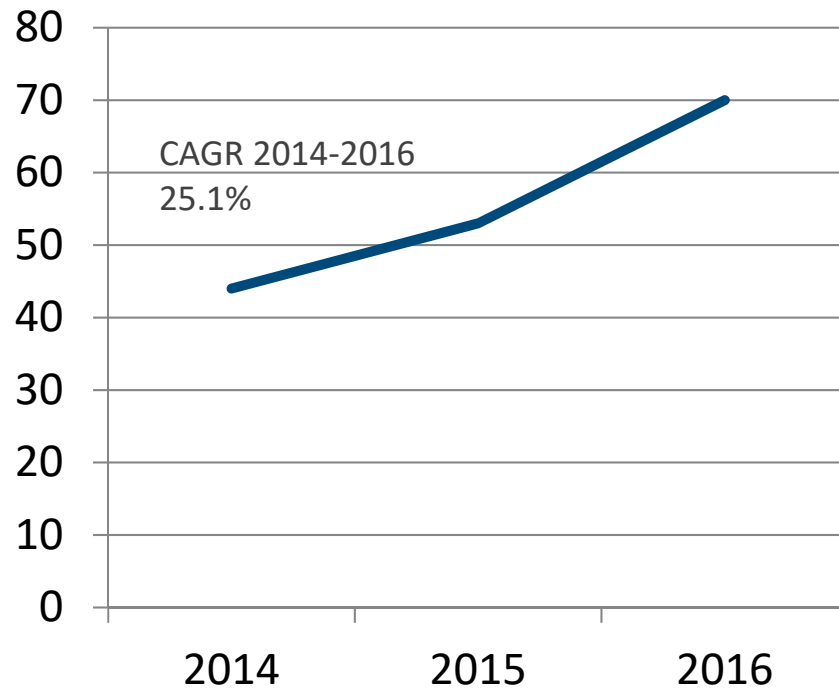


Source: [www.centerwatch.com](http://www.centerwatch.com) & [www.accessdata.fda.gov](http://www.accessdata.fda.gov)



# Growth in the Number of Drugs Approved for Self-Injection

Global sales of auto injectors  
2014-2016



(Unit: Millions)

Source: Quintiles IMS

## Of 28 first-time approvals for subcutaneous home injection:

- 6 are in ampoules/vials only
- 22 are with an advanced drug delivery system

## Devices help simplify drug application



**Complex**

**Simple**

Mixing station  
11/98

Vial adapter  
10/03

50mg PFS  
11/04

50mg auto injector  
7/06



X Steps

Y Steps

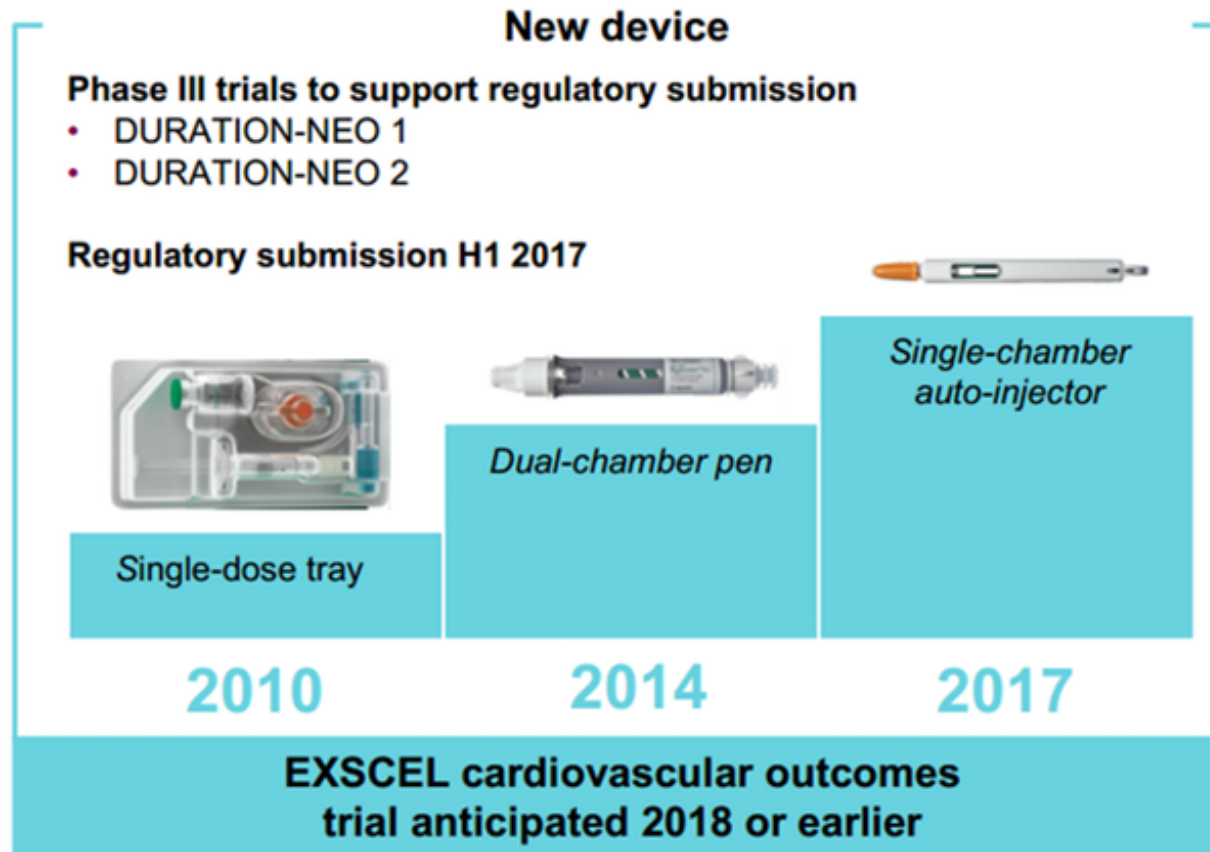
Z Steps

A-B-Click

Source: Amgen

Device evolution has yielded products that are more convenient and easier to operate

## Bydureon Innovations





Reservoir Inspection Window

### Amgen OnPro™ - Launched in 2015



Light for Visual Feedback

Source: Amgen



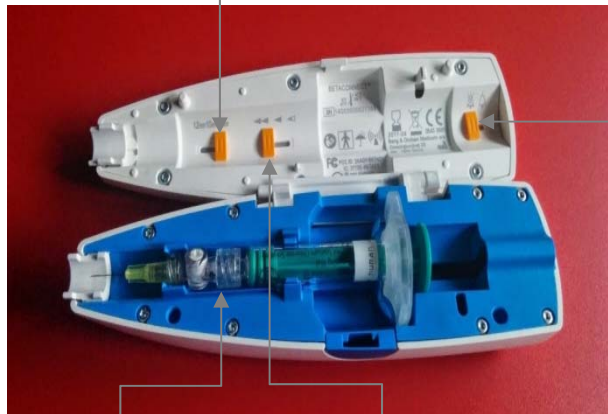
- Device in kit alongside Neulasta PFS
- Based on Insulet insulin pump
- Device actuated when drug reservoir is filled by HCP using Neulasta PFS
- Patient wears for 27 hours, dose is automatically administered through cannula
- 3Q 2017: 56% of patients converted to OnPro Kit

Device permits patients to get Neulasta without having to return to HCP the next day



### BetaConnect™ - Reusable Auto Injector

Adjustable Needle  
Penetration Depth



Sound On/Off

PFS After  
Reconstitution

Source: Bayer



- Electromechanical reusable auto injector
- Fixed dose, PFS-based
- Quiet motor driven device
- Connectivity feature: patient opts in
- Patient comfort settings: needle depth, injection speed, injection reminder
- One-touch injection button
- End-of-dose indicator

Typical MS therapy regimen requires 3 injections per week

### What is driving lifecycle management?

- Market trends
- Patients' needs and feedback
- Manufacturing improvements
- Competition products
- Regulatory issues



**Thank you for your attention**