



By your side
for a healthier world™

Advantages of Prefilled Syringes and Market Trends in Primary Packaging

Hands-on Training Course, PDA Universe of Prefilled Syringes

Thursday 9th November 2017 – [25 min]

Christa Jansen-Otten

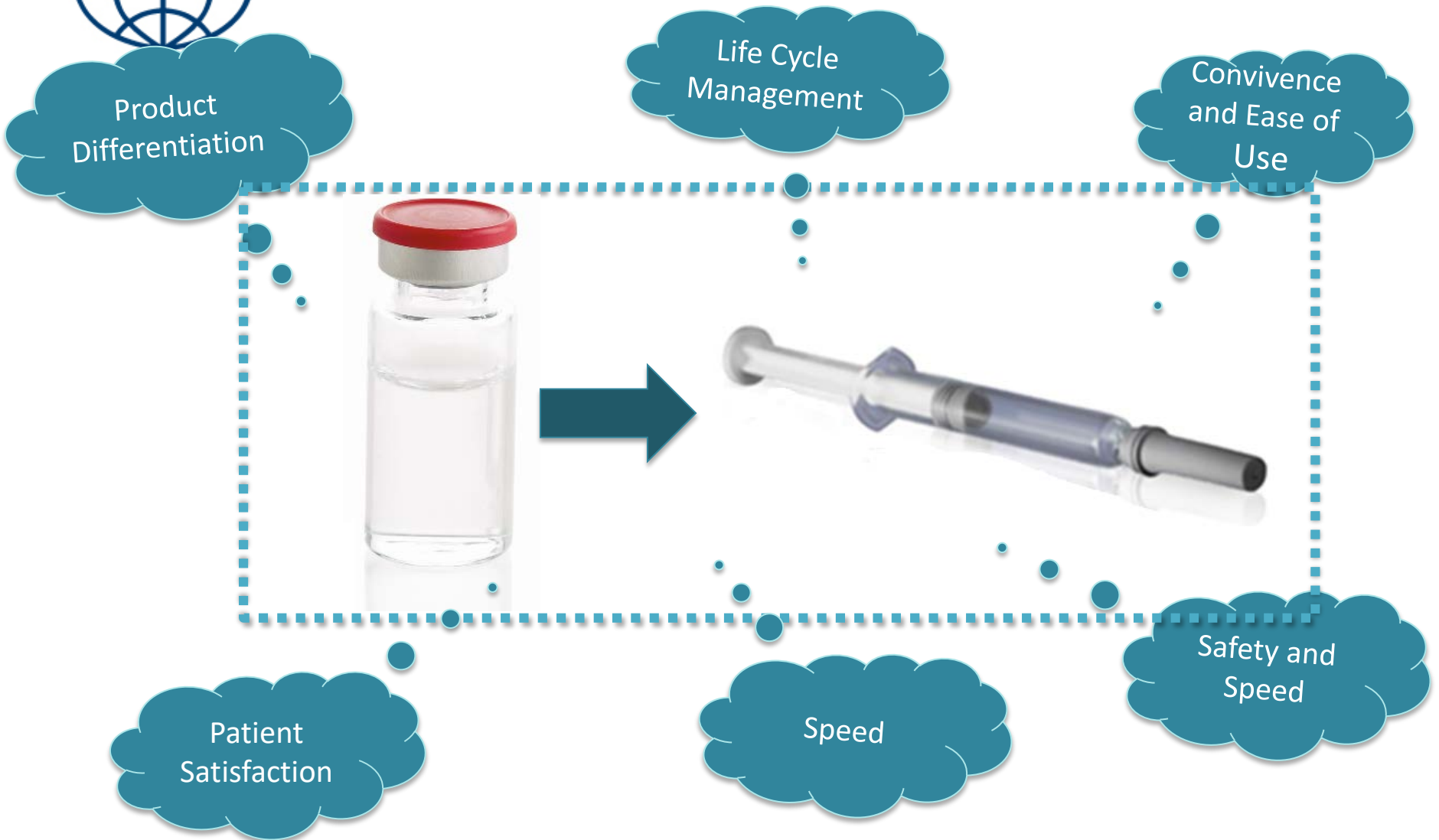
Advantages of Prefilled Syringes

Statistics

Market Trends



Why change from a drug filled in a vial to a pre-fillable syringe? - Some Thoughts







Preparing injection for
COPAXONE[®] filled in a vial

235 sec.



Preparing injection for
COPAXONE[®] filled in PFS

38 sec.

A typical patient is able to save about **20h a year** by using
Copaxone[®] in a PFS format

Copaxone[®] is a registered trademark of Teva Pharmaceutical Industries Ltd.

Steps to prepare Lyophilizate for Injection: the “old way”

- 1 • Take empty syringe
- 2 • Attach cannula
- 3 • Draw WFI from vial into syringe
- 4 • Change Cannula
- 5 • Pierce lyo stopper and insert water into lyo vial
- 6 • Dissolve lyophilizate
- 7 • Take new syringe and attach cannula
- 8 • Draw drug into syringe
- 9 • Attach injection cannula onto syringe
- 10 • Inject drug into patient

Steps to prepare Lyophilizate for Injection: the “optimized way”

- 1 • Open syringe and screw it onto the vial adapter
- 2 • Pierce lyo vial with the vial adapter and transfer WFI into syringe
- 3 • Dissolve lyo product
- 4 • Invert vial and withdraw drug into the same syringe
- 5 • Disconnect syringe from vial adapter and attach injection cannula
- 6 • Inject Drug into patient



Reduce the risk of microbial contamination
...which can occur from improper aseptic techniques.

Less overfill compared to MDV's (multi Dose Vials)

Reduce the Risk of Medication Errors
...Elimination of potential dosing errors – pre-measured doses

Ease of Use
Easier to apply for health care professionals and patients home use

Work well with safety devices and auto-injection systems
...making the injections easy, safe, and convenient.

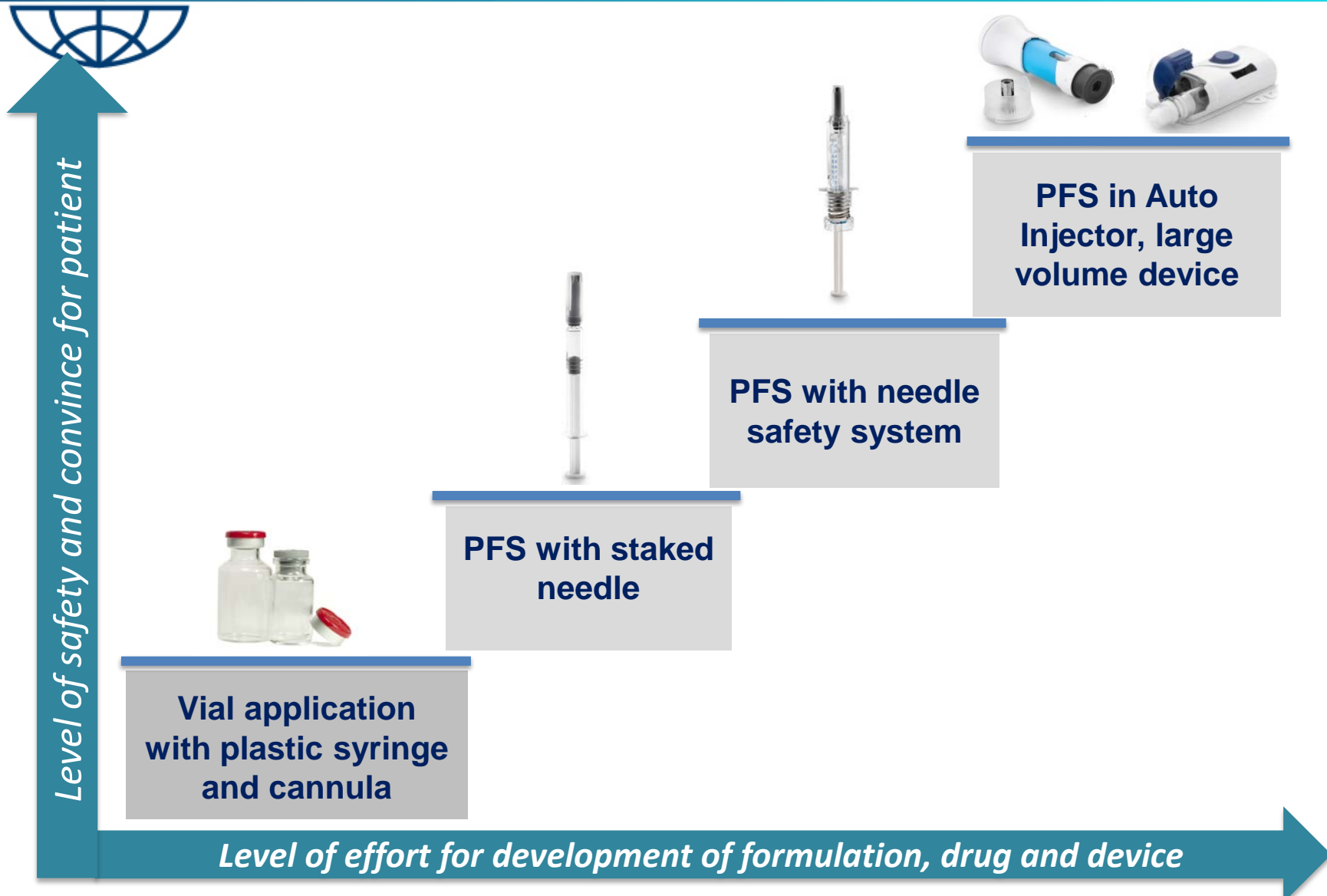


Safer injection
for both doctors and patients

Less wastage, disposal

Convenient for
Emergency Use

Less Time consuming
compared to MDVs





Statistics & Market Trends

- Global Pharma Market is forecasted to reach \$1.3 trillion by 2019, an increase of 30% over 2014
- Developed Market growth driven by innovation, new therapy class and expensive biologic drugs
- Pharmerging Market (21 countries) overall growth slowed down from 11% to a single digit of 5-8% to 2019

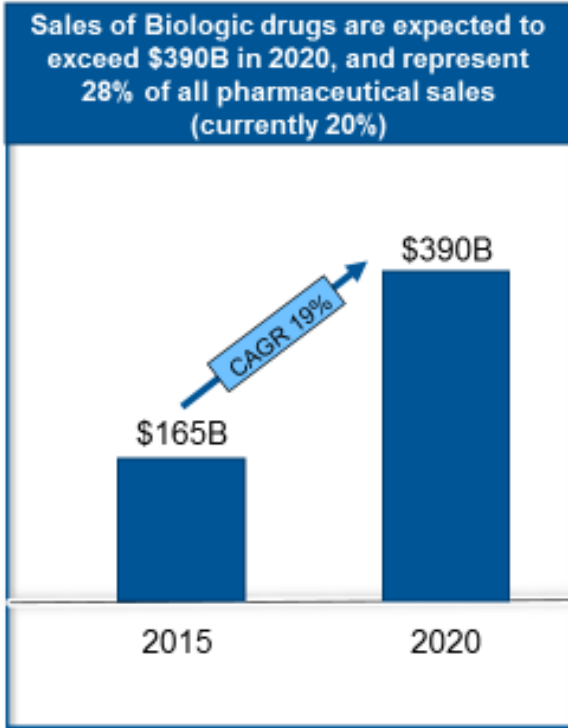
Developed Markets CAGR 2015 - 2019	
US	6% - 9%
Japan	0% - 3%
Germany	2% - 5%
UK*	4% - 7%
France	-2% - 1%
Italy	3% - 6%
Canada	3% - 6%
Spain	2% - 5%
Developed	4% - 7%

Pharmerging Markets CAGR 2015 - 2019	
China	6% - 9%
Brazil	1% - 4%
India	11% - 14%
Russia	-3% - 0%
Mexico	3% - 6%
Turkey	4% - 7%
Pharmerging	5% - 8%

- At par with region CAGR
- Lower than region CAGR
- Higher than region CAGR

Data Source: 2016 IMS Midas Audited Global Sales Data

The Landscape for Biologics Shows Significant Growth Compared to Other Segments

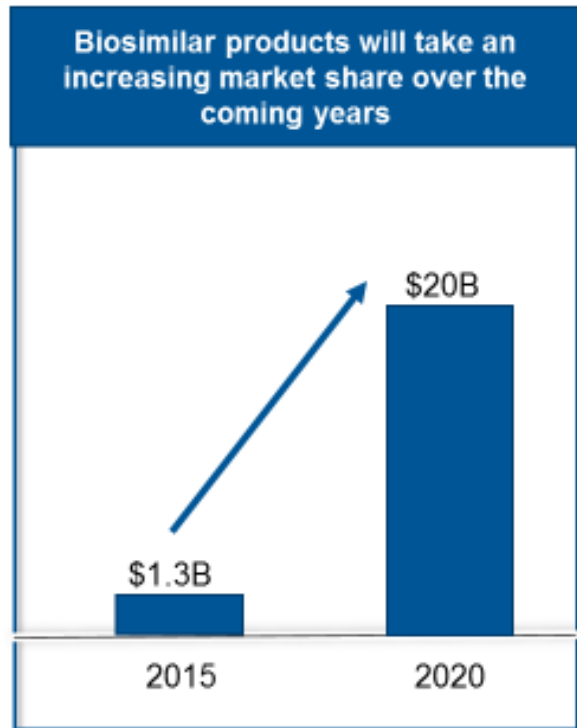


Source: IMS, March 2016. "Delivering on the promise of biosimilar medicines"

8 of top 10 drugs are Biologics, compared to 3 in 2010

Company	Drug	2015 sales (\$B)
abbvie	Humira	14.4
GILEAD	Harvoni	13.9
AMGEN	Enbrel	9.1
janssen	Remicade	9.0
Roche	Rituxan	7.3
SANOFI	Lantus	7.1
Roche	Avastin	6.9
Roche	Herceptin	6.8
Pfizer	Prevnar	6.2
Celgene	Revlimid	5.8

Source: MedAd news annual report Aug 2018



Source: IMS, March 2016. "Delivering on the promise of biosimilar medicines"

Continuing to grow faster than other segments

Strong pipeline, multiple companies, advent of biosimilars, new therapies (Cell/Gene)

Majority of biologics require injection

Transitioning the point of care

Hospitals > Clinics > Home

Trained professional > Patient

More sophisticated biologics drugs

Larger molecules = higher concentration = higher dose volume or viscosity

Increased sensitivity: Extractables/leachables, Silicone Oil, Particles

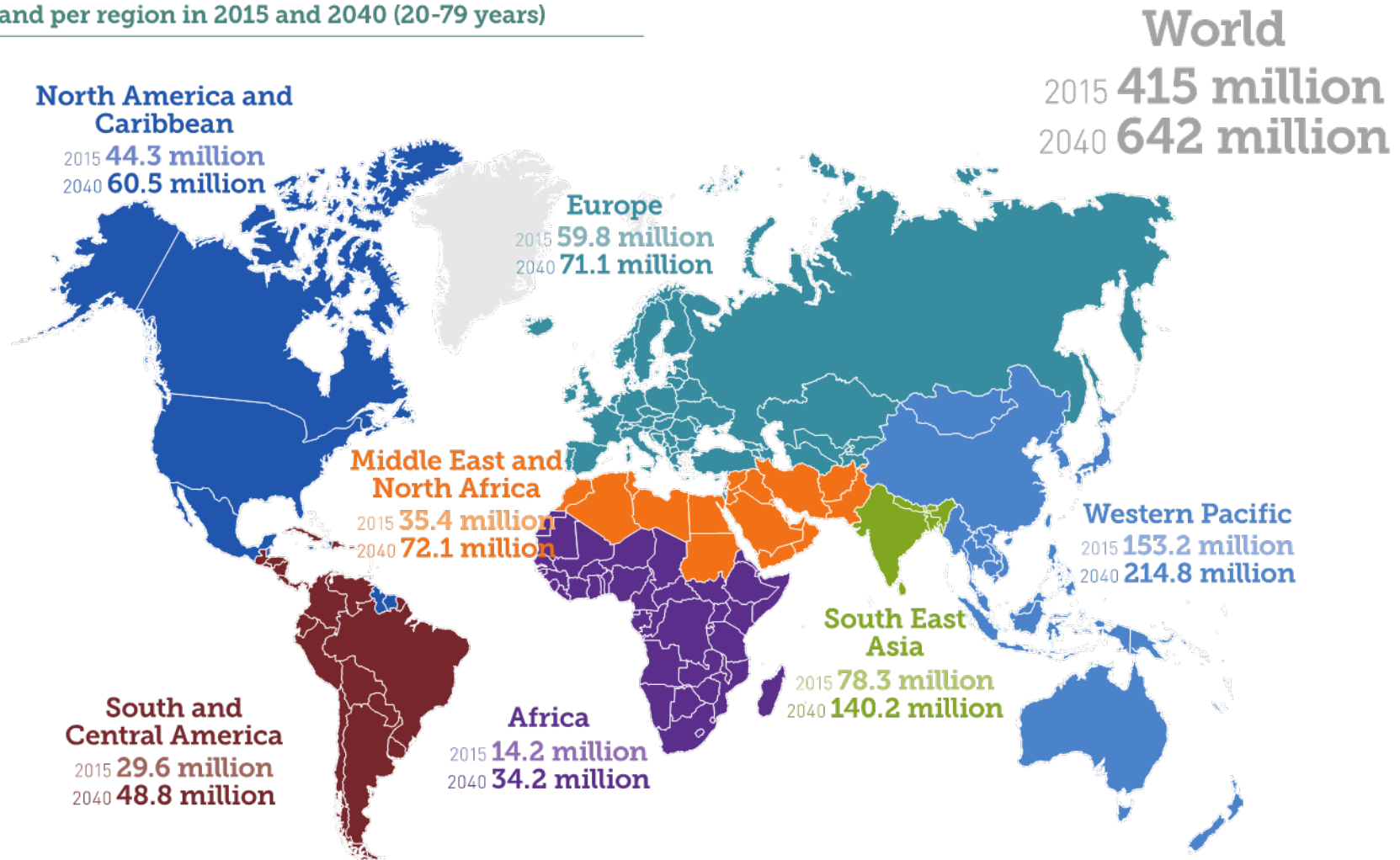
Increasing focus on Patient Outcomes and safety

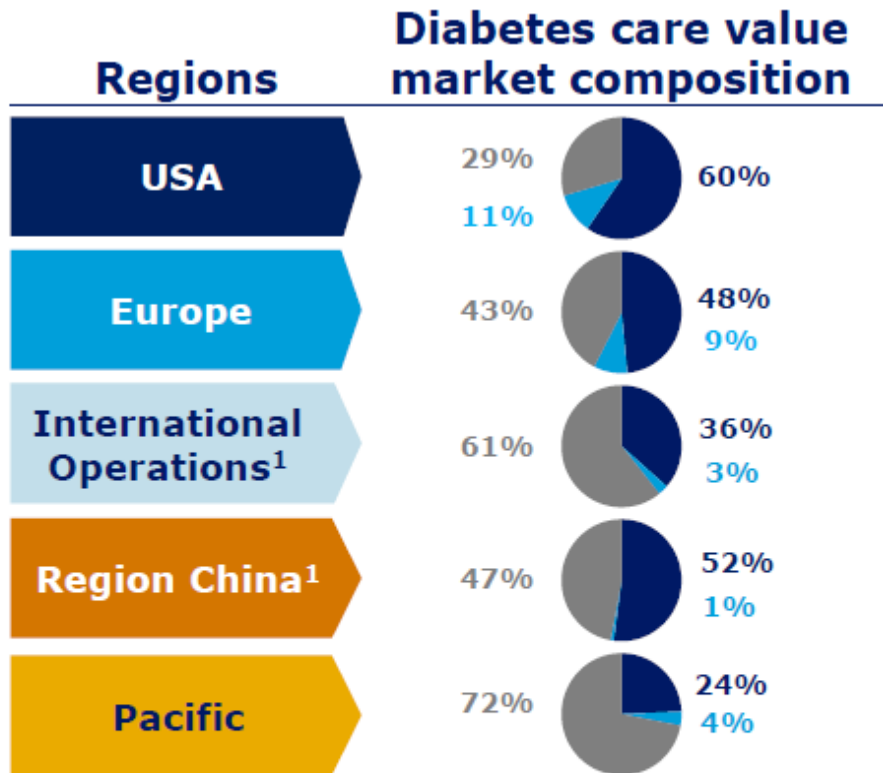
Adherence, Payment based on outcomes,

Drive towards zero defects

There will be 642 Million People with Diabetes by 2040

Estimated number of people with diabetes worldwide and per region in 2015 and 2040 (20-79 years)



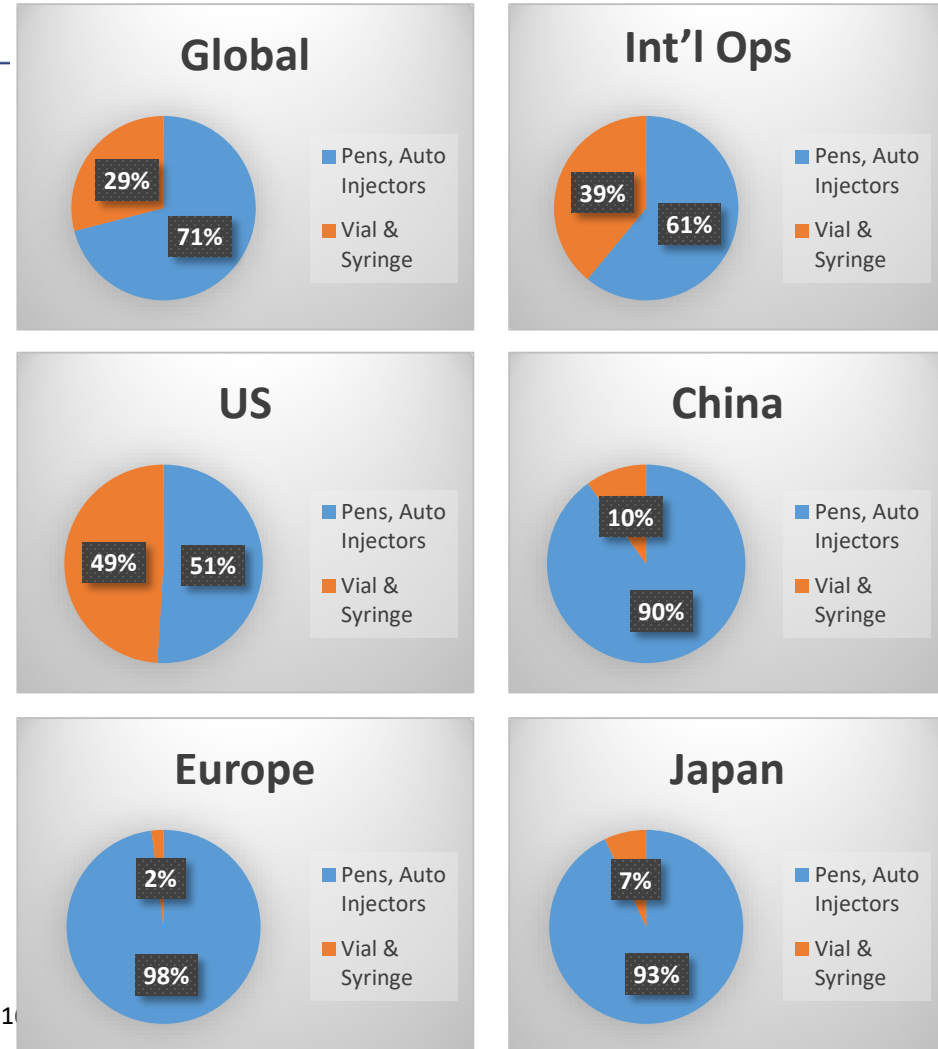


¹ IMS only covers part of the channels in International Operations and Region China
Source: IMS August 2015 & 2016 Monthly MAT volume and value (DKK) figures



■ Insulin
■ GLP-1
■ OAD

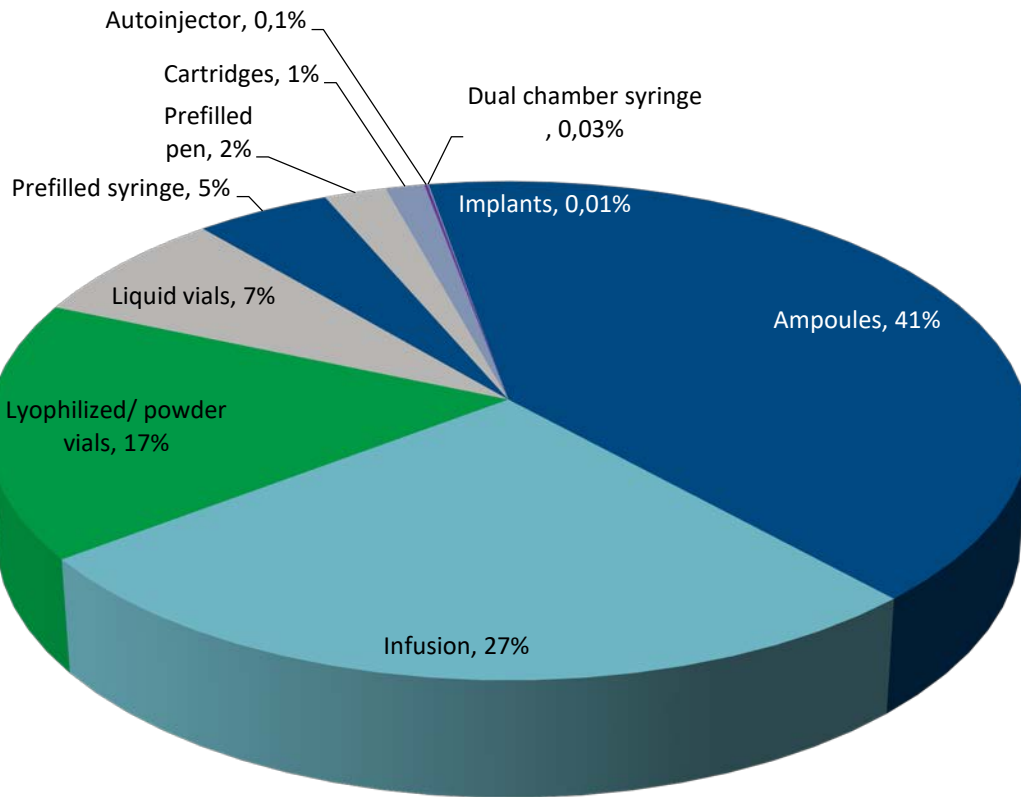
Parenteral Device Opportunity by Market



Source: Data taken from Novo Nordisk, Investor Presentation First Nine months 2016
Source: IMS Monthly MAT August, 2016 volume

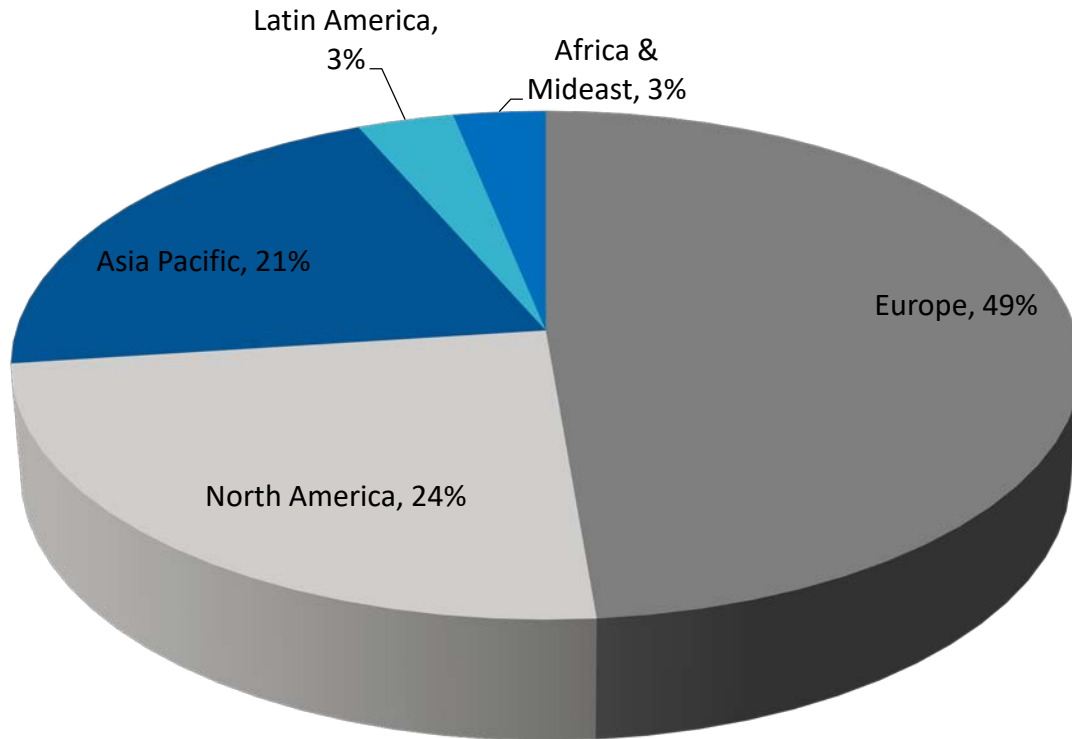
Global Injectable Drug Market Overview

- Volume Market Analysis



Forms	2016 Units Sold (million)	2010-16 CAGR%
Ampoules	17,682	3%
Infusion	11,461	7%
Lyophilized/ powder Vials	7,225	5%
Liquid Vials	3,171	2%
Prefilled Syringe	2,046	4%
Prefilled Pen with Cartridges	941	13%
Cartridges	589	4%
Autoinjector	49	17%
Dual Chamber Cartridge & Syringe	13	1%
Implants	3	9%
Total Injectable Market	43,180	5%

Data Source: 2016 IMS Midas Audited Global Sales Data



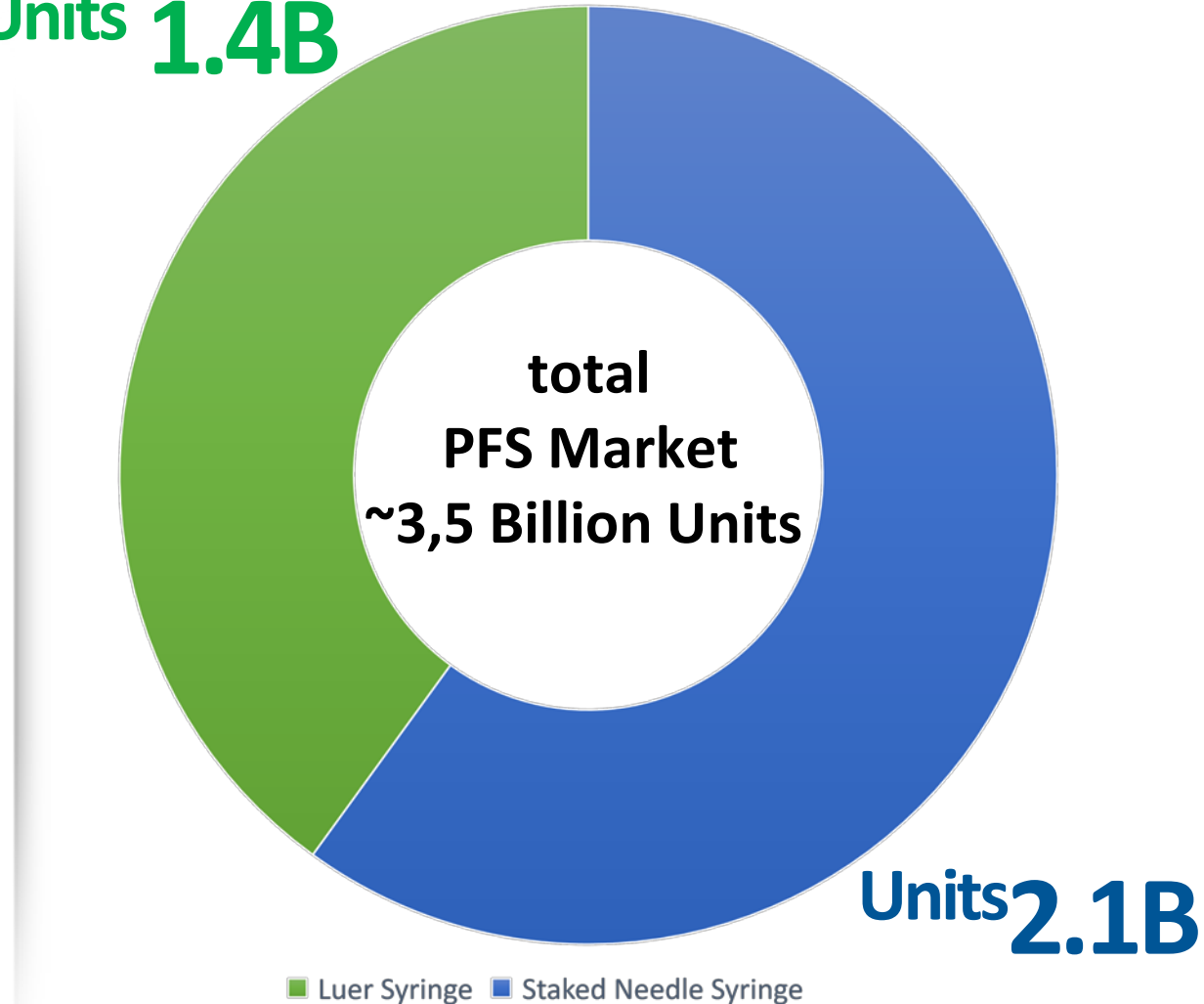
Global PFS Market by Region	2016 Total Units Sold (million)	2010-16 CAGR%
Europe	996	3%
North America	496	3%
Asia Pacific	420	7%
Latin America	68	4%
Africa, Mid. East	65	13%
Global Total	2,046	4%

Data Source: 2016 IMS Midas Audited Global Sales Data

Note: PFS market is under-stated due to the fact that IMS does not capture certain distribution channels for vaccines

- The global Prefilled Syringe market is estimated to continuously grow at mid-single digit
- The majority of staked needle syringe applications use RNS

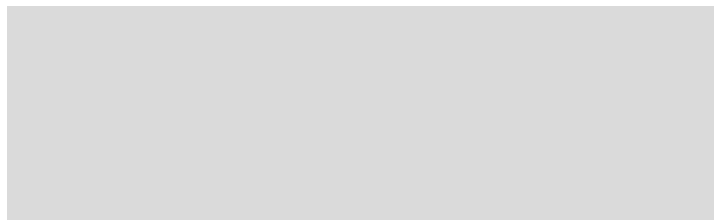
Units **1.4B**



Data Source: best estimate, multiple sources

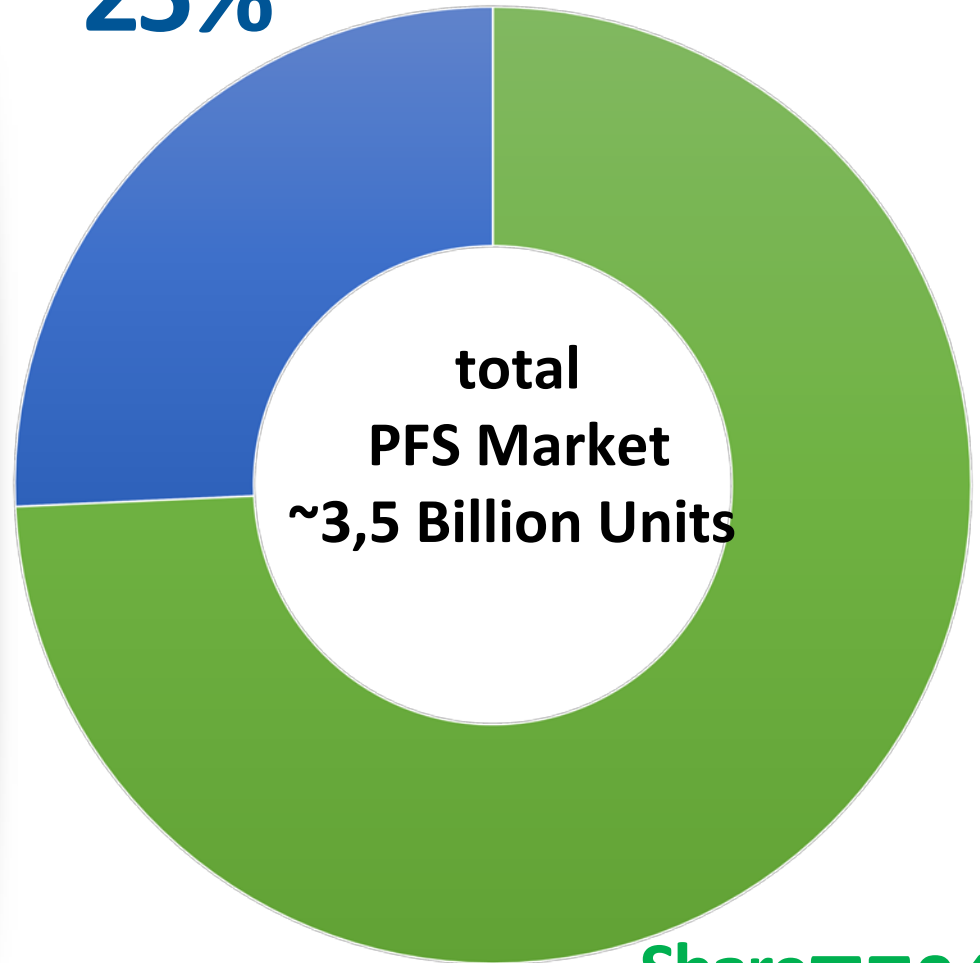


Ready-to-Use Nested glass syringes in tubs



Bulk glass syringes on rondo trays

Share **25%**



■ nested syringes ■ bulk syringes

Share **75%**

Drug Product Trends

Sensitive biologic drugs

Long-acting/depot injections

Smaller batch sizes

High concentration, larger dose volume

Viscosity

Delivery route increased self administration

Complex devices/combination products

Industry Trends

Increased regulatory scrutiny

Higher focus on Quality Risk Management

More advanced and rigorous testing and inspection of final drug products

Ever-increasing focus on patient safety

Flexible filling lines – vials, cartridges, syringes

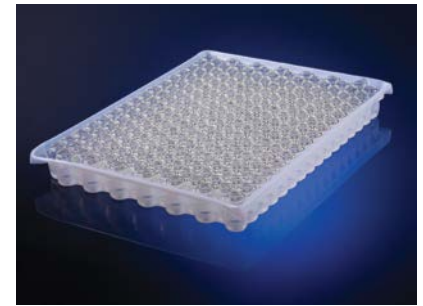
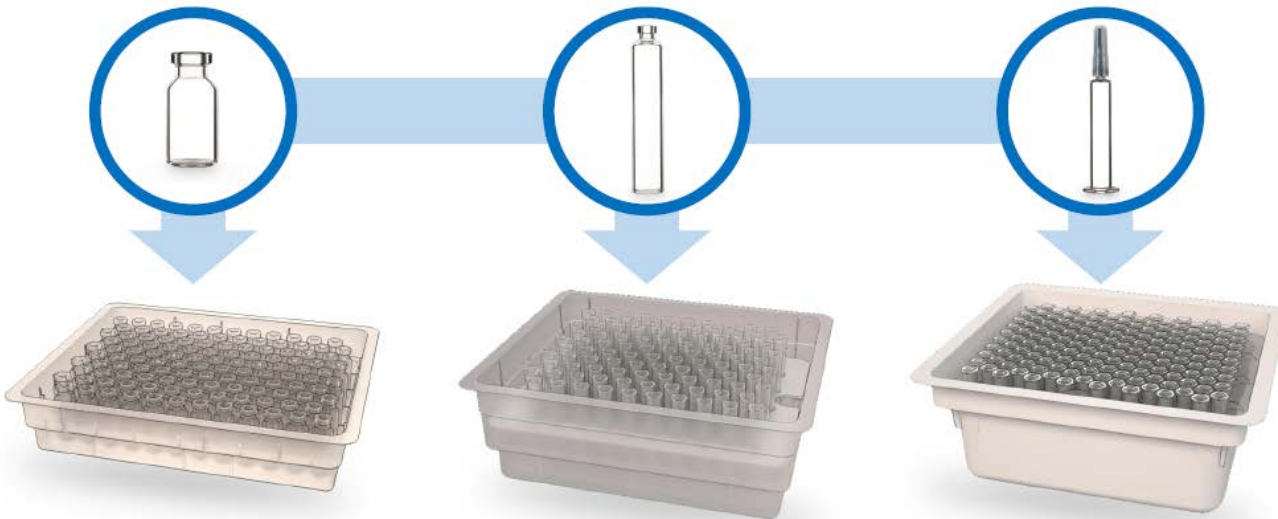
ICH 10 – Continual improvement of process performance and product quality

- Being offered by all major machine manufacturers
- Compatible with vials, syringes, and cartridges
- Decreased capital expenditure
- Decreased facility “footprint” utilization
- Rapid product change-over
- Limited equipment modification and format change-over
- Smaller batch sizes
- Require Ready to Use Container and Components





 **ompi** | ez-fill



A Complete Range of Sterile Containers

Clean Room



- Most installed aseptic production lines are still based on this technology
- No longer state of the art for new projects.

Barrier Systems

RABS

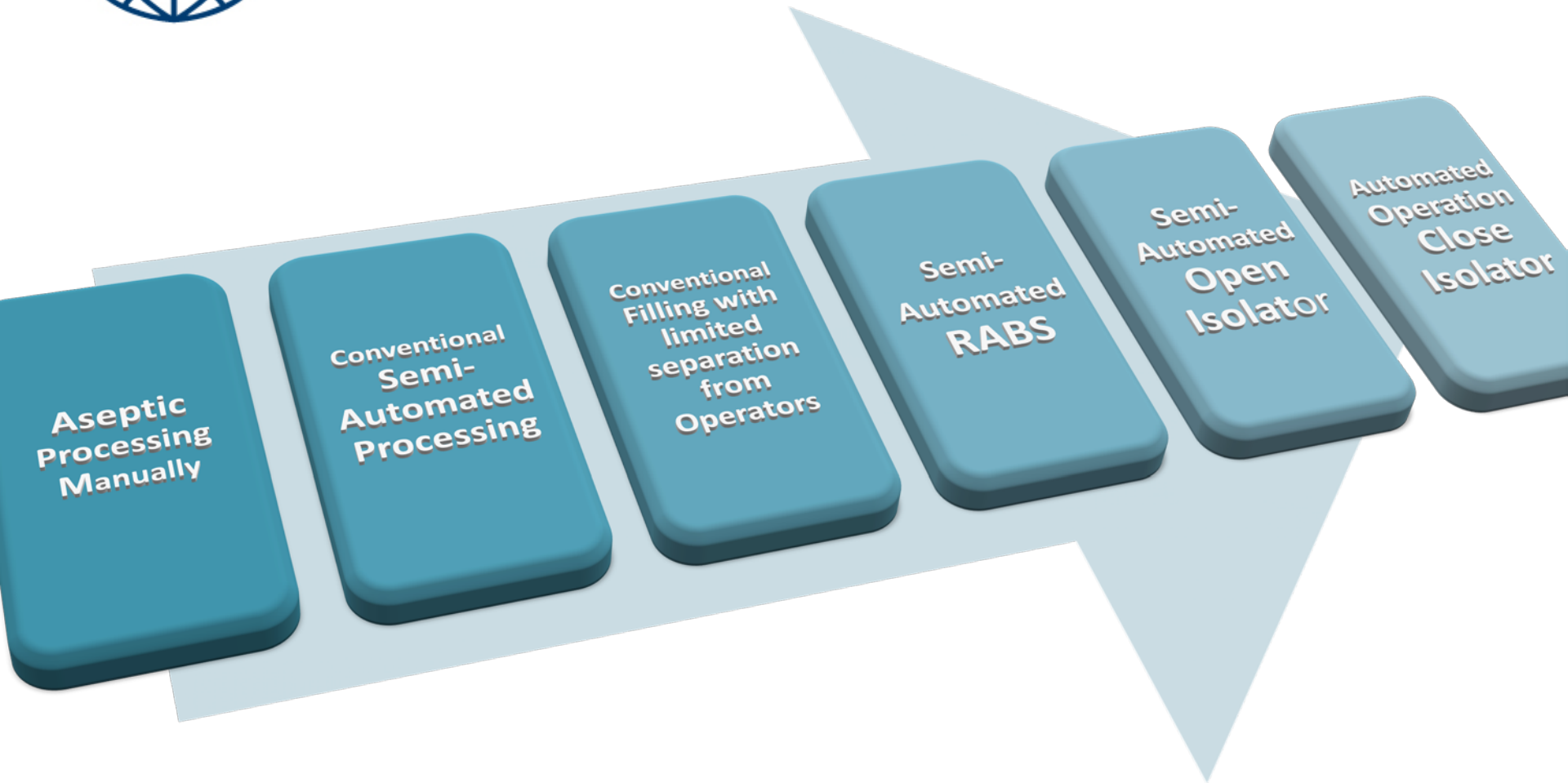


- Restricted Access Barrier Systems (RABS) provides a level of separation between operator and product that affords product protection superior to traditional systems.

Isolator



- Full isolation of machinery from environment
- Seen as future technology
- Since more than 15 years.
- Developing quite fast, started in EU.
- First choice technology for handling of high potent/cytotoxic drug.



Increasing automation leads to lower risk of personnel induced contamination

Source: Richard Johnson, PDA

Trend

Access to healthcare is becoming more sophisticated.

Healthcare moving from pay for product to pay for therapeutic outcome.

Patient's role is changing from recipient to active participant.

Change

→ Patient outcome is the measurement target for Pharma.

→ New drugs are patient centric and in self-injection devices.

→ Patients are scrutinizing product performance.



Vial (lyophilized)



Prefilled Syringe
(liquid drug)



Auto-Injector
(liquid drug)



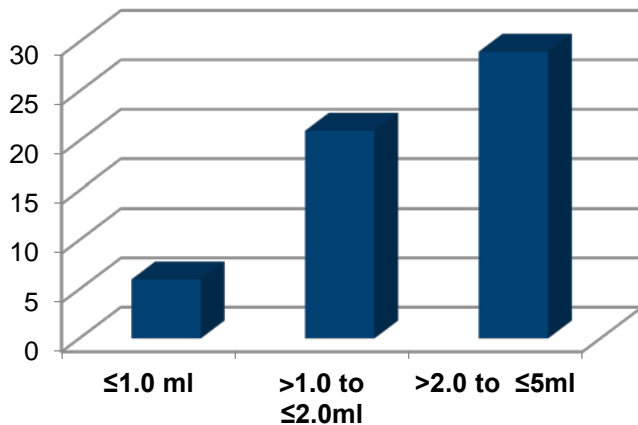
Patch-Injector
(liquid drug)

- Special wearable devices, sensors in mobile devices, even in implants
- Ranges from fitness applications to medical monitoring solutions
- Permanent data collection and analysis with connection to clinical institutions
- Out of clinical settings, supports healthy lifestyle and assists with emergencies
- Reduced costs

*Integrated Connected Health
Smart Dose – HealthPrize –
Wireless Device Connect*



Fill Volume Needs



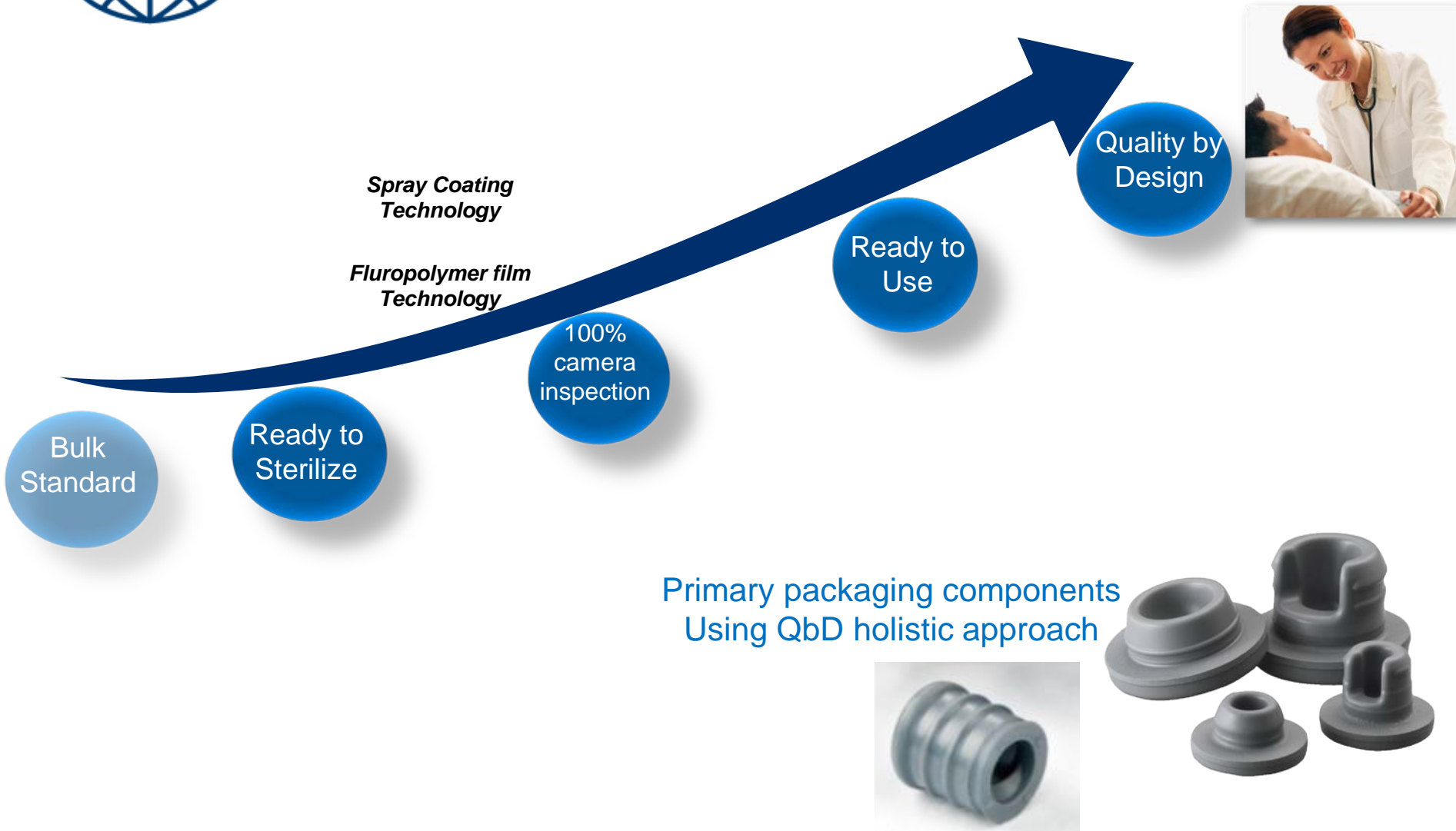
Data Source - West analysis (reference only)



Devices with higher injection volume capacity >1.0mL

- Drug-formulation development focused on larger molecules (biotech)
- Larger molecules and long-acting formulations increase viscosity (5–30cP)
- Higher payloads increase dose volume (1.0mL–3.5mL)
- More customized containers and device size needs



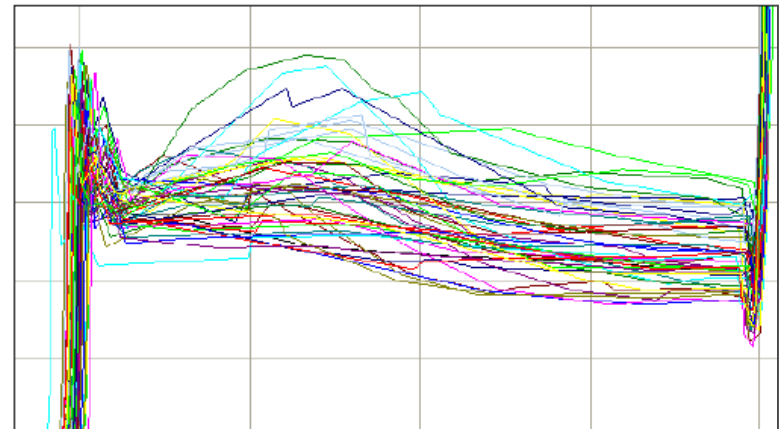
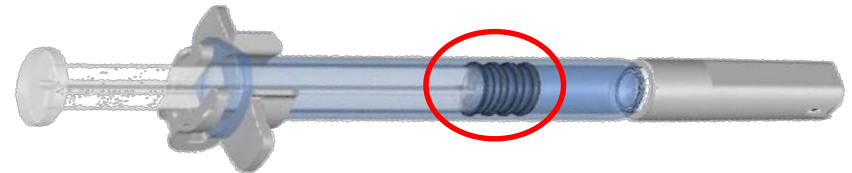


Complex container closure
Designed for manual injection
Top variations to overcome

- Dimensional
- Silicone oil
- Break loose and extrusion
- Visual Quality
- Potential extractables

Common Fluoropolymer coated plunger design

New Fluoropolymer coated plunger design





- Knowledge Management
- Extractables Check
- Sub-visible Control
- 100% Vision Verified
- Steam Sterilized
- Design History File
- Fit for Autoinjectors



**Thank you very much
for your attention!
Questions?**

Christa.jansen-otten@westpharma.com

West and the diamond logo, By your side for a healthier world, FluroTec, NovaPure and B2 are trademarks or registered trademarks of West Pharmaceutical Services, Inc., in the United States and other jurisdictions unless otherwise noted. Crystal Zenith is a registered trademark of Daikyo Seiko, Ltd. Crystal Zenith and FluroTec technologies are licensed from Daikyo Seiko, Ltd.